

Smoke and mirrors? Conflict of interest declarations in tobacco and e-cigarette-related academic publications

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Abstract

Objective: This research explored international tobacco control experts' level of satisfaction with conflict of interest (COI) declaration processes; and the transparency of COI declarations of identified authors publishing in the tobacco, e-cigarette, and related novel products academic literature.

Methods: This case study profiled 10 authors' (identified by expert panel) COIs pertaining to the tobacco industry; identified the 10 authors' publications (2010-2021); and assessed the transparency of the COI declarations within the publications.

Results: All authors received indirect or direct funding from the tobacco industry. On review of the authors' 553 publications, 61% of COI and funding declarations were accessible, 33% were partially accessible and 6% were inaccessible. Overall, 33% of authors provided complete COI declarations, 51% provided incomplete declarations, and 16% provided no declaration.

Conclusion: This research demonstrates existing guidelines and recommendations for reporting COI declarations are not sufficiently robust to ensure transparency in reporting of COI declarations within the field.

Implications for public health: Research outcomes have the potential to define public health discourse and influence public opinion, practices, and policy. It is critical that research remains independent and protected from the influence of the tobacco industry. Processes for monitoring and enforcing accurate reporting of COI declarations are needed.

Key words: conflict of interest, tobacco, industry, e-cigarettes, transparency

Background

Public health researchers and practitioners value research integrity, including open access to quantitative data, rigorous methodological standards, acknowledgement of bias and conflict of interest (COI) disclosure.¹ COI refers to situations in which personal considerations may compromise a researcher's judgement, potentially influencing numerous steps in the research process.² COI may be financial or non-financial, direct or indirect, individual or institutional and both actual and perceived.² Examples of COI include but are not limited to board membership, consultancy, employment, contract research, lectures and other educational events, royalties, funding, and

other personal or professional relationships that may influence or appear to exert influence.^{3,4}

Findings indicate that researchers with COIs are consistently more likely to design research and present conclusions that favour industries, including in the areas of tobacco and alcohol and other drugs, compared to researchers with no COI.^{1,2,5} There is also an association between financial COI and favourable recommendations of drugs and devices in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews.⁶ One study reported that biomedical researchers with COIs were more likely to choose comparators that would produce favourable results, selectively include only certain outcomes in published reports, publish conclusions that

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are inconsistent with the study results or complete a clinical trial without subsequent publication of the results.²

The tobacco industry has a long and well-documented history of engaging in strategies that seek to manipulate research relating to the risk associated with tobacco use.^{7,8} The tobacco industry has sought to manipulate evidence about its products by funding, publishing, and disseminating research that supports the continued sale of tobacco, and promotes e-cigarettes and related products as a harm reduction strategy while suppressing and critiquing research that does not support this position.¹ Research shows that approximately 30% of articles in tobacco, e-cigarette, and related product publications declared industry sponsorship.^{9–11} These affiliations are counter to the WHO Framework Convention on Tobacco Control (FCTC), which documents that due to irreconcilable conflicts between the tobacco industry and public health, they recommend limited interaction, the need to ensure transparency in any interaction, and not seeking to hide affiliations and parent companies or dismiss non-independence.¹²

More recent strategies adopted by the tobacco industry to exert influence on research findings include the use of front groups—organisations that purport to represent one agenda while in reality serving some other party or interest whose sponsorship is hidden or rarely mentioned—to distribute funding via an indirect pathway and obscure involvement in science.^{13–15} One such group is the Foundation for a Smoke-Free World (FSFW) whose stated goal is the end of tobacco use, achieved through funding research and promoting innovation.¹⁶ The FSFW identify as a scientific organisation that operates independently, whilst solely funded by Philip Morris International (PMI).¹⁶ PMI has been indirectly funding “harm reduction” research centres and providing grants to organisations using the FSFW as a conduit.¹⁵ Alongside research centres there are also healthcare consultancy companies, consumer groups and industry bodies that receive funding either directly or indirectly from the tobacco industry. Recent media in Australia revealed links between an Australian tobacco and e-cigarette-related charity and a global public relations firm with tobacco and e-cigarette industry ties.¹⁷

The International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE), two international bodies committed to improving ethical standards in publishing, recommend that journal editors require published statements declaring authors’ COIs that extend at least three years.^{4,18} The inclusion of a COI declaration provides an opportunity for editors, and readers, to assess the risk of bias and allow for such bias to be considered alongside other research confounders. Purposeful failure to fully disclose a COI relationship has been identified as a form of misconduct.^{4,18}

Journal policies regarding the disclosure of COI declarations are not standardised, are neither routinely monitored nor enforced, and rely on authors being fully compliant.¹⁴ Incomplete disclosures of COIs have been found to even extend to journals that are committed to ethical standards. Ruff describes examples of COPE member journals failing to comply with their code of conduct and highlights the failure of the existing mechanisms to protect scientific publications from COI.¹⁹ For example, there do not appear to be any sanctions or consequences for individuals not declaring COI, or declaring inaccurate COI. In addition, a number of journals preclude publication

by people with tobacco industry COIs, so there is essentially an incentive to hide these relationships.¹⁴ Despite the inadequacies of COI declarations being identified, there is a lack of evidence-based policy recommendations for addressing this issue.

It has been suggested that COI declarations could be improved by utilising taxonomy of disclosures with standardised nomenclature.^{20,21} The introduction of dichotomous (yes/no) questions in a COI form for a German peer-reviewed publication found that the number of authors declaring a COI doubled.²² The limitations of such strategies have been identified, with some believing that creating a single uniform disclosure form is an impractical exercise.²³ A publicly accessible, centralised registry for COI has also been proposed as a means to improve research integrity.²³ Proponents of the registry emphasise the importance of an enforceable, transparent, interoperable system to ensure success, and suggest looking to the successful implementation of clinical trial registries for lessons learnt.²

Transparency requires COI declarations to be accessible, accurate, complete, and clear.⁴ Despite these recommendations, COI declarations are frequently absent, inaccurate, or incomplete, and there is currently no agreed methodology to assess the transparency of COI declarations.^{19,24–28} This research aimed to explore international tobacco control experts’ level of satisfaction with current COI declaration processes; identify recommendations to improve these processes; and assess the transparency (accessibility and completeness) of COI declarations of identified authors acknowledged as having tobacco industry funding publishing in the tobacco, e-cigarettes, and related products academic literature. The research did not aim to determine the prevalence of inaccurate COIs in the field.

Methods

This case study of authors published in the academic tobacco, e-cigarette, and related products literature comprised four stages, adopting a content analytical approach, enabling data to be analysed both qualitatively and quantitatively.²⁹

Stage One

A panel of 10 international tobacco control experts (henceforth expert panel) who have published extensively in the tobacco control literature for > 20 years and with no current or historical affiliation with tobacco companies were purposefully identified and invited to participate in the research (August 2021). Purposive sampling was deemed appropriate as this research explored whether transparency issues exist in COI declarations, not the prevalence of inaccessible or incomplete declarations. An email invitation to the expert panel explained the purpose of the study and provided an opportunity to obtain informed consent and provide a link to an online survey. The survey asked the expert panel about their level of satisfaction with existing peer-reviewed journal COI assessment processes and ICMJE recommendations, using a Likert scale (satisfied; dissatisfied; neither satisfied nor dissatisfied); the adequacy of the three-year timeframe for capturing COI (Yes or No); and to provide feedback on a COI classification system developed by the researchers. Following this, the expert panel were asked to nominate authors publishing in the

tobacco, e-cigarette and related products field, who, to the expert panel's knowledge, may not adequately report their COIs.

Stage Two

Through a desktop review, the 10 most frequently nominated authors, identified by the expert panel, were confirmed to have COIs and to not adequately report them. These authors were further investigated by the research team to construct author profiles. The sources used to populate the author profiles were Tobacco Tactics, a regularly updated website managed by Bath University¹⁵; LinkedIn; and COI and funding declarations located in the nominated authors' portfolio of peer-reviewed publications. Profile data included research in the tobacco, e-cigarettes and other novel products area, affiliations with organisations and committees, and acquired funding (direct/indirect). *Direct* funding included funding from tobacco companies, e-cigarette and e-liquid companies, and related trade organisations and advocacy groups. *Indirect* funding included funding from FSFW or funding from FSFW via research centres and charitable organisations.

Stage Three

A systematic search of publications authored by the nominated authors was then undertaken using Web of Science and Scopus. The search strategy was: nominated author name[author] AND e-cigarette [All fields] OR "electronic cigarette" [All fields] OR 'electronic nicotine delivery'[All fields] OR tobacco[All fields] OR "heat not burn" [All fields] OR HNB[All fields] OR IQOS[All fields] OR "heated tobacco" [All fields]

OR pod[All fields] OR Juul[All fields] OR cigarette[All fields] OR vape[All fields]. Eligible publications were peer-reviewed primary research articles, reviews, letters, notes, and editorials, published in English between 2010 and 2021. Publications from the two databases were merged using Endnote (V9.3.3) and deduplicated. Titles and abstracts were screened by the primary researcher (AM) to ensure relevance and the following data were extracted and tabulated in Excel (V16.64): author, date of publication, journal, title, article type, COI declaration, funding declaration, and relevant acknowledgements.

Stage Four

The proposed COI classification system developed by the research team was refined following review by the expert panel. Two members of the research team (AM, JJ) independently assessed and categorised a random sample (n=25) of publications. Categorisations were compared and discrepancies were discussed, refined, and modified. A further random sample (n=25) of publications was independently assessed by the same researchers and the results were compared. This process resulted in the final classification system. One author (AM) completed the coding. The COI classification system was used to assess the transparency of COI declarations across two domains: (a) accessibility assessed the location and access to the author's COI and funding declaration; and (b) completeness/accuracy assessed the correctness of the author's COI declaration compared to the information within their constructed profile from the three years prior to the date of publication. See [Figure 1](#) for the description of categories.

Figure 1: Conflict of interest classification scheme.

<p><u>Accessibility domain for COI and funding declarations</u> (locating the information in the publication)</p> <p><i>Accessible</i></p> <p>a) <i>full</i> – both a clearly identifiable COI declaration and funding declaration provided in the publication.</p> <p>b) <i>supplemental</i> – either a clearly identifiable COI or funding declaration provided in the publication and supplementary information identified in the acknowledgment section.</p> <p><i>Partially accessible</i> – either a COI or funding declaration provided in the publication. No supplementary information identified in the acknowledgement section.</p> <p><i>Inaccessible</i> – no COI declaration, no funding declaration or supplementary information in the acknowledgement section.</p> <p><u>Completeness domain for COI declarations</u></p> <p><i>Complete declaration</i> – COI declaration provided, matched the compiled author profile.</p> <p><i>Incomplete declaration</i> – COI declaration provided in part (affiliation(s) was/were identified by name) but did not fully match the compiled author profile.</p> <p><i>No declaration</i> – no COI declaration provided despite the compiled author profile identifying existing COI.</p>

Results

Expert panel level of satisfaction with COI processes

Eight experts participated in Stage One of the study. Six experts expressed dissatisfaction with current COI declaration processes, four reported dissatisfaction with ICMJE recommendations, and five were dissatisfied with the three-year timeframe required for COI declarations.

Conflict of interest processes

Four experts broadly supported the ICMJE recommendations in principle. The ICMJE disclosure form was said to be a “great attempt to get more details” (respondent 5) and “pretty good for a disclosure form” (respondent 1); however, the failure of the recommendations to be adopted universally and a lack of procedures to ensure complete and accurate statements were identified as limitations in the declaration process. As one respondent stated, “often the form isn’t looked at and it is never checked for accuracy - feels like a box-ticking exercise much of the time” (respondent 2). Respondents also indicated that the ICMJE recommendations did not capture indirect funding “as due to the long history of [the] tobacco industry’s pernicious influence on science, conflict of interest related to these industries should be mentioned explicitly in the recommendations and the disclosure form” (respondent 8).

Dissatisfied experts pointed to a lack of consistency in journal policies concerning COI declarations. One respondent stated, “some journals are good, but the majority, even of reputable journals, do not have adequate policies that align with Article 5.3 of the FTC” (respondent 7). Respondents identified that journal policies lacked clear criteria for defining and declaring COIs and expressed that declarations were rarely verified by journals, with one respondent noting that “the system is entirely built on trust and self-management” (respondent 2).

The failure of the current COI declaration processes to capture indirect funding was also described. One expert noted that “disclosures... are hidden by front companies—using smoke and mirrors to try and distance themselves from tobacco industry funders” (respondent 1). This was seen as problematic because “the proliferation of indirect funding also makes it difficult ... to understand that any indirect funding through a foundation or research centre, it is still industry funding” (respondent 5).

Five experts stated that three years was not an appropriate timeframe to consider COI. “Given the time it takes to develop publications, three years is a very short space of time. This allows authors who may have fairly recent and substantial tobacco/vaping interests to declare no conflicts, which is quite misleading” (respondent 7). Conversely, one expert indicated three years was an appropriate timeframe when declaring a COI in other fields and stated that “funding and employment in the tobacco industry should be treated as a separate category with different, more stringent requirements” (respondent 8). Another respondent stated that the timeframe should depend on the type of COI: “it depends really a small thing like [the] reimburse [ment of] travel expenses versus a multi-million dollar grant need different reporting requirements” (respondent 2).

Recommendations to improve COI reporting processes

The expert panel identified three main strategies to improve the reporting of COI declarations. First, criteria relating to COI need to be

more clearly defined and comprehensive to capture both direct and indirect tobacco industry funding. Second, reporting of COI declarations should extend beyond three years, and third, COI declarations need to be verified. As one respondent stated, “editors should fact check any conflict of interest that may raise a question about the source of funding or affiliation” (respondent 6). The introduction of penalties, such as article retraction, was also recommended for authors who attempt to hide COIs. One expert stated, “the conflict of interest disclosure should be more extensive and explicit, and attempts to hide or make some conflict of interest vague should have penalties including retraction of [the] article” (respondent 4). Another expert recommended a centralised repository to store COI declarations suggesting a “central, open-access system used by all journals not on a per article, per submission, basis” (respondent 2).

It was also recommended that “tobacco industry-sponsored studies need to be disallowed in public health and tobacco control journals” (respondent 4) and “associated parties should not be able to publish in public health and associated journals due to the inherent conflicts that cannot be resolved, even through disclosure” (respondent 1). However, respondents noted that COI declarations do not resolve, address or manage the conflict disclosed, commenting, for example, “Disclosing a conflict of interest does not allow the peer review process to address this issue in itself, or even identify how the conflict of interest has impacted the research and science itself” (respondent 1).

Author review of COI declarations

Of the 27 authors identified by the experts, the 10 most frequently nominated were selected for investigation of their COI and funding declarations. Based on detailed profiling, four authors received ‘direct and indirect’ funding and six received only ‘indirect’ funding. After applying the inclusion criteria, 553 publications were identified from the 10 authors with known COI, with the majority representing research articles (see Table 1).

Among these publications, 61% of COI and funding declarations were rated as accessible, 33% were partially accessible and 6% were inaccessible. Overall, 33% provided a complete COI declaration that accorded with the detailed profiling data from the three years prior to the date of publication, 51% provided an incomplete declaration and 16% provided no declaration (see Table 2).

Discussion

True transparency, as defined by the ICMJE, requires COI declarations to be accessible and complete.⁴ We aimed to assess the transparency (accessibility and completeness/accuracy) of COI and funding declarations in peer-reviewed publications in the tobacco, e-cigarette, and related products field. The accessibility domain assessed the ease with which a reader can access an author’s COI and funding

Table 1: Publication type for identified author publication (2010–2021).

Publication type	Publications (n=553)	
	n	%
Research article	373	67.5
Review	57	15.0
Letter	83	10.3
Note	21	3.8
Editorial	19	3.4

Table 2: Accessibility and completeness of COI and funding declarations in publications (n=553).

	n	%
Accessibility (COI and funding declarations)		
Accessible		
a) Full	205	37
b) Supplemental	133	24
Accessible partial	182	33
Inaccessible	33	6
Completeness/accuracy (COI declarations)		
Complete	183	33
Incomplete	282	51
No declaration	88	16

declarations, while the completeness/accuracy domain examined the correctness of the author's COI declaration, compared to their established profile from the three years prior to the date of publication. These two domains were essential in making an overall assessment of the true transparency of authors' declarations, and to the best of our knowledge, this study was the first to assess both domains simultaneously.

Previous research investigating the transparency of COI declarations has been relatively limited. For example, factors associated with reporting COI in the scientific literature on e-cigarettes have been investigated,¹⁰ but the research did not assess the completeness/accuracy of the COI declarations. Previous studies in the surgical and pharmaceutical fields that assessed the accuracy of COI declarations were limited to financial COI disclosure only, relying on publicly available payment databases.²⁵⁻²⁸ Our research builds on extant research by creating an author profile using various sources (e.g. Tobacco Tactics, LinkedIn, and author publications), as no publicly available database exists. While these sources are available to assist in determining the accuracy of declarations in the tobacco, e-cigarette and related products field, in other fields this information may not be readily available, making the assessment of declarations even more challenging.

Profiling the identified authors revealed links, direct and indirect, to the tobacco industry during the study period (2010–2021). The emergence of the FSFW in 2017 has increased the pervasiveness of the tobacco industry's indirect funding; and adds support to the claim that front groups are used to infiltrate and shape public discourse.³⁰ These groups seek to present the tobacco industry in a positive light, create confusion regarding industry funding acceptance and legitimise tobacco industry findings, which are generally more positive.³⁰ In the e-cigarette and related products field, individuals with industry ties are more likely to reach favourable conclusions about these products.^{9,11}

The ICMJE recommends that journal editors require published declarations, along with supporting documents, such as the ICMJE COI disclosure form.⁴ However, the lack of labelled declarations and other relevant information indicates that many journals do not adequately implement or enforce policies that require such information before publication. This is consistent with previous research that found that 44% of public health journals did not require disclosure of non-financial COIs.²⁴ In our study only one-third (33%) of COI declarations were assessed to be complete and accurate. For

instance, one author, despite providing discursive COI declarations, consistently failed to disclose their direct relationship with a particular e-cigarette company. In addition, authors declared multiple COIs in some of their publications, while formally declaring no conflict in others. While it is impossible to comment on the reasons that disclosures were not provided, a purposeful failure to disclose a COI would be regarded as a form of misconduct by the ICMJE.⁴ Interestingly, some publications failed to declare 'no conflict', despite there being no apparent COI in the three years prior to the date of publication.

The findings of this research indicate that the current processes around COI declarations are inadequate in revealing direct and indirect links with the tobacco industry. This is concerning, due to the conflicting positions of the tobacco industry and public health. As outlined in the WHO FCTC,^{12,31} COI declarations must be wholly transparent, and should not seek to hide affiliations or dismiss non-independence. An author's relationships, activities, and interests that can potentially be a COI should be defined broadly to demonstrate commitment to transparency.⁴ A failure to provide truly transparent COI or funding declarations, stemming from a lack of information or inaccurate information, removes the ability of readers to make this assessment, and subsequently consider reporting bias. In addition, the inability to accurately assess COI declarations against published research findings has the potential to impact the development of public policy. Policy developed on this basis conflicts with Article 5.3 of the WHO FCTC, regarding the protection of public health policies.

While there is evidence that declarations of COI in absolute numbers are improving over time,³² it appears from our findings that the current ICMJE guidelines are not always being adopted, monitored, or enforced to ensure true transparency and research integrity. This is perhaps unsurprising in an opt-in system in a field with a history of industry manipulation.

Suggested strategies to improve transparency include using closed, explicit questions or taxonomy of disclosures with standardised terminology.^{2,20-21} The expert panel in this research identified the benefits of including the monetary value of financial COIs and extending the current timeframe of three years for which conflicts need to be considered. There is also scope for journals to improve the implementation and enforcement of policies relating to COI declarations. While these steps are likely to improve transparency, the findings from the publication review and the views of the international tobacco control experts would suggest that these steps are unlikely to go far enough.

A publicly accessible, centralised registry for COI declarations has been proposed as a means to improve research integrity.^{2,30-33} The findings from this research support that proposal and highlight the importance of such a registry in areas such as tobacco and e-cigarette and related products research. A standardised registry could be designed to capture details of funding and could remove the burden for both authors and journals, via an "enter once, use many times" process.²³ However, like any system, it needs to be enforced, transparent, and interoperable to enable success. It would require buy-in from academia, industry, government agencies, health organisations and academic journals. Alongside an improved system of governing COIs, there needs to be an associated focus on increasing public awareness of the strategies and sophistication of the tobacco industry.

Limitations

This research purposively selected an expert panel and the authors that were nominated as not adequately reporting their COIs. This research does not aim to generalise the findings to all authors in the tobacco, e-cigarette, and related products field but rather seeks to understand the existence of inadequacies and challenges around reporting COI declarations. In addition, the classification system relies upon access to reliable and detailed information to assess transparency in the completeness/accuracy domain. Funding trails and affiliations can be complex to navigate and verify and are further complicated by the presence of front groups, such as the FSFW.

Conclusion

Research outcomes have the potential to define public health discourse and influence public opinion, practice and policy. The direction of this influence in a rapidly developing evidence base, such as that of the e-cigarette and related products field, is critical and should be protected from the influence of the tobacco industry. COI declarations in academic publications provide a means to support research integrity and consequently must be truly transparent. Assessment of transparency using the classification system trialled in this research revealed an overall lack of transparency among the investigated authors. These findings are consistent with previous research which has reported that declarations are frequently absent, inaccurate, inaccessible, incomplete, and inconsistent. Existing guidelines and recommendations are not sufficiently robust to ensure transparency in the tobacco, e-cigarette, and related products field. New approaches should be trialled.

Ethical issues

The Curtin University Human Research Ethics Committee (HREC) approved the study (HREC2020-0392).

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Conflicts of interest

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