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Sophie Cook  
Head of Scholarly Comment  
*The BMJ*

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Re: Submission of revised Analysis article entitled, “Why disclosure practices have stalled efforts to address conflicts of interest in research”

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’ comments in the table below, noting the respective changes in the manuscript. The revised word count is 1960.

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>The editors appreciate the improvements you have made to the paper following our previous requests but we still feel there is some way to go to make this suitable for analysis. The article needs a stronger central point and narrative which is outlined early and carried through the piece, with each section used to back up the central argument. Reframing in this way will bring this more in line with a debate article rather than a research project. It would also help if you could rephrase the subheadings to reflect the points you are trying to make rather than to frame them around previous findings.</p>	<p>We have revised the manuscript to better align with the style of an Analysis article, including rephrasing the subheadings to reflect the key points. The central thesis is that current disclosure practices are plagued by reporting failures and thus, the policy conversation is fixated on disclosure rather than addressing conflicts of interest. The article is re-structured to describe the current “Muddy Waters” and problems with accessibility, semantics and relevance. Then, reflecting the standfirst, we propose a way forward, “Purposeful Transparency: What should happen next,” addressing structured reporting, enforcement, and processes for assessing relevance.</p>	<p>Revised headings and subheadings include:  Muddy Waters  The problem of accessibility  The problem of semantics  The problem of relevance</p> <p>Purposeful Transparency: What Should Happen Next  Structured reporting  Enforcement  Assessment of relevance</p>
<p>The introduction still seems lengthy and doesn't provide the reader with much novel information. This could be edited down to create more room to expand on the sections which are likely to move the debate forward.</p>	<p>We have edited down the introduction to focus on the key points:</p> <ol style="list-style-type: none"> <li>1) Conflict of interest disclosures act as a signal for risk of bias.</li> <li>2) Despite apparent policy consensus, current practices are muddy waters. Thus, though transparency is expected, it serves little purpose because disclosures are incomplete, inconsistent, and difficult to access at scale.</li> <li>3) Consequently, the policy conversation is fixated on the shortcomings of disclosure rather than addressing conflicts of interest.</li> </ol>	<p>The Introduction is revised as:  “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)</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</p>

		<p>Publication Ethics (COPE) recommend that journal editors require published statements declaring authors' conflicts of interest.(11, 12) Despite the apparent policy consensus, current disclosure practices are plagued by recurring issues with non-disclosure and other reporting failures. Thus, though transparency is expected, it serves little purpose because disclosures are incomplete, inconsistent, and difficult to access at scale.</p> <p>The result is that the policy conversation is fixated on addressing the shortcomings of the disclosure system rather than on how to address relationships that threaten research integrity. True transparency involves more than just making conflict of interest disclosures available; they need to also be accessible, accurate, complete, and meaningful. Enforced, structured reporting and processes to assess relevance to the work under consideration are required to make disclosures fit for purpose."</p>
<p>Where you say "The Institute of Medicine recommended standardising and harmonising conflict of interest reporting practices" it might be helpful for readers who are not familiar with this concept to appreciate what sort of power (or lack of power) they have. It would also be helpful to explain to readers whether COPE/ICMJE have changed their positions over the years and if so, how.</p>	<p>We have included a sub-section, "Enforcement" to describe how structured reporting of conflicts of interest might be better enforced. We note that organisations such as the IOM, ICMJE and COPE have limited power to enforce their recommendations, however, at minimum, COPE can deny membership to journals that fail to meet conflict of interest reporting standards. As collectives representing the leadership and consensus within scientific publishing, we also suggest that they might propose technical standards and requirements to third-</p>	<p>See revised text on pg 10, under "Structured reporting":</p> <p>"Most journals now employ third-party software to manage the publication process. With leadership from organisations like ICMJE and COPE, specifications and minimum standards for functionality and integrations related to conflict of interest disclosure could be delivered to these vendors who serve the scientific publishing</p>

	<p>party software vendors or publishers with whom journal editors work.</p> <p>We think it is beyond the scope of this article to review the history of ICMJE and COPE policy changes as these have not been well documented.</p>	<p>community. For example, journals could require software vendors to include an interface to allow authors to automatically export relevant disclosures from a registry such as ORCID during manuscript submission.(9)</p> <p>On pg 10-11, under “Enforcement,” “Recognizing that the ability for ICMJE to enforce their guidance is limited, at minimum, organisations like COPE should not permit membership to journals that do not conform to these standards.</p>
<p>Not all the editors were convinced that the initial opening example (fraud) is that fitting as the message of the paper seems to be that better reporting is required so the authors can do better research, not mitigating outright misconduct. While it might be appropriate to illustrate an example of when current processes have failed, including this could be viewed as doing what you are critical of others doing - focusing the policy discussion on addressing the shortcomings of the disclosure system rather than considering how to manage relationships threatening research integrity. It might be worth acknowledging that while high profile cases of failure do serve to highlight the issue, they also in fact tend to focus discussion on the wrong areas.</p>	<p>We have eliminated the opening example of the high-profile instance of non-disclosure covered by the international media. We have revised the introduction to reflect the editors’ point that high-profile instances of non-disclosure or reporting failures tend to focus discussion on the wrong areas.</p>	<p>See revised Introduction:  “Despite the apparent policy consensus, current disclosure practices are plagued by recurring issues with non-disclosure and other reporting failures. Thus, though transparency is expected, it serves little purpose because disclosures are incomplete, inconsistent, and difficult to access at scale.</p> <p>The result is that the policy conversation is fixated on addressing the shortcomings of the disclosure system rather than on how to address relationships that threaten research integrity.”</p>
<p>Where you mention that “journals could develop an interface”, most journals use</p>	<p>We have added some text to discuss the role of third-party software vendors in adopting and implementing</p>	<p>See revised text on pg 10 under “Structured Reporting”:</p>

<p>third party software - Editorial Manager, Scholar 1, Coko. These are the real power behind the technology that we're using. This warrants some consideration.</p>	<p>structured conflict of interest reporting. We suggest that an author-centric registry be conceptualised as infrastructure, and thus be publicly funded and publicly accessible (similar to Open Payments). ORCID is well-positioned to act as a repository; however, software integrations between ORCID and publication management software would be necessary. We suggest that organisations like ICMJE or COPE provide minimum specifications and standards to the software vendor community related to conflict of interest disclosures.</p>	<p>“Most journals now employ third-party software to manage the publication process. With leadership from organisations like ICMJE and COPE, specifications and minimum standards for functionality and integrations related to conflict of interest disclosure could be delivered to these vendors who serve the scientific publishing community. For example, journals could require software vendors to include an interface to allow authors to automatically export relevant disclosures from a registry such as ORCID during manuscript submission.(9)”</p>
<p>Not all of our readers will be familiar with ORCID so please briefly explain this to ensure all readers can follow the paper.</p>	<p>We have included an additional sentence to explain the role and mission of ORCID.</p>	<p>See pg 10, final paragraph under “Structured Reporting”:  “Organisations such as the Open Researcher and Contributor ID (ORCID) may be well-placed to act as a repository for such information given its international scope and strong uptake among biomedical journals. ORCID is a not-for-profit organisation, funded through member contributions, that provides researchers with a unique, persistent digital identifier and infrastructure to support automated linkages across a researchers’ professional activities.(30)”</p>
<p>Presenting the findings tabulated results n=657 etc contributes to the feeling that this is more akin to a research article than an analysis. We wondered if readers need all the different (but on the whole very similar)</p>	<p>We have eliminated all findings presented as tabulated results to enhance the readability and better conform to the style guidelines for Analysis articles.</p>	<p>Tabulated results deleted throughout manuscript.  See edits to Table 1.</p>

<p>types of statement tabulated within the document, or whether you could just give numbers and examples with all the extra detail in a supplementary appendix if it's felt to be necessary.</p>	<p>We have edited Table 1 to provide salient examples of the different meanings conveyed by the variable ways to state, "no conflicts of interest," rather than a comprehensive categorisation.</p>	
<p>Where you highlight the 130 ways of saying 'no COIs' we think this means that 130 different things are taken as "no COI" but in fact are not all the same so perhaps a question mark is needed in the subheading here.</p>	<p>We have edited the headers and sub-headers throughout the manuscript as suggested and thus have eliminated the header "130 ways of saying 'no conflict of interest.'"</p>	<p>Header deleted.</p>
<p>Where you say 'Coupled with enforcement mechanisms' - who is subject to these measures and what sort of enforcement is likely to be sufficiently impactful? Would it be the individual, their organisation, or the third party/commercial body that would be liable? Enforcement is noted in the stand first but this needs to be elaborated upon.</p>	<p>We have included a section under a new heading, "Enforcement" to expand upon the point made in the stand first. We note that the ICMJE recently revised their policy to consider purposeful non-disclosure a form of scientific misconduct, thus, journal processes and policies to deal with misconduct may serve as enforcement mechanisms. Further, we note that many journals benefit from the credibility and legitimacy granted by COPE membership, yet do not adhere to recommendations such as inclusion of conflict of interest statements. A second level of enforcement could thus be at the level of the journal and denial of membership in COPE on this basis. Finally, following the example of the Open Payments database discussed earlier in the manuscript, we note that ideally, legislation requires that companies be required to publicly report payments to all researchers and clinicians.</p>	<p>See text under "Structured reporting" (pg 9): "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 revised section, pg 10, "Enforcement": "The variability in how conflicts of interest are reported likely relates to differences in standards imposed by journals rather than a consequence of author intentions. Currently, the onus is on authors to disclose, which makes a breach of this honour system all the more a significant violation of trust, and on editors to ensure the accuracy and integrity of the published work.(32) Yet, journal editors are frequently without the information or resources needed to identify or verify authors' conflicts of interest.(32) The ICMJE recently revised their policy to include purposeful non-disclosure of</p>

		<p>conflicts of interest as a form of scientific misconduct.(11)</p> <p>However, a proportion of journals claiming to adhere to the ICMJE recommendations still do not routinely include conflict of interest statements.(15) Recognizing that the ability for ICMJE to enforce their guidance is limited, at minimum, organisations like COPE should not permit membership to journals that do not conform to these standards.”</p>
<p>We do not think the example of Dr Frog fits with the style of the manuscript and detracts from the serious nature of the topic making it feel less realistic. Please provide a fake but realistic example instead.</p>	<p>We have eliminated the example of Dr Frog and provided an alternative fictional, but more realistic case example.</p>	<p>See Box 3.</p>
<p>We felt Box 3 doesn't really do what it's described as in these sentences in the text: “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, authors should state which interests are relevant to the manuscript and why; this statement should be peer reviewed and adjudicated by editors (Box 3).” This section of the text is really the crux of the major suggestion and needs a bit more fleshing out, again perhaps with an example.</p>	<p>We have reorganised the text and reordered the Boxes for clarity. Box 2 (formerly Box 3) now comes at the beginning of the section, “Purposeful transparency: What should happen next,” and is followed by 3 sub-sections, reflecting the standfirst (Structured reporting, Enforcement, Assessment of relevance), that flesh out the recommendations in Box 2.</p>	<p>Box 2 (formerly Box 3) accompanies the text: “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,(25) and compare these to current ICMJE recommendations (Box 2).”</p> <p>Box 3 (formerly Box 2) accompanies the text: “We propose that authors make use of a public database to report and maintain a structured and comprehensive list of their disclosures and that these complete disclosures are made publicly available via a</p>

		<p>link placed in the article. Separately, we suggest that authors state which interests are relevant to the manuscript and why, that this statement is peer reviewed and adjudicated by editors and is visibly and succinctly included in all forms of the manuscript under the standard heading “conflicts of interest.” Box 3 provides a sample statement of this nature.”</p>
<p>One issue we struggled with here is that sometimes authors feedback to us that they are not clear what should and should not be declared. This issue isn’t really covered in the current paper and we wondered whether this is worthy of some discussion. Is there any agreement among governing bodies what should be declared? How could this issue be better navigated?</p>	<p>Given the variability across journals in disclosure requirements and practice, it is not surprising that this is a common editorial experience. In the revised section, “Structured reporting,” we point to the IOM taxonomy of conflicts of interest as a viable policy proposal for standardizing requirements across journals. However, this does not directly solve the problem of assessing relevance in terms of the connection, importance, and risk of bias to the work under consideration. Thus, we include another section, “Assessment of relevance” to propose that authors make a statement akin to the statement required by ICMJE on the role of the funder, that is reviewed by editors and peer reviewers. A sample statement is given in Box 3.</p>	<p>See text on pg 9, “Structured reporting”:          “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, 26) Viable proposals currently exist: the Institute of Medicine (IOM) proposed a detailed taxonomy for conflicts of interest,(26) 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 text on pg 11, “Assessment of relevance”:          “Though the ICMJE recommends that authors report details on the funding source and the specific role of the sponsor in the design, conduct and publication of the research, there is not an equivalent requirement for author conflicts of interest.(11) For example, when an author</p>

		<p>discloses personal fees from multiple entities, there is rarely information about the scope or extent of the relationships, how the scientific work relates to a company's products, or the specific reason for the receipt of payment.</p> <p>We propose that authors make use of a public database to report and maintain a structured and comprehensive list of their disclosures 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, that this statement is peer reviewed and adjudicated by editors and is visibly and succinctly included in all forms of the manuscript under the standard heading "conflicts of interest." Box 3 provides a sample statement of this nature."</p> <p>See Box 3.</p>
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