Conflicts of Interest Ethics: Silencing Expertise in the Development of International Clinical Practice Guidelines

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Background: It is unclear whether global experts with financial conflicts of interest (FCOIs) should be included in, be excluded from, or have a limited role in developing international clinical practice guidelines (CPGs). Optimal management of FCOIs to ensure independent, expert CPGs remains ethically contested.

Objective: To manage FCOIs and examine whether an ethics framework with discussion recusal by experts with FCOIs affects deliberations and voting on a CPG.

Design: Development of an ethics framework grounded on transparency and proportional management of COIs, including self-recusal, evaluation of the effect on COIs and CPG process by quantification of voting on recommendations, and qualitative assessment of experts' ethics dialogue.

Setting: International consensus meeting to formulate a CPG in gastroenterology.

Participants: 34 experts from 15 countries.

Measurements: Counting the votes of experts with and without declared FCOIs and qualitative assessment of ethics discussions.

Results: 62% of experts reported at least 1 FCOI. Eight out of 21 recommendations presented potential FCOIs. Experts with conflicts recused themselves from discussing 6 of the 8 recommendations, leaving a majority of nonconflicted discussants (median, 22; range, 19 to 26) for the 6 recommendations. Recusals did not affect voting outcomes but may have diluted the richness of the discussions. Ethics dialogue revealed accord on transparency but under-scored challenges to proportional management of COIs beyond basic disclosure. Concerns about bias, COI definitions, expertise, and integrity express important international ethics questions.

Limitation: Small participant numbers and application of the framework to only 1 meeting of 1 CPG.

Conclusion: An ethics framework may help to identify and manage COIs and catalyze both ethics dialogue and innovative COI standards that seek to balance impartiality and expertise for trusted CPGs. Optimal balancing remains contested. Recommendations include frameworks, interdisciplinary analysis, and international policy initiatives to better manage COIs in the CPG process.

Primary Funding Source: Canadian Association of Gastroenterology; European Association for Gastroenterology and Endoscopy; Asian Pacific Society of Digestive Endoscopy; and Institute of Diabetes, Metabolism, and Nutrition of the Canadian Institutes of Health Research.


* The Appendix (available at www.annals.org) provides a full list of the members of the International Consensus Upper Gastrointestinal Bleeding Conference Group.

Clinical practice guidelines (CPGs) are adopted to guide decisions and manage conditions by linking evidence with clinical judgment. Their contribution to standards of care presumes that they represent impartial expertise for the good of physician–patient decision making. However, that ethical foundation has come under challenge, as the relationship among industry, physicians, and CPGs generates debate on the standards, effect, and management of financial conflicts of interest (FCOIs).

Over the past decade—amid disclosure rates ranging from 3.7% to 71.2% (1–4)—FCOIs have been increasingly documented, as industry affiliations of CPG authors have sometimes reached 87% to 90% (5, 6). The relationship has been deemed a “pervasive” (7) and “profound and extensive problem” (8). It has attracted the scrutiny of a burgeoning interdisciplinary literature on bias (9, 10), which has questioned CPGs on cardiovascular conditions (11–13), sepsis (14, 15), anemia (16), and psychiatric disorders (6) for undisclosed, undocumented, or preponderant FCOIs.

In 2011, a French court annulled a government CPG on diabetes for apparent failure to adhere to COI law (17). Similar questions dog global public health guidance (18, 19); international organizations are thus refining COI procedures for their scientific panels (20). Professional societies (21–23); the Association of American Medical Colleges (24); industry (25); the Institute of Medicine (26, 27); and U.S. (28), pan-European (29), British (30), and French (31) government health authorities have recently revised COI policies or adopted reports.

Such reforms may soon inspire uniform, coherent, and detailed standards. Meanwhile, physicians’ codes of ethics (32, 33) compound ethical uncertainty by silence on the issue. Should experts with COIs be included in or excluded or limited from deliberating, drafting, or voting on guidelines?

We confronted this question for the discussion and voting of an international CPG (34). To address it, we...
developed a COI ethics framework under which experts recusing themselves from scientific discussions could nevertheless vote on CPG recommendations. We report on the COI ethics exercise by examining the content and implementation of the framework; recusals, outcomes, and expert perceptions; and critical ethics questions and policy recommendations for managing COIs in the CPG process.

METHODS

An international CPG on management of upper gastrointestinal bleeding (34) was developed by a multidisciplinary group of 34 experts from 15 countries. The CPG process followed national CPG standards (35), which adopted the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument (36).

CPG Meeting Process

In preparation for the meeting, a 4-member steering committee—all of whom had previously declared FCOIs—reviewed published guidelines on the topic and identified 20 previously published and 44 new potential recommendations that warranted updates or guidance. The selection was reduced to 21 draft recommendations (including 19 updates) through online voting by all participants.

The steering committee developed and approved search strategies for related evidence. Two participants sorted through literature by using predefined inclusion or exclusion criteria to identify pertinent evidence; a third party without conflicts validated the findings and extracted data from selected studies by using standardized forms. They then synthesized these data into systematic reviews (37–43) that were circulated to all CPG members. Final formulation of each resulting recommendation and grading of its evidence through use of the Grading of Recommendations Assessment, Development and Evaluation approach (44) by all participants followed a validated, modified Delphi process. Each recommendation was subsequently subject to a 6-point Likert scale to quantify agreement; 75% group approval was required for adoption.

An Ethics Framework for COIs

The process conformed to the ethics norms of the Canadian Association of Gastroenterology (45), the Canadian Medical Association (46), and the Accreditation Council for Continuing Medical Education (47). Such national norms afforded little detailed guidance on managing potential COIs with global experts.

An independent consultant advised the development of an ethics framework of integrated COI standards, process, and structures. It draws on evolving standards (24, 25, 28, 32, 46–51) and includes creation of a COI advisory committee and a COI “toolbox” (Table 1). The toolbox consists of transparency in financing and decisions, disclosure of COIs, firewallsing information, restricted roles or recusals of individuals with COIs, proportionality between COI risks and COI management strategies, and documenting COI process.

The COI advisory committee identified 4 likely loci of FCOIs: meeting funding by industry sponsors, industry relations with experts, discussion and voting process, and dissemination and publication of results. To evaluate FCOIs, each expert completed a mandatory premeeting financial disclosure form. The COI advisory committee defined “FCOI” as any financial relationship—encompassing actual, potential, and perceived FCOIs—that a professional shared in the past 2 years with commercial entities having economic, commercial, or competing scientific interests in decisions about the CPG (Table 2).

Financial declarations were reviewed by the Canadian Association of Gastroenterology office and COI advisory committee and distributed to participants before face-to-face deliberations. To maximize the integrity of the process and manage FCOI risks in the absence of uniform international definitional thresholds, the committee considered any FCOI “significant.” Significant FCOIs were presumed to invoke limitations on participatory roles in the meeting.

To frame the discussion, content experts (persons other than those who researched the literature to prepare systematic reviews) reviewed the prepared evidence for each recommendation before the face-to-face meeting. The content experts prepared slides based on the evidence reports; the slides were reviewed for bias by the COI advisory committee. Selected content experts were assigned to present slides for the different recommendations. However, draft CPG recommendations likely to implicate economic interests of medical device or drug manufacturers were identified as being at risk for FCOIs by the COI advisory committee and were managed differently.

Under the ethics framework, content experts presenting evidence for these recommendations identified as “at risk” were to be free from bias unless their expertise was deemed necessary to afford essential (that is, unique or otherwise unavailable) input (Table 1). For all recommendations at risk, experts with conflicts were invited to recuse themselves from discussions at the meeting but thereafter joined experts without conflicts in voting (Table 1).

Voting was done by private electronic touchpad, so no one knew how another person voted. All experts voted, because votes would be tracked and those of recused experts could be discounted if “conflicted” votes would determine the outcome of a recommendation. The meeting concluded with a group discussion about ethics that everyone attended and a postmeeting online COI dialogue.

Framework Evaluation: Quantitative and Qualitative Analyses

Participants were briefed on the COI ethics framework at the start of the meeting. However, to avoid affecting voting results, they were not informed beforehand that voting results could be discounted. They were so advised after voting had been completed. Written consent to use ano-
nymized data was obtained. Because the purpose of the exercise was policy formulation and evaluation, review of research ethics was not sought.

Elements of the applied ethics framework were examined, including the COI process, voting outcomes, and effect of recusals. Quantitative voting data were collected for each statement. Qualitative analysis of the ethics commentary was performed after coding and thematic grouping by using modified grounded theory (52).

Role of the Funding Source

Conference funding was provided by the Canadian Association of Gastroenterology; European Association for Gastroenterology and Endoscopy; Asian Pacific Society of Digestive Endoscopy; and Institute of Diabetes, Metabolism, and Nutrition of the Canadian Institutes of Health Research and by arms-length contributions from AstraZeneca Mölndal (Sweden), Abbott Canada, and Olympus Canada to the Canadian Association of Gastroenterology. The Canadian Association of Gastroenterology administered all aspects of the meeting and provided additional in-kind support. The funding sources had no role in developing recommendations, abstracting data, synthesizing results, grading evidence, or preparing or submitting the manuscript.

RESULTS

Types of COIs

Sixty-two percent of our CPG experts (21 out of 34) reported at least 1 FCOI in the following categories: speakers’ bureau (53%), research support (35%), consultant (26%), advisory board (18%), employee (0%), and stock or equity (0%) (Table 2). Experts with conflicts reported a median of 6 FCOIs (range, 1 to 15) and a median of 2 categories of FCOI (range, 1 to 4).

CPG Recommendations at Risk for FCOIs and Voting Outcomes

Eight of 21 recommendations were designated as being “at risk” for FCOI (34). Experts with potential FCOIs recused themselves from discussions for 6 recommendations; 2 recommendations prompted no self-recusals because no expert perceived a relevant FCOI. We required recourse to conflicted experts with unique expertise to discuss and give a presentation on evidence for 2 recommendations. The median number of recusals per recommendation was 12 (range, 8 to 15), leaving an average of 22 nonconflicted discussants (range, 19 to 26) per recommendation.

Fifteen recommendations were discussed and voted on by all 34 experts; 6 recommendations were voted on by all 34 on the basis of discussion by an average of 22 experts (Figure). The overall voting outcomes (agree vs. disagree) did not change when votes of recused members were included (Figure). No “conflicted” votes were discounted because none affected the outcome of a recommendation.

Qualitative Analysis: Ethics Concerns

All experts attended a postvoting ethics session; 14 of 34 joined a subsequent online ethics conversation. All acknowledged the importance of addressing FCOIs while air-
The exercise enabled us to document, evaluate, manage, and debate COIs in CPG development. An evaluation revealed no effect on CPG voting outcomes by experts with FCOIs, but an apparent effect on the richness of scientific discussion by the recusals was found. The exercise also identified key COI ethics issues. We elaborate the outcomes and policy issues through 10 critical questions that survive the exercise.

How Frequent Are COIs Among Authors of CPGs?

Our exercise suggests that the high incidence of financial relations between international clinician-investigators and industry presents serious challenges to developing guidelines with experts free of potential FCOIs. Paralleling previous reports of a 35% to 87% frequency of FCOIs among authors of CPGs (3, 5), 62% of our experts declared some financial relationship with industry. The most prevalent categories of FCOIs were speakers’ bureaus, research grants, and consultancies, even if not all of the declared interests presented FCOIs, because some were irrelevant or remote. However, without uniformity of COI definitions, declaration standards, and screening procedures, comparing such figures warrants caution.

What Is a “Significant COI”?

Conflicts of interest may divide loyalties and impair independent professional judgment. The concept has yet to yield a uniform global definition of “significant COI,” with “primary,” “direct,” qualitative, and quantitative thresholds (26, 29, 53). As a result, international CPGs rely on national or institutional norms.

DISCUSSION

Absent uniform and comprehensive standards, we developed and implemented an ethics COI framework grounded on the proposition that, for the integrity and credibility of an international CPG, it may be ethical in some circumstances to exclude global experts with significant FCOIs who are involved in the process. We premised the framework on a proportionality principle that CPG participatory standards should be commensurate with COI risks. Applying this principle yielded a process by which experts with conflicts who recused themselves from scientific discussions at the CPG meeting nevertheless voted on recommendations.

Table 2. Distribution of Declared FCOIs*

<table>
<thead>
<tr>
<th>Category of COI§</th>
<th>Participants With COIs, n (%)‡</th>
<th>Total COIs, n†</th>
<th>Median COIs (Range), n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speakers’ bureau</td>
<td>18 (53)</td>
<td>44</td>
<td>2 (1–8)</td>
</tr>
<tr>
<td>Research support</td>
<td>12 (35)</td>
<td>35</td>
<td>3 (1–7)</td>
</tr>
<tr>
<td>Consultant</td>
<td>9 (26)</td>
<td>24</td>
<td>2 (1–6)</td>
</tr>
<tr>
<td>Advisory board</td>
<td>6 (18)</td>
<td>14</td>
<td>1 (1–8)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (9)</td>
<td>3</td>
<td>3 (1–1)</td>
</tr>
<tr>
<td>Employee</td>
<td>0 (0)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Stock/equity</td>
<td>0 (0)</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Participants and COIs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COIs per participant per category total¶</td>
<td>48 (–)</td>
<td>120</td>
<td>–</td>
</tr>
<tr>
<td>Participants with at least 1 COI</td>
<td>21 (62)</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

COI = conflict of interest; FCOI = financial conflict of interest.
* Significant FCOI is defined as any financial relationship in the past 2 years—encompassing actual, potential, and perceived COIs—that a professional shared with commercial entities having an economic, commercial, or competing scientific interest in decisions of the conference.
† Total number of participants is 34, 21 of whom have declared COIs.
‡ Participants could declare more than 1 COI per category.
§ The Canadian Association of Gastroenterology’s 2007 disclosure form grouped financial declarations into these categories. The form was based on analogous policies of the Canadian Medical Association and the 2004 policy of the Accreditation Council for Continuing Medical Education (46, 47).
¶ Participation in educational activities, as reported by 3 participants.
† A maximum of 1 COI per category, even if many COIs were reported for that category.

Sample quotations illustrate some concerns: “Since most of these experts work with many others . . . isolating people from discussion really accomplishes very little since they have worldwide influence already”; “Most of us are biased, in some way or another; personal experiences, perceptions, your own research . . . .”; “I think the quality of our discussion was diminished by muzzling participants with important expertise”; “The best experts are also most likely to be at risk of COI/bias because they are sought out by the industry, government, academia, etc.”; “The public understands that we have biases . . . However, they actually trust us to resolve those conflicts in the patient’s favor.”

Figure. Selected voting results for “at-risk” recommendations.
On the spectrum of 1 to 5 years (20, 29, 54), we used a 2-year period for declarations (Table 2). Broadening definitions reflect a belief that most conflicts warrant identification (30, 55); thus, 2011 U.S. law decreased the threshold for a “significant financial interest” from $10 000 to $5000 (56). We found that a focus on FCOIs does not address bias from intellectual or nonfinancial interests, although policies increasingly address them (30, 57).

Do COIs Affect CPG Voting and Discussion?

Our exercise paralleled findings that COIs may not affect voted recommendations (58) and revealed no substantial differences in the adoption of recommendations that include conflicted experts. All recommendations were voted on by a majority of nonconflicted experts. The outcome suggests that CPGs voted by a minority of experts with conflicts are generally unlikely to have recommendations altered by COIs. This parallels reforms to limit experts with conflicts on committees to a “distinct minority” (26).

Our COI standards more likely affected discussion. Experts with conflicts recused themselves from discussing 6 out of 21 recommendations, leaving a majority of nonconflicted experts. Although the statistics suggest a modest effect, colleagues raised concerns about diluted scientific discussion. Future analyses of how recusals affect discussion may benefit from quality assessment measures beyond the scope of our exercise.

Does Disclosure Suffice?

Conflict of interest disclosure practices may be inaccurate (4), inconsistent, and incomplete (59) and may increase biased advice (60). Still, standard use of financial declarations in international CPG process underscores disclosure as a basic COI management tool for transparency (61). In our exercise, some persons argued that disclosure suffices, which echoes the practice of declaring COIs before participating fully in decisional meetings. Yet, our ethics framework and others consider disclosure insufficient (28, 49, 62).

Unconscious Bias: A Role?

Competing theories may explain divergent views. Does “disclosure suffices” reflect “unconscious bias”? It arises in dual-role professionals “seduced” (63) into moral complacency and bias by ethically gray practices that become community norms (64), for example, FCOIs from systemic industry–physician relations (65).

Believing in one’s objectivity, minimizing COIs, and “biased information processing” are consistent with unconscious bias (10, 64). Or, does “disclosure suffices” reflect conscious choice? Sometimes, tangible expertise bests perceived impartiality. Answers should build on ethics codes, fiduciary duties, and increasing insights from the behavioral sciences (66) and enable interdisciplinary knowledge.

Table 3. Ethics Concerns Identified by Qualitative Analysis

| Criteria for self-recusal by experts with an FCOI seem subjective, and bias seems impossible to eliminate. Although FCOIs are emphasized, nonfinancial interests also present COIs. Screening for COIs may weaken the scientific process by excluding participants with important expertise. Some argue that once potential biases are made explicit, experts with FCOIs should participate in the discussion or vote. Others argue that there is no effect on the process if members with FCOIs vote. Some think that disclosure is insufficient to manage FCOIs. Although professional conduct affects public confidence, few believed that experts with FCOIs should recuse themselves to further public trust. Recusal decisions should come from an ethics committee rather than the participant. |

COI = conflict of interest; FCOI = financial conflict of interest.

How High the COI Standard?: Proportionality

Disagreement over which COI management tool suffices also flows from differing answers to a question: To what standard should CPGs be held? Proportionality calibrates COI processes to risks. Low risks demand disclosure; high risks demand limitations or exclusion. We reasoned that commercial influence creates substantial risks, because CPGs influence clinical thought, standards, and patients (67). Thus, some call for CPGs to be held “to the most stringent of COI standards” (68).

Does doing so mean that we ban or manage COIs? We found that if blunt prohibitions silence expertise essential for informed discussion and decisions (69), they poorly serve scientific integrity. Then, the optimal option is to manage COI risks with proportionality.

How to Manage COIs Beyond Disclosure?

After disclosure, should experts with conflicts participate in CPGs? Responses range from case-by-case analysis to inclusion or presumptions against inclusion (24) to exclusion from leadership roles (70), unless exceptions apply (26). The spectrum bespeaks an ethical pluralism of no “absolute rules” (71). However, each option asks whether or where to strike a balance.

Our exercise echoes international uncertainty (62, 72) in that we identified no simple response or universal solution. Absent detailed global norms, we developed an ethics framework (73) of integrated standards, process, and structures (Table 1). The framework helped to identify and manage FCOIs, catalyze ethics dialogue, and innovate procedures and pilot COI recusals.

Conflicted Experts: Voting or Discussion Roles?

Our exercise indicates that comparative risk analysis of COIs may refine CPG participatory roles. We applied it to modify one standard approach under which conflicted experts participate in discussion but recuse themselves from voting. The logic of the standard approach is that colleagues advised of COIs benefit from and weigh conflicted expertise in discussions but are not bound by COIs in decisions because conflicted experts do not vote.
How to Balance Expertise and Impartiality?

To manage COIs, we calibrated voting and discussion roles to risk–benefit. Under our modified approach, the votes of conflicted experts count, unless they determine their participation is “necessary for essential expertise” (Table 1). We invoked the discussion exception for unique methodological expertise.

Like U.S. reforms (75), the exception relies on the necessity to reconcile and balance the expertise and impartiality on which trust in medicine depends (76). Nonessential, conflicted expertise is excluded. A CPG ethics standard that limits participation of global experts with significant COIs to instances of demonstrable necessity seeks optimal risk–benefit equipoise.

COI = conflict of interest; CPG = clinical practice guideline.

Table 4. Policy Recommendations for COI Management

<table>
<thead>
<tr>
<th>COI policy reform</th>
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<tbody>
<tr>
<td>Rigorous, detailed, and effective guidance on COIs in the CPG process should be developed by international organizations, professional groups, universities, and industry.</td>
</tr>
</tbody>
</table>

Ethics frameworks

CPGs should be guided by coherent ethics frameworks that identify and manage COIs with robust standards, effective procedures, and accountable structures. Standards should reflect proportionality between COI risks and management procedures, such as recusals and exclusion. As a part of frameworks, independent COI or ethics committees enable interdisciplinary COI review, advice, and education.

Model policies and best practices

Opinion leaders with particular expertise (e.g., Council for International Organizations of Medical Sciences, professional and medical associations, interdisciplinary ethics groups) should translate their expertise into model policies and revised practices that make reasonably uniform COI definitions, procedures, standards, and norms to balance CPG independence and expertise when they conflict.

Interdisciplinary research and analysis

The conceptual, definitional, ethical, legal, empirical, theoretical, and policy facets of COI in the CPG process demand more interdisciplinary research and analysis. A research agenda (26) that targets knowledge and policy gaps warrants priority development.

CPG funding

Experiences with pooled monies should inspire creative consideration of independent funding options; for example, medical specialty organizations, government, foundations, and industry might partner to fund independent CPGs by creating a blind CPG trust fund as a 5-year demonstration project.

Summit

An international conference should be convened to address harmonization of standards, major issues, and management of COIs in the CPG process.

Limitations

Our CPG ethics exercise had limitations. We relied on self-reporting and voluntary self-recusals for COIs, which may have affected accuracy. Our small numbers limited the sample size. Financial COI risks encountered here may differ from those in other clinical contexts. The scope of effect was limited by focusing the ethics framework on the CPG meeting phase rather than on the entire development process. Despite these limitations, the exercise evokes issues central to the ethics of COIs in CPG development.

Conclusion

Echoing the evolving international state of the art and debate, our ethics initiative expressed accord on basic principles like transparency but ethical uncertainty on how best, beyond disclosure, to manage COIs in CPG process. Some contend that it is unethical to include important, conflicted expertise in CPG development; others contend that it is ethical to do so.

A standard that, for the integrity of CPGs, limits participatory roles of experts with significant COIs to narrow circumstances of necessity seeks to balance the values of impartiality and expertise that underlie trusted scientific decision making. Optimal points of balancing remain contested. Because critical questions on COIs in the CPG process survive our exercise and reverberate through international medical practice and the literature, they demand concerted deliberation, debate, research, and ethics policy initiatives.

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