

ISTH Guidelines and Guidance

Conflict of Interest Policy

The International Society on Thrombosis and Haemostasis (ISTH) is a global not-for-profit membership organization advancing the understanding, prevention, diagnosis and treatment of thrombotic and bleeding disorders. ISTH is dedicated to transformative scientific discoveries and clinical practices, the development of young professionals, and the education of physicians, scientists and allied health professionals wherever they may live.

ISTH is committed to ensuring the integrity of its medical, scientific, educational, and research activities, including that of clinical practice guideline development. In keeping with ISTH's policy on disclosure and management of conflicts of interest for member activities within the Society, this document outlines the management of COI with respect to clinical practice guideline development.

The Institute of Medicine's (IOM) 2009 report on Conflict of Interest (COI) in Medical Research, Education, and Practice defined COI as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" (IOM, 2009, p. 46).

COIs may – consciously or unconsciously – influence an individual panel member's behavior. They may affect decisions about what questions the guideline should answer, how evidence should be interpreted, and most importantly, how recommendations should be drafted (Guyatt et al., 2010).

Management of COI requires us to be mindful of how conflicts may be perceived by guideline users. In its landmark 2011 publication, "Guidelines We Can Trust," the IOM underscores that regardless of the nature of COI or its effects on guideline development, perception of bias undermines guideline users' confidence in guideline trustworthiness as well as public trust in science.

We have developed a transparent process to collect, quantify and disclose potential COIs of individuals with ISTH's guideline, so end-users of the guideline will not perceive that potential conflicts have interfered with the rigor of the guideline, nor its ultimate recommendations.

Definitions of Interests

Financial/Material Interests

Financial/material interests are those that involve relationships with any entity producing, marketing, selling, re-selling, or distributing health care goods or services, which are consumed by healthcare professionals, healthcare organizations (such as hospitals or laboratories) and/or used on patients. The individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (like stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

Financial benefits are usually (but not always) associated with such roles as those of employee, manager, independent contractor (including contracted research), consultant, speaker/lecturer, faculty, member on advisory committees or review panels, board member, or any other role for which remuneration is received or expected.

Financial interests are considered significant if they involve relationships with commercial entities whose interests may be represented in the guideline recommendations. Financial interests are considered significant if the relationships are ongoing at the time of appointment to the Guideline Panel, or if they occurred during a discrete period within the past 12 months. Financial interests are considered significant if they involve the panel member or their spouse / partner.

Non-financial interest

Non-financial interests include personal beliefs, research interests, intellectual positions or opinions, institutional relationships, the potential for career advancement, organizational advocacy or policy positions, and professional specialization. Such interests may also be termed "interests that are not

mainly financial” because they may be interrelated with financial interests, e.g., they offer indirect or potential financial gain.

Individuals whose COI will be reviewed

Guideline Panel

The Guideline Panel will be struck by ISTH, with input from the Evidence Synthesis Team. It will be tasked with topic refinement, determining clinical questions, outcomes, and formulating recommendations based on a formal voting process. COI for members of the Guideline Panel will be collected, recorded, and published with the guideline.

Evidence synthesis team

The Evidence Synthesis team is contracted by ISTH. It will conduct the evidence reviews, gather data, evaluate data for risk of bias, and prepare Summary of Findings tables. COI for members of the Evidence Synthesis Team will be collected and recorded, but will not be published with the guideline. Members of the Evidence Synthesis Team will be required to divest themselves of any ongoing financial COI relevant to the guideline topic before the Guideline Panel is struck.

Guideline Panel COI Management

Panel member COI disclosure

ISTH will take primary responsibility for nominating potential panel members. The Evidence Synthesis Team may provide recommendations on panel composition to ISTH based on the needs identified in the scoping document. Panel nominees will disclose COI using the COI Questionnaire provided by ISTH staff. Forms will be assessed and scored by the Guideline Panel Leadership Team, and proposed for final judgement of conflicts determined by the Guidelines and Guidance Committee.

Composition of panel

The goal underlying creation of the Guideline Panel will be to minimize COI wherever possible, while still maintaining necessary clinical expertise in the guideline subject area. Our aim is for a panel that has a majority of individuals (50% or higher) with minimal or no COI.

As per IOM recommendations, the Chair(s) of the Guideline Panel must be an individual with no financial COI.

We recommend the appointment of two co-Chairs of the Guideline Panel: a Clinical Co-chair and a Methods Co-chair. Neither individual should have financial COI. It is also preferable that neither individual should have major non-financial COI.

Final panel selection

After the COI status of potential panel members are ascertained, ISTH will shortlist a potential Guideline Panel, chosen to maintain minimal COI, as well as balanced stakeholder, geographic, and gender representation.

Impact of COI on Panel Activities

ISTH suggests a maximum of 14-17 members for the Guideline Panel. At least 50% of the members of this panel must be free from any major COI. Recommendations must be endorsed by 75% of the panel.

A full COI disclosure for each member will be circulated to the Guideline Panel and the Evidence Synthesis Team, and presented visually at the beginning of each meeting of the Guideline Panel. A summary of each member’s COI disclosure will be reported in the final publication.

Recusal

Panel members will be asked to recuse themselves from voting on an individual recommendation if they have a moderate or major financial COI for that recommendation. Panel members may also voluntarily recuse themselves if they have other COI (non-major financial or non-financial) which they believe may unduly influence their vote on an individual recommendation. A Panel member who believes that s/he cannot participate impartially due to a COI is encouraged to discuss this with ISTH.

Emerging interests

During the guideline development process and until guideline publication, members of the Guideline Panel must actively avoid forming new COI, and immediately and proactively disclose any new relevant COI to ISTH. The Guideline Panel Leadership Team, and if necessary, the Guidelines and Guidance Committee Chairs, will judge if new interests must be managed through actions that may include divestment, disclosure, or removal from the panel. Panel members will be asked to review and update their COI declaration forms every year and 1 month prior to guideline draft submission to JTH.

GUIDANCE ARTICLES

In keeping with ISTH's commitment to ensure the integrity of its clinical practice guidance, ISTH collects and manages potential COIs of individuals involved in guidance article development.

Definitions of Interests

Definitions of interest would apply to guidance articles as stated above.

Guidance Panel COI Management

Panel member COI disclosure

SSC Subcommittee will take primary responsibility for nominating potential guidance article panel members. The Guidelines and Guidance Committee may provide recommendations on panel composition based on the needs identified in the guideline proposal. Panel nominees will disclose COI using the COI Questionnaire provided by ISTH staff. Forms will be assessed and scored by ISTH with input from guidance proposal submitter, and proposed for final judgement of conflicts determined by the Guidelines and Guidance Committee.

Composition of panel

In order to increase the trustworthiness of the guidance articles, the goal of Guidance Panel membership will be to minimize COI wherever possible, while still maintaining necessary clinical expertise in the guideline subject area. Our aim is for a panel that has a majority of individuals (50% or higher) with minimal or no COI and the first author of the guidance article must be an individual with no financial COI and no major non-financial COI.

Impact of COI on Panel Activities

A full COI disclosure for each member will be circulated to the Guidance Panel, and members who have scored as having major financial COI will be identified. A summary of each member's COI disclosure will be reported in the final publication.

Recusal

Panel members will be asked to recuse themselves from voting on an individual recommendation if they have a major financial COI for that recommendation. Panel members may also voluntarily recuse themselves if they have other COI (non-major financial or non-financial) which they believe may unduly influence their vote on an individual recommendation. A Panel member who believes that s/he cannot participate impartially due to a COI is encouraged to discuss this with ISTH.

Emerging interests

During the guideline development process and until guidance article publication, members of the Guidance Panel must actively avoid forming new COI, and immediately and proactively disclose any new relevant COI to ISTH. ISTH and first author, will judge if new interests must be managed through actions that may include divestment, disclosure, or removal from the panel. Panel members will be asked to review and update their COI declaration forms 1 month prior to guidance draft submission to JTH.