### **OPEN LETTER**

Check for updates

## **REVISED** Time for complete transparency about conflicts of

## interest in public health nutrition research [version 2; peer

## review: 2 approved]

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### Abstract

We are a group of researchers and academics with decades of experience in the protection and promotion of public health. We are writing to raise our concerns about how conflicts of interest are reported in public health nutrition research. We highlight examples of why it is important to accurately declare such conflicts, as well as providing examples of situations in which conflicts of interest have been inadequately reported. We call on researchers, and others, to be transparent about conflicts of interest in research. Journal editors in particular have an important responsibility in fully understanding how conflicts of interest can impact on research findings and interpretations. They need to agree and adopt clear guidelines on conflicts of interest and ensure that authors abide by these to facilitate trust in the scientific process and the credibility of published articles.

# Reviewer Status 💙 🗸

**Open Peer Review** 



Melbourne, Australia

2. Barrie Margetts, University of Southampton,

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### **Keywords**

Breastfeeding, commercial determinants of health, complementary feeding, conflict of interest, infant feeding, nutrition, public health, research funding Southampton, UK

Any reports and responses or comments on the article can be found at the end of the article.

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Author roles: Hennessy M: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Cullerton K: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Baker P: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Brown A: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Crawley H: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Hayes C: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Kearney PM: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Kelly C: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; McKee M: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Mialon M: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Petticrew M: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Rundall P: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Rundall P: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Rundall P: Conceptualization, Writing – Review & Editing; White M: Conceptualization, Writing – Original Draft Preparation, Writing – Original Draft Preparation, Writing – Review & Editing; White M: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; Redsell S: Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing

**Competing interests:** PR holds a small number of shares in Nestlé, for the sole purposes of raising concerns at their annual meetings. Other authors have no competing interests to disclose.

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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#### **REVISED** Amendments from Version 1

We thank the reviewers for their feedback on our open letter; we have addressed their comments as follows.

Lisa H. Amir:

- Abstract 2nd last sentence: "can impact on research findings" – you could add "and interpretations" or similar: We have added the suggested text.
- Letter 6th paragraph: first sentence needs a ref for ICJME guidelines: Reference added.
- Last sentence of this paragraph needs rewording of "its significance" which is confusing, to something like "the influence of funding on research reporting": We have added the suggested text.
- 7th paragraph: COI, personal communications. Should the name of the editor and/or date of personal communications be included here?: This is not a requirement of HRB Open Research; we did not seek permission from the editor to include this information and therefore have not included these details.
- Another thought it seems to me that public health journals could take a stance on these issues...: Thank you for this information. We have added the following sentence: "Some journals and search engines have clear policies around conflicts of interest. For example, it is the policy of the International Breastfeeding Journal to decline for publication any manuscript that has received funding, sponsorship or any other means of support from breast milk substitute manufacturers."

Barrie Margetts:

- I thought, but could not find the email links, that PubMed had agreed to include COI declarations in their abstracts - it would be good to check this out and add if confirmed: Thank you for this suggestion. We have added the following text: "Since March 8, 2017, PubMed has included conflict of interest statements below the abstract when these statements are supplied by the publisher".
- I have no substantive comments; one minor- WHO uses organization (not s). This has been amended.

See referee reports

Interactions between commercial food and drink companies<sup>1</sup> and professionals and bodies responsible for improving public health and health promotion have generated concerns for decades<sup>1-3</sup>. These interactions are often hailed as unique opportunities to make a difference to the public's health that would otherwise not be possible without industry involvement<sup>3</sup>. In late 2018, a series of events attracted considerable media attention in the United Kingdom and beyond. In September, Public Health England announced their partnership with the alcohol industry-funded body DrinkAware on a campaign called 'Drink Free Days', which has the stated aim of helping people cut down on the amount of alcohol they are regularly drinking. This

partnership was met with much criticism – with Public Health England's alcohol adviser, Sir Ian Gilmore, resigning from this role because of concerns that such interactions with alcohol industry actors and related industry-funded organisations come at the expense of public health<sup>4</sup>. Then, in late November, Diabetes UK announced that it had joined forces with sugar-sweetened beverage manufacturer Britvic in a three-year partnership. Again, this interaction was met with much public criticism, which Diabetes UK has rejected<sup>5</sup>. On a more positive note, in October 2018 the Dieticians Association of Australia terminated partnerships with food manufacturers and industry associations following longstanding criticism and internal member advocacy<sup>6</sup>.

Such interactions with industry are also common among individual researchers. In a recent article published in the British Medical Journal, van Tulleken reported that cow's milk allergy may be acting as a Trojan horse for the €44bn global breastmilk substitute industry to forge relationships with healthcare professionals in the UK and around the world<sup>7</sup>. He further highlighted that many of those involved in producing milk allergy guidelines declared interests with breastmilk substitute manufacturers either at the time of writing or subsequently. A series of recent studies have highlighted links between nutrition researchers and Coca Cola<sup>8,9</sup>, contributing to a narrative that pushes policy towards measures to increase exercise by children, which is of course a good thing, while deflecting attention from the role of sugarsweetened beverages in obesity and poor nutrition. Such interactions between public health, paediatric and nutrition experts and commercial food and drink companies can undermine trust in researchers and their scientific integrity<sup>10,11</sup>.

Concerns about interactions between researchers and commercial food and drink companies are well-founded as corporate interests typically prioritise investing in research that supports their policy and legal positions, and this can divert research attention away from questions that are more pressing for public health<sup>12,13</sup>. Such interactions are also more likely to lead to findings that confirm the benefits or lack of harm of the sponsor's products<sup>14</sup>, even when independently sponsored research comes to differing conclusions. As early as 1965 the US sugar industry began funding research to downplay the role of sugar as a dietary risk factor for coronary heart disease, shifting the focus towards cholesterol and fat instead, with decades-long implications for nutrition guidance and policy<sup>15</sup>. A Cochrane review concluded that industry sponsored studies more often report findings in a direction that favours the sponsor<sup>16</sup>. Similarly, in a systematic review of the effects of soft drink consumption on nutrition and health, the authors found that studies funded by the food industry reported significantly smaller effects than did non-industry-funded studies<sup>17</sup>. Such industry-funded research generates doubt among scientists, policy-makers and the public by generating conflicting or confusing results<sup>18</sup>. In the light of these and other revelations, members of the public are increasingly sceptical about research that is supported by commercial funding<sup>19</sup>, as are members of the research community<sup>20</sup>.

An important element of maintaining public trust in the scientific process and the credibility of published articles is whether

<sup>&</sup>lt;sup>1</sup>Those involved in the primary production, manufacturing, wholesaling, retailing of fresh, packaged, or hot or cold ready-to-eat foods and/or drinks, as well as third parties working for such companies, including trade associations and research bodies.

conflicts of interest are transparently disclosed during the planning, implementation, writing, peer review, editing, and publication of scientific work. Determining what constitutes a conflict of interest can be difficult for researchers and editors as there is limited guidance available. However, when researchers receive funding from a commercial company to undertake research related to their products, brand or area of interest, a conflict of interest exists<sup>21</sup>. Although this seems obvious, a number of corporations have supported positions that seek to dismiss concerns about such conflicts by arguing that everyone has some interest, for example, in progressing their scientific reputation to attract further funding, so commercial sponsorship should not raise particular concerns<sup>22</sup>.

Procedures for the reporting of conflicts of interest are covered within the International Committee of Medical Journal Editors (ICJME) guidelines<sup>23</sup>. Where authors do not conform to ICJME guidelines, journal editors must take responsibility for encouraging full disclosure. A common sentiment within the research community is that transparency is the key to appropriately managing and avoiding conflicts of interest; that is, as long as the authors are fully transparent, then readers can make up their own minds about conflicts of interest. However, this sentiment fails to acknowledge the limited understanding both academic and clinical researchers have on this issue<sup>24,25</sup>. Of particular concern is the limited awareness of how research funding and unconscious bias work together. This relationship can result in researchers being influenced by funding even when they think they are being unbiased<sup>26</sup>. Further limitations of disclosure are apparent from research showing that it may give licence to researchers to exaggerate their findings, while reviewers often fail to take adequate account of the influence of funding on research reporting<sup>27</sup>.

Recently in a scientific article published ahead of print in Annals of Nutrition and Metabolism, the authors of the article stated that they had "no conflicts of interest or financial ties to disclose" despite declaring that the writing of the article was supported by Nestlé Nutrition Institute<sup>28</sup>. This Institute has clear links with Nestlé<sup>29</sup>, the world's biggest breast-milk substitute and complementary baby food manufacturer<sup>30</sup>, and therefore it has a clear financial interest in the study<sup>31</sup>. We wrote a Letter to the Editor of the journal to raise our concerns about how conflicts of interest were reported therein. The Editor declined to accept our letter for publication asserting that the authors had disclosed their funding source and that readers could apply their own interpretation. The Editor further stated that the Editorial Board would critically review and question conflict of interest (COI) statements where questions may arise, but added that COI declaration remains the responsibility of the authors (personal communications, 11 November 2018). While COI is the responsibility of the authors to declare, it is the responsibility of the journal to have robust policies and to clearly explain them in a way that leaves no room for ambiguity.

The practice of declaring no conflicts of interest while also reporting financial support from vested interests is not uncommon in early life nutrition research. This occurs despite the World Health Organization highlighting the need to avoid conflicts of interest in all areas relating to infant and young child feeding in at least eight World Health Assembly resolutions. In a paper outlining the recommendations of an International Expert Group around follow-up formula for infants, several authors reported financial ties with breast-milk substitute companies yet declared that "none of the authors reports a conflict of interest"32. Shortcomings in editorial policies toward conflicts of interest (financial and nonfinancial) of editors and other staff involved in manuscript decisions have previously been highlighted<sup>33</sup>. Indeed, the ICJME guidelines state that all those involved in the peer-review and publication process, including authors, peer reviewers, editors, and editorial board members of journals, must consider their conflicts of interest and disclose all relationships that could be viewed as conflicts of interest.

Researchers and journals have important responsibilities regarding conflicts of interest<sup>34</sup>. Some journals and search engines have clear policies around conflicts of interest. For example, it is the policy of the International Breastfeeding Journal to decline for publication any manuscript that has received funding, sponsorship or any other means of support from breast milk substitute manufacturers<sup>35</sup>. Since March 8, 2017, PubMed has included conflict of interest statements below the abstract when these statements are supplied by the publisher<sup>36</sup>. It is time to for researchers, journals, funders and others involved in the research process, to engage more critically with the challenges of conflicts of interest in research. This requires clear understanding of what is, and is not, a conflict of interest, how to identify them, the impacts of conflicts of interest on scientific integrity, how to prevent them, and greater transparency in the reporting of conflicts of interest in research, something that is often lacking<sup>37</sup>. Journal editors in particular have an important responsibility in fully understanding how conflicts of interest can impact on research findings and the credibility of published articles for journals and authors.

Clear guidelines on managing interactions with commercial food and drink companies, including avoidance of damaging conflicts of interest, are urgently needed. Journals will need to play an important role in implementing such guidance. To aid in this process, a project funded by the UK's Medical Research Council has reviewed evidence and built international consensus on the principles that underpin governance of interactions between researchers and commercial food and drink companies. Guidance for researchers, journals and funders will be published in 2019<sup>38</sup>. It will enable researchers to identify and assess conflicts of interest at different stages of the research process and suggests governance strategies to manage these.

Journals – as well as research institutions, professional bodies and funders – should use this forthcoming guidance to formulate or update their own conflict of interest policies and ensure that authors, peer reviewers, editors, and editorial board members abide by these to promote trust in the scientific process and the credibility of published articles.

### Disclaimer

The views expressed in this article are those of the author(s). Publication in HRB Open Research does not imply endorsement by the Health Research Board of Ireland.

#### **Data availability**

No data is associated with this article.

#### Grant information

MH is a PhD Scholar funded by the Health Research Board under SPHeRE/2013/1. The Health Research Board had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

KC is funded by a grant from the Australian Government's Medical Research Future Fund.

MM received a grant number 2017/24744-0, from the São Paulo Research Foundation (FAPESP), Brazil. The authors are solely responsible for the opinions, hypotheses and conclusions or recommendations expressed in this publication, and they do not necessarily reflect FAPESP's vision.

MW holds grants from the UK Medical Research Council to develop guidance on managing interactions between researchers and commercial food and drink companies; and with the UK National Institute of Health Research (NIHR) to evaluate the UK's Soft Drinks Industry Levy. MW is also funded as Director of NIHR's Public Health Research Programme.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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## **Open Peer Review**

## Current Peer Review Status:

Version 1

Reviewer Report 11 February 2019

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### **Barrie Margetts**

Faculty of Medicine, University of Southampton, Southampton, UK

This is a very a timely and well written article that highlights a key issue in research. Stronger guidance for journals (and funding and reporting in general) is key to a clearer objective evidence base, upon which decisions for action can be made. I thought, but could not find the email links, that PubMed had agreed to include COI declarations in their abstracts - it would be good to check this out and add if confirmed.

I have no substantive comments; one minor- WHO uses organization (not s).

### Is the rationale for the Open Letter provided in sufficient detail? Yes

### Does the article adequately reference differing views and opinions?

Yes

## Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Yes

### Is the Open Letter written in accessible language?

Yes

### Where applicable, are recommendations and next steps explained clearly for others to follow?

Yes

*Competing Interests:* For complete transparency, I am a Trustee of Firststeps nutrition, which is run by one of the authors. I have not discussed this paper with any of the authors, but feel I

should inform the readers.

Reviewer Expertise: Public Health Nutrition

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 11 Feb 2019

Marita Hennessy, NUI Galway, Galway, Ireland

**Dear Professor Margetts** 

Thank you for reviewing our open letter, and for your positive feedback. I have sourced confirmation regarding the addition of COI declarations by PubMed (https://www.nlm.nih.gov/pubs/techbull/ma17/ma17\_pm\_update.html) and will add details to a revised version of the manuscript.

Best wishes Marita

Competing Interests: No competing interests were disclosed.

Reviewer Report 04 February 2019

### https://doi.org/10.21956/hrbopenres.13963.r26488

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### Lisa H. Amir 匝

Judith Lumley Centre, La Trobe University, Melbourne, Vic, Australia

This letter summarises recent events in which companies involved in manufacturing food and drink products have provided funding for public health organisations or research leading to outcries and media attention. The authors argue that since this type of funding can influence the direction taken by organisations/researchers, relationships with industry funders must be more transparent.

Abstract - 2<sup>nd</sup> last sentence: "can impact on research findings" – you could add "and interpretations" or similar.

Letter – 6<sup>th</sup> paragraph: first sentence needs a ref for ICJME guidelines.

Last sentence of this paragraph needs rewording of "its significance" which is confusing, to

something like "the influence of funding on research reporting".

7<sup>th</sup> paragraph: COI, personal communications. Should the name of the editor and/or date of personal communications be included here?

Another thought – it seems to me that public health journals could take a stance on these issues. As the founding editor of the *International Breastfeeding Journal*, I decided not to publish research that had been funded by infant formula manufacturers, as explained in this editorial<sup>1</sup>. Over the years, I have rejected a number of papers funded by dairy companies and infant food manufacturers prior to inviting peer reviewers. This decision has not always been popular, but it has saved reviewers and readers having to decide whether the research findings being considered for publication or published in this journal have been influenced by funding.

### References

1. Beasley A, Amir L: Policy on infant formula industry funding, support or sponsorship of articles submitted for publication. *International Breastfeeding Journal*. 2007; **2** (1). Publisher Full Text

Is the rationale for the Open Letter provided in sufficient detail?

Yes

Does the article adequately reference differing views and opinions?

Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Yes

Is the Open Letter written in accessible language?

Yes

# Where applicable, are recommendations and next steps explained clearly for others to follow?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Breastfeeding research.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 12 Feb 2019

Marita Hennessy, NUI Galway, Galway, Ireland

Dear Dr Amir

Thank you for taking the time to review our open letter, and for your positive comments. We will address the points you highlighted when preparing a revised version.

Best wishes Marita

*Competing Interests:* No competing interests were disclosed.