

**2012 UPDATED CHAPTER G:
DISCLOSING CONFLICTS OF INTEREST**

**SECTION 1:
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**SECTION 2:
CHAPTER SUMMARY**

What is this quality dimension?

After reviewing the interim evidence, the authors of this chapter would now define this quality definition as follows (changes from original definition in italics):

“Does the decision aid:

- report *prominently and in plain language* the source of funding to develop and distribute the patient decision aid?
- report *prominently and in plain language* whether funders, authors or their affiliations stand to gain or lose by choices patients make after using the decision aid?”

Furthermore, based on a consensus that simple disclosure is insufficient to protect users from potentially biased information, the committee recommends that the IPDAS Steering Committee consider adding the following criterion when the IPDAS consensus process is next conducted:

“Does the decision aid:

- report no funding from commercial, for-profit entities that produce or distribute tests or treatments included as options in the decision aid?”

What is the theoretical rationale for including this quality dimension?

A definition of conflict of interest that is commonly used by medical journals is, “a set of conditions in which professional judgment concerning a primary interest (such as patients’

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welfare or the validity of research) tends to be unduly influenced by secondary interest (such as financial gain)". Practitioners and scientists who read research reports and reviews in medical journals represent a relatively well-educated audience, yet journal editors remain concerned about adequate disclosure of potential conflicts of interest by the authors of those papers. Users of patient decision aids often come from the lay public, and their ability to detect and evaluate the influence of potential conflicts of interests on the content of the programs they use may be poorer compared with medical professionals. Thus, patients may be more vulnerable to any bias incorporated into patient decision aids than medical professionals are to biases that may enter into scientific papers in medical journals. Moreover, patient decision aids may be developed and disseminated for use by patients or members of the public without the benefit of scrutiny by independent peer reviewers or an independent editor.

The committee felt that disclosure alone is not sufficient to protect lay users from potential bias in decision aids resulting from funding of decision aids by commercial, for-profit entities that produce or distribute tests or treatments included as options in the decision aid. This change in theoretical rationale provides the basis for the recommendation to the IPDAS Steering Committee that an additional criterion be added to the definition of this quality dimension

What is the evidence to support including or excluding this quality dimension?

The empirical evidence on the effect of conflicts of interest on behavior, and particularly the effect of conflict-of-interest policies on mitigating these effects, is relatively limited. As an IOM report summarizes, "Empirical data on conflict of interest policies are limited, have methodological shortcomings, and tend to focus on academic institutions." Nevertheless, evidence reviewed for this chapter suggests funding from industry can bias clinical trial reporting and often leads to poorer prescribing practices, while patients and research participants generally feel financial ties to industry should be disclosed.

A systematic review identified 57 drug trials published between 2002-2009. The review found that trials funded by manufacturers yielded more favorable results than in independently financed trials; this difference was not explained by differences in methodological quality between the two groups of trials. A systematic review of studies published up to 2008 found 38 studies reporting an association between exposure to information from pharmaceutical companies and lower-quality prescribing, while 13 did not. A systematic review of studies of patients', research participants', and journal readers' attitudes toward financial disclosure through 2009 found 20 relevant articles. Six addressed patients' reactions to disclosure of financial ties in clinical care, and five readers' reactions to disclosure of financial ties in research. Ten addressed the importance of disclosing financial ties in clinical care and research. In clinical care, patients believed financial ties decreased the quality and increased the cost of clinical care, and in research, financial ties affected perceptions of study quality. Most studies found the majority of patients and research participants believed financial ties should be disclosed.

**SECTION 3:
DEFINITION (CONCEPTUAL/OPERATIONAL) OF THIS QUALITY DIMENSION**

a) Original Definition

In the IPDAS 2nd Round Voting Document, the conceptual definition of “disclosing conflicts of interest” was stated as:

To be open and honest in stating:

- the funding source for creating and producing patient decision aids,
- the financial support for practitioners who are responsible for creating the patient decision aid, and
- the affiliations of patient decision aid developers that might influence the content of patient decision aids.

In the ultimate IPDAS checklist, this operational definition emerged:

Does the decision aid:

- report source of funding to develop and distribute the patient decision aid?
- report whether authors or their affiliations stand to gain or lose by choices patients make after using the decision aid?

b) Updated Definition

Based on a review of the interim evidence, the committee recommends the definition of the quality criterion be changed as follows (change in italics):

Does the decision aid:

- report *prominently and in plain language* the source of funding to develop and distribute the patient decision aid?
- report *prominently and in plain language* whether funders, authors or their affiliations stand to gain or lose by choices patients make after using the decision aid?

The committee judged that this criterion should not be considered met unless users could readily find the disclosure information and could interpret it correctly.

By “prominently”, the committee means that disclosure information should be provided along with the body of clinical information in the decision aid and not separately—say, on a web site or in a separate technical document. Disclosure information should be presented in a similar font to clinical information and not in the “fine print”.

By “plain language”, the committee means that the disclosure information should be provided in simple, straightforward language and not in technical jargon that would be difficult for lay users to comprehend.

Furthermore, based on a consensus that simple disclosure is insufficient to protect users from potentially biased information, the committee recommends that the IPDAS Steering Committee consider adding the following criterion when the IPDAS consensus process is next conducted:

“Does the decision aid:

- report no funding from commercial, for-profit entities that produce or distribute tests or treatments included as options in the decision aid?”

c) **Emerging Issues/Research Areas in Definition**

Further research is clearly necessary, especially research applying directly to the relationship between funding sources and bias in decision aids. This work will need to include fundamental methodological studies of how bias in decision aids can be accurately and reliably judged. In addition, more research is needed on the necessary level of granularity and prominence of disclosure statements in decision aids, particularly in multimedia presentations.

**SECTION 4:
THEORETICAL RATIONALE FOR INCLUDING THIS QUALITY DIMENSION**

a) **Original Theoretical Rationale**

A definition of conflict of interest that is commonly used by medical journals is, “a set of conditions in which professional judgment concerning a primary interest (such as patients’ welfare or the validity of research) tends to be unduly influenced by secondary interest (such as financial gain)” (Thompson, 1993). Practitioners and scientists who read research reports and reviews in medical journals represent a relatively well-educated audience, yet journal editors remain concerned about adequate disclosure of potential conflicts of interest by the authors of those papers. Users of patient decision aids often come from the lay public, and their ability to detect and evaluate the influence of potential conflicts of interests on the content of the programs they use may be poorer compared with medical professionals. Thus, patients may be more vulnerable to any bias incorporated into patient decision aids than medical professionals are to biases that may enter into scientific papers in medical journals. Moreover, patient decision aids may be developed and disseminated for use by patients or members of the public without the benefit of scrutiny by independent peer reviewers or an independent editor, as would generally be the case for papers in most peer-reviewed medical journals.

Therefore, it seems reasonable that requirements for disclosure of potential conflicts of interests should be at least as stringent as disclosure requirements for medical journals. In addition, for a lay audience, explaining how the financial interests of any commercial funders relate to the patient decision aid’s content seems like a reasonable approach to help patients and practitioners decide whether a program is likely to be biased by such interests. While a professional viewer might know that a particular funder makes or sells a product described as an option in the patient decision aid, a lay viewer might not.

b) **Updated Theoretical Rationale**

Committee members were uncomfortable, even in the absence of direct evidence addressing this quality dimension, that simple disclosure is sufficient to protect lay viewers from potentially biased information in decision aids. Lay viewers wrestling with fateful decisions about their health care may not appreciate to the degree health care professionals might the potential for bias when commercial, for-profit entities provide funding for decision aids that discuss their own products. This discomfort on the part of the committee parallels a growing sense in the literature, including in a recent comprehensive IOM report (see below), that disclosure is necessary but not sufficient to avoid bias in research publication, guideline development, medical education, and clinical care.

Based on our review of the interim evidence, the writing committee decided that the theoretical rationale for this quality criterion be extended. The committee felt that disclosure alone is not sufficient to protect lay users from potential bias in decision aids resulting from funding of decision aids by commercial, for-profit entities that produce or distribute tests or treatments included as options in the decision aid. This change in theoretical rationale provides the basis for the recommendation to the IPDAS Steering Committee that an additional criterion be added to the definition of this quality dimension (see Section 3b above).

c) **Emerging Issues/Research Areas in Rationale**

See reviews of literature, below

**SECTION 5:
EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION**

a) **Summary of the Original Evidence Base**

The original chapter did not cite any direct evidence pertaining to whether disclosure of potential conflicts of interest mitigated concerns about poor health care decisions resulting from biased patient decision aids. Rather, the need for disclosure was assumed to be equally as great as the widely-accepted need for disclosure of potential conflicts of interest in other areas of health care including research publication, guideline development, medical education, and clinical care. The writing committee decided to conduct a systematic review to determine whether any direct evidence had emerged since the original chapter was published.

b) **Updated Evidence Base**

Primary Literature Review

The committee decided the goal of the literature review was to seek articles addressing the question, "What is the evidence that disclosure of conflicts of interest in patient decision aids reduces biased decision-making?" The PubMed database was searched back ten years from the date of the search, May 11, 2011. Several preliminary searches were done to inform the development of a search strategy maximizing sensitivity at the cost of some specificity. The final

search strategy used the terms: ((shared decision making) OR (patient centered decision) OR (decision aid) OR (decision support) AND (disclos* OR (conflict of interest))).

This search yielded 874 titles. The titles were scanned by two committee members and abstracts or full text articles as necessary were retrieved for articles flagged as potentially relevant to the research question by either reviewer. Ultimately, two articles were judged to be relevant. One (reassuringly) was the original IPDAS paper in the *British Medical Journal* describing the development and validation of the IPDAS quality criteria, including disclosure of conflicts of interest (Elwyn, 2006). The other paper, judged to be only marginally relevant, was a systematic review of decision support technologies for the decision about amniocentesis (Durand, 2008). While this paper documented that five patient decision aids on this topic generally included disclosure of potential conflicts of interest, there was no information on the effect of those disclosures on women's decisions.

Secondary Literature Review

Based on this literature review, the committee concluded, as in the original chapter, that there was no direct evidence to bring to bear on this quality criterion. The rationale would need to continue to be based on indirect evidence on the importance of disclosure of conflicts of interest in other spheres of health care, including research and publication, medical education, and clinical care. A complete systematic review of all this evidence is beyond the scope of this chapter, but the committee members' personal bibliographies were reviewed for summaries of this evidence, and a search was conducted on September 29, 2011 going back 5 years for systematic reviews addressing conflicts of interest in medical research and clinical care. Using the search terms (disclos* OR (conflict of interest)) AND systematic review, we identified 1305 titles of which 31 were selected as potentially relevant. Review of abstracts or full text articles yielded four relevant systematic reviews. The key new evidence uncovered by the systematic review and the members' bibliographies is summarized below.

Reports

A comprehensive report on conflicts of interest by the Institute of Medicine (IOM) of the National Academies in the United States was identified, which was judged to be a key new reference supporting the original IPDAS criteria on conflict of interest.

In 2009, the IOM of the National Academies in the United States released a comprehensive report on conflicts of interest in medical research, education, and practice. The committee summarized the problem as follows:

“...financial ties between medicine and industry may create conflicts of interest. Such conflicts present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine.”

The key recommendations of the report included the following:

“The committee recommends that medical institutions-including academic medical centers, professional societies, patient advocacy groups, and medical journals-establish conflict of

interest policies that require disclosure and management of both individual and institutional financial ties to industry.”

The report went on to acknowledge that disclosure was only the first step in identifying and responding to conflicts of interest. The committee went on to recommend a national reporting program accessible to the public disclosing industry payments to physicians, researchers, health care institutions, professional societies, patient advocacy groups, and medical education providers that would permit verification of adequate disclosure by those patients.

In addition, the report singled out concerns about conflicts of interest in the development of clinical practice guidelines, stating:

“Clinical practice guidelines influence physician practice, quality measures, and insurance coverage decisions...The committee recommends that professional societies and other groups that develop practice guidelines not accept direct industry funding for guideline development and generally exclude individuals with conflicts of interest from panels that draft the guidelines. In addition, these groups should make public their conflict of interest policies, their funding sources, and any financial relationships panel members have with industry.”

Editorials

In his 2006 editorial, Richard Smith (Smith, 2006) pointed out how ubiquitous conflicts of interest were in health care. He opined about the evidence that conflicts of interest affects the referral of patients and the interpretations of studies, as well as the importance of disclosure in health care and the threshold levels of conflict that might rule out people from referring patients or writing editorials. In a 2008 editorial, editors of the *Journal of the American Medical Association* (DeAngelis, 2008) wrote, “*Primum non nocere* does not only hold true for physicians directly treating patient, but also holds true for all involved in medical research, biomedical publication, and medical education.”

In fact, by 2008, most medical journals with high impact factors had author Conflict of Interest (COI) policies, although how they were operationalized varied considerably (Blum, 2009). Similarly, a survey of US medical schools in 2007 revealed that most had conflict of interest policies addressing clinical care, though they were rather weak (Chimonas, 2011).

Empirical Evidence

Despite the strong opinions expressed in the IOM report and these editorials, the empirical evidence on the effect of conflicts of interest on behavior, and particularly the effect of conflict-of-interest policies on mitigating these effects, is relatively limited. As the IOM report summarizes, “Empirical data on conflict of interest policies are limited, have methodological shortcomings, and tend to focus on academic institutions.” For example, several studies have shown conflicting results in terms of physicians’ financial disclosures on patient trust (Pearson, 2006; Sah 2011).

Our search for systematic reviews yielded evidence on some of these aspects of disclosure. Perhaps the strongest empirical evidence on the effect of conflicts of interest in medicine comes from the domain of publication of research findings. A systematic review identified 57 drug trials published between 2002-2009 found that trials funded by manufacturers were found to

yield more favorable results than in independently financed trials; this difference was not explained by differences in methodological quality between the two groups of trials (Schott, 2010). The results of this review were consistent with earlier systematic reviews on this topic; a review of systematic reviews between 2003 and 2006 by Sismundo found that 17 systematic reviews published in this period (either addressing drug trials in general or trials of specific drug classes, such as antidepressants) found an association between industry support and published pro-industry trials, while two did not (Sismundo, 2008). However, studies of the effect of disclosure of sources of funding for published research on perceived credibility of the research among practicing clinicians have yielded mixed results (Silverman, 2010; Lacasse, 2011).

Another area with empiric evidence supporting the impact of conflicts of interests on behavior is the effect of information from pharmaceutical companies on clinicians' prescribing behavior. In a systematic review of studies of this influence published up to 2008, Spurling et al. found 38 studies reporting an association between exposure to information from pharmaceutical companies and lower quality prescribing, while 13 did not; however, the observational nature of these studies was a major limitation (Spurling, 2010).

Licurse and colleagues conducted a systematic review of studies of patients', research participants', and journal readers' attitudes toward financial disclosure (Licurse, 2010). A search through 2009 found only 20 relevant articles. Six addressed patients' reactions to disclosure of financial ties in clinical care, and five readers' reactions to disclosure of financial ties in research. Ten addressed the importance of disclosing financial ties in clinical care and research. In clinical care, patients believed financial ties decreased the quality and increased the cost of clinical care, and in research, financial ties affected perceptions of study quality. Most studies found the majority of patients and research participants believed financial ties should be disclosed.

Summary Based on Literature Reviews

In summary, based on the IOM report and the data from the systematic reviews on this topic, there is broad consensus that disclosure of conflicts of interest is desirable in such areas as research publication, guideline development, medical education, and clinical care. Moreover, people—whether as patients or research subjects—generally feel financial ties between clinicians or researchers and industry should be disclosed. Patient decision aids are designed to provide patients with unbiased information about their options and the pros and cons of those options to help them work with their clinicians to make informed, value-based decisions for their personal health care. The potential for bias in patient decision aids due to conflicts of interest seems as great as in these other areas of health care. Moreover, the consequences of patients making suboptimal decisions based on biased information might have even more drastic consequences, particularly for “high stakes” decisions about diagnosis and treatment of serious medical conditions. Therefore, it continues to feel important to require disclosure of potential conflicts of interest as a quality criterion, both in terms of funding for the development of patient decision aids, as well as funding for the authors responsible for the content of the aids.

c) Emerging Issues/Research Areas In Evidence Base

After reviewing the literature, the committee considered whether disclosure itself is sufficient protection against bias in patient decision aids. The IOM report concludes that disclosure is only a first necessary step in the management of conflicts of interest. In the final analysis, the committee felt that conflicts of interest that rise to the level described below should be a bar to awarding this quality criterion. The committee felt that the literature on conflict of interest in other areas in health care made it reasonable to bar funding from commercial, for-profit entities that produce or distribute tests or treatments included as options in the decision aid in order to award the quality criterion.

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**APPENDIX:
ORIGINAL CHAPTER G**

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Original Rationale/Theory

Patient decision aids should present unbiased information about the pros and cons of different management options for a medical problem. Bias can influence a patient decision aid’s content either intentionally or unintentionally. Often, decisions about screening, diagnostic testing or treatment have financial implications for practitioners, their institutions, and for commercial companies that make and sell diagnostic or therapeutic products. These financial interests have the potential to bias the content of a patient decision aid, particularly when individuals or groups who stand to gain (or lose), depending on the management decision, are involved with the development and production of the patient decision aid. Ideally, individuals and groups with a financial interest in the management decisions addressed by a patient decision aid should not be involved in the development and production of that patient decision aid. However, at minimum, individuals or groups who had a potential financial interest in the content of the patient decision aid should be clearly and prominently acknowledged to users (patients and practitioners).

A definition of conflict of interest that is commonly used by medical journals is, “a set of conditions in which professional judgment concerning a primary interest (such as patients’ welfare or the validity of research) tends to be unduly influenced by secondary interest (such as financial gain).” (Thompson, 1993). Practitioners and scientists who read research reports and reviews in medical journals represent a relatively well-educated audience, yet journal editors remain concerned about adequate disclosure of potential conflicts of interest by the authors of those papers. Users of patient decision aids often come from the lay public, and their ability to detect and evaluate the influence of potential conflicts of interests on the content of the programs they use may be poorer compared with medical professionals.

Thus, patients may be more vulnerable to any bias incorporated into patient decision aids than medical professionals are to biases that may enter into scientific papers in medical journals. Moreover, patient decision aids may be developed and disseminated for use by patients or members of the public without the benefit of scrutiny by independent peer reviewers or an independent editor, as would generally be the case for papers in most peer-reviewed medical journals. Therefore, it seems reasonable that requirements for disclosure of potential conflicts of interests should be at least as stringent as disclosure requirements for medical journals. In

addition, for a lay audience, explaining how the financial interests of any commercial funders relate to the patient decision aid's content seems like a reasonable approach to help patients and practitioners decide whether a program is likely to be biased by such interests. While a professional viewer might know that a particular funder makes or sells a product described as an option in the patient decision aid, a lay viewer might not.

Financial interests and professional biases may not be the only concerning influences on the content of patient decision aids. Practitioners-investigators may have built their academic careers by espousing a particular point of view that may then be reflected in a patient decision aid. Moreover, the scientific content on which a patient decision aid is based is itself subject to myriad potential conflicts of interest. However, these subtler forms of bias may be harder for lay viewers of patient decision aids to evaluate and understand based on an increasingly complex disclosure statement.

Original Evidence

Inventory of Available Patient Decision Aids

One of the CREDIBLE criteria for the evaluation of patient decision aids asks, "Was sponsorship free from perceived conflicts of interest?." In the most recent Cochrane review inventory of patient decision aids, reviewers rated 131 recently updated patient decision aids on this criterion. The ratings were as follows: 'yes' 96.2%; 'no' 0.8%; 'not ascertainable' 3.1% (O'Connor et al., 2003). These data suggest the reviewers usually found enough information about the funding sources of the patient decision aids to make a judgment regarding potential conflicts of interest, and that it was unusual to identify potential conflicts when funders were identified.

There are essentially no data on the impact of funding sources or specialty orientation on the perceived balance of patient decision aids. In fact, in the Cochrane review, data on ratings of patient decision aid balance could not be ascertained for 90.8% of patient decision aids.

Other Evaluative Studies

However, data from the world of medical scientific publishing and the relationships between professional specialty and variations in medical practice strongly suggest that financial interests or specialty-specific management preferences could bias patient decision aids. For example, in scientific articles, an analysis by Stelfox and colleagues (1998) found that journal articles about the use of calcium channel blockers were more positive about those uses when the authors had financial relationships with pharmaceutical companies that make and sell calcium channel blockers. While Barnes and Bero (1998) found that authors of reviews about the health effects of passive smoking were less likely to describe a negative relationship if the authors were funded by tobacco companies. Most remarkably, in both these cases, only the minority of relevant financial relationships on the part of the original authors were actually disclosed as part of the publication process; the authors of systematic reviews usually had to root them out through direct contact with the original authors. Specialty perspective can also have a strong effect on views regarding optimal medical management. For example, for clinically localized prostate cancer (a common topic for patient decision aids), urologic surgeons are much more positive about radical

prostatectomy while radiation oncologists are much more positive about radiation therapy as a treatment option (Fowler et al., 2000). In cardiovascular care, cardiologists are more likely to recommend diagnostic modalities such as exercise tests and coronary angiography than primary care physicians are for the same patients.

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