

Management of Conflicts of Interest in the Development of Clinical Practice Guidelines by the American Society of Hematology

As described in Policy 8 of the American Society of Hematology (ASH) Conflict of Interest Policy (2014), special policies apply to the development of ASH clinical practice guidelines. This document describes those policies.

Definitions

Conflict of interest

A situation in which a reasonable person would consider that an individual's judgments or actions regarding any aspect of the guideline development process is, or could be perceived to be, influenced by an outside interest.

Financial interest

A position or relationship held by an individual that offers potential gain or loss of monetary value, such as employment, stock ownership, payment for services, or gifts given with the expectation of reciprocity.

Direct financial interest

A financial interest that is owned by the individual or received directly by the individual.

Indirect financial interest

A financial interest that is owned or received via an intermediary, e.g., research funding to an individual received through the individual's academic institution.

For-profit healthcare company

"A for-profit entity that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients" (Council of Medical Specialty Societies' "Code for Interactions With Industry" 2015). This definition is furthermore not viewed by ASH to include companies that provide accredited continuing medical education or that publish scientific or educational content.

Sponsorship and Funding

ASH does not accept direct support from **for-profit healthcare companies** for the development of ASH guidelines or for the initial printing, publication, or distribution of ASH guidelines. After guideline development and initial printing, publication, and distribution is complete, such company funding may be accepted to support further distribution, translation, or repurposing of the guideline content.

Governmental, nonprofit, or individual philanthropic funding of ASH guideline development and publication may be accepted. In such cases, the role of the funder in the development of the guideline is determined on a case by case basis by the ASH Guideline Oversight Subcommittee. External sources of funding and the role of the funding organizations or individuals are described in the published guideline.

Eligibility for Appointment to an ASH Guideline Panel

- For all roles on an ASH guideline panel, individuals are preferred who do not currently have any of the following interests and have not any such interests within the past 24 months:
 - **Direct financial interests** of >\$5,000/year in any **for-profit healthcare company** or >\$5,000/year in aggregate from such companies
 - Public statements expressing a strong intellectual position on a guideline question
 - Paid leadership role (e.g., board member or director) for: (a) any **for-profit healthcare company**; or (b) a non-profit organization that reasonably could be directly affected by the guidelines
 - Patents or other ownership interests in products that could be affected by the guidelines
 - Recent speaking on behalf of a **for-profit healthcare company** (e.g., speaker bureaus, but not including accredited CME)
 - On a case-by-case basis, any **conflict of interest** judged to be important by the ASH Guideline Oversight Subcommittee
- Individuals who have had such interests within the past 24 months, but do not currently hold them, may be considered for appointment if they offer crucial expertise, are willing to comply with this Policy, and the nature of their past interest(s) is such that the interest(s) can be appropriately mitigated given the make-up of the remainder of the panel.
- Chairs are additionally preferred to not have current a leadership role (e.g., principal investigator) for a research study that addresses a guideline question.
- If by special exception a chair is allowed to have any of the conflicts described above, a co-chair and a vice-chair must not have the same or similar conflict.
- Individuals considered for a guideline panel often have **indirect financial interests** in **for-profit healthcare companies**, e.g., research funding, as well as intellectual, professional, or reputational interests in the guideline topic. Guideline panels will be intentionally composed with the goal of avoiding a majority of the panel having the same or similar **conflict of interest**, including conflicts that are indirectly financial or not mainly financial.
- Eligibility will be determined through a variety of approaches, including interview, disclosure collection, and checking of public records.

Policies and Procedures During Guideline Development

Disclosure

Upon submission of an application for appointment to an ASH guideline panel, individuals must disclose: (a) for themselves and their partner or spouse all **direct financial interests** in **for-profit healthcare companies** held currently and/or within the past 24 months; (b) for themselves, all **indirect financial interests** in **for-profit healthcare companies** held currently and/or within the past 24 months; and (c) for themselves, all other current financial interests (i.e., in other entities, patents, etc.) that may be affected by the subject matter of the guidelines, and any relevant nonfinancial interests.

Panelists must maintain disclosures throughout the guideline development process. ASH will prompt for updates.

Disclosures are published with the guidelines.

New Conflict Avoidance

From time of appointment to publication of the guidelines, individuals on the guideline panel, regardless of role, must:

- Not accept direct payments or transfers of value >\$5,000/year in aggregate from **for-profit healthcare companies**.
- Not accept paid speaking (“speaker bureaus”) positions from **for-profit healthcare companies**.
- Disclose any new **direct and indirect financial interests** with **for-profit healthcare companies** and any new relationships with other entities that reasonably could be expected to be relevant to the guidelines.
- Check disclosures made to ASH against publicly available information such as Open Payments and explain discrepancies.
- Avoid simultaneous participation in guideline efforts by other organizations on the same topic.
- Attest compliance with the above when requested by ASH.

Management of Allowed Conflicts

- All allowed conflicts are managed through disclosure and group discussion.
- A senior member of the guideline panel who is not a chair will serve as the COI Compliance Officer. Throughout the development process, the COI Compliance Officer will review disclosures, facilitate discussions by the panel about conflicts before each call or meeting, and facilitate recusal or other mitigation methods when required as described below.
- On a recommendation by recommendation basis, certain conflicts also may be managed through recusal:
 - Current direct payments or transfers of value >\$5,000/year in aggregate from **for-profit companies** that could be directly affected by that recommendation, i.e., in rare cases where the individual is not dismissed for same
 - Leadership role (e.g., principal investigator) for a research study relevant to the guideline question
 - Other important conflicts at the discretion of panelists, chairs, or the Guideline Oversight Subcommittee
- Final decisions about recusal (e.g., in the case of disagreements) are made by the ASH Guideline Oversight Subcommittee.
- Recused individuals may participate in question formulation, review and discussion of evidence, and manuscript writing but are recused from making judgments about evidence or decisions about the direction or strength of recommendations.
- Recused individuals may be asked to leave the room. This will be decided by ASH staff and the Guideline Oversight Subcommittee on the basis of risk of influence.
- If >49% of the panel must be recused for a guideline question, the panel may not address the question. ASH may appoint a different panel to address the question.

Deviations from Policy

- Individuals who do not substantially abide by the above policy or procedures will be dismissed from the guideline panel. On guideline publication, the participation of dismissed individuals will be described or acknowledged, but dismissed individuals will not be listed as authors.
- Individuals who do not substantially abide by the above policy or procedures will not be invited to participate in future ASH guideline efforts.
- On a case-by-case basis, minor deviations from policy may be managed through disclosure or other means, including by describing the deviation within the guideline publication. The Guideline Oversight Subcommittee will judge if a deviation is “minor.” In general, a “minor deviation” must meet all of the following conditions: (1) occur unintentionally, (2) be unlikely to have influenced any recommendations, and (3) be unlikely to be perceived by guideline users as important.
- Dismissed individuals will generally not be replaced with new panelists. Instead, guideline panels will be initially composed with the expectation that during the development process, some individuals will drop out or be dismissed. For example, usually at least 21 people will be initially appointed to the panel, with the goal of retaining at least 17.
- Decisions about how to manage deviations from policy, including through dismissal, will be by the ASH Guideline Oversight Subcommittee.

Guideline Publication

- A section of the published guidelines, “Guideline Funding and Management of Conflicts of Interest,” describes how conflicts were managed.
- Complete disclosure forms are published as a supplement to the guidelines.
- For 1 year after publication, all panelists are discouraged from speaking on behalf of **for-profit healthcare companies** that could be affected by the guidelines.

Bibliography

American Society of Hematology. Conflict of Interest Policy. Washington, DC: Author. Accessed June 30, 2014. <http://www.hematology.org/About/Governance/380.aspx>.

Council of Medical Specialty Societies. Code for Interactions With Companies. Washington, DC: Author, 2015. <http://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations.pdf>.

Institute of Medicine. Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press, 2011. <http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx>.

Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, Macbeth F, Phillips SM, Robbins C, van der Wees P, Qaseem A. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. *Annals Internal Medicine* 2015; 163:548-553.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P, Board of Trustees of the Guidelines International Network. Guidelines International Network: Toward international standards for clinical practice guidelines. *Annals Internal Medicine* 2012; 156:525-531.