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Sophie Cook
Head of Scholarly Comment
The British Medical Journal

June 28, 2019

Re: Submission of revised Analysis article entitled, “Muddy waters: Variability in the reporting of conflicts of interest in the biomedical literature”

Dear Dr. Cook,

Thank you for the opportunity to revise the above-named manuscript and for the constructive feedback. We have addressed each of the editors’ and reviewers’ comments in the table below, noting the respective changes in the manuscript. The revised word count is 1999.

Thank you for your time in consideration of this manuscript.

Sincerely,

Quinn Grundy

Adam Dunn

Lisa Bero

Editor's comments	Authors' response	Relevant changes
<p>This is an interesting and important topic but we did wonder how novel this argument is. Could you make more of a case for why this needs to be aired/revisited now? How does this paper move the argument further along?</p>	<p>Conflict of interest policies in major biomedical journals and “sunshine” legislation are now at least a decade old in many instances. Yet, disclosure continues to be inadequate as shown by multiple examples of non-disclosure or partial disclosure of financial ties. Disclosure policies have largely failed to achieve the desired transparency.</p> <p>We present new data that highlights the challenges we faced in our recent efforts to estimate the prevalence of disclosed conflicts of interest in order to unpack the key elements that would make transparency purposeful, i.e. accessibility, meaningfulness and relevance. We synthesise previous recommendations related to standardizing and harmonizing disclosure practices.</p> <p>However, efforts to enhance transparency and standardize disclosures (e.g. the Open Payments database) have not directly addressed the problem of relevance. We suggest the development of novel processes to evaluate and communicate relevance and offer a sample disclosure statement.</p>	<p>We have re-written the manuscript to better communicate these key points.</p> <p>Box 3 outlines policy and process recommendations to address the problems illustrated in the body of the manuscript.</p> <p>Box 2 illustrates a sample disclosure statement that communicates relevance.</p>
<p>We did find some repetition within the article and think that this could be addressed in a revision, particularly when it comes to describing the different ways to describe COIs.</p>	<p>We have reduced the length of the manuscript to 1999 words by eliminating repetition. We have consolidated the sections related to describing terminology used to refer to conflict of interest and introduced a Box that contains all of these terms.</p>	<p>See Box 1, “Headings and keywords used to indicate conflict of interest statements.”</p>
<p>Should it really matter that much that the headings for COI sections vary in wording across journals? With XML, they can all be tagged the same even if they use different lingo to describe related concepts? Some further</p>	<p>Even where an article uses an XML schema, the inconsistent headings and location of disclosures in articles creates a challenge for extraction because there is no consistent schema used across all journals and publishers (not to mention across webpages versus PDFs). It would be challenging to convince all publishers to use a consistent standard. For example, JATS is a schema for representing journal articles but it is only used by a handful of publishers despite</p>	<p>We have added Box 1 to illustrate the variability in headings and keywords used to indicate conflict of interest disclosures.</p> <p>In the section, “Problem of accessibility”, we discuss the inclusion of conflict of interest</p>

<p>discussion on this would be helpful.</p>	<p>being around for more than 15 years; Elsevier uses their own unique XML scheme.</p> <p>Instead, we include discussion about the inclusion of conflict of interest information as meta-data in PubMed as an alternative means of improving accessibility of conflict of interest disclosures.</p>	<p>meta-data in PubMed as an example of how to address this issue (p 4, lines 45-54):</p> <p>“Conflict of interest statements are identified by diverse and often synonymous headings or keywords (Box 1), making it challenging to automatically extract this information, even from well-structured webpages. Since March 2017, some publishers have included conflicts of interest in the metadata used by PubMed,(19) which suggests a way to improve accessibility by centralising where disclosures are recorded.”</p>
<p>We thought the recommendations needed further distilling. You recommend a global registry, and if that doesn't happen, Box 1 (pages 10-11) which needs a bit more unpicking. Under “Identification” in Box 1, who are authors disclosing to e.g. who are authors supposed to disclose dollar values on all financial relationships? To editors only? Or in the manuscript? It's unclear at present and needs some further explanation.</p>	<p>We suggest that authors provide comprehensive and detailed disclosures to editors and peer reviewers, but also that they provide a statement indicating which interests are relevant to the submitted work and why. The relevance of a disclosure may not be readily apparent to people who are not experts or working in a particular field, for example. Then, editors and peer reviewers could review this statement, which would be included in the body of the manuscript. A link to the full, structured and detailed disclosures should be made available in the manuscript. Following previous recommendations made by the Institute of Medicine and the example of the Open Payments database, we suggest that dollar values of all payments are disclosed within the fully detailed, linked disclosure statement.</p>	<p>We have added text on page 10, lines 10-35 that better describe the recommendations included in Box 3 (formerly Box 1):</p> <p>“In the absence of a comprehensive registry, we propose recommendations to assist authors, editors and peer reviewers with identifying, evaluating, and reporting conflicts of interest, drawing from the work of the ICMJE,(11) IOM,(8) and Open Payments implementation(31) (Box 3). We propose that authors make comprehensive, structured disclosures to editors and peer reviewers and that these complete disclosures are made publicly available via a link placed in the article. Separately, we suggest that authors state which interests are relevant to the manuscript and why and that this statement is peer reviewed and</p>

		<p>adjudicated by editors (Box 3). There is a growing body of meta-research associating conflicts of interest with risks of bias; organisations such as COPE or the ICMJE might consider preparing evidence-based guidance to help authors, peer reviewers and editors make such judgements. A statement summarizing relevant conflicts of interest and the risk of bias should be visibly and succinctly included in all forms of the manuscript under the standard heading “conflicts of interest.”</p> <p>We have added Box 2 as an example of a summary statement explaining the relevant relationships that could be included in the body of the manuscript.</p>
<p>We think it would also be of interest to readers to see a mock model COI statement for a journal article so readers can better appreciate what you are suggesting becomes the new norm.</p>	<p>We have developed a sample disclosure statement, filled out by a fictional researcher, based on the completed sample disclosure form on the ICMJE website. However, we also emphasise that this is merely a proposal and requires further development and testing to ensure acceptability, usability, and impact.</p>	<p>We have added Box 2 as an example of a summary statement explaining the relevant relationships.</p>
<p>One recommendation is for reporting how COIs were assessed and whether AND how they were managed, traffic light labels, etc. We imagine this taking up considerable space, especially on papers with many authors, how would this work in practice?</p>	<p>Our suggestion of a traffic light system, inspired by the Cochrane risk of bias tool, was simply one idea to illustrate what we mean by “novel ways to quickly and clearly communicate the presence of relevant conflicts of interest.” Traffic lights, for example, would take up less space than text describing how a COI and how it was managed. We emphasise that research is needed in this area to develop and test such ideas.</p>	<p>We have edited the recommendations in Box 3 for clarity.</p> <p>The sentence beginning on page 11, line 50, and ending on page 12, line 6 calls for future research to test disclosure practices and to experiment with novel approaches for communicating this information:</p>

	<p>We have clarified that the recommendation related to reporting “how conflicts were managed” relates to journal policy: for example, precluding individuals with certain ties from authoring certain types of articles.</p>	<p>“Future work should also consider randomised trials of novel structured reporting interventions to assess author, editor, peer reviewer, and consumer usability and acceptability, and the effect on assessment of risk of bias in published work.”</p> <p>We have added Box 2, which includes a summary statement that could be included in the body of the manuscript.</p>
<p>You call for a public database of financial interests and suggest ORCID. There is already a related system - http://www.convey.org/ - could you reflect on what it would take to get global buy-in to such a system?</p>	<p>Convey is a repository system for financial interests developed and operated by the Association of American Medical Colleges (AAMC). Shortly after the release of the 2012 IOM discussion paper referenced by Reviewer 2, the IOM working group asked the AAMC to develop a centralized, harmonized system. Although free to individuals, organisations that receive disclosures pay an annual fee based on the volume of disclosures it receives. There appears to have been limited adoption of the Convey system (https://www.medpagetoday.com/publichealthpolicy/ethics/75429). Convey could be used for journals to extract relevant conflicts of interest for inclusion in their disclosure statements. However, these data are not made publicly available and thus, this type of registry does not fully account for the problem of accessibility.</p> <p>In the manuscript, we explicitly reflect instead on the development of the Open Payments database, as suggested by Reviewer 2, as an example of a successful effort to standardize and enforce disclosure in a way that is purposeful and accessible to both researchers and the public. Users of the information can judge the relevance and importance of the COI for themselves. We also believe this is a successful model because it is treated as infrastructure: it is publicly funded and enacted through legislation.</p>	<p>On page 7, lines 8-31, we reflect on the development of the Open Payments database as a model:</p> <p>“Organisations such as ORCID may be well-placed to act as a repository for such information given its international scope and strong uptake among biomedical journals; journals could develop an interface to allow authors to automatically export relevant entries during manuscript submission.(9) The Open Payments database, created through the United States Physicians Payments Sunshine Act, is a notable model in achieving transparency, though it is limited in terms of its national scope, and restriction to prescribing clinicians and certain manufacturers. Due to the availability and accessibility of these detailed, accurate, structured data, researchers have an unprecedented ability to understand the extent and the impact of</p>

		<p>physicians' relationships with pharmaceutical and medical device companies.(23-25) The success of the Open Payments database suggests that any sort of registry should be conceptualised as infrastructure: publicly-funded and coupled with enforcement mechanisms."</p>
<p>Pubmed is now capturing COI statements automatically from many journals, including The BMJ. It seems this might have happened in part as a result of some of your work - might you reflect on this development?</p>	<p>We were co-signatories on a letter to the National Library of Medicine lobbying for the inclusion of conflict of interest disclosures in abstracts in PubMed. We received a response in April 2016 that indicated the NLM was developing a proposed strategy to prospectively include conflict of interest information in PubMed, though separately from abstracts. In March 2017, PubMed began prospectively posting conflict of interest disclosures.</p> <p>Journals now submit metadata about conflicts of interest to Medline/PubMed that are indexed under a standardized heading. This is a highly useful development in terms of providing structured data that is accessible and amenable to analysis. However, there may still be problems related to semantics and relevance as conflict of interest information is extracted verbatim from the published article. We propose means to address these latter issues in this manuscript.</p>	<p>See page 4, lines 45-54 reflecting on the inclusion of conflict of interest meta-data in PubMed:</p> <p>"Conflict of interest statements are identified by diverse and often synonymous headings or keywords (Box 1), making it challenging to automatically extract this information, even from well-structured webpages. Since March 2017, some publishers have included conflicts of interest in the metadata used by PubMed,(19) which suggests a way to improve accessibility by centralising where disclosures are recorded."</p> <p>Box 2 is a sample structured disclosure to address the problem of relevance.</p>
<p>Box 1 appears to be the biggest advance here, which is the beginnings of a guideline or policy. This is useful but we don't hear much about how you reached these recommendations or use a consensus</p>	<p>We have developed our recommendations based on a synthesis of previous recommendations from the ICMJE, the IOM and subsequent IOM working groups, and the implementation of the Open Payments database. We have more explicitly drawn on their recommendations and cited these sources in the manuscript. Due to resource constraints, we have not conducted an international consultation and consensus process although we would see this as a useful next step (e.g. to develop a COI reporting guideline).</p>	<p>See page 10, lines 10-36:</p> <p>"In the absence of a comprehensive registry, we propose recommendations to assist authors, editors and peer reviewers with identifying, evaluating, and reporting conflicts of interest, drawing from the work of the ICMJE,(11) IOM,(8) and Open</p>

<p>process. Please could you discuss this further?</p>		<p>Payments implementation(31) (Box 3). We propose that authors make comprehensive, structured disclosures to editors and peer reviewers and that these complete disclosures are made publicly available via a link placed in the article. Separately, we suggest that authors state which interests are relevant to the manuscript and why and that this statement is peer reviewed and adjudicated by editors (Box 3). There is a growing body of meta-research associating conflicts of interest with risks of bias; organisations such as COPE or the ICMJE might consider preparing evidence-based guidance to help authors, peer reviewers and editors make such judgements. A statement summarizing relevant conflicts of interest and the risk of bias should be visibly and succinctly included in all forms of the manuscript under the standard heading “conflicts of interest.””</p> <p>See Box 2 and 3.</p>
<p>Are there any similar guidelines (perhaps not ICMJE ones?) we were a little surprised that no one has tried to create a taxonomy similar to the CRediT taxonomy.</p>	<p>In designing our study of the prevalence of disclosed conflict of interest, we searched for taxonomies that could be used to manually code and categorise disclosure statements. We too, were surprised to find few workable taxonomies for the types of conflicts of interest in biomedical research. The ICMJE form, the 2012 IOM report, and the structure of the Open Payments database came the closest. We have included mention of Open Payments as the closest working example to a standardized and harmonized disclosure system.</p>	<p>See page 7, lines 8-31 for a discussion of how the Open Payments database has enabled analysis of the extent and impact of conflicts of interest due to standardisation:</p> <p>“Organisations such as ORCID may be well-placed to act as a repository for such information given its international scope and strong uptake among biomedical journals; journals could develop an interface to allow</p>

		<p>authors to automatically export relevant entries during manuscript submission.(9) The Open Payments database, created through the United States Physicians Payments Sunshine Act, is a notable model in achieving transparency, though it is limited in terms of its national scope, and restriction to prescribing clinicians and certain manufacturers. Due to the availability and accessibility of these detailed, accurate, structured data, researchers have an unprecedented ability to understand the extent and the impact of physicians' relationships with pharmaceutical and medical device companies.(23-25) The success of the Open Payments database suggests that any sort of registry should be conceptualised as infrastructure: publicly-funded and coupled with enforcement mechanisms.”</p> <p>See paragraph beginning on page 6, line 45 and ending on page 7, line 6 for a synthesis of recommendations related to a taxonomy and standardisation of conflict of interests:</p> <p>“To strengthen transparency while minimising burden on authors and editors, the biomedical research community should develop a public, comprehensive, structured, author-centric database of financial interests.(9, 10, 22) The Institute of Medicine (IOM) proposed a detailed</p>
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		<p>taxonomy for conflicts of interest,(22) which could serve as a structured, standardized, digital template for disclosure, while providing adequate detail about the nature of the relationship or interest.”</p>
<p>We didn't wonder if the content of the article itself would have resolved the opening example which is out right non disclosure rather than lack of clarity - please could you comment on this?</p>	<p>The opening case of non-disclosure is simply one of several examples that illustrate that the current system for disclosure is not working. We have reworked the manuscript to emphasise not only non-disclosure, but the ways that the signal for risk of bias is obscured by variable reporting practices for conflict of interest. In doing so, we have de-emphasised this example, but have retained it to illustrate why this problem remains highly relevant even though conflict of interest policies in major biomedical journals and “sunshine” legislation is now at least a decade old in many instances. We have reorganised the introduction to foreground the argument that conflict of interest disclosure is necessary as a signal for risk of bias. Though non-disclosure remains problematic, current reporting practices also serve to obscure this risk of bias.</p>	<p>See Introduction, page 3, lines 3-33:</p> <p>“Conflict of interest disclosures act as a signal for risk of bias in the design, conduct, and reporting of biomedical research. Researchers have explored the relationship between author financial conflict of interest and bias in research results and interpretation across a variety of fields; some have found a positive association(1-4) and others, no association.(5-7) Knowledge of conflicts of interest is thus necessary for understanding the potential for bias.</p> <p>Ten years ago, and reiterated since,(8, 9) the Institute of Medicine recommended standardising and harmonising conflict of interest reporting practices.(10) The International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE) recommend that journal editors require published statements declaring authors' conflicts of interest.(11, 12) Despite these policy developments, non-disclosure and other reporting failures persist. For example, the Chief Medical Officer of Memorial Sloan Kettering, Dr José Baselga, recently resigned after revelations</p>

		that he failed to disclose millions of dollars in compensation from pharmaceutical and biotech companies in more than 100 publications since 2013 and in 87% of articles that he authored in 2017.(13)”
Reviewers’ comments to author	Authors’ response	Relevant changes
Reviewer: 1, Shannon M Brownlee, Senior Vice President, Lown Institute		
<p>Thanks to the authors for an interesting article and to the editors of BMJ for the opportunity to review it.</p> <p>Unfortunately, like the little kid in the old joke who is looking for a pony in a pile of manure, I’m sure there’s a terrific article here, it’s just that it’s hidden under a pile of unclear writing. This article, despite the heading, is not an analysis, it’s a commentary, which happens to have at its disposal some interesting new data. But that commentary is obscured by murky writing.</p> <p>I think this article would be strengthened considerably if it were rewritten to follow a simple line of argument. The main points appear to be the following: 1) COI is an important signal for potential bias in the design, execution, and reporting of</p>	<p>We have considerably restructured the manuscript to make the following key points:</p> <ol style="list-style-type: none"> 1) Disclosure of conflict of interest is necessary as a signal for risk of bias and required by the ICMJE, COPE and numerous biomedical journals, yet non-disclosure persists 2) Current practices (lack of accessibility, variable semantics, failure to define relevance) obscure this risk of bias; 3) This shoddy, inconsistent, and murky reporting serves to distract everybody from the conversation that we need to have about how to manage and control the potential ill effects of COI on research integrity. 4) True transparency requires that disclosures are not only available (ie disclosed) but accessible, meaningful, and relevant. <p>We provide more detailed recommendations for enforced, structured reporting, drawing from the IOM, ICMJE, and Open Payments database.</p>	<p>Please see the tracked changes manuscript for detailed account of changes.</p>

<p>scientific research; 2) despite the fact that ICJME and COPE agree that COI should be reported, much COI routinely goes unreported in the journals; 3) when it is reported, it is done so in such a way that the reader must search high and low to find it, and/or must work hard to interpret what the authors mean (130 ways to say “no conflicts”); 4) this inconsistent reporting is partly the fault of the authors who do not follow directions and/or mendaciously try to hide their financial relationships, and partly the fault of the journals, which do not do their due diligence to ensure that authors are not shirking their duty to report; 5) this shoddy, inconsistent, and murky reporting serves to distract everybody from the conversation that we need to have about how to manage and control the potential ill effects of COI on research integrity.</p>		
<p>There is one section of this article that is clear, concise, and needs very little rewriting: pages 10-11. The authors' recommendations make sense and are clearly articulated.</p>	<p>Thank you. We have left these recommendations intact, but have relocated these paragraphs to better integrate our data, and the discussion to conform to the style of an Analysis article.</p>	<p>Please see tracked changes manuscript for detailed account of moved text.</p>

<p>I recommend that the editors of BMJ ask for a revision of this article.</p>		
<p>Reviewer: 2, Timothy Anderson, Clinical Instructor, UCSF</p>		
<p>This manuscript covers the important and timely topic of variation in conflict of interest disclosures in biomedical journal articles. I enjoyed reading this article and felt it contributed a valuable viewpoint, however at times the message was lost in the length and conceptual jumps between sections of the manuscript. The article is anchored in exploring the challenges of variable processes of disclosure encounter by the authors while collecting data for the author's original research manuscript previously published in JAMA which quantitatively described rates of conflict of interest and disclosure in a random sample of journal articles. While I was not previously familiar with the BMJ "analysis" article type, the journal's stated goals are to make an argument supported by a strong evidence base using engaging journalistic language.</p>	<p>We have significantly restructured the article in an attempt to better integrate the discussion with the presentation of our data.</p>	<p>Please see the tracked changes manuscript for detailed account of changes.</p>

<p>1. The introduction is clearly written and easy to follow though it does not clearly state the author's stance, rather it states the article's goal is to highlight challenges with the current disclosure process. Including a declarative statement of the central argument – which I infer to be that just having COI statements available is not sufficient and they need to be informative (akin to the first sentence of the discussion or the conclusion sections) earlier on would help orient readers and fit the article type.</p>	<p>We have included a declarative statement of our central argument in the Introduction, which was moved from the first sentence of the Discussion.</p>	<p>The sentences at the end of the Introduction on page 4, lines 8-13 read:</p> <p>“True transparency involves more than just making conflict of interest disclosures available; they need to also be accessible, accurate, complete, and detailed. Enforced, structured reporting and processes to assess relevance are required to make disclosures purposeful.”</p>
<p>2. The article could be made stronger by developing a clearer link between the first half which discusses the author's prior work and the second half which dives into the author's views on how COI disclosure could be improved. Right now the article reads more as an original research publication with a results and discussion section, rather than a flowing journalistic style argument.</p>	<p>We have restructured the article in an attempt to better integrate our data and the relevant discussion. We have changed the major headings so they no longer reflect results and discussion, but the revised, integrated content.</p>	<p>The revised headings now read: The problem of accessibility The problem of semantics The problem of relevance Purposeful transparency</p>
<p>3. The manuscript is long, longer than the recommended word count, and drags in the section focused on the author's prior</p>	<p>We have cut the length of the article to 1999 words. In doing so, we have eliminated repetitive content in the sections, “Problem of accessibility” and “Problem of semantics” and added a Box that</p>	<p>See revisions within the sections “The problem of accessibility” and “The problem of semantics.”</p>

<p>paper. The sections “Problem of accessibility” and “Problem of semantics” cover very similar issues and could be condensed for a more engaging read, particularly as some of their content is repeated in Table 1.</p>	<p>succinctly highlights the variability in terminology used to refer to conflicts of interest.</p>	<p>See Box 1.</p>
<p>4. Because the manuscript is focused on the author’s previously published manuscript, there are missed opportunities to discuss other published expert guidance on this topic. The authors discuss ICJME standards but fail to discuss prior publications which have noted problems with COI accessibility including the Institute of Medicine reports on Conflict of Interest in Medical Research, Education and Practice (2009) and Harmonizing the Reporting of Potential Conflicts of Interest (2012). For full disclosure, I was a co-author on the second report which the authors cite. But the article does not discuss the fact that the prior IOM report and other perspectives articles have previously raised the issue of lack of accessibility and harmony in COI reporting between biomedical journals as well as</p>	<p>Thank you for these suggestions. We want to explicitly acknowledge that these insights are not new and that policy conversations related to the problems associated with conflict of interest disclosures have occurred now for decades. We have now referenced these conversations and initiatives in the introduction and accompanying our recommendations. We have synthesised recommendations from the ICMJE, IOM, and Open Payments databases to develop policy recommendations in the text and Box 3. We offer this analysis as a means to advance these policy conversations by taking into account not only accessibility and standardisation (which would be addressed through a registry or database like Open Payments), but also relevance. To that end, we include Box 2, which provides a sample statement that addresses the problem of relevance.</p> <p>We agree that these issues are not unique to journals and that these recommendations could be adapted to other settings and processes within biomedicine. However, given the length and focus of this article, we have retained the focus on journals and the role of authors, editors, and peer reviewers.</p>	<p>See Introduction, page 3, lines 15-33:</p> <p>“Ten years ago, and reiterated since,(8, 9) the Institute of Medicine recommended standardising and harmonising conflict of interest reporting practices.(10) The International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE) recommend that journal editors require published statements declaring authors’ conflicts of interest.(11, 12) Despite these policy developments, non-disclosure and other reporting failures persist. For example, the Chief Medical Officer of Memorial Sloan Kettering, Dr José Baselga, recently resigned after revelations that he failed to disclose millions of dollars in compensation from pharmaceutical and biotech companies in more than 100 publications since 2013 and in 87% of articles that he authored in 2017.(13)”</p> <p>See discussion of IOM recommendations beginning on page 6, line 45 and ending on page 7, line 6:</p>

<p>between funding agencies, academic institutions, and government regulators. I think it is important to note the points the authors raise are not unique to journal articles but have implications to other parts of biomedical science.</p>		<p>“To strengthen transparency while minimising burden on authors and editors, the biomedical research community should develop a public, comprehensive, structured, author-centric database of financial interests.(9, 10, 22) The Institute of Medicine (IOM) proposed a detailed taxonomy for conflicts of interest,(22) which could serve as a structured, standardized, digital template for disclosure, while providing adequate detail about the nature of the relationship or interest.</p> <p>See section, “Purposeful transparency,” beginning on page 9, line 45.</p> <p>See Box 2 and Box 3.</p>
<p>5. The article does not mention the US Sunshine Act, which requires US and international companies to disclose payments to US physicians through a standard public reporting system (the Open Payments database). This database has its flaws, largely tied to lack of verification of reporting and a narrow window of entities required to report payments, but as the closest thing to a standardized reporting database available, it could serve as a starting point for standard reporting elements that the</p>	<p>We agree that the Open Payments database is the closest example of how conflict of interest disclosures might be made more accessible and meaningful. We have included discussion of the Open Payments database to illustrate how it particularly addresses the problem of accessibility from a public and a research perspective. However, it also illustrates how standardizing disclosures can make them more purposeful – we include references to some impactful research that used Open Payments data to understand the extent and impact of conflicts of interest on health care and patient outcomes.</p>	<p>See page 7, lines 8-31 for a discussion of how the Open Payments database has enabled analysis of the extent and impact of conflicts of interest due to standardisation:</p> <p>“Organisations such as ORCID may be well-placed to act as a repository for such information given its international scope and strong uptake among biomedical journals; journals could develop an interface to allow authors to automatically export relevant entries during manuscript submission.(9) The Open Payments database, created through the United States Physicians Payments Sunshine Act, is a notable model in achieving transparency, though it is</p>

<p>authors recommend. Some biomedical journals, mainly orthopedic journals, now include a hyperlink to the authors's Open Payments database page to accompany published articles.</p>		<p>limited in terms of its national scope, and restriction to prescribing clinicians and certain manufacturers. Due to the availability and accessibility of these detailed, accurate, structured data, researchers have an unprecedented ability to understand the extent and the impact of physicians' relationships with pharmaceutical and medical device companies.(23-25) The success of the Open Payments database suggests that any sort of registry should be conceptualised as infrastructure: publicly-funded and coupled with enforcement mechanisms.”</p>
<p>6. I found Box 1 helpful, as it specifically lists recommendations for COI reporting. I think it could also be helpful to provide a Box with an example journal disclosure section that would meet these recommendations.</p>	<p>Thank you for this suggestion. We have developed an example conflict of interest disclosure statement, drawing on the sample disclosure form available on the ICMJE website (for Dr Kermit the Frog). However, we also emphasise that this is merely a proposal and requires further development and testing to ensure acceptability, usability, and impact.</p>	<p>Please see Box 2.</p> <p>Please see the sentence calling to develop and test novel means to communicate conflict of interest disclosures (beginning on page 11, line 50 and ending on page 12, line 6):</p> <p>“Future work should also consider randomised trials of novel structured reporting interventions to assess author, editor, peer reviewer, and consumer usability and acceptability, and the effect on assessment of risk of bias in published work.”</p>
<p>7. The final section of the discussion on accountability is highly important but under-developed. Either it should be</p>	<p>We have decided that given the focus of this article and the space limitations to delete the section on accountability and hope to develop this in future work.</p>	<p>Text related to accountability has been deleted.</p>

expanded with how the authors suggest accountability should be handled by academia and journals or it could be removed.