



POLICY ON THE APPLICATION FOR, AND IMPLEMENTATION OF, CLINICAL PRACTICE GUIDELINES

Clinical Practice Guidelines (CPGs) are essential to keep CAG members abreast of the best clinical practice in new areas as well as updated on existing areas.

In order to provide appropriate guidance, a process is required to ensure that the CAG produces CPGs that are required, credible and applicable. The CAG will bring forward CPGs that are deemed required by the membership and as evidence based as the literature will provide for.

PROCESS

The following seven key decision points will be addressed in the production of any CAG CPG. CAG CPGs will adhere to the CMA Code of Ethics. A check list has been included (Appendix 1) to facilitate review and preparation of a CPG proposal to the CAG.

1. Selecting a topic:

- a) CPGs will be brought forward if they are deemed required by/for the membership. Proposals for CPGs must be brought forward by one or more active CAG Full Members and must include a formal proposal that outlines the rationale for the CPG. The proposal should address, but is not limited to, the following key elements; needs assessment, scientific advancement, and changing clinical/epidemiological parameters.
- b) CPGs will address topical, current issues as well as update existing/established areas.
- c) CPGs will only be considered **IF** there is literature available to support an evidence-based approach.
- d) Proposals will be made to the CAG National Office.
- e) Proposals will be reviewed on a biannual basis by the CAG Clinical Affairs Committee, engaging the key CAG committees (Education, Research, Ethics) and Executive in the decision process.
- f) **NOTE, applications must be received no later than February 1st or September 1st. Applicants will be informed accordingly, in April or November.** Optimally, applications will be submitted for proposals 9 to 12 months in advance.
- g) ALL initiatives will be administrated via the CAG in unison with the organizer(s). If another organization is proposed, justification must be provided within the proposal.

- h) Funding of CPG development must balance feasibility and practicality. Clearly, the CAG is not in a situation to solely fund the development of large numbers of CPGs. If industry support is sought, multi-sponsorship is advantageous/will be sought. Only in extraordinary circumstances will single industry sponsorship be considered, with prior approval from the CAG Executive. Funding sources for any CPG will be disclosed during the process and in any publication. Funding will be transparent, as reported in the audited financial statements of the Association. Funding sources will not influence the CPG process in any way. In the situation where there is an excess of funds, these will be either; be applied to publication and dissemination of the CPG, and/or towards development of necessary CPGs that lack a funding base.
- i) All financial aspects MUST be directed by the CAG National Office.
- j) The Canadian Institutes of Health Research (CIHR) offers workshop grants (~ \$5,000.00) under their Industry Partners Workshops and Symposium Program (<http://www.cihr-irsc.gc.ca/>). All CAG approved CPG applications are expected to submit an application for a CIHR Workshop Grant, which if successful, will add further credibility to the end product. CAG approval of the CPG application is not contingent on concurrent approval for a CIHR Workshop Grant.

2) Picking the consensus group:

- a) The CAG Clinical Affairs Committee will assign the CPG organizer and make recommendations on the membership of the committee involved in implementation and production of any CPG. This will include the Chair who **will not** be involved with the submission of the application nor organization of the CPG (to ensure a third party, objective running of the meeting and review of the data). The final participant list for the CPG will be reviewed and approved by the CAG Clinical Affairs Committee.
- b) It is anticipated that the majority of participants will be CAG members, while particular CPGs covering broad topics might require representation from participants chosen from other disciplines. Consideration may be given, on a case-by-case basis, to invitation of International Experts. An alternative is to engage International Experts in the review process of the draft CPG.
- c) The participant list for the CPG must be established, taking into consideration variables such as expertise, academic and community based, CAG committee representation (as applicable), regional distribution, affiliated health professionals, International experts, and gender.

3) Providing background preparation:

The key is early consensus building and a large part of the background work and initial diffusion of the statements should be circulated well in advance of the planned consensus meeting.

4) Identifying information inputs:

Literature review methods for relevant articles should include MEDLINE searches and manual searches of bibliographies of key published articles, using appropriate search terms and databases. Past reviews, meta-analyses, and published consensus conferences may be considered to summarize historical data. Systematic reviews should be conducted on data from at least the past 10 years. Consideration may be given to economic data where applicable and available. Data available only in abstract form should, as a rule, not be considered.

5) Choosing a group judgment process:

It is critical that within the judgment process, set guidelines are followed surrounding the

- a) grading of the evidence
- b) grading of the recommendation(s)
- c) voting percentage on evidence and recommendation(s).

An example of the approach expected, is included (Table 1).

6) Defining the statements for recommendations:

The choice of these should be driven by clinical relevance and adequacy of available evidence in the literature at the time of the CPG process initiation. The list of statements should be one of the first topics on which to achieve a consensus as part of a Delphi process prior to the actual CPG conference.

7) Choosing a report preparation procedure and format:

- a) The draft CPG **MUST** be prepared within 4-6 months of the CPG meeting. If this timeframe is not met, the CAG Executive must be notified and will reconsider endorsement of the CPG.
- b) The draft CPG will be posted on CAG website for a period of 2 weeks for membership review and input. **Note**, only feedback that identifies grave errors, or is factual and supported by published evidence, will be considered by the CPG Working Group regarding changes, as it conflicts with accepted CPG development methodology to consider subsequent changes to an evidence based CPG production process.
- c) Considerations should be given to publication in the *Canadian Journal of Gastroenterology*, however this will not be mandatory.

8) Ethical Issues:

All participants must provide a complete list of all possible conflicts of interest and fill out an ethical questionnaire related to perceived influence of sponsors on the given guideline process. The entire process will be reviewed by the CAG Ethics Committee. All conflicts, as well as recognition of sponsorship, must be explicitly listed in the final report and any dissemination materials.

DISSEMINATION

Please also review the CAG policy on the Dissemination of CAG Material at <http://www.cag-acg.org/about/policies.aspx> under “Dissemination Policy”.

In particular, for CPGs, the following guidelines will apply:

- a) The CPG must be submitted to a peer review process with the intent of publication. It will be decided by each particular steering committee as to the exact publication plan and journal. The CPG will not be released in full or part, prior to final publication.
- b) Requests for dissemination **will not** be entertained from parties that were not sponsors of the CPG development / consensus process.
- c) The CAG will contact all sponsors of each particular CPG, to advise on publication, and to source interest in further dissemination initiatives. This will be done simultaneously, with proposals (as noted below) reviewed and considered on a first-come, first-serve basis.
- d) The CAG **must** be involved in further dissemination of a CPG (beyond original publication), in whole or part, which includes any reference to the CAG. Interested parties should contact the CAG directly with a proposal, inclusive of project details, timelines, and budget.

1. Lomas J. Words without action? The production, dissemination, and impact of consensus recommendations. *Annu Rev Public Health*. 1991;12:41-65. Review.
2. Canadian Medical Association. Code of Ethics. (update 2004); http://www.cma.ca/index.cfm/ci_id/53556/la_id/1.htm .
3. Canadian Task Force on Preventative Health Care. New grades for recommendations from the Canadian Task Force on Preventative Health Care. *CMAJ* 2003; August 5,169(3):207-208.
4. Barkun A, Bardou M, Marshall JK; Nonvariceal Upper GI Bleeding Consensus Conference Group. Consensus recommendations for managing patients with nonvariceal upper gastrointestinal bleeding. *Ann Intern Med*. 2003 Nov 18;139(10):843-57.
5. Armstrong, D, Marshall JK, Chiba N, *et al*. Canadian Consensus Conference on the management of gastroesophageal reflux disease in adults – Update 2004. *Can J Gastroenterol*. 2005;19:15-35.
6. Clinical practice guidelines and conflict of interest. *CMAJ* 2005; November 22, 173(11): 1297.

Table 1. Categorization of Evidence, Classification of Recommendations, and Voting Schema

Category and Grade	Description
Quality of Evidence	
I	Evidence obtained from at least 1 properly randomized, controlled trial.
II-1	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case--control analytic studies, preferably from more than 1 center or research group.
II-3	Evidence obtained from comparisons between times or places with or without the intervention, or dramatic results in uncontrolled experiments.
III	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
Classification of Recommendations	
A	There is good evidence to support the procedure or treatment.
B	There is fair evidence to support the procedure or treatment.
C	There is poor evidence to support the procedure or treatment, but recommendations may be made on other grounds.
D	There is fair evidence that the procedure or treatment should not be used.
E	There is good evidence that the procedure or treatment should not be used.
I	There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making
Voting on the Recommendations	
a	Accept completely.
b	Accept with some reservation.
c	Accept with major reservation.
d	Reject with reservation.
e	Reject completely.

APPENDIX 1

Table 2: Checklist for a CPG Proposal to the CAG

- We have provided the rationale that supports the need for this CPG (needs assessment, scientific advancement, changing clinical/epidemiological parameters).
- Yes, there is literature available to support an evidence-based approach
- We have provided a proposed timeline for development of this CPG and listed the anticipated output and publication(s).
- We request that the CAG administrate this initiative, otherwise, we have provided a rationale for this initiative to be administered beyond the CAG.
- We understand that the CAG will source multi-sponsorship for this initiative. Where sponsorship is already available, or interest has been indicated, we have provided a list of the sponsor(s) and their commitment.
- We agree that ALL funding related to this initiative will be administered by the CAG, or where funds will not be administered by the CAG, we have provided justification for this.
- We have provided a list of proposed CPG Consensus members and Chair, listing the rationale for each candidate (CAG Committee representative, regional representation, expertise, etc.).
- We understand that the CAG will appoint a Chair (who will not be one of the organizers) for this CPG after discussion with the CPG organizers and we have provided a list of proposed individuals for this role.
- We agree with the process outlined by the CAG *Policy on the Application for, and Implementation of, Clinical Practice Guidelines*. Any modification of these guidelines, with respect to this initiative, has been explained thoroughly.
- We agree to abide by the ethical principles and requirements, as outlined in these guidelines