

Conflict of Interest Policy & Procedures for Endocrine Society Clinical Practice Guidelines

Introduction

There are many sources of guidance on conflict of interest (COI) as it relates to establishing guideline writing groups and the production of guidelines themselves. The Endocrine Society's Clinical Guidelines Committee (CGC) [formerly Clinical Guidelines Subcommittee] finds guidance provided by the Guidelines International Network (G-I-N) to be clear and concise, and a document published by G-I-N in 2015¹ forms the primary basis of this COI policy. However, standards from the Institute of Medicine's (now the National Academy of Medicine's) *Clinical Practice Guidelines We Can Trust*², other similar documents, and the COI policies of other medical societies have also informed the content of this policy.

Policy

1. Optimally, the Society's guideline Writing Committees (WC) would only include members who are free of COIs relevant to the topic of the guideline. The Society will strive to achieve this ideal whenever possible.
2. Acknowledging that establishing a COI-free WC is particularly challenging in many fields of endocrinology, the Society will meet the following minimum standards:
 - a. WC Chairs: The WC Chair and Co-Chair must be free of relevant COI³;
 - b. WC Members: A majority (>50%) of non-Chair WC members must be free of relevant COI;
 - c. Expert Reviewer and Publisher's Reviewer: Individuals asked to review guideline drafts in the capacity of Expert and Publisher's Reviewer must be free of relevant COI;
 - d. Advisors: Individuals who are not members of the WC but who are asked to act in a formal advisory capacity to the committee are not required to be COI-free but will be required to disclose all relationships in line with the policies identified herein.
3. When appointed to a WC, chairs and members must refrain from adding new relevant industry relationships throughout the guideline development process, until publication.
4. Primary authors of recommendation-related guideline sections (i.e., sections of text pertaining to individual recommendations or topically-organized sections of text pertaining to multiple recommendations) must be individuals without conflicts of interest relevant to that section.

¹ Schünemann et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med.* 2015; 163: 548-53.

² Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Board on Health Care Services, Institute of Medicine of the National Academies. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press; 2011.

³ For the purposes of this policy, a "relevant" COI is defined as a potential COI that could plausibly influence (or could have the appearance of influencing) the direction or strength of one or more guideline recommendations.

Implementation

COI Disclosure

1. Complete disclosure is the foundation of an effective COI policy and ensures that each WC complies with the Society's COI policy. Individuals being considered as chair or member of a guideline WC, as an advisor, Expert Reviewer or Publisher's Reviewer must submit details of all their relationships (and all known immediate family member relationships⁴), irrespective of whether the candidate considers them to be relevant to the scope of the guideline.
2. When requested, COI information must be provided (or updated) using the Endocrine Society's online Conflict of Interest Form (accessed from endocrine.org) unless the candidate previously completed this form within the last 90 days *and* the candidate confirms no interim changes in her/his COI information.
3. When COI information is requested, candidates are required to disclose all relationships for the prior 12-month period. This is consistent with the reporting time-frame for the National Institutes of Health and the Food and Drug Administration.
4. Organizational relationships should be declared including all relationships with commercial, non-commercial, governmental, and patient/advocacy organizations. This includes employment, consultancy, interests in start-up companies and/or in those where stock is not publicly traded, ownership interests in publicly-traded companies such as stock options (excluding indirect investments through mutual funds), research funding directly paid to the individual, research funding paid to employer organization or other research institution with whom the individual is involved, serving as a Principal Investigator, honoraria, royalties, paid or unpaid expert testimony, speaking engagements, speaker's bureaus, etc. Leadership positions and memberships of other entities (paid and unpaid) including Data Standards Monitoring Boards, non-profit or for-profit advisory boards and committees must also be disclosed.
5. When available, Endocrine Society guidelines staff will use publicly available information (e.g., from CMS's Open Payments database⁵) to provide the CGC Chair with additional information on a candidate's historic COI profile.
6. Candidates will be asked for additional and/or clarifying information where this is needed to determine the relevance of specific relationships and the extent of any potential conflict.

⁴ For the purposes of this policy, "immediate family member" refers to a spouse/partner or a first-degree relative (parent, child, sibling). WC candidates need only disclose relevant family relationships that are already known to the candidate: when the candidate knows of no such relationships, the candidate need not directly solicit such information from family members. However, when a candidate is aware of a potentially-relevant relationship on the part of an immediate family member, but does not know details about said relationship, collection of additional information may be required to establish the relevance (or non-relevance) of such relationships. Note that similar disclosure should also be provided for any person with whom a candidate has a very close personal relationship *if* such could be seen as a plausible conflict of interest on the part of the candidate.

⁵ Open Payments is relevant to physicians in the United States only. Whenever relevant, available, and feasible, similar databases in other countries will be queried as well.

COI Review, Vetting and Decision-Making

Initial COI information requests are sent by Endocrine Society staff who combine the information received from candidates with public information from the Open Payments website. Review of such COI information will be conducted as follows:

1. [*WC Chairs*](#): The CGC Chair reviews all COI information and determines whether any relationship represents a potentially relevant conflict of interest. The CGC Chair's final recommendations are submitted to Endocrine Society Council for approval.
2. [*WC Members*](#): The WC Chairs review all COI information and determine whether any relationship represents a potentially relevant conflict of interest. Decisions on the relevance of relationships/conflicts to each guideline topic/section—in addition to the overall acceptability of a candidate's COI—will be made by the WC Chairs in collaboration with the CGC Chair, who will have veto power.
3. [*Expert and Publisher's Reviewer*](#): The CGC Chair reviews all COI information and determines whether they represent a potentially relevant conflict of interest. The CGC Chair's decision is final.
4. [*Advisors*](#): CGC staff collects and records COI information and shares it with the WC chairs and members and the CGC Chair to ensure transparency.

Information to be Considered when Establishing Relevance of COI Relationships

- **Type of relationship:** Employment, consultancy, interests in start-up companies, stock options, research funding, serving as a Principal Investigator, paid or unpaid expert testimony, speakers bureau, advisory board/committee, etc.
- **Type of organization with which the relationship exists:** Pharmaceutical company, health care delivery institution, academia, medical society, association, disease advocacy organization, etc.
- **Time frame of the relationship:** Long-term vs. short-term relationship, previous vs. ongoing relationship, etc.
- **Specific nature of the relationship:** Specific pharmaceutical product or device forming the basis of the relationship, other pharmaceutical products or devices manufactured/marketed by the organization, type of research support, leadership role and/or duties within an organization, etc.
- **Type of payment:** Food and beverage, travel reimbursement, direct compensation, honoraria, royalties, stock options, etc.
- **Amount of remuneration received as payment for the relationship:** Dollar amounts received from organization for services rendered.

Processes

The process of selecting chairs, co-chairs and members of guideline WCs is as follows:

- The Chair of the CGC seeks nominations for WC chairs from several sources, including CGC members and Endocrine Society Council members.

- The Chair of the CGC selects WC Chairs and Co-Chairs, based on the COI information received, the individuals' clinical expertise, leadership skills, commitment to the Society's guideline development process, and their availability for a long-term project.
- The CGC Chair submits their nominees for Chair and Co-Chair to Endocrine Society Council which reviews and endorses the nominees⁶ or suggests changes if appropriate.
- Upon confirmation, guideline Chairs and Co-chairs are contacted to determine their willingness to serve and to establish the continued absence of relevant COI.
- The CGC Chair works with the Chairs and Co-Chairs to select non-Chair members of the WC in addition to other guideline-development participants (e.g., advisors to the WC). Decisions will be based on the COI status of each candidate, the representation needs of the committee (e.g., involvement in other societies, etc.), the individuals' clinical expertise, commitment to the Society's guideline development process, and their availability for a long-term project.
 - When the WC Chair and Co-Chair request inclusion of a WC member with relevant COI, they must carefully describe the reason(s) for proposed inclusion.
 - The CGC must approve all non-Chair members of the WC (including plans for COI management as appropriate).
 - When the WC includes members with relevant COI, the following must be carefully documented by WC Chairs:
 - reasons for inclusion;
 - proposed plans for COI management; and
 - implementation of COI management strategies throughout the guideline development process.
- Following initiation of the committee, COI information will be updated at regular intervals.
 - WC members will complete the Endocrine Society's online Conflict of Interest Form (as described above) at least once a year.
 - At the beginning of every in-person meeting and of most conference calls, WC members will describe all interim changes to their COIs.
 - WC members with interim changes to their COIs will be required to update their COI information via completion of the Endocrine Society's online Conflict of Interest Form.
 - When a WC member has interim changes to her/his COIs, the CGC Chair and WC Chairs must determine whether the new COI represents a relevant industry relationship⁷ and whether/how that COI should be managed.
 - At periodic intervals post-publication

⁶ Endocrine Society Council endorsement will indicate agreement that the Chair and Co-Chair are free of relevant COI.

⁷ According to this COI policy, new industry relationships relevant to the guideline are prohibited.

- WC Chairs/members who perform post-publication surveillance (to identify changes in the field that may indicate a need for CPG updating) will update their COI information periodically (e.g., once a year) via completion of the Endocrine Society's online Conflict of Interest Form.

Writing Committee Chairs, members and society staff must be alert for situations which might present a potential or perceived conflict of interest and be ready to act accordingly.

Managing Conflicts of Interest

The process of managing conflicts of interest is as follows:

- **Disclosure:**
 - All COI of each WC member should be reported and discussed by the WC prior to the start of guideline development.
 - If a member is aware of another person who might have a conflict and has not declared it for some reason, they are obliged to bring this to the WC Chair's attention.
 - Any individuals who are not members of the WC but who are asked to either review guideline drafts or act in a formal advisory capacity to the committee will be required to disclose all relationships in line with the policies identified above.
- **Divestment:** Members of the WC (and their immediate family members) must divest themselves of direct financial investments (e.g., direct ownership in stock or other form of equity⁸) with entities that may have a potential financial interest in the contents of the guideline. WC members must also refrain from participating in the marketing activities or advisory boards of such entities. A candidate's commitment to such divestment will be a requirement for selection as a WC member. Such divestment must be maintained at least until guideline publication. In addition, divestment must be maintained for as long as a WC member participates in post-publication surveillance (to identify changes in the field that may indicate a need for CPG updating).
- **Recusals:** WC members who have conflicts that are directly relevant to specific sections of the guideline are required to recuse themselves from all formal decision-making processes related to those sections.
 - WC members are prohibited from drafting guideline sections directly related to her/his COI.
 - WC members are prohibited from determining the strength and direction of a recommendation directly related to her/his COI.
 - WC members are prohibited from voting on matters directly related to her/his COI.
 - The WC Chairs should ensure that such recusals are carried out and that all COI management strategies are carefully documented.

⁸ Ownership of managed fund portfolios (e.g., mutual funds) is not prohibited.

- Given that a WC member with relevant COI may have important insights that should be carefully considered, the WC Chairs may elect to allow the WC member to participate in discussions related to guideline sections directly related to her/his COI. However, at the WC Chair and Co-Chair's discretion, they may require such members to recuse themselves from all activities (including discussions) related to their COI. Such decisions should be carefully documented and approved by the CGC Chair.
- **Transparency:**
 - The Society will include details of all relevant conflicts of interest of members of the WC in a detailed table within the published guideline.
 - More detailed COI documentation will be made available as needed in the form of supplemental materials (available online). Such documentation will include CGC determinations regarding relevance of relationships and a description of the ways that relevant COI was managed throughout the guideline development process.

Policy Oversight

This policy was developed by the Chair of the Clinical Guidelines Committee (CGC). An initial version was approved and provisionally implemented by the CGC in February 2019. The policy was reviewed/discussed by Endocrine Society Council in March 2019, and several policy clarifications were requested. A revised policy was approved by the CGC in May 2019 and by Endocrine Society Council in June 2019.