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Conflicts of interest (COIs) have been defined by the American Thoracic Society as “a divergence between an individual’s private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are motivated by personal gain, such as direct financial, academic advancement, clinical revenue streams, or community standing.” In the context of guideline development, the concerns are not simply about identifying and disclosing direct financial or indirect COIs. Despite this recognition, the management of COIs in guidelines is often unsatisfactory. In response to requests from its international membership and informed by existing syntheses of the evidence and policies of international organizations, the Guidelines International Network Board of Trustees developed guidance on the disclosure of interests and management of COIs.

In the context of guidelines, one can broadly describe conflicts of interest (COIs) as direct financial COIs that refer to financial relationships with entities that have investment in products or services directly relevant to the guideline topic and indirect COIs that relate to such issues as academic advancement, academic revenue streams, and community standing (1, 2). These COIs may ultimately lead to indirect financial gain related to salaries or other benefits resulting from academic advancement. Although COIs are often hard to detect, evidence suggests that all types of COIs can influence guideline recommendations. For example, authors with recent publications about the management of breast disease were more likely to make recommendations for breast cancer screening than those without recent publications (4).

Because COIs create a risk of bias in decisions or recommendations (5), systematic approaches to the disclosure of interests and COI management are necessary to minimize potential bias (6). Discussions about COIs are not only about understanding and reporting direct financial interests but also about managing COIs (7–10). Despite recognition of these issues, guideline developers’ disclosure and management of COIs are often unsatisfactory (11, 12).

Established in 2002, the Guidelines International Network (G-I-N) (www.g-i-n.net) is a network of guideline developers, comprising 100 organizations and 127 persons from 48 countries. The G-I-N has published guideline development standards that emphasize the importance of disclosing and managing COIs, but these standards do not elaborate on specific COI management (9). Yet, when surveyed, the 94 participating G-I-N members indicated that managing COIs was one of the areas that needed further guidance (13).

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Writing for the G-I-N Board of Trustees (BoT), we reviewed the recent research and developments in managing direct financial and other COIs by using examples from several organizations and state the consensus-based principles of the G-I-N BoT for managing COIs. The Table describes the types of COIs. Here we reiterate that G-I-N recognizes the potential for indirect financial or other gains that may represent COIs. For simplicity, we will use the phrase “direct financial and indirect COIs.”

METHODS

The G-I-N BoT, comprising 12 guideline developers from most regions of the world with backgrounds in evidence-based medicine and guideline development, used a consensus-based process to develop the principles for managing COIs. Two members of the BoT developed the idea, and 11 BoT members formed a writing group.

We consulted published articles on managing COIs in guideline development (1, 3, 8, 13), reviewed empirical research (14, 15), and updated a targeted literature search by reviewing PubMed on 1 December 2014 to identify work on the topic that was published after our previous search in 2011 (13). In our search, we combined the terms “conflict of interest” and “guidelines or recommendations.” We also used a comprehensive review of existing policies and guideline manuals that abstracted information about COI declaration and management (16), and we reviewed the policies of...
organizations that board members belonged to or had worked with previously. The authors and nonauthor members of the BoT reviewed manuscript drafts to arrive at consensus-based principles for dealing with COIs in guidelines. Disagreement was resolved by in-depth discussion during board meetings and teleconferences among the authors or in-depth conversations between the first author and individual board members. Final written agreement on the principles was obtained from all board members. The G-I-N provided travel support for participants, but the study was not otherwise funded.

**REVIEW FINDINGS**

**What Types of COIs Are Relevant to Guideline Development?**

Influential organizations, such as the Institute of Medicine (IOM), have recognized the need to declare, disclose, and manage financial and intellectual COIs in guidelines (9). The World Health Organization (WHO) asks advisors about financial COIs and queries, “Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?” (17). The National Institute for Health and Care Excellence has a written policy on managing COIs for all its employees; board members; and members of advisory bodies, including guideline groups (18). Its policy classifies interests as being “personal nonpecuniary” (an intellectual or academic interest), “personal pecuniary,” “nonpersonal pecuniary,” (payment to a department or organization managed by someone), and “personal family.” The latter 3 may be either specific to the topic under consideration or non-specific, which means that there is an interest in “the manufacturer or owner of the product or service, but... unrelated to the matter under consideration” (19). Management of COIs for the U.S. Preventive Services Task Force (USPSTF) requires that members who participated in determining the direction and strength of a recommendation must have no substantial financial, intellectual, or other conflicts

(20). For the management of nonfinancial (indirect) COIs, the American College of Physicians, American Thoracic Society (ATS), American College of Chest Physicians (ACCP), and other organizations review leadership or persons with close involvement in an advocacy group; persons who are chairs or members of other guideline committees; and expert witnesses or persons with personal relationships that may interfere with an unbiased publication process at the stages of authorship, peer review, editorial decision making, or publication (1, 3, 21).

The description of COIs applies to all members of a guideline development group. Thus, health care professionals, patients, and policymakers who participate in guideline panels are all at risk for being unduly influenced by COIs related to specific recommendations.

**Health Professionals**

For many health professionals engaged in guideline development, financial COIs are the most problematic (22). However, health professionals may also be conflicted when considering procedures that they currently perform or if their practice prevents them from approaching a question with an open mind. For example, they may find it difficult to recommend new treatments and procedures that they are unfamiliar with because of the need for training or investment. Indirect COIs may also result if health professionals emphasize the importance of their own research. Health professionals are included for their expertise, but that expertise may lead to COIs (3). One solution for dealing with such COIs is to allow these persons to provide information about the topic but minimize their influence by working with them as external advisors or nonvoting panel members.

**Patients**

Patients, like other guideline panel members, may have a COI if they receive support from external organizations that receive industry funding. Patients should
not be bound to the view or ideology of specific organizations and must bring their own experience and expertise to the panel. This may result in a contradiction because patient representatives are asked to represent the patients’ voice and act in the interest of patients, but they should avoid taking an advocacy role for an organization. Patients may also be biased about a particular intervention if they believe they have personally benefited from or been harmed by it.

Policymakers

Policymakers, including health program managers, who participate in guideline development may benefit by enhancing their public profile if they recommend or agree to reimburse specific interventions. They may, however, lose professional standing for recommending or reimbursing interventions that might be costly to implement. Policymakers may also support guideline topics that are important for their constituency but not necessarily important for public health.

Financial Amounts, Degree of Involvement, or Relevance

Although evidence suggests that any financial benefit can influence judgments about interventions in guidelines (23), direct relevance and larger amounts are considered more important than indirect relevance and lesser amounts. However, varying income and resource structures make defining such a scale challenging. The ATS has used rating scales to define both the degree and relevance of COIs (Appendix Tables 1 and 2, available at www.annals.org). Chairs, organizers, and others responsible for reviewing COIs should follow step-by-step procedures that clearly articulate the process, including what happens and who is responsible at each stage of disclosure and review; further, these procedures should provide guidance on evaluating the relevance and significance of COIs and determining the appropriate methods of resolution (1). What Processes Do Guideline Development Groups Use to Manage COIs?

The IOM report suggests generally excluding persons with financial COIs from guideline development panels. However, because obtaining the necessary expertise from persons without conflicts (for example, in rare conditions or specific settings) may sometimes be impossible, the IOM requires the following: chairs should have no COIs, only a small minority of panel members should have COIs, members with COIs should be precluded from voting on topics in which they have a financial interest, and members with COIs should be prohibited from drafting and deciding on specific recommendations (9). The IOM also calls for guideline development groups to involve the public in attempts to identify experts without COIs and to disclose publicly any COIs of persons selected for membership on panels. The IOM report included specific recommendations made by a WHO working group for dealing with COIs (8, 13).

The Agency for Healthcare Research and Quality manages COIs for the USPSTF and, on review of members’ COIs, makes recommendations in 4 categories: no action (no relevant COIs), information disclosure to USPSTF only (member may participate as a topic lead and may discuss and vote on the topic), recusal from participation as lead of the topic workgroup (member may discuss and vote but not lead the topic), and recusal from all participation (member will leave the meeting room for all discussion and voting) (20).

Work by the ATS and a committee advising on guideline development at the American College of Chest Physicians considered in the IOM report defined indirect financial and intellectual COIs and provided suggestions for management strategies (1, 3). Practical application of COI management principles supports the conclusion that disclosure is insufficient and approaches that are consistent with recusal and managed participation of conflicted experts are a possible solution (1, 3, 14, 24).

Thus, major organizations have recognized the importance of disclosing and managing both direct financial and nonfinancial interests, as the Table defines. Organizations agree that all interests should be made public, including monetary amounts for direct financial and indirect COIs. Further, organizations agree that persons with a leading role in a guideline panel (for example, chairs and persons summarizing the evidence) should be free of relevant COIs.

However, the inclusion of guideline development group members with COIs in other roles than chair can be necessary and unavoidable, such as when dealing with rare conditions, in settings or jurisdictions with a small pool of potential guideline panel members, or when the most informed persons are those who have led the research and development of an area of focus. Pluralism of stakeholders is a desirable feature of guideline panels and may reduce the risk of bias resulting from COIs and lead to balanced final decisions (25).

What DOES the G-I-N RECOMMEND? G-I-N PRINCIPLES

The G-I-N BoT agreed on and suggests applying 9 principles for disclosing interests and managing COIs.

Principle 1: Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.

Although the G-I-N recognizes the need for exceptions when this is not practical, such issues should not diminish the importance of this principle. 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 develop-
ment 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.

As part of this disclosure, the guideline development group should disclose all specific monetary values because COIs may arise at different levels in different settings. Reporting of actual or approximate amounts, if known, increases transparency. Registries of disclosures could be used (6).

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.

A relevant COI exists if it influences the direction or strength of a recommendation. 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.

In some settings, persons who fulfill this role may be considered expert advisers who are neither voting nor nonvoting members of the guideline development group.

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

These members should not participate in this phase of guideline development. They should be physically absent from the discussion about the direction and strength of the recommendation.

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

The oversight committee should address issues of dispute and advise the chair of the guideline development group on determining who is a voting or nonvoting member and who should be designated as an expert adviser.

How Can Guideline Developers Implement the G-I-N Principles?

The guiding principles for defining, disclosing, and managing COIs should be similar across jurisdictions, regions, and countries; however, the details of implementation may vary. Therefore, we are proposing principles rather than standards. The use of forms (such as the Declaration of Interests for WHO Experts) and rules based on these principles will permit a fairer and more transparent guideline development process, which will help prevent concerns and criticism of bias after the guideline is published (Principle 3). These forms should specify a period in the past for which interests should be declared, and participants should provide consent that future COIs should be avoided. Transparency not only involves full disclosure of COIs but also a clear description of the process used to identify and manage them for each recommendation because COIs may differ from each recommendation in a guideline.

Recognizing the inherent direct and indirect COIs of health care providers and patients, one may ask why they should be included in a guideline development group. Content and patient experts are essential for defining key health care questions because they often have unique insight into the clinical, public health, or policy problems. They can explain what is relevant to practice and persons with the condition; interpret how directly the evidence applies to the actual question by describing professional and patient preferences, safety, equity, and effectiveness; consider if resources are spent appropriately; and balance the considered options fairly. Avoiding bias may be achieved by careful and astute chairing of the guideline development group that reinforces management of COIs, ideally by a guideline methodologist who has in-depth understanding of research question formulation, evidence synthesis, evidence to recommendation processes, and guideline panel leadership. Further, oversight committees, which should also be responsible for handling disputes about COIs, may classify panel members as either “voting” or “nonvoting.” This classification will identify persons who can actively participate in defining a recommendation and those who may participate in discussion but not decision making about recommendations; further, formal voting should rarely be necessary if appropriate consensus-finding approaches are used and a guideline panel is well-chaired. Organizations could also consider involving persons with declared substantial conflicts as informants or expert advisors but not official guideline development group members (Principle 7). A clear description of members’ and expert advisors’ COIs and their involvement (for example, voting or nonvoting) in each recommendation should be included in the final guideline documents. In addition, the process for the development of recommendations and management of COIs should be clearly articulated before the establishment of the group (6). Having clear rules in place will be particularly important for guideline developers who are not part of a national quality assurance program that supervises or
oversees guideline production, dissemination, and implementation.

The degree to which COIs affect the risk of bias will be influenced by how other steps in guideline development are handled. For example, the use of systematic methods to synthesize and assess evidence, formal processes to reach consensus, or the involvement of methodologists without COIs will probably reduce the effect of COIs. In addition to the G-I-N standards for guideline development, a partnership between G-I-N and McMaster University provides a comprehensive checklist for the guideline development process (16, 26). Thus, managing COIs will be of greater importance when such standards or processes for guideline development are not closely followed or are not overseen by quality assurance programs (Principle 9).

SUMMARY

The G-I-N BoT provides guidance for its members and other organizations on disclosing and managing COIs. The G-I-N BoT emphasizes that because COIs cannot usually be eliminated completely, the challenge lies in judicious management. The G-I-N BoT looks forward to seeing further research that evaluates the proposed principles.

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G-I-N Principles for Conflicts of Interest in Guidelines


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APPENDIX: G-I-N BoT and Contributions

All persons named in the byline were authors and members of the G-I-N BoT at one point during the preparation of the manuscript. Membership on the BoT changed in August 2013 and August 2014, and the following persons were additional members of the board who approved this manuscript as nonauthor contributors: Richard Rosenfeld, MD (United States); Susan Huckson, PhD (Australia); Duncan Service, PhD (Scotland); and Joan Vlayen, PhD (Belgium).

Drs. Schünemann and Qaseem (immediate past G-I-N BoT chair) had the idea for this manuscript. Dr. Schünemann drafted the initial manuscript and was responsible for writing all other versions of the manuscript. Drs. Komulainen, Macbeth, Phillips, van der Wees, and Qaseem; and Ms. Al-Ansary and Ms. Kersten provided detailed feedback on early drafts of the manuscript, provided examples, and critically reviewed the manuscript. Drs. Forland, Kopp, and Robbins critically revised drafts and provided feedback, and all other G-I-N BoT members commented on or approved an early version of the manuscript and the final version.
**Appendix Table 1.** "Weight" of potential conflict of interest based on "value."**

**User instructions**
Step 1. In Table A1, select a monetary and/or nonmonetary "value" on the scale labeled adding up all declared values for the 3 years prior to submission of the project or application per company or commercial sponsor (see examples in the legend to the table).
Step 2. Determine the "weight" using the column labeled "weight."

<table>
<thead>
<tr>
<th>Value Category (Monetary and/or Nonmonetary)*</th>
<th>Weight†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Up to $1,000‡</td>
<td>1</td>
</tr>
<tr>
<td>2. $1,001–5,000§</td>
<td>2</td>
</tr>
<tr>
<td>3. $5,001–10,000¶</td>
<td>3</td>
</tr>
<tr>
<td>$10,001–50,000</td>
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</tr>
<tr>
<td>$50,001–100,000</td>
<td></td>
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<tr>
<td>$100,001 or more</td>
<td></td>
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</tbody>
</table>

* 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 ATS Committee on Ethics and Conflict of Interest) in US$; amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public, with the exception of ATS official documents, where the dollar amount range of each participant's relationship per company or commercial sponsor (for the 3 years prior to submission of the draft document to the ATS Board of Directors) should be included in the disclosure statement that is published with the document. This information will be available ONLY to chairs and organizers of official ATS activities who will evaluate the COI disclosures and to the ATS Board of Directors and the Committee on Ethics and Conflict of Interest, if necessary.
† Used with relevance rate (see Table A2) to calculate significance.
‡ 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.
## Appendix Table 2. Relevance to the topic.*

**User instructions:**
Step 3. Rate the “Relevance” of a potential conflict of interest by choosing descriptor or number:

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<table>
<thead>
<tr>
<th>Relevance</th>
<th>None</th>
<th>Very Low</th>
<th>Low</th>
<th>Moderate</th>
<th>Moderate to High</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Topic of interest is not relevant and unrelated to a competing interest</td>
<td>Topic of interest is somewhat relevant and related to a competing interest</td>
<td>Topic of interest is highly relevant or directly related to the declared competing interest</td>
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<tr>
<td><strong>Examples</strong></td>
<td>A statistician involved in conducting meta-analysis on implementing pneumonia guidelines who consulted for a spirometer device company</td>
<td>A methodologist has given a methods focused presentation at an event sponsored by a for-profit organization whose products will be discussed by a guideline panel</td>
<td>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 guideline panel</td>
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<td></td>
<td>A researcher has received personal honoraria for speaking about a medication that will be the topic of a recommendation in a guideline</td>
<td>A researcher’s career is focused on the exploration of a topics about which a recommendation for additional resources will be made to a funding agency</td>
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<td></td>
<td>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 guideline panel. The guideline panel may make recommendations for its use</td>
<td>A researcher is the owner or major shareholder of a company that produces a devise or medication about which a recommendation will be formulated by a guideline panel</td>
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