

Response to "Industry Payments to American Society of Hematology Clinical Practice Guideline Authors"

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Abstract:

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Commentary - ASH Guideline Oversight Subcommittee Response to Jacobs et al. (Industry Payments to ASH Guideline Panelists)

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Management of conflicts of interest (COIs) during the development of clinical practice guidelines (CPGs) is essential. A COI describes a situation in which the judgment of an individual or group is at risk of bias from a secondary interest. COIs involve both financial and non-financial interests, e.g., interests that are academic, personal, political, or social.

There are limited data on how COIs actually impact clinical practice guideline recommendations.¹ However, bias may be actual or perceived. Actual bias may affect guideline validity, while perceived bias may affect credibility. At the same time, survey data show that ASH members trust guidelines by known experts.² Such experts, when they have worked for decades in a field of interest, commonly have potential COIs, such as conducting research studies funded by industry.

Like most guideline developers, the American Society of Hematology (ASH) uses practical policies and procedures to manage both real and perceived COIs, with the goal of producing guidelines that healthcare professionals, patients, and policymakers can trust. In this context, we read with interest the quantification by Jacobs et al. of all financial payments by industry to all authors of ASH guidelines from 2018 to 2023, using information from the Centers for Medicare and Medicaid Services' database OpenPayments (openpaymentsdata.cms.gov).³ They report that 77% of United States (U.S.) guideline authors received financial payments, with 59% of payments exceeding \$5,000. The majority of these payments (>90%) were related to research.

There are several limitations to this analysis. First, the completeness, precision, and accuracy of OpenPayments – a publicly accessible database of payments that drug and medical device companies make to U.S. physicians and other healthcare professionals - has been criticized.^{4,5} Second, OpenPayments only tracks U.S.-based physicians. As noted by Jacobs et al., fewer than one-third of the authors of the included ASH guidelines were U.S.-based. Third, Jacobs et al. conflate authors with guideline panelists; under ASH policies, only guideline panelists make decisions about recommendations.

In addition to these obvious limitations, there are logical flaws in the analysis. Most notably, Jacobs et al. equate *any* financial interest reported in OpenPayments with a *direct* financial payment to a panelist. Both OpenPayments and ASH policies distinguish direct financial interests (e.g., payments to an individual for consulting or speaking, equity or ownership, employment) from indirect financial interests, such as research funding paid to an individual's institution rather than directly to the individual. Under ASH policies, indirect financial interests are managed differently than direct financial interests (Appendix).

Furthermore, Jacobs et al. give no consideration to how COIs may be appropriately managed when judged to be present. ASH policies and procedures around COI are regularly reviewed and revised. They aim for all financial and non-financial interests to be transparently disclosed and appropriately managed during the entire guideline development process. ASH's Guideline Oversight Subcommittee, a group whose mandate is to ensure the rigor and transparency of guidelines, appoints an ex officio member to each guideline panel; this individual's chief responsibility is to elicit and analyze COIs, and ensure ASH policies and processes are being followed. The Society collects interests for potential guideline panelists *a priori*, sets a threshold beyond which direct interests automatically exclude an individual from panel participation, and encourages open discussion of all interests during guideline panel meetings. For example, on a recommendation-by-recommendation basis, any panelist with a potential COI may be recused from making judgments about evidence and from making decisions about the direction or strength of the recommendation. All such recusals are then documented within the guidelines.

Every published ASH guideline describes all disclosed interests by authors and guideline panelists, ASH's judgments about those interests, and specific management strategies taken to mitigate COI; this allows users to develop informed opinions about risk of bias.

In summary, Jacobs et al. find that some authors of ASH guidelines have financial relationships with industry. However, they fail to consider how panelist COIs were managed, including with recusal. ASH continues to be committed to management of financial and non-financial relationships, to promote transparency, equity, and the development of trustworthy guidelines. We welcome additional analysis.

References:

1. Norris SL, Holmer HK, Ogden LA, Burda BU. Conflict of interest in clinical practice guideline development: a systematic review. *PLoS One*. 2011;6(10):e25153. doi:10.1371/journal.pone.0025153
2. Byrne M, Mattison R, Bercovitz R, et al. Identifying experts for clinical practice guidelines: perspectives from the ASH Guideline Oversight Subcommittee. *Blood Adv*. 2023;7(16):4323-4326.
3. Jacobs J, Booth GS, Stephens LD, et al. Industry Payments to American Society of Hematology Clinical Practice Guideline Authors. *Blood Adv*. Apr 3 2024;doi:10.1182/bloodadvances.2023012527
4. Lawrence L. Physicians still foggy on accuracy of Sunshine Act data. ASH Clinical News Web site. <https://ashpublications.org/ashclinicalnews/news/1985/Physicians-Still-Foggy-on-Accuracy-of-Sunshine-Act>. Published 2017. Accessed April 18, 2024.
5. Office of Inspector General. *Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting*. <https://oig.hhs.gov/reports-and-publications/all-reports-and-publications/open-payments-data-review-of-accuracy-precision-and-consistency-in-reporting/>. 2018. Accessed April 18, 2024