**Addressing conflicts of interest in health and medicine: current evidence and implications for patient decision aid development**

**ABSTRACT**

**Background** More stringent policies for addressing conflicts of interest have been implemented around the world in recent years. Considering the value of revisiting conflict of interest quality standards set by the International Patient Decision Aid Standards (IPDAS) Collaboration, we sought to review evidence relevant to two questions: (i) What are the effects of different strategies for managing conflicts of interest? and (ii) What are patients’ perspectives on conflicts of interest?

**Methods** We conducted a narrative review of English language articles and abstracts from 2010 to 2019 that reported relevant quantitative or qualitative research.

**Results** Of 1,743 articles and 118 abstracts identified, 41 articles and 2 abstracts were included. Most evidence on the effects of conflict of interest management strategies pertained only to subsequent compliance with the management strategy. This evidence highlighted substantial non-compliance with prevailing requirements. Evidence on patient perspectives on conflicts of interest offered several insights, including the existence of diverse views on the acceptability of conflicts of interest, the salience of conflict of interest type and monetary value to patients, and the possibility that conflict of interest disclosure could have unintended effects. We identified no published research on the effects of IPDAS Collaboration conflict of interest quality standards on patient decision-making or outcomes.

**Limitations** Because we did not conduct a systematic review, we may have missed some evidence relevant to our review questions. Additionally, our team did not include patient partners.

**Conclusions** The findings of this review have implications for the management of conflicts of interest not only in patient decision aid development but also in clinical practice guideline development, health and medical research reporting, and health care delivery.

**INTRODUCTION**

In the last decade, mounting concerns about the prevalence and consequences of conflicts of interest among people who influence patient care and outcomes have prompted significant shifts in corresponding policies, standards, and procedures. Transparency initiatives that either mandate or encourage public disclosure of financial relationships between health professionals and pharmaceutical or medical device companies have been implemented in several countries (1). The ﻿International Committee of Medical Journal Editors (ICMJE) has adopted uniform requirements for disclosure of financial and non-financial competing interests by authors publishing in member journals (2). Additionally, organizations responsible for developing clinical practice guidelines have imposed more rigorous processes for preventing and managing financial and non-financial conflicts of interest among guideline contributors.

The move toward more stringent approaches to conflicts of interest is not yet reflected in the quality standards set by the International Patient Decision Aid Standards (IPDAS) Collaboration. The Original IPDAS Checklist –a framework of 74 decision aid quality criteria developed through a robust and inclusive consensus process in 2005 (3)– includes four universal criteria pertaining to conflicts of interest. These criteria require that decision aids disclose the “source of funding to develop and distribute the patient decision aid” and “whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid” (4). However, the three subsequent variants of the checklist – the IPDAS Instrument (﻿IPDASi v3)(5), the Short Form IPDAS Instrument (﻿IPDASi-SF) (5), and the IPDAS Minimum Standards (IPDASi v4) (6) – are decidedly less concerned with conflicts of interest, requiring disclosure of only sources of funding for decision aid development and not relevant author interests, relationships, or conflicts of interest.

Advances in thinking and practice have also revealed some shortcomings in the process of developing conflict of interest criteria for the Original IPDAS Checklist and in the criteria themselves. First, disclosure to advisees was the only conflict of interest management strategy considered as the original criteria were decided (7,8). Although more stringent approaches have since been advocated by us and others in the decision aid scientific community (9,10), these have not yet been formally debated. Second, there is ambiguity in the scope of the disclosure requirements set out in the criteria. For example, they refer to decision aid authors’ ‘affiliations’ without stipulating whether this is intended to mean employers, family members, professional societies or affiliations, or indeed any person or group with which authors have a relationship. They refer to being in a position to ‘gain or lose’ from patients’ choices without qualifying whether this is intended strictly in a financial sense or also in non-financial ways. They also do not impose timeframes for required disclosures. Third, the criteria do not suggest who should determine if disclosures are warranted or how disclosures should be made in decision aids. In particular, they do not require that disclosures be prominent or written in plain language (10).

Considering the potential value of revisiting conflict of interest quality standards set out in the Original IPDAS Checklist and subsequent variants, we accepted an invitation from the IPDAS Collaboration to compile an updated review of evidence relevant to conflicts of interest and patient decision aids. In undertaking this review, our objective was to collate and critically analyze contemporary evidence relevant to conflict of interest management that could be considered alongside ethical perspectives on the issue. Cognizant of the multitude of conceptualizations and definitions of conflicts of interest that have been used in research and practice, we elected not to constrain our evidence review by adopting any single operational definition of conflicts of interest. Additionally, given that a past review on this topic identified limited evidence of direct relevance to patient decision aid development (10), we chose not to restrict our review only to research on patient decision aids. Rather, we sought to answer three broad review questions, two of which are the focus of this paper: (i) What are the effects of different strategies for managing conflicts of interest? and (ii) What are patients’ perspectives on conflicts of interest? The remaining review question (i.e., What are the effects of conflicts of interest?) will be the focus of a forthcoming paper.

**METHODS**

**Review approach**

Given the broad scope of our review questions, we conducted a narrative review to collate and critically analyze relevant evidence.

**Inclusion criteria**

Eligible for inclusion were English language journal articles and conference abstracts published from January 1, 2010 to December 31, 2019 that reported original quantitative or qualitative research relevant to at least one of our review questions. This timeframe was chosen based on our interest in summarizing contemporary evidence relevant to conflict of interest management. The articles and abstracts that were considered relevant to each review question are explained below. Ineligible for inclusion were articles describing case studies, brief reports, and non-research articles (e.g., commentaries, editorials, position statements, letters to the editor, article responses and replies).

***Question 1: What are the effects of different strategies for managing conflicts of interest?***

Articles and abstracts considered relevant to this review question were those that provided evidence on the effects of a specific strategy for managing conflicts of interest in the context of patient decision aid development, clinical practice guideline development, health and medical research reporting, or health care delivery. Articles and abstracts were not required to have used the term ‘conflicts of interest’ or adopted any specific operational definition of conflicts of interest to be considered relevant to this review question. Management strategies could have included, for example, disclosing conflicts of interest to advisees (e.g., decision aid users, guideline users, readers of research articles, patients) or restricting the roles of people with a conflict of interest. Outcomes could have included, for example, compliance with the management strategy or the knowledge, attitudes, beliefs, preferences, or behavior of advisors (e.g., health professionals) or advisees (e.g., patients).

***Question 2: What are patients’ perspectives on conflicts of interest?***

Articles and abstracts considered relevant to this review question were those that provided evidence on the perspectives of patients and the public on conflicts of interest in the context of patient decision aid development or health care delivery. We did not seek to include evidence on the perspectives of patients and the public on conflicts of interest in the context of clinical practice guideline development or health and medical research reporting, as patients and the public are not the primary advisees in these settings. Again, articles and abstracts were not required to have used the term ‘conflicts of interest’ or adopted any specific operational definition of conflicts of interest to be considered relevant to this review question. Patients and the public were considered to exclude health professionals and trainees, health administrators, policy makers, and industry representatives. Perspectives could have included, for example, which interests or conflicts of interest, if any, are problematic, whether conflicts of interest should be disclosed to advisees (e.g., patients), or how conflicts of interest should be managed.

**Information sources and search strategy**

We searched for articles and abstracts using the PubMed database and in International Shared Decision Making conference abstract books. For the database search, we used a relatively broad set of search terms to capture articles relevant to all review questions in a single search (see Box 1). We searched for these terms in the title field only to enhance precision given their frequent inclusion in abstracts unrelated to the topic of interest. Our search was limited to English language articles with a publication date between January 1, 2010 and December 31, 2019. For the abstract book search, we used a series of terms (see Box 1) to search seven abstract books from the five International Shared Decision-Making conferences held between 2010 and 2019. Only English language abstracts of oral and poster presentations were searched; abstracts pertaining to workshops, symposia, keynotes, and special interest groups were not searched. For poster presentations from the 2015 International Shared Decision-Making conference, only titles could be searched as abstracts were not published.

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| **Box 1** Search terms**Database search**:(conflict of interest OR conflicts of interest OR competing interest\* OR financial interest\* OR industry relationship\* OR industry payment\* OR industry funding OR financial tie\* OR industry tie\* OR financial relationship\* OR non-financial) OR ((review OR analysis OR content OR environmental scan) AND decision aid\*)**Abstract book search**: conflict of OR conflicts of OR competing OR financial OR industry OR non-financial OR disclos OR IPDAS OR International Patient |

**Article screening, article review, and data extraction**

For articles identified through the database search, both title and abstract screening and full text review were completed in Covidence (11). XX screened all titles and abstracts. XX and XX conducted duplicate full text review of 50 articles to help establish uniform application of our inclusion criteria and XX conducted full text review of the remaining articles. For abstracts identified through the abstract book search, XX screened all titles and abstracts. XX conducted all data extraction.

**Evidence synthesis**

We adopted a narrative approach to synthesizing evidence because we anticipated substantial methodological heterogeneity across identified studies.

**Role of the funding source**

This evidence review was undertaken without dedicated external funding.Sources of financial support for authors’ time had no role in the work.

**RESULTS**

**Included articles and abstracts**

The database search identified 1,743 articles of which 41 were included (see Figure 1). The conference abstract book search identified 118 abstracts of which 2 were included (see Figure 1).

- Insert Figure 1 here -

**What are the effects of different strategies for managing conflicts of interest?**

We identified 30 articles that provided evidence on the effects of a specific strategy for managing conflicts of interest[[1]](#footnote-1) in the context of patient decision aid development, clinical practice guideline development, health and medical research reporting, or health care delivery(see Tables S1 - S4). The articles described studies that assessed five broad management strategies: conflict of interest disclosure to advisees, conflict of interest disclosure to others (e.g., conveners, co-advisors), role or group composition restrictions, divestment, and exclusion. Although some articles provided evidence on the effects of the management strategy on advisee perceptions, attitudes, or beliefs, most described studies that focused simply on compliance with the management strategy.

***Patient decision aid development***

Five articles provided evidence on the effects of a conflict of interest management strategy in the context of patient decision aid development (12–16) (see Table S1). All five articles described document analysis studies that assessed compliance with the strategy of conflict of interest disclosure to advisees, although researchers made no attempt to verify the accuracy of disclosure statements when assessing compliance. One article described a study that assessed compliance with the disclosure requirements of the Original IPDAS Checklist (12), one with the IPDAS Instrument (13), two with the Short Form IPDAS Instrument (14,15), and one with the IPDAS Minimum Standards (16). Across articles, 50-100% of decision aids were determined to be in compliance with disclosure requirements (12–16).

***Clinical practice guideline development***

Twelve articles provided evidence on the effects of a conflict of interest management strategy in the context of clinical practice guideline development (17–28) (see Table S2).

Eight articles described studies that used document analysis and/or analysis of linked datasets to assess compliance with the strategy of conflict of interest disclosure to advisees (17,18,21–26). When researchers made no attempt to verify the accuracy of disclosures, 93-100% of guidelines and 84-98% of guideline authors were determined to be in compliance with disclosure requirements (17,18,21–24). However, when researchers used public industry payment data to verify the accuracy of disclosures, up to 23% of guideline authors were found to have omitted one or more financial relationships from their disclosures (18,25,26).

Two articles described document analysis studies that assessed compliance with the strategy of pre-selection disclosure of potential conflicts of interest to guideline development group conveners (21,27), two articles described document analysis studies that assessed compliance with the strategy of advance discussion of member conflicts of interest by the prospective guideline development group (21,27), and one article described a document analysis study that assessed compliance with the strategy of explaining to guideline development group members how identified conflicts of interest could influence group decisions (27). The guideline development group(s) assessed were determined to be in compliance with pre-selection disclosure and advance discussion requirements but not to be in compliance with the requirement to explain possible effects of identified conflicts of interest (21,27).

Four articles described studies that used document analysis and/or analysis of linked datasets to assess compliance with the strategy of excluding people with conflicts of interest from leadership roles and none of the guideline development groups assessed were determined to be in compliance with this requirement (18,21,27,28). Two articles described studies that assessed compliance of a single guideline development group with the strategy of excluding people with conflicts of interest from decision-making roles (19,20). One study conducted an analysis of linked datasets and the other interviewed guideline panelists. Both articles reported non-compliance with exclusion requirements (19,20). Three articles described document analysis studies that assessed compliance with the strategy of ensuring that a majority of the guideline development group is free of conflicts of interest (21,27,28). One of the guideline development groups assessed was determined to be in compliance with this requirement while two were not (21,27,28).

Two articles described document analysis studies that assessed compliance with the strategy of divestment from relevant financial interests by guideline development group members and their families and neither of the groups assessed was determined to be in compliance with this requirement (21,27). One article described a document analysis study that assessed compliance with the strategy of excluding people with conflicts of interest from guideline development group membership where possible and again, the guideline development group assessed was determined not to be in compliance with this requirement (27). A final article described a document analysis study that assessed compliance with the strategy of excluding guideline funders from participation in guideline development and the guideline development group assessed was determined to be compliance with this requirement (21).

***Health and medical research reporting***

Nine articles provided evidence on the effects of a conflict of interest management strategy in the context of health and medical research reporting (29–37) (see Table S3).

Six articles described studies that used document analysis, presentation analysis, and/or analysis of linked datasets to assess compliance with the strategy of conflict of interest disclosure to advisees (29–34). When researchers made no attempt to verify the accuracy of disclosures, 70-100% of conference presenters were determined to be in compliance with disclosure requirements (29–33). However, when researchers used public industry payment data to verify the accuracy of disclosures, they found that 33% of presenters who had received payments had omitted or under-disclosed them (34).

Three articles described studies that assessed the effects of the strategy of conflict of interest disclosure to advisees on advisee perceptions, attitudes, or beliefs (35–37). All studies had an experimental design and simulated the effects of one or more disclosure policies by exposing health professionals to different versions of an article or abstract. Outcomes assessed included perceptions of the methodological quality of the study, confidence in the study conclusions, and reported likelihood of changing one’s practice based on the study. None of the three articles reported effects of the article or abstract version on participants’ perceptions, attitudes, or beliefs (35–37).

***Health care delivery***

Four articles provided evidence on the effects of a conflict of interest management strategy in the context of health care delivery (38–41) (see Table S4). All four articles described studies that assessed the effects of the strategy of conflict of interest disclosure to advisees on advisee perceptions, attitudes, or beliefs. All studies had an experimental design and simulated the effects of one or more disclosure policies by exposing people to different physician disclosures or health care scenarios. Outcomes assessed included perceptions of the physician’s expertise, knowledge, moral character, and focus on patient interests; trust in the physician; insinuation anxiety (i.e., worry that deviation from physician recommendations would signal distrust (38)); and reported likelihood of choosing the physician and following their advice. All four articles reported at least some effects of the scenario or disclosure on participants’ perceptions, attitudes, or beliefs (38–41) (see Table S4).

**What are patients’ perspectives on conflicts of interest?**

We identified 15 articles and abstracts that provided evidence on the perspectives of patients and the public on conflicts of interest in the context of patient decision aid development or health care delivery (see Tables S5 - S11). Articles and abstracts described nine studies conducted in the United States (39,40,42–48), one in Canada (49), one in the United States and Canada (50), and four in unreported locations (51–54). There was considerable heterogeneity in study methods, perhaps due to the absence of any overarching methodological framework to guide evidence generation. For example, studies varied widely in their approach to assessing and analyzing participant perspectives (e.g., how questions were framed, how missing data were treated) and in the extent to which participants were provided with education on conflicts of interest prior to the elicitation of their perspectives. Studies also varied in setting and participant characteristics, although most used small convenience samples and a surprising number assessed perspectives on conflicts of interest in the specific care context of musculoskeletal surgery. The evidence described in these articles and abstracts spanned seven broad domains, as elaborated below.

***Awareness of the existence or extent of conflicts of interest in health and medicine***

Three articles provided evidence on patient and public awareness of the existence or extent of conflicts of interest in health and medicine (43,49,50) (see Table S5). Articles that described survey studies reported that 55-70% of participants were aware that doctors could have financial relationships with drug companies (50) and 36-58% were aware that surgeons could have financial relationships with device companies (43,50). An article that described an interview study similarly reported greater patient awareness of financial relationships between physicians and the pharmaceutical industry than between surgeons and surgical device manufacturers (49).

***Perspectives on the acceptability of conflicts of interest in health and medicine***

Five articles provided evidence on patient and public perspectives on the acceptability of conflicts of interest in health and medicine (42,43,50–52) (see Table S6). All articles described survey studies and reported that 46-53% of participants found it acceptable (and 25-32% unacceptable) for surgeons to receive direct payments from device manufacturers (50), 21-69% found it acceptable (and 15-49% unacceptable) for surgeons to have income-generating ownership interests (50), 11-52% found it acceptable (and 31-63% unacceptable) for surgeons to receive gifts from industry (50,52), 31-53% found it acceptable (and 28-62% unacceptable) for surgeons to have financial relationships or conflicts of interest in general (42,43), and 82% found it acceptable (and 18% unacceptable) for surgeons to have non-financial relationships with industry (51).

***Perspectives on the attributes of people with a conflict of interest***

Four articles provided evidence on patient and public perspectives on the attributes of people with a conflict of interest (39,43,44,49) (see Table S7). An article that described a survey study reported that 8-11% of participants considered surgeons with a conflict of interest to be less trustworthy, 11-16% considered them to prioritize income generation over patient care, 26-36% considered them to be more competent, 35-37% considered them to be more devoted to their profession, and 72-74% considered them to be the top experts in their field (43). Articles that described other survey, interview, and focus group studies also reported both positive and negative attributes ascribed to doctors and surgeons with a conflict of interest (39,44,49).

***Perspectives on the effects of conflicts of interest on health care quality and costs***

Four articles provided evidence on patient and public perspectives on the effects of conflicts of interest on health care quality and costs (39,43,51,52) (see Table S8). With respect to health care quality, articles that described survey studies reported that 18-69% of participants felt that financial relationships between surgeons and industry would have a positive effect, 6-39% felt they would have a negative effect, and 25-76% felt they would have no effect (43,51,52). An article that described another survey study reported that participants commonly felt that some financial relationships between doctors and industry (e.g., receipt of free drug samples) would have a positive effect on health care quality while others (e.g., stock ownership, receipt of travel, meals, and entertainment) would have a negative effect (39). With respect to health care costs, an article that described a survey study reported that 7-14% of participants felt that financial relationships between surgeons and industry would have a positive effect, 29-34% felt they would have a negative effect, and 57-63% felt they would have no effect (43).

***Perspectives on the effects of learning of a conflict of interest***

Five articles and one abstract provided evidence on patient and public perspectives on the effects of learning of a conflict of interest (42,45,46,48,50,53) (see Table S9). The outcomes assessed included perceptions of a health professional with the conflict of interest, the likelihood of choosing them to provide care or perform a procedure, and the likelihood of following their advice. Articles that described survey studies reported that 55-62% of participants felt that learning of receipt of direct payments would have an effect (42,45), 62% felt that learning of receipt of research funding would have an effect (42), 21-68% felt that learning of income-generating ownership interests would have an effect (42,45,46), 65% felt that learning of receipt of gifts would have an effect (45), 24-78% felt that learning of financial relationships or conflicts of interest in general would have an effect (42,46,50), and 66-83% felt that learning of non-financial relationships with industry would have an effect (42,45). An article and an abstract that described other survey studies reported perspectives that learning of a conflict of interest would influence therapeutic preferences or decisions (48,53).

***Perspectives on the salience of conflict of interest type or monetary value***

Seven articles provided evidence on patient and public perspectives on the salience of conflict of interest type or monetary value (39,40,42,45,46,49,53) (see Table S10). With respect to conflict of interest type, an article that described a survey study reported that 74% of participants felt that the type of physician-industry relationship would affect how they viewed the relationship (53). The same article reported that some physician-industry relationships were more widely viewed as posing a conflict of interest than others (53). Articles that described other survey or interview studies similarly reported that participants considered some physician-industry relationships to be more ethical, acceptable, or concerning than others (39,45,49) but also that a majority felt that patients should be informed about each of seven types of relationship (i.e., stock ownership, royalty payments, speaking fees, free drug samples, lunch for office staff, payments for consulting on new drug development, travel) (39). With respect to conflict of interest monetary value, articles that described survey studies reported that 58% of participants felt that the dollar amount involved in a physician-industry relationship would affect how they viewed the relationship (53) and 52% wanted to know the extent of their surgeon’s financial conflicts of interest (42). Another reported that the amount of industry payments physicians received was negatively correlated with patients' ratings of trust (40). Articles describing survey studies also reported a range of perspectives on the monetary threshold at which their trust would be affected (46) or a conflict of interest posed (53).

***Support for conflict of interest management strategies***

Eleven articles and two abstracts provided evidence on patient and public support for conflict of interest management strategies (39,42–44,46–54) (see Table S11).

Nine articles and two abstracts described studies that assessed support for the strategy of conflict of interest disclosure to advisees (39,42–44,46–48,50–53). With respect to general support for disclosure, articles that described survey studies reported that 42-91% of participants endorsed disclosure of physicians’ relationships or conflicts of interest to at least some of their patients (42,43,46,51,52) but also that only 13% had previously sought out information on their physicians’ financial relationships (46). Articles that described other survey and focus group studies reported that participants commonly felt that information on physician compensation should be made available to all patients, expected full disclosure of physicians’ conflicts of interest, and felt that this was a valuable use of physicians’ time (44,53).

With respect to support for different approaches to disclosure, articles that described surveys studies reported that 42-53% of participants endorsed verbal disclosure, 38-77% endorsed written disclosure, and 30-38% endorsed online disclosure (50,53). They also reported that 32-52% of participants felt they would make use of online information on physician-industry relationships (39,50). An abstract that described another survey study reported that a majority of participants wanted to learn about clinic profit associated with therapeutic options from doctors during the visit (48) while an article that described a focus group study reported wide support for both advance provision of accessible written information on doctors’ conflicts of interest – including contact details for further information – by office staff and verbal disclosure and explanation of conflicts of interest by doctors during relevant visits (44). A final abstract that described a survey study pertained specifically to patient decision aid development and reported that participants slightly favored disclosure of competing interests and/or the relevant competing interest policy in a supporting document over the decision aid itself (47).

Five articles described studies that assessed support for the strategy of conflict of interest oversight, whether by individuals themselves, professional bodies, employers or institutions, government, or industry (43,49–51,54). Articles that described survey studies reported that 78-81% of participants endorsed oversight by individuals, 83% endorsed oversight by professional bodies, 60-61% endorsed oversight by employers or institutions, and 24-35% endorsed oversight by government (43,50). Articles that described other survey and interview studies also reported more widespread support for some approaches to conflict of interest oversight than others (49,51,54).

A final article described a study that assessed support for the strategy of avoidance of conflicts of interest (43). The article described a survey study and reported that, while 12% of participants agreed with the notion that surgeons should not have any relationships with industry, 78% did not (43).

**DISCUSSION**

This evidence review summarizes an important and growing literature on both conflict of interest management in health and medicine and patient and public perspectives on conflicts of interest. Evidence on the effects of conflict of interest management strategies highlights substantial non-compliance with prevailing requirements in settings of patient decision aid development, clinical practice guideline development, and health and medical research reporting, particularly where requirements were more stringent than simple disclosure (e.g., Institute of Medicine clinical practice guideline standards, American College of Chest Physicians Antithrombotic Guidelines requirements). The effects of conflict of interest management strategies on other outcomes remains largely uncertain, due both to the small volume of research and to the use of simulated studies with modest real world relevance. Evidence of patient perspectives on conflicts of interest provides insights in several areas, including general awareness of conflicts of interest, the attributes ascribed to people with a conflict of interest, and the acceptability of both conflicts of interest and conflict of interest management strategies. Particularly notable was evidence that conflict of interest type and monetary value are highly salient to patients.

This review also highlights gaps in evidence on conflict of interest management and key research directions for the field. Most of the evidence on management strategy effects pertains only to compliance, often at a superficial level, precluding understanding of whether approaches have achieved their intended outcomes. In the setting of decision aid development, for example, there is no published research on the effects of IPDAS Collaboration conflict of interest quality standards on patient decision-making or outcomes. Research addressing whether conflict of interest management strategies meet their objectives is a priority but also requires that those implementing strategies be explicit about what those objectives are. Evidence of patient perspectives on conflicts of interest was generated predominantly in North America via surveys of small and selective samples. Although surveys like these can provide useful insights into a group’s perspectives irrespective of knowledge, they would be complemented by approaches such as ﻿citizen juries that enable us to understand the perspectives of a group representative of the population of interest after being fully informed on the issue (55). More broadly, the studies described in articles and abstracts included in this review were characterized by substantial methodological heterogeneity which impeded both synthesis of evidence and the generation of possible explanations for discrepant findings. Adoption of an overarching methodological framework to guide evidence generation in the field of conflict of interest management may improve the coordination, compatibility and completeness of research.

The limitations of our review warrant discussion. Because we did not conduct a systematic review, we may have missed some relevant evidence and did not formally assess the quality or risk of bias of included studies. Additionally, we were unable to include patient partners in our review team, which restricted the perspectives that shaped our interpretation of evidence and subsequent recommendations. But these limitations are balanced by several strengths. Our team was international and multidisciplinary, with diverse expertise in patient decision aids, health care delivery, and the law. The breadth of our review questions led us to collate a large and diverse body of evidence on conflict of interest management that has relevance for a variety of knowledge users and contexts. Additionally, our inclusion of a review question dedicated to the perspectives of the beneficiaries of patient decision aids (i.e., patients and the public) on conflicts of interest enables the appropriate consideration of this evidence alongside evidence of the effects of conflict of interest management strategies and ethical perspectives.

**Conclusions and recommendations**

The findings of our review have important implications for the management of conflicts of interest in health and medicine, including in clinical practice guideline development, health and medical research reporting, and health care delivery. For example, evidence of substantial non-compliance with prevailing conflict of interest disclosure requirements and other management strategies suggests the need to pay more attention to issues of implementation and enforcement when designing and adopting these strategies. Additionally, although a minority of articles and abstracts provided evidence directly from the setting of patient decision aid development, there are significant implications of our review findings for the approach to conflict of interest management adopted by the IPDAS Collaboration as we outline below.

First, evidence of non-compliance with existing IPDAS quality standards suggests that it is prudent to take further steps to ensure expectations for conflict of interest disclosure by decision aid developers are clear and well understood. In particular, this evidence suggests the importance of addressing the definitional and other ambiguities we identified in existing conflict of interest quality standards before conducting this review. We therefore recommend that the IPDAS Collaboration clarify the scope of existing conflict of interest disclosure requirements either by revising the criteria to include definitions of key terms (e.g., ‘affiliations’, ‘gain or lose’) and relevant disclosure timeframes or by publishing a supplementary resource that serves this purpose. We also recommend that the IPDAS Collaboration consider offering other materials (e.g., procedural guidance in identifying conflicts of interest and constructing suitable disclosures) and services (e.g., pre-publication disclosure review) to decision aid developers.

Second, evidence of patient perspectives on conflict of interest disclosure approaches suggests that, if disclosure to advisees remains the conflict of interest management strategy adopted by the IPDAS Collaboration, there may be benefit in decision aids providing more information than is currently required by the quality standards. Under such circumstances, we would therefore recommend that the IPDAS Collaboration expand the scope of disclosure requirements to include the nature and monetary value of any disclosed conflicts of interest, the relevance of disclosed conflicts of interest to decision aid subject matter, and contact details for a person equipped to answer further questions about the disclosure. Such information may be valued not only by patients using decision aids but also by those responsible for purchasing, incentivizing, mandating, and disseminating them.

Finally, evidence suggesting that conflict of interest disclosure may have effects potentially counter to those anticipated when IPDAS quality standards were developed (for example, may increase trust in decision aids written by authors with certain conflicts of interest) as well as evidence that many patients find at least some types of conflicts of interest unacceptable in those who deliver health care indicates it may now be opportune to move to strategies for addressing conflicts of interest in decision aid development that go beyond mere disclosure. This notion is also consistent with our and others’ views on this issue (9,10) and with approaches in clinical practice guideline development (56). We therefore recommend that the IPDAS Collaboration consult with patients, decision aid developers, and other stakeholders on the desirability and feasibility of implementing more stringent conflict of interest management strategies for patient decision aid development, as well as approaches for promoting and monitoring compliance with them.

**ACKNOWLEDGEMENTS**

See Title Page for Acknowledgements

**DECLARATION OF CONFLICTING INTERESTS**

See Title Page for Declaration of Conflicting Interests

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**FIGURE LEGENDS**

**Figure 1** Articles and abstracts identified, screened, reviewed, and included

1. Throughout the remainder of this paper, we use ‘conflicts of interest’ as a catch-all term. Information on the precise interest(s), relationship(s), or situation(s) of focus in each study is provided in the Supplementary File. [↑](#footnote-ref-1)