

POLICY FOR MANAGEMENT OF CONFLICTS OF INTEREST IN THE DEVELOPMENT OF CAG CLINICAL PRACTICE GUIDELINES

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PURPOSE

Because conflicts of interest create a risk of bias in decisions or recommendations, the Canadian Association of Gastroenterology (CAG) has taken steps to strengthen the disclosure and management of potential conflicts of interest (COI) of clinical practice guideline (CPG) panel members in accordance with the principles developed by the Guidelines International Network (G-I-N).¹ This policy provides an approach to managing COI in the development of CPG that is consistent with the expectations of the guideline development community, health care professionals, the public, payers, and regulatory bodies to ensure independent assessment of evidence and decision-making, as well as high confidence in guideline quality and integrity. It is important to note that many major guideline societies have already adopted similar disclosure and management of COI policies in accordance with the G-I-N principles.²⁻⁸

CAG adheres to the nine G-I-N principles for disclosing interests and managing COIs:

Principle 1. Guideline developments should make all possible efforts to not include members with direct financial or relevant indirect COIs. In situations in which panel members have COIs, conflicted members should represent a minority on a guideline panel and the guideline developer should be transparent about the reasons for including conflicted members and the management of COIs.

Principle 2. The definition of COI and its management applies to all members of a guideline development group, regardless of the discipline or stakeholders they represent, and this should be determined before a panel is constituted.

Principle 3. A guideline development group should use standardized forms for disclosure of interests.

Principle 4. A guideline development group should disclose interests publicly, including all direct financial and indirect COIs, and these should be easily accessible for users of the guideline.

Principle 5. All members of a guideline development group should declare and update any changes in interests at each meeting of the group and at regular intervals.

Principle 6. Chairs of guideline development groups should have no direct financial or relevant indirect COIs. When direct or indirect COIs of a chair are unavoidable, a co-chair with no COIs who leads the guideline panel should additionally be appointed. An example of a co-chair without such conflicts is a methodologist who has no interest related to the direction or strength of the recommendation.

Principle 7. Experts with relevant COIs and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion among those sought to provide input.

Principle 8. No member of the guideline development group deciding about the direction or strength of a recommendation should have a direct financial COI.

Principle 9. An oversight committee should be responsible for developing and implementing rules related to COIs.

DEFINITIONS

In the context of CPG, a conflict of interest (COI) exists when an individual's personal interests (e.g. direct and indirect financial or intellectual) have the potential to compete with or influence behavior related to the individual's professional interests or obligations (i.e. evaluating the evidence and developing recommendations for clinical practice guidelines).

Direct financial COIs refer to financial relationships with entities that have investment in products or services directly relevant to the guideline topic. These personal financial interests include employment, consultancies, paid expert testimony, stock holdings, endowments, patents, royalties, honoraria, and in-kind gifts (e.g. travel, accommodation, meals, frequent flier miles). **Indirect COIs** relate to such issues as academic advancement, clinical revenue streams, and community standing. **Intellectual COIs**, including attachment to ideas or "academic activities that create the potential for an attachment to a specific point of view" belong in the latter category. These COIs may ultimately lead to indirect financial gain related to salaries or other benefits resulting from academic advancement.

In relation to CAG guideline development process, "conflict of interest" applies to current or planned interests. CAG has defined current interests as those that have arisen during a period of **2 years preceding the invitation to participate on the guideline panel and during the guideline development process**. In this regard, the term "conflict of interest" does not apply to past interest that have expired or that no longer exist nor does it apply to possible interests that may arise in the future but are not planned.

REQUIREMENTS

DISCLOSURE

To whom: All individuals who are invited to participate in a guideline panel (co-chairs, committee members, GRADE methodologists, moderators) must disclose to CAG all COI and, if the guideline is co-sponsored by another society, to that society if requested. A standardized declarations of interest form (**DOI Form**) must be completed by the individual and evaluated by the **Ethics and Conflict of Interest (COI) Committee**, before the guideline process begins. Approved guideline panel members must also disclose their COI to the other panel members at the beginning of each meeting.

The CAG will review declared COI and determine whether or not any of the disclosed conflicts are manageable for the particular panel and, if manageable, how they should be managed.

When: Co-chairs will submit DOIs as part of their CPG proposal in order to be approved by the Ethics and COI Committee. Following this approval, co-chairs are able to begin work on the guideline. All other invitees must submit their disclosures before they can be confirmed as members of the committee and begin guideline development. If a potential COI arises **during guideline development**, it must be disclosed promptly to CAG CPG Project Manager. It is advised that approved panelists consult CAG CPG Project Manager before engaging in any activity that may result in a COI related to guideline development. Guideline panel members should be apprised of the declared COI of all other participants **before and also at the face-to-face meeting**. COI should be acknowledged in **any published guideline document**, with footnotes that allow users of the document to access the policies that safeguard COI during the guideline development process.

What: Panelists must disclose the following relationships if held by them or their immediate family members **at the time they are invited to participate on the guideline panel or if held during the preceding 2 years or during the guideline development process**:

1. **Personal financial interests in a commercial entity** with an interest relevant or potentially relevant to the topic(s) of the guideline. This includes, but is not limited to, employment by a commercial entity, consultancy, board or advisory board, lecture fees paid by commercial entity, expert witness, industry-sponsored grants (received or pending) including contracted research, patents received or pending, royalties from a commercial entity, equipment / supplies paid for by commercial entity for personal or professional practice, meals / travel / accommodations paid for

by commercial entity to attend conference / symposium / educational events, and stock ownership or options.

2. **Personal financial interests in a non-commercial entity** with an interest relevant or potentially relevant to the topic(s) of the guideline (e.g. a government source such as CIHR or NIH, or a foundation, or other non-profit source).
3. **Institutional financial interests in a commercial entity** with an interest relevant or potentially relevant to the topic(s) of the guideline. In this regard, CAG does not require individuals to make specific inquiries of the authorities of their institution.
4. **Interests that are not mainly financial**, and may be relevant to the topic(s) of the guideline including but not limited to strong personal beliefs, previously published opinions, institutional relationships, career advancement, advocacy and policy positions, professional specialty, and expected new financial or non-financial interests.

Experts are expected to have and assert their own views and opinions on the topics under review, and in a sense that is why CAG wishes to invite them; what should be considered for the purpose of these guidelines are views and opinions that could be perceived as affecting the impartiality of the expert. Evidence of such bias could, for example, be identified through public statements made and positions held as part of a regulatory or judicial process. **Whereas it could be important for guideline users to be aware of such public statements or positions, the potential bias may, but does not necessarily, constitute COI.** However, in situations where there is significant directly related interest or duty of the individual, for example, as the head or as part of the leadership of an organization or other professional society that has publicly and repeatedly taken a fixed public position on an issue that is under review by the guideline process, then a bias in such a situation may constitute an interest to be disclosed and managed. This would be the case because such a person could be expected to represent or defend the interests and the position espoused by the organization.

REVIEW AND CATEGORIZATION OF CONFLICTS OF INTEREST

The COI disclosures of individuals who are invited to participate in a CAG guideline panel are reviewed by the **CAG Ethics and COI Committee** prior to the individuals being accepted as panel members. To ensure transparency and objectivity in this process, the **Significance Scale** (developed by the American Thoracic Society) is used as a guide in assessing the significance of COI and in determining the level of resolution needed.²

A COI assessment essentially involves carrying out a “balancing test”. In carrying out such a balancing test, the Ethics and COI Committee, while fully considering the contribution, tasks

and function of the expert as well as the availability of alternative experts with the required expertise, must weigh:

- *The nature, type and magnitude of the expert's interest and therefore the degree to which the interest may be reasonably expected to influence the expert's judgment against*
- *The adequacy of measures / options available to protect the independence and integrity of the decision-making process.*
- *The level of unique expertise not otherwise represented in the CPG membership*

Based upon the assessment of the COI disclosures with the Significance Scale, proposed panelists are considered as either having no or minimal relevant COI, having significant COI that require management, or having disqualifying COI that must be terminated in order to serve a member of the guideline panel. Experts in this subject matter of the guideline that have disqualifying COI may be permitted by CAG to participate as non-voting expert contributors.

The COIs must be reviewed for the entire committee at one time, to be able to ensure the required threshold of 51% non-conflicted can be achieved. This requirement stems from the Institute of Medicine Current Best Practices and Proposed Standards for Development of Trustworthy Clinical Practice Guidelines 2.4: *"members with COIs should represent not more than a minority of the guideline development group."* Only once this is done can the committee members be confirmed.

It should be noted that at this early stage of the guideline process, the PICO questions will have not been finalized; however, the scope of the guideline will already be known and most relevant interventions, tests and comparisons can still be predicted.

At a later stage, once the PICO questions have been finalized, the COIs must be reviewed once again to ensure the threshold of 51% non-conflicted is achieved. If that threshold is not reached for some PICO questions, the potential solutions would be to either recruit additional unconflicted panel members or randomly select conflicted members at the face-to-face meeting to recuse from voting. The choice between the two options will be influenced by the flexibility of the budget, the magnitude of imbalance, and the stage of the guideline. If the proportion of non-conflicted panel members unexpectedly drops below 51% at a very late stage (e.g. because of additional COI, or because one or more unconflicted members are no longer able to participate), the only option would be to randomly select conflicted members at the face-to-face meeting to recuse from voting.

No Relevant Conflicts of Interest: Individuals with no relevant COI are approved for full participation. Individuals classified as without relevant COI may participate in determining the scope and PICO questions to be addressed in the guidelines, review and discuss the evidence, formulate and grade the strength of recommendations, vote on recommendations, and write the document. Moderators and GRADE methodologists should be free from any relevant COI.

- Research funding that is free of direct or indirect industry funding or control, such as that provided by a government program or a non-profit organization that does not

receive industry funding and uses an award mechanism and oversight that is independent of industry, is not regarded to be a COI.

- Service on a data and safety monitoring board for such research is also not considered to be a COI.

Minimal Conflicts of Interest: A declared interest is minimal if it is unlikely to affect or be reasonably perceived to affect, the expert's judgment. Individuals with minimal COI may be allowed to participate in the discussion and vote on all recommendations. Normally, minimal interests are:

- Unrelated or are only tangentially related to the subject of the activity or work and their outcome;
- Nominal in amount or inconsequential in importance;
- Expired or are unlikely to affect current behavior
- Delivery of non-promotional talks in which the speaker has full control of the content and is either unpaid or paid by a third party that is responsible for ensuring that the event is free of influence of relevant industry (i.e. if the event has industry financial support, all planning and content must be free of industry influence, and any payment of expenses and honoraria must occur through a third party, such as the medical society or institution sponsoring the event, or an event manager acceptable to them, rather than directly by a commercial entity with an interest in guideline subject matter or its agent).

Moderate or Significant Conflicts of Interest that require management include:

- A. Research funding from an industry grant that is paid to the participant or the participant's institution for research related to the content of the guideline, conducted by the participant as an investigator;
- B. Research funding from a government program or non-profit organization that receives funding from industry with business interests in the content of the guideline;
- C. Participation on a data and safety monitoring board concerned with research that is relevant to the content of the guideline and is funded by an industry with business interests in the content of the guideline, or by a government program or non-profit organization that receives funding from industry with business interests in the content of the guideline;
- D. Participation in industry-funded research, scientific advisory committees, consulting roles, non-promotional speaking engagements, or expert testimony on matters that are unrelated to guideline subject matter but the company involved is known to have business interest in the guideline subject matter;
- E. If a potential recommendation of the guideline would jeopardize or enhance the panelist's professional work or professional group fundamentally (definition of intellectual COI of the Institute of Medicine, National Academy of Sciences, Clinical Practice Guidelines *We Can Trust*, 2011).

Individuals with manageable COI as defined in categories A through E above (depending on the degree and relevance of the COI with the topic(s) of the guideline) may or may not be

permitted to participate in discussions about the evidence, but must be recused from decision making, including formulating, voting on, grading, and writing specific recommendations related to their COI (i.e. recommendations addressing a product of the commercial entity with which they have a relationship or addressing a product of a competitor of the commercial entity with which they have a relationship). This measure in managing relevant COI is termed **partial exclusion**. In all cases, the reported interest must be publicly disclosed to other meeting participants and must be recorded and disclosed in the report of the meeting and/or relevant publications or work products. Partial exclusion may only be used to enable other members to listen to the results of research or views held by the best-qualified experts, while bearing in mind the expert's potential bias. As well, public disclosure of an expert's interest does not eliminate the COI but rather mitigates it by making others aware of the interest thereby enabling them to exercise an appropriate degree of critical assessment about the views or recommendations that are made by that expert.

Individuals with a COI requiring management as defined in category E above will be permitted to participate in discussions about the evidence, but must attest that the intellectual conflict will not bias their participation in the panel, and may be required by CAG to recuse themselves from decision making on relevant recommendations if CAG thinks that there is a high likelihood that guideline readers would regard the individual's participation in decision-making on the relevant recommendation as lessening reader confidence that the recommendation was developed in a manner independent of any financial or intellectual consequences for panelists. Determination of the need for recusal of panelists with a manageable COI as defined in category E above will be made by the CAG Ethics and COI Committee.

It is the responsibility of the guideline un-conflicted co-chair and the moderator to ensure that individuals with manageable COIs are recused as described above. Both co-chairs and the moderator will be advised by the CAG Ethics and COI Committee in managing panel members with a COI requiring management, and in summarizing management actions for CAG and within the methods section of the guideline. These members, although conflicted in some aspects, are still authors on the guideline.

Excessive Conflicts of Interest: In this case, the expert is excluded from the CPG altogether, where the nature of the COI is considered too excessive vis-à-vis the overall objective, or where limiting the expert's involvement to only a portion of the meeting or CPG is not feasible (because, for example, the expert's participation in the remainder of the meeting would have little or no value). Excessive COI that cause disqualification for membership on a CAG guideline panel include:

- A. A direct financial relationship with a commercial entity that has an interest in the content of the guideline (a "relevant company"), exclusive of the research and data and safety monitoring board activities noted above. Such direct financial relationships include the following, whether paid to or held by the individual directly or issued to another entity at the direction of the individual (such as to the panelist's institution):

- Payment of wages, consulting fees, honoraria, or other payments (in cash, in stock or stock options, or in kind) by a relevant company as compensation for the individual's services or expertise, exclusive of the research and data and safety monitoring board activities noted above. Examples of such services are: participation on relevant scientific advisory committees; consulting; non-CME speaking engagements and inclusion in a speaker bureau; expert testimony on matters related to guideline content provided on behalf of a relevant company or a law firm representing a relevant company; employment by a relevant commercial entity (such as relevant pharmaceutical or medical device company or a third party payer that has financial interests in guideline content).
 - Investments in relevant companies by the panelist or the panelist's spouse or life partner (exclusive of general mutual funds).
- B. A patent or other intellectual property that is relevant to the guideline's subject matter and has resulted or could result in payments to the panelists or the panelist's institution.

Proposed panelists with disqualifying COI will be notified by the Chair of Ethics and COI Committee. The disqualified panelist may be permitted to serve if the disqualifying relationship is terminated prior to when the panel begins its work. Permission requires consideration of the matter by the CAG Ethics and COI Committee, and assurance by the proposed panelist that CAG requirements for remediation of the disqualifying relationship will be met. These requirements include:

- A. Termination of the COI as far in advance of panel activity as possible to avoid any appearance of influence on panel participation, and
- B. The panelist must refrain from disqualifying or significant relationships throughout the period of guideline development and for a period of at least one year following publication of the guideline;
- C. Disqualifying or significant relationships that are terminated prior to when the panel begins work, in order to allow panel participation, must also be disclosed to the CAG and panel members and treated as manageable COI that requires appropriate management, including recusal from decision-making on recommendations that address a product of the commercial entity with which the panelist had the disqualifying relationship, or a product of a competitor of the commercial entity with which he or she had the disqualifying relationship. The existence of the relationship will also be reported within the author disclosures that accompany the guideline when published.

Non-voting Expert Contributors: CAG recognizes that experts in the subject matter of a guideline may be unable to serve as CAG guideline panelists due to financial relationships that cause disqualification. These experts often possess unique insight into guideline-relevant content and their observations may provide valuable insight into a topic. For example, the experts may be aware of relevant information about study design and conduct that is not easily

identified in published articles. Proposed panelists with disqualifying COI who decline to terminate their disqualifying relationship(s) cannot become panel members; however, they may be permitted by CAG to participate as “non-voting expert contributors” to the guideline. They may participate in discussions of the evidence related to their specific expertise, but may not participate in discussions about any recommendations, regardless of whether the recommendations are related to their disqualifying relationship. Non-voting expert contributors must meet all CAG disclosure requirements (as stated earlier for panelists), and be approved by the CAG Ethics and COI Committee, prior to any participation. These people would not be listed as authors in the manuscript, but would be listed in the acknowledgements sections.

GUIDELINE DEVELOPMENT PANEL COMPOSITION

One co-chair and the majority (i.e. > 51%) of guideline development panel members must be free from relevant COIs. The majority threshold is meant to be the minimal acceptable standard; guideline development panels should strive to maintain as large a proportion of individuals free from relevant COI as possible, while maintaining the necessary expertise to develop the guidelines.

OTHER REQUIREMENTS

Confidentiality: All discussions and work by the guideline development panel must remain strictly confidential. Every member of a guideline development panel will be required to sign a Memorandum of Understanding document which contains a confidentiality agreement to participate in the project. The confidentiality requirement begins the moment that an individual is accepted onto the guideline development panel and continues until the document is published in a peer-reviewed journal. This includes discussions with co-workers, colleagues, and other CAG members. In addition, consistent with the expectation that CPG be developed in a manner that is independent of business interests, panelists are not permitted to discuss a guideline’s development with employees or representatives of the entities with vested interest in guideline subject matter. Guideline panels may not accept unpublished data from industry. Guideline panel members will not permit individuals employed by industry or acting on behalf of industry to review guidelines in draft form. **The above confidentiality requirements exclude CAG-approved presentations prior to publications (e.g. in Canadian Digestive Disease Week).** Potential penalties for violating the confidentiality agreement include the following:

- A. Immediate removal from the guideline development panel;
- B. Elimination of any opportunities for authorship associated with the guideline;
- C. Disqualification from participation in any future CAG clinical practice guidelines;
- D. Reasons for removal will published in the actual guideline document.

Publication of disclosures: A completed DOI form is a confidential working document of CAG and should not be distributed or made public, also to protect legitimate privacy concerns of the experts. Information stated on the DOI form is only used to evaluate whether an expert's declared interests constitute a real, potential or apparent COIs. In this regard, relevant information (as opposed to the DOI form itself) may be summarized and publicly disclosed. All relevant COI of guideline panel members that were in existence during guideline development and the 2 years prior to being invited to participate, and known by CAG, will be published together with the CAG CPG document. All CAG guideline documents should include a Methods section describing in sufficient detail the processes used to identify and manage COI during guideline development. In addition, each CAG CPG should describe the decision-making process, instances of substantial disagreement, reasons for that disagreement, and the results of voting. In disclosing the financial interest of an expert, the guideline publication should either use general characterizations or ranges of amounts depending on the particular circumstances involved.

Examples of disclosure statements:

- Significant shareholding in company XYZ
- Short-term consultancy for company ABC
- Travel and/or accommodation paid by company ABC
- More than CAN \$1000 but less than CAN \$5000 in speaking fees over the past xx years received from company XYZ
- Is the holder of a patent related to a drug (or device) used in the treatment of...
- Is the licensee of technology related to...
- Less than CAN \$100,000 in income received from company ABC over the past xx years
- Has 3000 shares in company with a value in excess of CAN\$5000
- Has an insignificant shareholding in company ABC
- Has provided expert testimony to a parliamentary or congressional committee, or within a judicial proceeding, on the subject matter of the CPG
- Minor income received in respect of a consultancy conducted for company ABC during year XXXX

Record retention: DOI forms should be retained by the CAG office for at least ten years after publication of the CPG. The DOI forms should be filed and maintained in a manner consistent with general procedures for the retention of confidential documents.

Speaking related to the guideline topic (Dissemination): Prior to publication, no speaking events for the CPG should be undertaken by co-chairs or committee members without written approval through the CAG. Guideline panel members are permitted to engage in speaking activities related to the guideline's subject matter for any CAG accredited program. As well, Industry must use guideline panel members as content developers or speakers for any CAG accredited program related to the guideline's subject matter. Guideline panel members, however, should not develop content or engage in speaking activities related to the guideline's subject matter at any unaccredited Other Learning Activity (OLA) such as "satellite symposia".

Procedures for handling disputes in COI resolution: The CAG Ethics and COI Committee should develop and oversee the procedures and instruments used to disclose, review, and resolve COI, and should advise and assist co-chairs and Clinical Affairs throughout the guideline process. In instances where determination of COI and actions taken to resolve COI in CPG process has been formally disputed in writing to Clinical Affairs, an *ad hoc* adjudication committee of members appointed by the CAG President should be convened to address the matter. Such an *ad hoc* adjudication committee should include the CAG Chair of the Ethics and Conflict of Interest Committee, CAG Practice Affairs Lead, CAG VP Clinical Affairs, CAG Past-President (or designee), a CAG Operation Committee Member (in addition to the CAG VP Clinical Affairs), and the unconflicted co-chair(s) of the CPG. If any of the above CAG executive members have been involved in the guideline under consideration (as panel members, methodologists or moderators), they will have to recuse themselves from the *ad hoc* adjudication committee and will be replaced by additional members of the CAG Board of Directors or CAG Operation Committee.

Failure to disclose: Any guideline panel member who is suspected of having failed to disclose a relevant COI at the time of disclosure to CAG or having failed to disclose to CAG a new COI acquired during the time since he or she was appointed to the panel will be contacted by the CAG Ethics and COI Committee and asked to update their disclosures. Previously undisclosed COI that are confirmed will be categorized as manageable or disqualifying as described above. The panel member will be permitted to remain on the panel if the COI is regarded by the CAG Ethics and COI Committee as a manageable COI, but will need to either resign from the panel or be permitted by CAG to immediately discontinue the pertinent relationship if the COI is regarded as a disqualifying COI. In either case, any matters in which the panelist participated in decision-making related to their COI will need to be reconsidered, including formulating, writing, voting on, and grading recommendations. In keeping with the CAG policy on professionalism and ethical conduct, failure to disclose COI in a manner that appears to CAG to be deliberate rather than inadvertent may result in penalties that could include the following:

- A. Immediate removal from the guideline development panel;
- B. Elimination of any opportunities for authorship associated with the guideline;
- C. Disqualification from participation in any future CAG clinical practice guidelines;
- D. Reasons for removal will published in the actual guideline document.

Undisclosed COI that are discovered following publication will necessitate publication of an erratum that describes the failed disclosure.

References:

1. Schunemann HJ, Al-Ansary LA, Forland F, et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med* 2015;163:548-53.

2. Schunemann HJ, Osborne M, Moss J, et al. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *Am J Respir Crit Care Med* 2009;180:564-80.
3. Kelsall D. Updated CMAJ policy on undisclosed competing interests. *CMAJ* 2019;191:E116-E117.
4. Qaseem A, Wilt TJ, Clinical Guidelines Committee of the American College of P. Disclosure of Interests and Management of Conflicts of Interest in Clinical Guidelines and Guidance Statements: Methods From the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med* 2019;171:354-361.
5. BMJ. BMJ policy on conflict of interest, 2014.
6. Hill J, Bullock I, Alderson P. A summary of the methods that the National Clinical Guideline Centre uses to produce clinical guidelines for the National Institute for Health and Clinical Excellence. *Ann Intern Med* 2011;154:752-7.
7. Ngo-Metzger Q, Moyer V, Grossman D, et al. Conflicts of Interest in Clinical Guidelines: Update of U.S. Preventive Services Task Force Policies and Procedures. *Am J Prev Med* 2018;54:S70-S80.
8. American Gastroenterological Association (AGA)/AGA Institute Policy on Disclosure of Potential Conflict of Interest.

CAG ETHICS AND CONFLICT OF INTEREST COMMITTEE

TERMS OF REFERENCE

Ethics and Conflict of Interest Committee members are encouraged to use (a) the following definition of conflict of interest and (b) the **significance scale** accompanying this document as a guide in determining significance and the level of resolution needed. The Committee should also be familiar with the **Policy for Management of Conflicts of Interest in the Development of CAG Clinical Practice Guidelines**.

Definition of Conflict of Interest (COI):

In the context of CPG, a conflict of interest exists when an individual's personal interests (e.g. direct financial and indirect COIs such as academic advancement, clinical revenue streams, community standing, and scientific interest) have the potential to compete with or influence behavior related to the individual's professional interests or obligations (i.e. evaluating the evidence and developing recommendations for clinical practice guidelines).

In relation to CAG guideline development process, "conflict of interest" applies to current interests. CAG has defined current interests as those that have arisen during a period of **2 years preceding** the invitation to participate on the guideline panel. In this regard, the term "conflict of interest" does not apply to past interest that have expired or that no longer exist nor does it apply to possible interests that may arise in the future but which do not currently exist.

Significance Scale

(see Significance Scale that accompanies this Procedures document to recommend course of action for each panel member)

Recommended actions may include:

- **Minimal COI (only public disclosure)**: panel members may be allowed to participate in the discussion and vote on all recommendations
- **Moderate COI (Recusal from voting)**: panel members may be allowed to participate in the discussion related to the declared interest, but will be excluded from voting on specific recommendations
- **Significant COI (Recusal from discussion and voting)**: panel members may not be allowed to participate in the discussion related to the declared interest, and will be excluded from voting on specific recommendations
- **Excessive COI (Total exclusion from the CPG)**

Methods of Resolution

The following are regarded by CAG as appropriate methods of resolving COI affecting CPGs. Circumstances may warrant more than one of the following:

1. Balance of opinion:

CPGs should be designed to reflect a balance of opinion. However, structuring the format of an activity to be “balanced” does not alone resolve an identified COI. Other methods of resolution as recommended here should also be used.

2. Recusal from discussion or voting on particular recommendations when appropriate
Once the CPG panel has been assembled, COI of members should be discussed before beginning discussion of the evidence or developing recommendations during the face-to-face meeting. Co-Chairs and moderator should ensure that panel members are reminded of the specific COI before discussion of individual PICO or recommendations on which those COI bear. If the COI are significant, the participants should be recused from discussions or decision-making on particular recommendations.

3. Peer review to ensure recommendations reflect the best available evidence
Recommendations should always reflect the best available evidence. Where significant COI has been identified, peer review of content by CAG Clinical Affairs, and/or outside peer reviewers can attest that the content is evidence-based.

4. Disclosure to consumers of CPG documents
The perception of COI in CAG CPG should be minimized. Though it is likely impossible to have CAG CPG without any potential COI, the process for declaring and resolving COI can be made transparent. COI should be published with CPG documents, and reference should be made to the policies and processes used to identify and resolve COI.

5. The individual does not participate in the CPG
At times, CAG (i.e. Ethics and Conflict of Interest Committee, Clinical Affairs) may judge that an individual’s COI cannot be adequately resolved through the above methods, and it would be in the best interests of CAG for the individual not to participate in the CPG.

PROCEDURE FOR RESOLVING CONFLICT OF INTEREST (COI)

CPG proposal submission to include DOI forms from both potential co-chairs

Ethics and COI Committee review the DOI forms for both potential co-chairs as well as GRADERS and methodologists

Co-chairs are either approved with no COI issues (or one can have manageable COI). If both are conflicted, then a replacement co-chair needs to be found

Once MOUs are signed, approved co-chairs & methodologists can begin developing PICO questions

CAG Project Manager asks guideline panel members to complete and submit DOI forms

1-A

Ethics and COI committee review the DOI forms for each invited panel member using the "significance scale"

1-B

If no COI issues are determined, Go to Step 2

If significant COI issues are determined, Use one of the Step 1-C

1-C

Panel member decides not to resolve the significant COI issues and declines the invitation to participate in the CPG

Resolve according to the definition of COI and the "significance scale" and methods of resolution of COI provided to the Ethics and COI Committee.

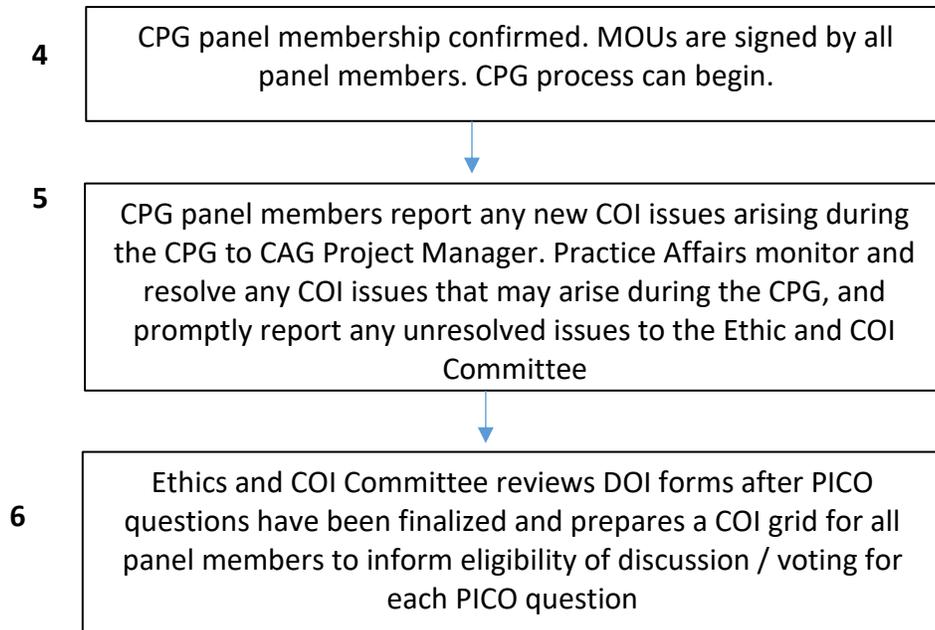
If help is needed to resolve:
1) Consult Ethics and COI committee
2) Clinical Affairs may be contacted for assistance at any point.

2

Ethics and COI Committee report to Practice Affairs the results of their COI review and management, using the Summary Form

3

CAG Project Manager and Practice Affairs review the Ethics and COI Committee reports and confirm to VP Clinical Affairs that the COI process has been completed appropriately.



Note: CAG project manager for CPG should be copied on all correspondence in regard to the above processes as described for resolving COI. An electronic log of all correspondence will be kept in the CAG office.

CANADIAN ASSOCIATION OF GASTROENTEROLOGY
METHOD FOR EVALUATING THE SIGNIFICANCE OF A POTENTIAL COI:
SIGNIFICANCE SCALE
Adapted from the American Thoracic Society

User instructions

Step 1. In Table A, select a monetary and/or nonmonetary “value” on the scale labeled adding up all declared values on the DOI form.

Step 2. In Table A, determine the “weight” using the column labeled “weight”.

Step 3. In Table B, rate the “Relevance” of a potential COI by choosing a descriptor or number.

Step 4. Calculation:

Total score = weight (Table A) x relevance (Table B)

Score range: 0 to 18

Use this Total score to determine the action required to manage or resolve COI (see Step 5).

Step 5. Interpretation and suggested action(s):

Total score 0 to 2: no further action required.

Total score 3 to 18: evaluate whether further action is required, including in regard to membership on a guideline panel or refraining from specific activities such as discussing and/or voting on specific recommendations. **Suggested actions:**

Minimal COI (3 to 6): Only public disclosure. May be allowed to participate in the discussion and vote on all recommendations

Moderate COI (7 to 10): Recusal from voting. May be allowed to participate in the discussion related to the declared interest, but will be excluded from voting on specific recommendations

Significant COI (11 to 14): Recusal from discussion and voting. May not be allowed to participate in the discussion related to the declared interest, and will be excluded from voting on specific recommendations

Excessive COI (15 to 18): consider total exclusion from this CPG

Examples of interpretation:

A statistician has received \$30,000 in consulting fees and \$25,000 as research grant from an endoscopic device company “X” (Company X: Value category 3, weight 3). He is invited to work on immunization in inflammatory bowel disease guideline by CAG. The Ethics and conflict of interest committee judges that the involvement with company “X” has no relevance to the guideline (relevance: 0). The total score = weight 3 x relevance 0 = 0. No further action is required.

A clinical researcher has received a honoraria (\$10,000) from a for-profit sponsor company “X” (Company X: Value category 3, weight 3) that is related to exploring the efficacy of a medication that will be discussed as one of many medications by a guideline panel making recommendations for this and other interventions (relevance 3). The total score = weight 3 x relevance 3 = 9. Actions by the Ethics and Conflict of Interest Committee may include the request for the panel member to refrain from voting on specific recommendations about this particular product.

Table A. “Weight” of Potential Conflict of Interest (COI) Based on “Value”

Value Category (Monetary and/or Nonmonetary)*	Weight
Up to \$1000	1
\$1001 - \$5000	2
More than \$5000	3

* Select a value category for the potential COI that reflects both monetary and non-monetary value combined (see ‡, §, ¶ below to determine any non-monetary value). Include direct or indirect financial interests such as research grants or similar (based on categories and ranges specified by the CAG Ethics and Conflict of Interest) in CAN\$.
 ‡ Example of nonmonetary value in category 1: a pen, pencil, cell phone.
 § Example of nonmonetary value in category 2: paid tickets to the Super Bowl or World Cup final for the family.
 ¶ Example of nonmonetary value in category 3: free first-class ticket to Australia from North America for spouse or family.

Table B. Relevance to the Topic

	None	Very Low	Low	Moderate	Moderate to High	High	Very High
Relevance	0	1	2	3	4	5	6
Description	Topic of interest is not relevant and unrelated to a competing interest			Topic of interest is somewhat relevant and related to a competing interest			Topic of interest is highly relevant or directly related to the declared competing interest
Examples	A statistician involved in a CPG on immunization in IBD who consulted for an endoscopic device company	A methodologist has given a methods focused presentation at an event sponsored by a for-profit organization whose products will be discussed by a CPG panel	A researcher has received personal honoraria for speaking about medications that is produced by a sponsor. Other products of this sponsor will be discussed by a CPG panel.	A researcher has received personal honoraria for speaking about a medication that will be the topic of a recommendation in a CPG.	A researcher’s career is focused on the exploration of a topic about which a recommendation for additional resources will be made to a funding agency.	A clinical researcher has received a research grant and/or honoraria from a for-profit sponsor that is related to exploring the efficacy of a medication that will be discussed by a CPG panel. The CPG panel may make recommendations for its use.	A researcher is the owner or major shareholder of a company that produces a device or medication about which a recommendation will be formulated by a CPG panel.