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ORIGINAL ARTICLE

A framework is proposed for defining, categorizing, and assessing conflicts of interest in health research

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Abstract

Objective: We propose an operational definition of conflicts of interest (COI), a framework for categorizing interests, and an approach to assessing whether an interest qualifies as a COI.

Study Design and Setting: We reviewed the literature and conducted methodological studies to inform the development of a draft framework for classifying interests.

Results: We developed the following operational definition: ''a conflict of interest exists when a past, current, or expected interest creates a significant risk of inappropriately influencing an individual's judgment, decision, or action when carrying out a specific duty''. Interest refers to a benefit (e.g., money received from industry) or to an attribute of the individual (e.g., having specific religious beliefs). The proposed framework includes seven types of interests relating to individuals (direct financial benefit, benefit through professional status, intellectual, and personal) or their institution (direct financial benefit to the institution, benefit through increasing services provided by the institution, and nonfinancial). When assessing whether an interest qualifies as a COI, one could consider its relevance, nature (e.g., cash vs. educational support), magnitude, and recency.

Conclusion: The proposed operational definition and categorization framework may help journals, guideline organizations, professional societies, and healthcare institutions enhance transparency in health research.

Keywords: Relationship of interest; Conflict of interest; Declaration of interest; Conflict of duty; COI; DOI

1. Introduction

Throughout areas of health practice [1], education, and research, conflicts of interest (COI) have proved common. The potentially negative impact of COI was recently observed during the COVID-19 pandemic, with the case of remdesivir being a good illustrative example [2]. In that case, one of the trials that impacted practice reported that one of the investigators was an employee of the drug manufacturer (Gilead) and six other authors had financial ties to that company. Traditionally, COI concerns have focused on individual financial interests. Indeed, financial COIs are associated with recommendations that favor drugs and devices [3]. Nonfinancial COIs have, however, been gaining increasing attention [4–9], with evidence suggesting that they may affect judgments of individuals conducting health research [5,8,10].

The under-reporting of financial COIs by health science researchers is pervasive [11]. A systematic survey

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What is new?

Key findings

- We propose an operational definition for COI and categorization framework that includes seven types of interests relating to either individuals or their institution.
- We suggest considering relevance, nature (e.g., cash vs. educational support), magnitude, and recency of an interest when assessing whether it qualifies as a COI.

What this adds to what was known?

- We propose a clear and comprehensive framework for categorizing COIs, particularly those related to nonfinancial and institutional interests.

What is the implication and what should change now?

- Journals, guideline organizations, professional societies, and healthcare institutions may use the proposed definition and categorization of interests to enhance transparency in health research.

of 27 studies that assessed the concordance of financial COI disclosures with payments' databases in multiple disciplines found that the median percentage of authors with inaccurate disclosures was 81% [11]. This under-reporting may be related to confusion over definitions, to different understanding regarding what is relevant to disclose or to the lack of a standard way of categorizing those COIs. Also, the clarity of COI definition and characterization of COI among journals and publishers could improve the consistency of COI disclosures.

Recently, to address some of these concerns, the International Committee of Medical Journal Editors (ICMJE) proposed changes to its disclosure form [12]. These include requirements to disclose 'relationships and activities' instead of 'potential COI'. The proposed ICMJE form does not, however, provide guidance for categorizing nonfinancial or institutional relationships. A clear and comprehensive framework of the relationships of interest may help journals and organizations in developing and implementing their COI disclosure policies. We propose in this article an operational definition of COI, a framework for categorizing interests, and an approach to assessing whether an interest qualifies as a COI. In developing our framework, the goal was to be comprehensive. We thus include all types and categories that authors have proposed, including those which remain controversial: nonfinancial, institutional, and personal conflicts.

2. Materials and methods

2.1. Scope

Our authorship team including individuals with expertise in reporting and verification of COI herein propose a definition and framework for health research. Both the definition and framework are relevant to any type of research design (e.g., randomized studies, nonrandomized studies, systematic reviews, practice guidelines), to any research field (e.g., preclinical, clinical, public health, and health policy), and to all roles relevant to the research process (e.g., researchers, funders, journal editors, peer reviewers). The definition and framework are not meant for health provision (e.g., clinical services or public health programs).

2.2. Background research

First, the team reviewed the literature addressing COI definitions, COI types, disclosure policies and tools, and management policies. We then conducted a first series of methodological studies in which we reviewed the websites of peer-reviewed journals to examine their COI disclosure policies; these studies included journals in the clinical (n = 116 [13] and n = 183 [14]), health policy (n = 67) [15], and public health fields (n = 163) [16] (Appendix 1, Table 1). We conducted a second series of methodological studies examining how original publications reported on COI and funding; these studies addressed publications of primary studies and systematic reviews in the clinical (n = 200 randomized controlled trials [17] and n = 200 systematic reviews [18]) and health policy fields (n = 200 systematic reviews [19] and n = 200 systematic reviews [20]) (Appendix 1, Table 2). Finally, we conducted a methodological study of guideline-producing organizations' policies on COI disclosure, management, and reporting (n = 96, unpublished) (Appendix 1, Table 3).

2.3. Development approach

We conducted a content analysis of 23 published definitions of COI (Appendix 2) in which we identified the themes and concepts they addressed and generated a definition capturing those concepts. In parallel, we drafted a framework capturing the variety of COIs. We presented the framework in the context of scientific meetings (G-I-N 2016 Annual Conference, 2016 Cochrane Colloquium) and incorporated feedback from those attending. We assessed whether the framework captured the types of COIs reported in the different methodological studies. In conducting these studies, the team iteratively refined the framework until we were satisfied with its performance. Finally, we used the findings of studies on the COI policies of journals and of guideline-producing organizations to propose an approach to assessing whether an interest qualifies as a COI. We did not follow any specific theoretical orientation in conducting this work.

Box 1 Examples of how interests expected in the future may create a COI

- 'The revolving door between government and industry': one study assessed the later employment of 55 unique hematology-oncology experts following their work as medical reviewers at the US Food and Drug Administration (FDA) [21]. Of 26 who left the FDA, 15 (58%) later worked for or consulted for a biopharmaceutical company. The behavior of these individuals while at the FDA may have been influenced by their concern regarding prospects of subsequent industry employment.
- A cross-sectional study of five guidelines on acute ischemic stroke found that two of 76 authors engaged in new industry employment following the publication of the guidelines [22]. As with the previous example, these authors' contribution to the development of the guidelines may have been shaped by the prospects of industry employment.
- Members of a guideline panel may be influenced to vote for a strong recommendation in favor of a specific policy, hoping the implementation of that recommendation would create more opportunities for them as researchers to conduct studies on the implementation of the policy.
- To increase chances of being invited back to serve on a prestigious or attractive panel (e.g., World Health Organization), members of a public health guideline panel may vote in a way that satisfies the guideline developer.

3. Results

3.1. Operational definition of conflicts of interest

Based on the analysis of 23 identified definitions of COI, we developed the following operational definition:

A COI exists when a past, current, or expected interest creates a significant risk of inappropriately influencing an individual's judgment, decision, or action when carrying out a specific duty.

The definition avoids equating the interest with COI to avoid the misinterpretation that an interest on its own is problematic. Instead, what is problematic is the situation that brings together the interest and the specific duty, which creates the COI.

The term interest may refer to a benefit (e.g., money received from industry) or to an attribute of the individual (e.g., having specific religious beliefs). This definition recognizes that although COI has been typically considered for past or current interests, there is some emerging evidence that interests expected in the future are also relevant (examples in Box 1).

The definition refers to 'risk' because it does not require that an inappropriate judgment, decision, or action has taken or will take place, only that a risk exists [23]. Consequently, the term 'potential COI' represents a nonsequitur, as all potential conflicts would qualify, even in the absence of demonstrable inappropriate judgment, decision, or action as COI. In that spirit, the recently proposed change to the ICMJE form does not ask authors to judge what relationships constitute potential COI. Instead, it asks authors to disclose their relationships and activities so that ''readers can decide whether these relationships or activities should influence their assessments of the work'' [12].

A COI may contribute to an inappropriate judgment (e.g., misjudging whether the evidence implies that a new drug is safe or not), a decision (e.g., recommending in favor of a drug in which harms outweigh benefits), or an action (e.g., preventing a legitimate publication or discrediting sound research work).

Although the term 'primary interests' has been commonly used in COI definitions, it may not intuitively capture the intended concept. In reviewing the explanations supporting those definitions, the team concluded that 'primary interest' refers to a 'duty' that an individual assumes. Examples of a duty in the context of health research include making a clearly rationalized decision when deciding on what data to report on as a member of a trial team, making an objective judgment when deciding on study eligibility as a member of a systematic review team, and making an objective judgment when voting on a recommendation as a member of a guideline panel. The term 'duty' not only more clearly captures the intended meaning but also brings in the sense of responsibility of an individual to deliver a disinterested judgment, decision, or action. Similarly, 'secondary interest' is commonly used in COI definitions and is intended to refer to the interest of the individual or his/her institution. Simply using the term 'interest' helps avoid the confusion of how 'primary' and 'secondary' interests differ.

3.2. The framework for categorizing interests

The proposed framework categorizes interests as per their level (individual or institutional) and their type (e.g., financial, intellectual, personal) (Fig. 1). Box 2 lists the different types of interests and their subtypes, when applicable. Tables 1−7 in Appendix 3 provide more detailed descriptions of the different types with one or more examples for each type or subtype.

Of the types of interests, financial apply to both the individual and the institutional levels, although intellectual and personal conflicts apply only to the individual level. Individual interests relate to the individuals themselves or their close associates (e.g., family members). Intellectual conflicts

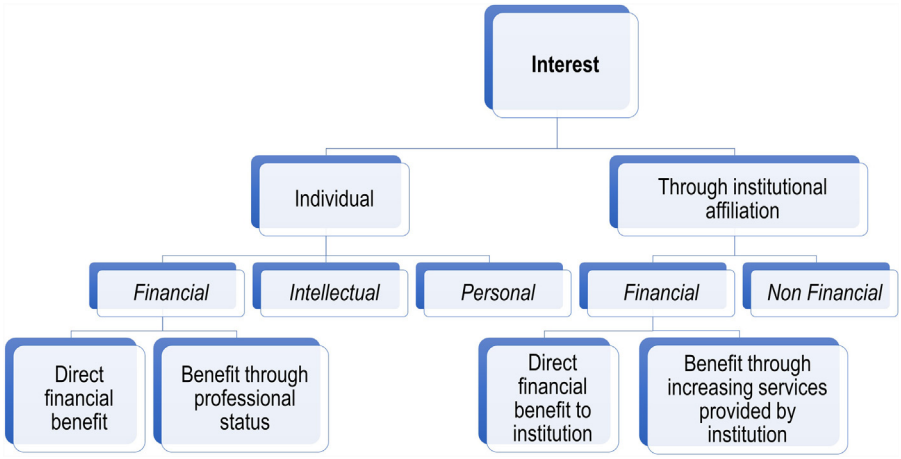

Fig. 1. Framework for categorizing interests in health research.

Box 2 The different types of interests and their subtypes, when applicable

- Individual financial interests with direct financial benefit
  - Grant
  - Employment income
  - Personal fees (other than employment income)
  - Nonmonetary support
  - Study supplies
  - Patents
  - Stocks and other securities
- Individual financial interests with benefit through professional status
- Individual intellectual interests
  - Participation in primary studies.
  - Participation in secondary studies.
  - Participation on guideline panel.
  - Public expression of opinion.
- Individual personal interests
  - Beliefs (religious, political, and philosophical).
  - Personal characteristics (gender, age, race, physical/psychiatric condition, and sexual orientation).
- Institutional financial interests with direct financial benefit to the institution
  - Institution received gifts, endowments, or grants from commercial entities.
  - Institution holds intellectual property rights of programs or services, patents, equity positions, or options in biotechnology, pharmaceutical, or medical device companies.
  - The government has formal or informal partnerships with commercial entities (relevant to governmental officials).
  - Senior officials who act on behalf of the institution have personal financial interests.
- Institutional financial interests with benefit through increasing services provided by the institution
- Institutional nonfinancial interests
  - Institution focuses on a specific topic of research.
  - Institution involved in advocacy in a specific area.

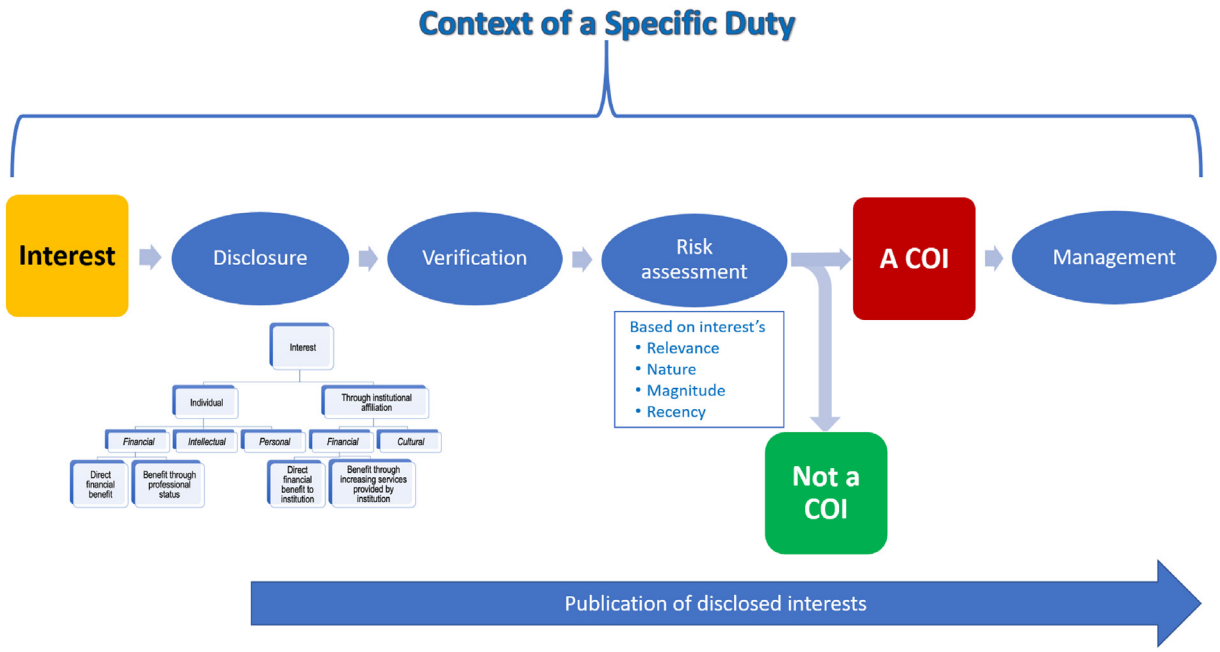

Fig. 2. Situating the categorization of the interests and their risk assessment in health research in the broader context of conflicts of interest policies.

represent academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation [24]. Institutional interests relate to the institution with which the individual is affiliated but only to those interests of which the individual is aware. Indeed, one would not expect an individual to be aware of all the interests of their institution or to investigate all institutional interests. For example, the British Association of Dermatologists' policy for declaring COIs states the following with regards to the declaration of 'nonpersonal financial interests': 'members covered by this policy document are not obliged to seek out knowledge of work done for, or on behalf of, the commercial sector within the departments where the guideline development group member is employed, if normally they would not expect to be informed.' [25].

3.3. Assessing whether an interest qualifies as a conflict of interest

Assessing whether an interest qualifies as a COI requires the evaluation of whether it increases the risk of inappropriate judgment, decision, or action. One could consider the following factors:

- Relevance of the interest to the duty the individual is assuming. For example, in the context of judging the effectiveness of a specific medication for a specific health condition, relevance is higher for an honorarium for a presentation on the use of that same medication for that specific condition versus an honorarium for a different medication used for a different health condition.
- Nature of the interest (e.g., higher risk with a cash honorarium versus educational support).
- Magnitude of the interest (e.g., higher risk with a larger monetary value of an honorarium).
- Recency of the interest (e.g., higher risk with an honorarium received 1 month ago versus 5 years ago).

Although risk of influence resulting in an inappropriate judgment represents a continuum, one could, for practical purposes, use a classification into discrete categories, for example, major and minor, important or unimportant. For example, the American College of Physicians (ACP) classifies COIs into "high-level, moderate-level, or low-level" [26]. Typically these categories are associated with different management actions [27]. The distinction between categories could rely on one or perhaps more usefully on several of the factors used to assess the risk of inappropriate judgment, decision, or action. The parameters (e.g., thresholds, scales) needed to assess those factors would need to be set by the entity assessing those interests.

Figure 2 situates the categorization of the interests and their risk assessment in the broader context of COI policies. It shows that research organizations (e.g., granting agencies, guideline developers, journals) expect individuals to disclose their interests and assess whether the risk associated with the reported interests qualify them as COIs. It clearly shows that transparency in declaration is necessary but not sufficient for mitigating the impact of COI.

4. Discussion

4.1. Summary

In this article, we propose an operational definition of COI in the area of health research, a framework with seven categories of interests (Fig. 1; Box 2), and criteria for deciding whether an interest qualifies as a COI. The framework reflects what the health research community has considered to be an interest requiring disclosure.

The proposed definition builds on a careful content analysis of existing definitions of COI, although avoiding the use of abstract concepts. The framework for categorization of interests arising from the definition supports its potential usefulness. We refined that framework by assessing whether it captured the different types of COIs reported in a wide variety of publications. One limitation of the framework is that further validation and assessment of feasibility are still required.

In applying our framework, one must distinguish between the funding of a study and the COIs of individuals involved. Funding is an attribute of the study itself, although a COI is an attribute to the individual involved, which might relate to benefits unrelated to that study, for example, receiving funds from a drug company sponsoring unrelated projects. Although both increase the risk of biasing the study results, those risks are assessed differently. To address possible bias from study funding, one would typically evaluate the degree of involvement of the funder in the design, conduct, and reporting of the study. For individuals' COI, one would evaluate the relevance, nature, magnitude, and recency of their declared interest.

To avoid the misinterpretation that an interest is problematic on its own, our definition does not equate an interest with a COI. This is particularly important for nonfinancial interests (i.e., intellectual and personal) that require a more cautious approach than financial interests. For example, some have raised concerns regarding how putative intellectual COI could result in possibly inappropriate exclusion of individuals from guideline panels. Specifically, there are several examples in which the FDA is thought to have excluded panelists whose positions are not proindustry because of what may be an inaccurate or inappropriate concern regarding intellectual COI [28]. Indeed, there is an ongoing debate about whether nonfinancial interests should be considered as COIs [29,30].

Similarly, individuals' disclosure of personal characteristics (e.g., sexual orientation, mental illness) or beliefs (e.g., political or religious affiliation) can be associated with potential harms, such as stigma and discrimination. Considering personal interests should probably be restricted to exceptional situations in which the risk of COI is high and the harms of disclosure are carefully mitigated. One example relates to the disclosure of religious affiliation and circumcision history by an author of a systematic review on neonatal herpes simplex virus infection and Jewish ritual circumcision with oral suction [31].

In its seminal report on 'Conflict of Interest in Medical Research, Education, and Practice', the Institute of Medicine provided a table of a ''candidate list of basic categories of the relationships to be disclosed'' [32]. All listed categories represent strictly individual financial COIs and still do not include the category of 'nonmonetary support'. As mentioned earlier, the ICMJE recently published an improved disclosure form [12]. Although that form provides a comprehensive list of financial interests, it does not detail the different types of nonfinancial or institutional interests. Also, the form requires authors to disclose their relationships and activities to allow readers to decide whether that disclosure should affect their assessments of the work [12]. However, it is unclear whether it is feasible to have authors report all sorts of interests that may be completely irrelevant to the duty at hand. Also, such a broad disclosure may muddle the relevant conflicts.

4.2. Implications for practice

Our framework for COI may help to meet increasing expectations of transparency in health research among stakeholders, including citizens [33]. Having an explicit and operational definition and framework may help individuals disclosing their interest consider all potential types of interests that they might need to declare. Also, it may help health journals implement a clear and coherent approach to COI reporting [34]. Guideline organizations and professional societies could use this framework as the basis for their COI disclosure policy and their COI disclosure forms, including those embedded in web-based repositories such as Convey (http://www.convey.org). The use of the framework could lead to use of a consistent terminology in the explicit acknowledgment of all types of COI. Finally, classifying interests under specific types may, given they will differ by type, facilitate implementing appropriate management actions [27].

4.3. Implications for future research

Future research may continue to refine and validate our approach to categorizing interests and may explore the nature and impact of the less well-understood aspects of COI, in particular intellectual COI. Such research may use a theoretical approach that considers different theoretical orientations [35–37]. Investigators may conduct randomized trials to assess the effects of different approaches to disclosures of interest on author, editor, peer reviewer, and consumer usability and acceptability. Also, researchers studying COI may use the framework to ensure a lucid and consistent characterization of the extent and impact of COI. Finally, there is a need for empirical research addressing the assessment of relevance of an interest to a specific duty.

CRediT authorship contribution statement

Elie A. Akl: Conceptualization, Methodology, Investigation, Formal analysis, Visualization, Writing − original draft. **Maram Hakoum:** Investigation, Formal analysis, Writing − review & editing. **Assem Khamis:** Investigation, Formal analysis, Writing − review & editing. **Joanne Khabsa:** Investigation, Formal analysis, Writing − review & editing. **Matt Vassar:** Formal analysis, Writing − review & editing. **Gordon Guyatt:** Conceptualization, Methodology, Formal analysis, Writing − review & editing.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2022.06.001.

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