Introduction

The American College of Chest Physicians (CHEST), through its Guidelines Oversight Committee (GOC), is committed to the development of independent, trustworthy, high-quality, evidence-based guidelines and consensus statements that are free from the influence of industry. To limit the potential for bias, CHEST both adheres to strict methodological standards related to the identification and assessment of available literature and enforces a strict panelist conflict of interest review and management process. While CHEST strives to form guideline panels that are free from financial and/or intellectual conflict, the inclusion of recognized clinical experts who have relationships deemed to be manageable ensures the involvement of the leading, content scientists and clinicians in the field. Accordingly, members of the Professional Standards Committee (PSC) will apply the standards delineated in this document as they review and make decisions on panelist participation based on their disclosed conflicts of interests (COIs), and the guideline panel chair and GOC will carry out necessary management terms.

General Policies

1. In creating evidence-based guidelines and consensus statements that clinicians and the public will trust, CHEST must limit the potential for bias through careful vetting, evaluation, and management of the financial relationships and intellectual activities of each potential participant.
2. All potential panelists will be required to submit a complete disclosure prior to the initiation of guideline/consensus statement development. Panelists’ disclosures and contributions to the field will be reviewed both as individuals and in aggregate to achieve a balanced group.
3. The scope of disclosure will include a three-year period and will report both personal potential COIs and those of any first-degree relative (parents, siblings, children) and the potential panelist’s spouse/domestic partner. For financial disclosures, dollar amounts must be provided for monetary and in-kind remuneration. The PSC will take into account a person's ability to divest of activities that may be viewed as disqualifying conflicts and may include divestment as a management condition for specific COIs.
4. All panelists will agree to adhere strictly to any COI management terms and will not assume any new relationships until a minimum of one-year post-publication of the document (or another time period to be designated by the GOC). Each panel meeting will begin with verbal notice of any new disclosures, and new written disclosures will be collected annually. Panelists will also be asked to complete the CHEST journal COI form on submission of the manuscript for consideration by the Journal.
5. All COIs and management terms will be published with the final article, and the COI management process will be addressed in the methodology section of the final guideline/consensus statement.

Definitions

- Commercial interest is any for-profit entity producing, marketing, re-selling, or distributing health care goods to be consumed by or used on patients (e.g., pharmaceutical or device companies).
- Conflict of Interest (COI) refers to any relationship or other set of known circumstances that has the potential to bias, or that might be reasonably perceived by others to bias, an individual's judgment, conduct, or other work.
- **Financial COIs** include any relationship for which one receives remuneration or in-kind benefits that could be perceived to affect one’s judgment in the evaluation of specific recommendations.
- **Intellectual COIs** include any activities that create the potential for attachment to a specific predetermined point of view that could be perceived to affect one’s judgment in the evaluation of specific recommendations or suggestions.
- **Related content areas** are those that are aligned with the clinical questions and/or PICO elements (patient-intervention-comparator-outcomes) to be addressed within the guideline.

**Guideline Development Roles**

- **Executive Committee** consists of the guideline Chair, Co-Chair/Vice-Chair/Topic Chair, lead methodologist, GOC liaison, and staff project manager who collaborate on a guideline. The group may exist formally when multiple aspects of a broad content area are being addressed simultaneously through the living guidelines model and prioritization among clinical questions and targeted updates is necessary.
- **GOC Chair/Vice-Chair** oversees all guideline development, training, and dissemination/implementation activities and provide support and advice to GOC Liaisons and guideline Chairs as needed.
- **GOC Liaison** is a standing member of the GOC who, together with GOC leadership, carries responsibility for overseeing all guidelines and consensus statements developed in a particular content domain and serves as an advisor to the Chair and panelists. The GOC liaison supports the Chair by providing oversight of COI management terms for assigned projects and ensures management plans are approved by the GOC leadership.
- **Chair (Co-Chair/Vice-Chair/Topic Chair)** is the lead of the guideline effort and should have relevant clinical expertise and experience in the subject area; and is responsible for defining the initial scope and clinical questions, making recommendations on panelists, and retaining oversight of COI management terms.
- **Panelist** is any person who contributes to the work of developing the guideline (eg, defining the scope, forming the clinical questions, searching and evaluating the literature, developing recommendations or suggestions, voting, and drafting the manuscript) and includes an expectation of authorship, provided they meet the criteria defined by the International Committee of Medical Journal Editors.

**Process**

**Guideline Approval, COI Collection, Panel Formation**

1. On submission of a new guideline topic for GOC consideration (or on the proactive decision to update a guideline in a specific content area), the GOC liaison for that content area is engaged, and the submitter is asked to generate a list of proposed guideline panelists, noting the recommended Chair and/or Vice-Chair/Co-Chair (if someone other than themselves).
2. Staff will initially send the disclosure of the proposed Chair and/or Vice-Chair/Co-Chair and Domain Liaison to PSC to review with the proposal itself so that a Chair can be finalized and staff can work to complete the rest of the proposed panelists.
3. Proposed panelists are invited by staff to submit their COI disclosure within a period of two weeks. Failure to submit disclosure forms in this time period may be treated as declining participation. Disclosures will form part of the submission packet for GOC consideration and must be available on final approval of the topic.
4. Once GOC formally approves the guideline topic, disclosure forms will be sent to the PSC in aggregate with the draft clinical questions (and their PICO elements) to be addressed by the guideline so that PSC can review conflicts, relevance, hold discussions, and make determinations on individual panelists related to these clinical questions. In the rare
circumstance that PICOs are not available, panelists who are approved with management will be re-reviewed once the PICO questions are defined.

5. A grid of all decisions made—or requests for additional information—on a panel will be sent to the GOC Chair and Vice-Chair, Domain Liaison and Panel Chair/submitter.

6. Each candidate receiving a management plan or disapproval will receive a call from the Chair or Vice-Chair of PSC prior to the formal decision letter being sent. Discussion will include divestment from COI, management terms, the process to vet any new COIS that occur while on the guideline and a review of the appeal process.

7. Staff will issue final decision letters on behalf of the PSC.

8. Each approved candidate will sign a formal panel member agreement.

9. All guideline panelists will update their COI annually.

Convening a preliminary group to define the scope of a particular guideline or to prioritize the clinical questions to be addressed may be necessary. Such groups must be convened by the GOC Domain Liaison, who will communicate that no expectation of panel membership or appointment prior to the formal disclosure and review process should be held by group members. In instances in which such individuals are unable to participate on a panel, their contributions to defining the scope should be included in the acknowledgments section of a published manuscript.

Appeals

Decisions related to panelist participation and/or management terms made by the PSC may be appealed through written request. The submitter should include any additional information and the potential justification for determination of a different decision. The appeal will be considered by a joint group of five individuals from the PSC and GOC, led by the Chair of PSC, and will serve as the final arbiter. The appeals body includes the (1) PSC Chair, (2) PSC Vice-Chair, (3) GOC Chair, (4) GOC Vice-Chair, and (5) GOC Domain Liaison.

Review and Categorization of COIs

In reviewing submitted disclosure forms, determining the relevance of each disclosure is paramount. Conflicts that relate directly to the interventions being evaluated are said to be primary; those that do not relate directly are characterized as secondary. This distinction will often form the basis for differentiating between manageable and disqualifying conflicts. The scope of an individual's activities is also considered in aggregate. While a dollar amount on a single activity may not be particularly high, a large number of relationships (e.g., advisory board activities) that total a substantial dollar amount may lessen public trust in the document that results. In reviewing grant-related relationships, it is important to take into account who receives the funding (institution vs individual) and whether direct salary support is provided.

Disclosure of COIs over the last three years is required; however, emphasis will be placed on the last year of COIs when vetting candidates for guideline panel positions. COI disclosures must clearly explain the relationship and related disease topics involved in the relationship and include dates of payment for stated services.

In evaluating total panelist participation, constructing a panel wherein only a minority of members have conflicts of interest requiring management is ideal. All conflicts of interest, including those deemed acceptable and those deemed manageable, will be reported throughout the guideline development process and disclosed in final publication.

Acceptable Relationships and Activities

In general, acceptable relationships and activities include those that are:
1. Intellectual in nature and lacking direct and indirect financial benefit; or
2. Unrelated to the content area and focus of the guideline.

Where intellectual conflicts exist, relationships should be disclosed to the group of panelists throughout the development process and included in the final publication. The remaining types of activities listed require disclosure but no proactive management.

Examples of acceptable activities may include:

- Authoring publications in peer reviewed journals
- Producing educational content for medical textbooks and other resources (with or without earning royalties)
- Leading or participating in grant-funded research from non-profit, government, or university-awarded research or educational grant
- Leading or participating in grant-funded research from commercial entities in unrelated content areas
- Leading or participating in grant-funded research from commercial entities when the support is paid to the institution, not the individual
- Speaking, teaching, or developing content for CME or MOC activities, including those supported by commercial interests
- Participation in a data-safety monitoring board
- Holding patent rights or having an application pending on a patent in an unrelated content area
- Ownership of stock or shares, exclusive of mutual funds, in an unrelated content area

Manageable Relationships and Activities

For certain types of relationships, the GOC, through the Chair (and Vice-Chair/Co-Chair) and GOC Domain Liaison, will develop and oversee individualized, formal, and transparent management plans that will delineate any limitations on participation defined as a result of the relationships. See “Decisions and Management Terms” for details. Management plans will be published with the final document.

Examples of manageable activities may include:

- Leading or participating in grant-funded research from commercial entities in a directly related content areas where the funds are paid directly to the individual
- Participation in consulting, speaking, or advisory board activities that are purely scientific or educational in nature
- Receipt of travel support from commercial entity (may review activity and reason for support)
- Making public statements or serving as expert witness to litigation in an unrelated content area

Dollar amounts or the scope of relationships when taken in aggregate may lead to disqualification.

Disqualifying Relationships and Activities

The scope or nature of some relationships negates management and will sometimes outweigh the content expertise an individual may bring by serving as a full panelist, resulting in disqualification.

Examples of disqualifying activities may include:
- Investments, exclusive of mutual funds, or consulting for tobacco companies
- Full or part-time employment with a commercial interest
- Participation in consulting, promotional speaking, or advisory board activities on behalf of a commercial interest
- Holder of patent rights or pending application in a directly related content area
- Ownership of stock or shares, exclusive of mutual funds in a directly related content area
- Making public statements or serving as expert witness to litigation in a directly related content area

In some cases, a potential panelist may be given the opportunity to divest of a relationship(s) instead of being disqualified. Participant must divest prior to initiating work on the guideline and for a minimum duration of one year post-publication, with the final duration to be determined by the GOC.

Review of Chair/Vice-Chair/Co-Chair/Domain Liaison

The guideline or consensus statement Chair or Chair and Vice-Chair/Co-Chair and Domain Liaison oversee all aspects of the process, including developing and prioritizing the key clinical questions to be addressed in the document. They must have an intimate knowledge of the literature and applicable clinical experience that informs how the literature translates to practice. They should also have experience with or exposure to the science of evidence-based medicine through past participation on a guideline panel or in the development of systematic reviews and a solid understanding of how to objectively assess the literature and apply tools, such as the evidence-to-decision framework, that limit the introduction of bias into the process of developing clinical recommendations and suggestions. The Chair must also ensure the regular reporting of any new conflicts during any panelist interaction and carry out the management terms assigned to individual panelists, including him/herself.

While it is ideal to have Chairs and Domain Liaisons who are free of conflict, it may be unlikely to identify someone with the desired degree of expertise who is devoid of all potential financial and intellectual relationships. If the best choice for Chair and/or Domain Liaison has conflicts deemed to be manageable, CHEST in collaboration with the GOC Chair, will seek to identify a Co-Chair with no conflicts, who will be asked to lead the following activities:

- Drafting of recommendations/suggestions
- Discussion of recommendations/suggestions
- Grading of recommendations/suggestions
- Voting on recommendations/suggestions
- Provision of writing assignments to panel members

Decisions and Management Terms

The decisions of the PSC will result in one of the following actions:

1. Appointment
2. Appointment with management
3. Disapproval

For those individuals who are approved with management, the specific terms of management should be set forth by the PSC. Management terms may include one or more of the following:

□ Divest of specific relationships (note relationships).
- May participate in discussions, but may **not** draft, vote, or grade recommendations relevant to specific conflicts (note content/clinical question).
- Writing must be reviewed by the Chair and/or GOC Domain Liaison to ensure balanced reporting and bias-free summaries of the research studies and other text.

The PSC sets these terms but relies on the Chairs and GOC Domain Liaison to control the participation of those panelists who are approved with management to ensure that the terms are upheld.