PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Trustworthy patient decision aids: a qualitative analysis addressing the risk of competing interests
AUTHORS	Elwyn, Glyn; Dannenberg, Michelle; Blaine, Arianna; Poddar, Urbashi; Durand, Marie-Anne

VERSION 1 - REVIEW

REVIEWER	Ray Moynihan Bond University, Australia The Dartmouth Institute is a co-partner, with my institution in organizing a series of international conferences, called Preventing Overdiagnosis. The next conference is in Barcelona, in September 2016 .
REVIEW RETURNED	25-May-2016

GENERAL COMMENTS	Page 4. Small Point. Perhaps say something explicit about decision aids in the 1st paragraph – it feels odd that they are not explicitly mentioned. Small point. In the Introduction, it would be good to try and make clear that there is a distinction between moving to more transparency/disclosure- and moving to reduce competing interests of those involved in guidelines/decision-aids. Ie disclosure and disentanglement/exclusion are two separate responses to the problem of competing interests. As becomes clear during the paper later, sometimes – depending on the extent of the financial relationships—transparency/disclosure may be sufficient – but increasingly there is a view that influential panels (including those who make decision aids) should be free of certain kinds of competing interests – and as your study shows, some organisations already allow (but don't mandate) the exclusion of contributors with competing interests. Currently this distinction is a little blurred in the Introduction. Page 5 It strikes me there is a strictness in the inclusion criteria (ie had to have maintained and updated tools, that should be mentioned as a limitation on generalizability) Page 13, Line 12. You might consider adding a sentence, highlighting that there is a trend in analysis and commentary on this subject to urge more independence in these influential guideline panels – ie transparency alone is no longer considered an adequate response- and sometimes exclusion is needed. Page 13 Line 19. This sentence is not exactly clear – needs to be made clearer and

	linked into your argument better. “In a recent review, Barry and colleagues were not able to assess the degree of risk to patient decision making posed by competing interests.[9]” Page 123, Line 57 Consider adding a few words to the last line “….disclosed, managed, reduced and in certain circumstances, eliminated.”

REVIEWER	Angela Coulter University of Oxford and Informed Medical Decisions Foundation, based in UK I undertake paid consultancy for the Informed Medical Decisions Foundation which is now part of Healthwise, one of the decision aid developers that participated in this study.
REVIEW RETURNED	05-Jul-2016

GENERAL COMMENTS	This paper describes a study to investigate competing interest policies adopted by developers of patient decision aids. The methods appear appropriate and the paper is clearly written on the whole, though it could be clearer in places. However, the study seems to lack clear criteria for judging the adequacy of the policies and the conclusions are overstated, see details below. General comments: Twenty five organisations were contacted and policies or competing interest forms gathered from eight of these were analysed and described thematically, but the standard against which the policies are being judged is not clearly stated in the paper. In the absence of anything else, it would have made more sense to use the IPDAS standard, as modified by Barry et al (2013) as follows: 1) Report prominently and in plain language the source of funding to develop or exclusively distribute the patient decision aid; 2) Report prominently and in plain language whether funders, authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aids; 3) Report that no funding to develop or exclusively distribute the patient decision aid has been received from commercial, for-profit entities that sell tests or treatments included as options in the patient decision aid. These criteria were not explicitly adopted for this study, so for example, Table 2 says nothing about whether competing interests were displayed prominently in plain language on the patient decision aid. As far as I can see, the authors did not examine decision aids to check whether the policies were implemented, including whether declarations were published at all and if so, whether they were prominent and in plain language. The lack of an explicit standard means that the main conclusion, that processes are “insufficiently robust to minimise the risk that the information contained in these knowledge tools may be biased” is

	not justified by the available data. Timeframe (p.10): What exactly is meant by 'historical' and 'future' interests? What about current interests – surely the policies covered this? These terms should be defined and explained. Main findings (p. 12): "No policies definitively prohibited the involvement of individuals with competing interests" – It would be interesting to hear from the authors how this might be done in practical terms, especially if it applies to non-financial interests. Is this really feasible? Authorship contributions (p. 14): This hints but does not explicitly state that some of the paper's authors may have had a competing interest in respect of this paper in that they are involved in the Option Grid Collaborative. This may be clear in the Unified Competing Interest form but I believe it should be made explicit here, especially in view of the subject matter of the paper! I note that one of the authors provided advice on interpreting the results from a legal standpoint but I was disappointed to see no legal analysis of the findings described in the paper.

VERSION 1 – AUTHOR RESPONSE

RAY MOYNIHAN COMMENTS
Moynihan Comment 1: Page 4. Small Point. Perhaps say something explicit about decision aids in the 1st paragraph – it feels odd that they are not explicitly mentioned.

Response: We thank the reviewer for his comment and have added the following sentence:

"When similar information is developed for patients, such as in the form of a decision aid, it becomes even more important to minimize competing interests"

Moynihan Comment 2: Small point. In the Introduction, it would be good to try and make clear that there is a distinction between moving to more transparency/disclosure- and moving to reduce competing interests of those involved in guidelines/decision-aids. Ie disclosure and disentanglement/exclusion are two separate responses to the problem of competing interests. As becomes clear during the paper later, sometimes – depending on the extent of the financial relationships—transparency/disclosure may be sufficient – but increasingly there is a view that influential panels (including those who make decision aids) should be free of certain kinds of competing interests – and as your study shows, some organisations already allow (but don't mandate) the exclusion of contributors with competing interests. Currently this distinction is a little blurred in the Introduction.

Response: We value this comment and have changed the text as follows:

"Working to increase transparency and perhaps minimise competing interests by excluding contribution has even more relevance when developing information sources for patients…"

Moynihan Comment 3: Page 5. It strikes me there is a strictness in the inclusion criteria (ie had to have maintained and updated tools, that should be mentioned as a limitation on generalizability).

Response: The "Study Strengths and Weaknesses" section mentions this limitation, as shown below.

We have added the sentence in bold to better address the reviewer's comments:

"We used multiple sources to identify patient decision aid organisations, and subsequently limited our focus to those who had developed and were actively maintaining five or more tools. These organisations therefore represent the most active organisations committed to the development of evidence-based knowledge tools designed to support patient-facing decision making processes. Other organisations may exist that develop fewer tools but it is unlikely that they have significant numbers of patients accessing their products. The included organisations are likely to be aware of criteria published by the International Patient Decision Aids Standards Collaboration, which include recent recommendations regarding competing interest disclosure.[9] Some organisations declined participation, and although we are confident that we identified the most relevant organisations, it is possible that other organisations exist.

Moynihan Comment 4:
Page 13, Line 12. You might consider adding a sentence, highlighting that there is a trend in analysis and commentary on this subject to urge more independence in these influential guideline panels – i.e. transparency alone is no longer considered an adequate response- and sometimes exclusion is needed.

Response: We value this comment and have modified the text as follows:

"At the same time, the topic of competing interests among members of clinical guideline panels has also been under increasing scrutiny [12][13][14], with recent calls to minimize or avoid financial and professional conflicts during the development of guidelines. [14]"

Moynihan Comment 5: Page 13 Line 19. This sentence is not exactly clear – needs to be made clearer and linked into your argument better. "In a recent review, Barry and colleagues were not able to assess the degree of risk to patient decision making posed by competing interests.[9]"

Response: We agree and have amended the text as follows:

"In a systematic literature search of articles from 2001-2011, Barry and colleagues found no articles that examined the impact of COI disclosure in patient decision aids on reducing bias in decision making, showing a lack of attention to the topic in the scientific community [9].
Moynihan Comment 6:
Page 13, Line 57 Consider adding a few words to the last line
"….disclosed, managed, reduced and in certain circumstances, eliminated."

Response: We agree and have amended the text as follows:

"The competing interests of contributors, authors, and editors will influence the process of evidence synthesis, especially for patient facing-materials, and how they need to be disclosed, reduced and managed--and, in certain cases, eliminated."

ANGELA COULTER COMMENTS
Coulter Comment 1: This paper describes a study to investigate competing interest policies adopted by developers of patient decision aids. The methods appear appropriate and the paper is clearly written on the whole, though it could be clearer in places. However, the study seems to lack clear criteria for judging the adequacy of the policies and the conclusions are overstated, see details below.

General comments: Twenty five organisations were contacted and policies or competing interest

forms gathered from eight of these were analysed and described thematically, but the standard against which the policies are being judged is not clearly stated in the paper. In the absence of anything else, it would have made more sense to use the IPDAS standard, as modified by Barry et al (2013) as follows:

1) Report prominently and in plain language the source of funding to develop or exclusively distribute the patient decision aid;

2) Report prominently and in plain language whether funders, authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aids;

3) Report that no funding to develop or exclusively distribute the patient decision aid has been received from commercial, for-profit entities that sell tests or treatments included as options in the patient decision aid.

These criteria were not explicitly adopted for this study, so for example, Table 2 says nothing about whether competing interests were displayed prominently in plain language on the patient decision aid. As far as I can see, the authors did not examine decision aids to check whether the policies were implemented, including whether declarations were published at all and if so, whether they were prominent and in plain language.

The lack of an explicit standard means that the main conclusion, that processes are “insufficiently robust to minimise the risk that the information contained in these knowledge tools may be biased” is not justified by the available data.

Response: We thank the reviewer for commenting on the appropriateness of the methods and we will address where we consider there to be a lack of clarity.

In response to the reviewer’s concern about the criteria against which the decision aids were judged, we would like to provide some additional explanation.

Regarding whether each decision aid producer made a disclosure on the decision aids themselves: This information was included in the text, as follows: “Five organisations disclosed competing interests on their patient decision aids, directly (Emmi Solutions, Ottawa Hospital Research Institute, and PATIENT+) or by using associated web links (Agency for Healthcare Research and Quality and Healthwise).” A row has also been added to Table 2 to reflect this information.

In response to the reviewer’s question about making disclosures in Plain Language, we agree that this has been suggested as best practice. However, although recommended by Barry et al, this recommendation has not yet been formally adopted by the IPDAS standards and we have therefore decided not to report on the “prominent and plain language” nature of the COI disclosures.

Finally, we take the view that the implementation of strong competing interests policies by decision aid producers is a more important step for protecting the public than the exact wording of to the disclosure, given the difficulty that the public often encounters when trying to evaluate competing interests statements.

Coulter Comment 2: Timeframe (p.10): What exactly is meant by ‘historical’ and ‘future’ interests? What about current interests – surely the policies covered this? These terms should be defined and explained.

Response: We thank the reviewer for this comment. To improve clarity, we have changed the

"historical" code to "past", included a "current" code, and a "past and current" code. We have made the necessary adjustments to the data and revised the text to define and explain these terms.

The text has been changed from: "Four policies and two disclosure forms mentioned timeframes, two documents considered past competing interests only (Healthwise and PATIENT+), one considered current competing interests only (Health Dialog) and three considered past and future interests (Agency for Healthcare Research Quality, Cincinnati Children's Hospital Medical Center, and Option Grid Collaborative)." To: Six organisations (four policies and two disclosure forms) mentioned timeframes for disclosure relevance. Healthwise considered past competing interests only, defined as those "received in the last year". Health Dialog considered current competing interests only. Four organisations (Agency for Healthcare Research Quality, Cincinnati Children's Hospital Medical Center, Option Grid Collaborative, and PATIENT+) considered both past and future interests. Of those who specified that past interests must be declared, the applicable time period ranged from 12 to 36 months. We assume 'future interests' to imply current interests at time of disclosure. Similar inconsistent approaches were found regarding the timing at which information about interests was collected - whether at the start of development, or on a regular basis. Only four organisations requested proactive reporting of any changes in disclosures if new competing interests arose.

Coulter Comment 3: Main findings (p. 12): "No policies definitively prohibited the involvement of individuals with competing interests" – It would be interesting to hear from the authors how this might be done in practical terms, especially if it applies to non-financial interests. Is this really feasible?

Response: This is indeed an open debate in the community. Some organisations are approaching this issue by having different thresholds for competing interests based on the extent of the individual's involvement. The Institute of Medicine is an excellent example of this. This approach is likely motivated by the reality that it can be difficult to find a team of experts that is wholly un-conflicted.

We have inserted the following into the "Discussion" section of the article:

"The management of non-financial competing interests - e.g, surgeons benefitting from a general uptake of surgical procedures in their discipline is a matter of ongoing debate. Some guideline producers, for example the Institute of Medicine and the National Institute for Health and Care Excellence are addressing this challenge by requiring higher standards from those who have ultimate editorial power, such as chairs of guideline panels."

Coulter Comment 4: Authorship contributions (p. 14): This hints but does not explicitly state that some of the paper's authors may have had a competing interest in respect of this paper in that they are involved in the Option Grid Collaborative. This may be clear in the Unified Competing Interest form but I believe it should be made explicit here, especially in view of the subject matter of the paper!

Response: We appreciate the need to make this even more transparent. In addition to the existing sentences in the "Data Analysis" section ("Authors who were also members of the Option Grid Collaborative did not extract, code, or analyze data from that organisation. Option Grid Collaborative data were handled by UP and MD."), and in the "Study Strengths and Weaknesses" section ("Data provided by the Option Grid Collaborative were not extracted, coded or analyzed by members of that organisation (AB, M-AD or GE."), we will request that the journal also add this information to the Competing Interests section.

Coulter Comment 5: I note that one of the authors provided advice on interpreting the results from a legal standpoint but I was disappointed to see no legal analysis of the findings described in the paper.

Response: We thank the reviewer for this comment. Our legal expert has reviewed the results from a

legal standpoint and had no further comments to make. As the recent statement from the IOM makes clear, there is no specific law that applies to this area, and it is clear that best practice is emerging as awareness of the risk increases, see quote below:

“The aspirational goal reflected in the IOM report was that each CPG development group is chaired by an individual with no conflict of interest in the management area under consideration, and that at least 50% of the members of the committee be from a discipline other than the primary specialty associated with the aspect of care addressed by the guideline.” (http://growthevidence.com/the-institute-of-medicine-standards-for-trustworthy-clinical-practice-guidelines-4-years-later/)