Commentary

An International Federation of Clinical Chemistry and Laboratory Medicine Policy on Managing Conflict of Interest in Laboratory Medicine Practice Guidance Documents

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Abstract

Evidence-based laboratory medicine practice guidance (LMPG) documents are essential to the standard practice of laboratory medicine. The adoption of well-developed guidance documents can harmonize practices with the ultimate goal of improving the quality of patient care. Guidance documents rely on systematic critical appraisal of available evidence and expert opinions. The latter requires mitigation of any conflicts of interest (COI) that may influence or compromise these recommendations. To ensure trustworthiness of the documents, there should be clear mechanisms to manage COI in guidance document development. Therefore, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Taskforce on Laboratory Medicine Practice Guidelines and Taskforce on Ethics (TF-Ethics) have jointly developed this policy to manage COI when developing IFCC laboratory practice guidance documents, adopting principles from the Guidelines International Network (GIN). A total of nine principles are outlined herein to help manage COI and avoid bias, specifically in LMPG development and revision.

Background

The standard of practice in (laboratory) medicine is underpinned by evidence-based laboratory medicine practice guidance (LMPG) documents, including guidelines, recommendations and position statements, developed by a body of experts [1,2]. Adoption of well-developed guidance documents may harmonize standard of practice and improve quality of care. The development of a practice guidance document involves systematic critical appraisal of available evidence as well as expert judgement call, which has an inherent degree of subjectivity [1]. The writing members of the document must balance the benefits against the harms and costs, bearing in mind the best interest of the patients, when making recommendations [3,4]. The presence of conflicts of interest (COI) may influence these judgements leading to biased recommendations that may deviate from available evidence or compromise the interests of the patients or lead to harm.

Because of the high potential for practice guidance documents to influence laboratory practice, the process of developing such documents must avoid actual bias and minimize perceived bias that may arise from COI [3-5]. This is particularly important to ensure trustworthiness of the documents among healthcare professionals, public and government sectors. Recent evidence has found that COI are prevalent in the development of clinical guidelines and they may not be disclosed or managed appropriately. Moreover, there is evidence that these COI may exert undue influence on the guidelines [6]. This has led to significant scrutiny of the professional bodies and guidance documents, eroding the trust of the professionals/ practitioners and public [5,6]. This in turn impedes the adoption of the guidelines and reduces compliance with the recommendations, which ultimately defeats the objective of clinical guidelines – to improve patient care and outcomes. It should be emphasized that trustworthiness of a guidance document must be maintained to influence practice (and outcomes), and trust is difficult to earn and easy to lose.

There can be several forms of COI as outlined in Guidelines International Network (GIN) [4]. These include direct and relevant indirect COI. Direct COI occur when there are immediate financial ties with a commercial interest in the direct subject matter of the guideline being developed. It can include interests or payments in the form of employment, consultancies, or direct honoraria. Relevant indirect COI can be further separated into two categories: financial/professional or intellectual. The former arises from relationships or situations where a direct payment from a commercial interest does not occur. However, this type of COI can create tangible benefits such as opportunities for academic advancement, research funding or other revenue streams related to the document. The relevant intellectual COI can occur (consciously or unconsciously) when there may be a strong point of view from a guideline development member due to prior publications or well-recognized clinical protocol.

Managing COI in guidance document development the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Taskforce on Laboratory Medicine Practice Guidelines and Taskforce on Ethics (TF-Ethics) have jointly developed this policy to manage COI when developing IFCC laboratory practice guidance documents, reproducing principles from the GIN [4]. The purpose of this policy is to describe the process for managing COI to mitigate and avoid bias, specifically in LMPG development and revision.

The 9 principles reproduced from the GIN are [4]:
Principle 1: Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COI.

Although the GIN recognizes the need for exceptions when this is not practical, such issues should not diminish the importance of this principle. In situations in which panel members have COI, conflicted members should represent a minority on a guideline panel and the guideline developer should be transparent about the reasons for including conflicted members and the management of COI.

Principle 2: The definition of COI and its management applies to all members of a guideline development group, regardless of the discipline or stakeholders they represent, and this should be determined before a panel is constituted.

Principle 3: A guideline development group should use standardized forms for disclosure of interests.

At the time of writing, the TF-E is working in collaboration with the IFCC Executive Board to develop and standardize disclosure forms for the organization as a 2026-2027 priority.

Principle 4: A guideline development group should disclose interests publicly, including all direct financial and indirect COI, and these should be easily accessible for users of the guideline.

As part of this disclosure, the guideline development group should disclose all specific monetary values because COI may arise at different levels in different settings. Reporting of actual or approximate amounts, if known, increases transparency. Registries of disclosures could be used [6].

Principle 5: All members of a guideline development group should declare and update any changes in interests at each meeting of the group and at regular intervals (for example, annually for standing guideline development groups).
Principle 6: Chairs of guideline development groups should

have no direct financial or relevant indirect COI. When direct or indirect COI of a chair are unavoidable, a co-chair with no COI who leads the guideline panel should be appointed.

A relevant COI exists if it influences the direction or strength of a recommendation. An example of a co-chair without such conflicts is a methodologist who has no interest related to the direction or strength of the recommendation.

Principle 7: Experts with relevant COI and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion among those sought to provide input.

In some settings, persons who fulfill this role may be considered expert advisers who are neither voting nor nonvoting members of the guideline development group.

Principle 8: No member of the guideline development group deciding about the direction or strength of a recommendation should have a direct financial COI.

These members should not participate in this phase of guideline development. They should be physically absent from the discussion about the direction and strength of the recommendation.

Principle 9: An oversight committee (e.g., IFCC TF-Ethics) should be responsible for developing, updating and implementing rules related to COI.

Public disclosure of COI

All COI and the corresponding management should be included in the appropriate section (e.g. acknowledgement or COI) of the final guidance document. This could be accomplished through a required checklist at manuscript submission to ensure all the principles were reviewed for each guideline development participant.

Conclusion

This IFCC policy provides a robust framework for disclosing and managing COI when developing a guidance document that is high quality and trustworthy. It also aligns the principles and standards of the IFCC guidance documents with the wider clinical community. The TF-Ethics shall be responsible for reviewing unclear or contentious COI on behalf of the TF-LMPG and making recommendations on their management to the IFCC Executive Board for final approval.

Acknowledgement

None.

Ethical Approval

Not required as study does not involve human subjects or data.

Conflict of interests

None.

CRediT statement

JRW and TPL conceived and wrote the first draft of the manuscript. JV and MMD reviwed and edited the subsequent drafts. All authors agree to the content of the submitted manuscript.

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