ANALYSIS

# Managing conflicts of interest in the development of health guidelines

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Public awareness regarding the importance of disclosing and managing conflicts of interest (COIs) during the development of clinical practice and public health guidelines is growing, owing to recent high-profile news stories within and outside Canada.[1–9] Despite the existence of guidance on the development of high-quality guidelines,[10] and although a broad range of standards, principles and policies have been developed for mitigating the effects of COIs on guidelines,[11–19] specific approaches vary widely among guideline producers. Some organizations take a stricter approach — excluding participants with any COI from guideline development — while others have no publicly available policies to indicate how COIs are managed.[20,21]

We discuss best practices for managing COIs in the development of health guidelines, drawing on the approach articulated by the Guidelines International Network (GIN),[12] as well as on an environmental scan of the Canadian and international landscape, interviews with Canadian guideline developers and feedback received from various stakeholders through a Canadian Institutes of Health Research (CIHR) Best Brains Exchange[22] (Appendix 1, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.200651/tab-related-content). We also provide an online toolkit to support the implementation of robust processes for COI management (https://wiki.gccollab.ca/PHAC_Conflict_of_Interest_Toolkit_for_Guideline_Development).

### KEY POINTS

- Disclosures of interests and appropriate management of conflicts of interest (COIs), when identified, are essential to producing high-quality, credible health guidelines.
- Through environmental scanning of the Canadian and international landscape and feedback from various stakeholders, we identified a need within the Canadian guideline community for leadership and advice on implementing best practices on COI.
- We have developed practical guidance and a toolkit to help guideline developers implement the Guidelines International Network principles on COI, resulting in stronger policies on COI and protecting the scientific integrity of Canadian health guidelines.

## Why is it important to carefully manage COIs in the development of guidelines?

Guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[11] When developed using transparent and rigorous methods, guidelines can help practitioners to deliver care that is consistent with the best available evidence. Guideline development requires judgments about which evidence to include; the certainty of that evidence; the balance of benefits, harms and other desirable and undesirable consequences; and the strength of recommendations.

Conflicts of interest represent situations in which the judgment of an individual may be unduly influenced (consciously or not) by a secondary interest, such as the opportunity to derive personal benefit.[11] Although COIs can be financial, they can also be nonfinancial, arising from a competing professional, academic, personal or political role. Not all interests constitute a COI, and an assessment is needed to make this determination.[23] Conflicts of interest can bias recommendations (e.g., overly strong or enthusiastic for a particular intervention) and ultimately be harmful to patients and the health system if biased recommendations are implemented.[21] Guidelines for which COIs have not been appropriately managed may not be credible to stakeholders, in turn diminishing their impact or reducing confidence in the guideline endeavour.[24]

The involvement of individuals with content expertise is essential for enhancing the value of guideline recommendations. For example, content experts can provide unique insight into published research, help to identify relevant data or suggest clinically important nuances for interpreting the evidence. However, these individuals may have interests that could lead to COIs. Therefore, guideline development requires striking a balance between the needs to inform the guidance by sufficient expertise and to minimize the impact of COIs. Further, COIs are not restricted to content experts: they may arise for anyone who participates in guideline development, including funders of guidelines, systematic review authors, guideline panel members, patients or their representatives, peer reviewers, and

researchers who advance scholarship in guideline development methods, dissemination and implementation. Finally, COIs can arise at any stage of guideline production, from topic selection to incorporating comments received during peer review. These considerations highlight the importance of a deliberate and thoughtful approach to avoiding and managing COIs in guideline development.

## What approaches have been developed for managing COIs in guideline development?

### International approaches

The World Health Organization,[23] the National Institute for Health and Care Excellence,[25] the United States Preventive Services Task Force[26] and the American College of Physicians[27] have all recently updated their policies and procedures on COIs, including those for mitigating guideline-related COIs. All policies define which financial and nonfinancial interests should be disclosed, describe the core elements of disclosure (such as whether both individuals and family members are covered), state the look-back period and specify how often disclosures are to be made. These organizations have also clarified how interests will be assessed and provided a range of options for the management of COIs (Table 1).[23,25–27]

Legislation in France requires all participants involved with health-related guideline development to make comprehensive declarations of interest and prohibits individuals with COIs from participating in guideline-related activities.[28] Individuals who do not disclose a relevant interest can be liable for up to 5 years' imprisonment and €75 000 in fines. Further, decisions and advice from the Haute Autorité de Santé can be stricken or reversed by legal authorities if it is deemed that interests were not properly disclosed and managed.[28]

The International Committee of Medical Journal Editors (ICMJE) has also revised its guidance to authors about the importance of disclosing COIs in scientific publications, specifying that "purposeful failure to disclose conflicts of interest is a form of scientific misconduct."[29] Additionally, the ICMJE has proposed updates to its widely used disclosure form, improving clarity with respect to what financial and nonfinancial interests need to be reported, and clarifying that disclosed interests are not necessarily COIs.[30] The committee also suggested mechanisms for reducing the workload associated with disclosure, such as online repositories like Convey,[31] and encouraged "the development of other repositories as necessary to meet regional, linguistic and regulatory needs."[30]

Finally, in 2015, the GIN, a global network of guideline developers that aims to promote best practices in the development of high-quality guidelines,[32] developed a set of 9 principles (Box 1) to provide guidance on how financial and nonfinancial COIs should be both disclosed and managed, based on a review of the published literature and organizational policies.[12]

### Canadian developments

The Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec recently updated its COI policy, bringing it into alignment with the GIN principles and differentiating between interests and COIs, outlining how interests will be assessed for COI and how COIs will be managed when identified.[33] The Canadian Task Force on Preventive Health Care also recently reviewed its policies on COIs to ensure consistency with GIN and has included an assessment of the specific actions taken in response.[34]

Shortly after the CIHR 2019 Best Brains Exchange[35] meeting on COIs in guidelines,[22,36] *CMAJ* announced a new approach to managing COIs, generally[37] in response to the revised ICMJE guidance, and specifically in guidelines,[38] indicating that all guidelines submitted to the journal from 2020 onward must adhere to the GIN principles to be eligible for publication.[38]

Groups that develop or fund guidelines, such as governments, nongovernmental organizations, specialty groups and others across Canada, will need to work together to support more consistent implementation of best practices. While gathering feedback from stakeholders (Appendix 1), we found that guideline developers requested leadership and advice on how to implement the GIN principles, and we aim to meet that need in this article.

## How can guideline developers overcome challenges that may arise when implementing the GIN principles?

### Defining key terms

Immediate tasks for each guideline developer will be to define key terms. For example, developers could define financial COIs using thresholds that are more (e.g., any amount of financial relationship) or less (e.g., payments of > $10 000) stringent. Definitions of nonfinancial COIs can encompass a wide range of secondary interests, and overly broad interpretation of such interests as conflicts could make nonfinancial COIs "appear so pervasive that they cannot be avoided but only disclosed."[39,40] Guideline developers should therefore take care to identify factors that differentiate interests from COIs (such as if a reasonable person would consider the interest to unduly influence the individual's judgment as a member of the guideline panel[26]). Developers may also consider that overly inclusive lists of nonfinancial interests that constitute COIs could inappropriately burden, infringe on the privacy of, or lead to discrimination against those who must fill out disclosures.[40] Developers seeking to implement the GIN principles may wish to consult other groups that have established definitions.[12,20,21,23,25–27,28]

### Guideline panel composition

Once key terms have been defined, developers can operationalize and implement the GIN principles (expanded guidance can be found in Appendix 2, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.200651/tab-related-content, and a checklist for GIN principle implementation in Appendix 3 at www.cmaj.ca/lookup/doi/10.1503/cmaj.200651/tab-related-content). Principle 1 states that only "a minority" of panel members should have COIs, without specifying a proportion.[12] Developers may feel that a more restrictive threshold (i.e., closer to 0%) will reduce the expertise of the panel, thereby compromising the value of the recommendations. However, if a less-stringent threshold is chosen (i.e., closer to 49%), the panel may have too high a burden of conflict for the guideline to be credible. Developers should also consider that not all COIs are necessarily equal. For example, the presence of just 1 or 2 panellists with substantial financial COIs could unduly compromise the credibility of the panel.

**Table 1: Options for the management of conflict of interests from various organizations**

| | Group | | | |
|---|---|---|---|---|
| **Option "category"** | **National Institute for Health and Care Excellence (2018)[25]** | **United States Preventive Services Task Force (2018)[26]** | **Guidelines International Network (2015)[12]** | **World Health Organization (2014)[23]** |
| Full involvement (disclosure only) | No action other than the process of open declaration — the person can engage in all aspects of the committee's work. This is usually because nothing is considered to represent a perceived COI, but may in some circumstances be because an open declaration is considered sufficient to mitigate any risk of conflict. Open declaration will usually be sufficient if a financial interest occurred in the last 12 months and is no longer held; for example. In these cases, the potential to benefit has ceased. | Information disclosure only. Member may participate as primary lead,* and discuss and vote on the topic. | Not applicable | No action required beyond declaration at the guideline development group meeting and reporting in the published guideline. |
| Limited involvement | The person can engage in committee discussion or provide advice (for example, because of their expert knowledge), but is excluded from developing recommendations and decision-making on the matter relating to their declared interest. Involvement may be limited to answering questions from the committee. | • Member may not participate as the primary lead of the topic specific to the conflict, but may serve as a nonprimary lead* on the topic workgroup and discuss and vote on the topic.<br>• Member may not participate as the primary spokesperson for the topic specific to the conflict, but may serve as a nonprimary lead on the topic workgroup and discuss and vote on the topic.<br>• Member may not participate as a lead in the topic workgroup specific to conflict, but may discuss and vote on the topic. | • Panel members with any form of COI cannot be chairs of the working group.<br>• A co-chair with no COIs can be appointed if a chair with COI is unavoidable.<br>• Panel members with a relevant financial COI should not be involved in deciding about the direction or strength of a recommendation. These members should not participate in this phase of guideline development and should be physically absent from the discussion about the direction and strength of the recommendation. | • The individual with the conflict may be excluded from the formulation of specific recommendations but allowed to participate in all discussions.<br>• The individual with the conflict may be barred from participating in discussions as well as in the formulation of the recommendations. They can be asked to leave the meeting during the development and ratification of any recommendations related to their COI. |
| No involvement (complete exclusion) | The person can have no input to a specific topic, either from the start (nonappointment) or for part of the committee's work relating to that topic. It may be appropriate in these cases to withhold any confidential meeting papers for that item, especially when the person could benefit from the information. | Member may not participate as a lead on the topic workgroup specific to the conflict, or discuss or vote on the topic. Member will leave the meeting room for all discussion and voting. Member's recusal will be denoted in the publicly released recommendations. | Not applicable | No participation is allowed — the COI is deemed serious enough to preclude membership in the guideline development group or participation as a contractor for the World Health Organization in a specific guideline development process. |

Note: COI = conflict of interest.
*"Each topic team (see US Preventive Services Task Force Procedure Manual Section 1.9) includes the Agency for Healthcare Research and Quality Medical Officer, a Task Force chair or co-vice chair, representatives from the evidence-based practice center conducting the systematic evidence review, and several Task Force members, known as 'leads.' One of the Task Force leads serves as the primary lead for that topic."[2]

We suggest that the allowable threshold for panel members with COIs should be developed on a group-by-group basis, considering their thresholds for different forms of COI in the context of their panel's mandate, as well as the following points. First, GIN principle 7 suggests that expert input can be obtained from individuals who are not members of the panel, such as expert advisers. In such cases, the guideline panel could be composed primarily of panellists without COIs who seek input from these advisers to inform

**Box 1: Guidelines International Network: principles for disclosure of interests and management of conflicts in guidelines[12]**

- Principle 1: Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect conflicts of interests (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 (for example, annually for standing guideline development groups).
- 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 be appointed.
- 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.



their judgments about the relative benefits and harms of an intervention.[41,42] By analogy, a judge ruling on a case of breach of contract for construction services does not need to be an expert in construction standards. Rather, the judge is an expert in jurisprudence who weighs the evidence from both parties, together with input from content experts (e.g., engineers).

Second, to find panellists without COIs, developers might consider broadening their search beyond their usual pool of candidates to include those at earlier career stages, from other clinical areas or even from other disciplines, provided that they have the requisite skills for guideline development; this will also increase the diversity of perspectives in the process. Third, panels may also obtain expert input through consultations, peer review or other external review processes — although disclosures of interests should be completed by all reviewers for panels to consider when interpreting comments.

Fourth, organizations should develop clear policies for how COIs will be managed, so that rules for participating are clear to prospective panellists. The knowledge that receiving financial benefits from an entity may preclude future participation in a guideline panel (see principles 6 and 8) will place the responsibility of accepting such benefits on the prospective panellist. Fifth, once policies are finalized, developers will need to consider the anticipated total number of recusals for discussions on any given topic when selecting panel members. As this can be challenging, an approach that recruits panellists without COIs is preferable.

### Establishing procedures

Principle 6 states that the panel chairs must be free of COIs.[12] Principles 7 and 8 indicate that experts and panellists with COIs may be permitted to participate in panel discussions, but that members with financial COIs should be physically absent from discussions "about the direction and strength of the recommendation."[12] Managing the restrictions of principle 8 will require strong leadership from panel chairs, along with explicit policies to guide how input is sought and incorporated. For example, groups should determine and describe in advance the potential management options when a COI is identified, enabling transparency and consistency in application.[23,25–27]

### Transparency

Public disclosure of COIs, regular updating of COI information and declaration of interests by panellists are addressed by principles 3, 4 and 5.[12] Implementation of these principles will require the availability of suitable forms for recording secondary interests and decisions regarding COIs and a platform for making this information publicly accessible. Groups should also consider whether they will verify COI declarations, and how they will deal with inaccurate declarations. The online toolkit (https://wiki.gccollab.ca/PHAC_Conflict_of_Interest_Toolkit_for_Guideline_Development) includes sample forms for collecting COIs. Groups may also consider using or adapting the updated ICMJE forms, or online repositories, as appropriate.[30]

### Oversight committee

Principle 9 specifies that guideline developers should strike an oversight committee to develop, manage and implement COI policies, including much of the work described above.[12] Oversight committees may be asked to make decisions about how to deal with unique COI situations of various panellists and experts. As with guideline development itself, these decisions will require judgment, which can be facilitated by transparent rules and procedures for identifying and managing COIs.

Although the GIN principles do not explicitly say so, members of oversight committees should be free of COI, and these committees may include independent members drawn from outside the guideline developer's organization. When an organization developing a guideline depends on industry funding and produces guidelines related to products from industry partners, the oversight committee would ideally be extra-organizational.[43]

## What tools are available to assist Canadian guideline developers?

At the Best Brains Exchange, participants highlighted the need for national leadership to help Canadian developers improve the disclosure and management of COIs in guidelines. Accordingly, as mentioned earlier, the Public Health Agency of Canada's Guidance Innovation Hub offers an online toolkit (https://wiki.gccollab.ca/PHAC_Conflict_of_Interest_Toolkit_for_Guideline_Development)

to assist internal and external developers of guidelines in implementing the GIN principles and other best practices for disclosing and managing COIs. In addition to providing sample COI forms, the toolkit highlights resources from various groups that describe how hypothetical financial and nonfinancial COIs might be handled by developers, including a discussion of factors that might be considered when making these judgments.

## What important issues have not been addressed by the GIN principles?

Although the GIN principles are an important framework for assessing and managing COIs, they are not exhaustive, and additional challenges remain. The GIN principles do not require sponsoring or funding organizations to disclose their interests and do not address other institutional conflicts of interest, such as funding from industry to universities, but the principles suggest that public and standardized disclosure forms are used that should include such funding, if known.[44] Because industry funding is common among Canadian guideline producers, more work will be required on how to ensure that these COIs are appropriately disclosed and managed.[43,45] Patient involvement in guidelines, particularly if patient partners receive funding to advocate for their condition, must also be considered. In addition to the potential future expansion of the GIN principles, journal editorial requirements and tools for evaluating guidelines[46–48] could both play a role in addressing these gaps. For example, one new tool obtains information directly from guideline group members on whether COIs were managed appropriately during development.[48]

## Conclusion

Conflicts of interest represent a potential threat to the trustworthiness, credibility and utility of guidelines produced in Canada and abroad. The GIN principles represent a rigorous approach to identifying and managing such interests. Although implementation may pose challenges, international and domestic examples suggest that this goal is feasible. Implementing the GIN principles will help to protect the integrity, scientific rigour, transparency and accountability of Canadian guidance.

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