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ORIGINAL ARTICLE

Development processes for e-cigarette public health recommendations lacked transparency in managing conflicts of interest

Marissa J. Smith*, S. Vittal Katikireddi, Shona Hilton, Kathryn Skivington

MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, 99 Berkeley Square, Glasgow G3 7HR

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Abstract

Objectives: To investigate how guideline development groups collect and manage conflicts of interest (COI) when producing electronic cigarette (e-cigarette) recommendations.

Study Design and Setting: Public health bodies that had produced e-cigarette recommendations were identified from four purposively selected jurisdictions (World Health Organization, United Kingdom, Australia, and United States). We analysed their COI policies and conducted 15 interviews with guideline methodologists, policymakers, and academics in guideline development groups.

Results: Only five of 10 public health bodies had a publicly available COI policy. Participants discussed the importance of those involved in the development process declaring COI. However, there were differences in who had to report COI, the time period asked about, and what and how declarations are made. COI policies and participants discussed a range of approaches for managing COI, from limiting involvement to disqualification from the recommendation development process. Participants considered the current processes for collecting and managing COI insufficient due to their open interpretation and possibility for partial declarations of interest.

Conclusion: The management of COI varies across public health bodies, with little standardization and lack of transparency. To improve the collection and management of COI, and ultimately increase the trustworthiness of recommendations, guideline development groups should draw upon a comprehensive and accessible COI policy.

Keywords: Public health; Electronic cigarettes; Conflicts of interest; COI declaration; COI management; Declaration of interest

1. Background

Conflicts of interest (COI) may threaten the integrity of scientific investigations, undermine the evidence base, and risk threatening the trustworthiness of public health policies, guidelines, and recommendations if not appropriately managed [1]. A COI can be defined as ‘‘circumstances that create a risk that professional judgments or actions regarding a primary interest (e.g., validity of research) will be unduly influenced by a secondary interest (e.g., financial gain)’’ [1]. COI can arise from financial and nonfinancial interests. Nonfinancial COI can range from personal, political or religious beliefs, professional experiences, social

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* Corresponding author. MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, 99 Berkeley Square, Glasgow G3 7HR. Tel.: +44-0141-353-7500; fax: +44-0141-332-0725.

E-mail address: marissa.smith@glasgow.ac.uk (M.J. Smith).

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What is new?

Key findings

- Half of the public health bodies included in this study do not have publicly available COI policies.
- Despite there being general agreement about the importance of disclosing COI, public health bodies across four jurisdictions vary in their approach to collecting and managing COI, including how they define a 'conflict of interest'.

What this adds to what is known?

- It is recommended that public health bodies should have a well-defined and robust process to assess and manage COI, but our findings suggest that no consensus appears to exist on what that process should be.

What are the implications and what should change now?

- Public health bodies that produce public health policies and recommendations should ensure that their COI policies are publicly available, as this will improve the transparency and trustworthiness of the policies and recommendations produced and also of the public health body themselves.

relationships, or institutional relations [2]. Financial COI are often the most evident and research has shown an association between financial relationships of the author and/or sponsor/funder and industry-favourable results in tobacco research [3,4] and other public health topics [5–7]. A recurring critique of COI policies is that they overlook nonfinancial interests [8,9], although there is debate surrounding their relevance, with some arguing that they do not present a COI [10]. Although nonfinancial COI have been much less studied than financial interests, emerging evidence indicates that they can affect research and policy. For example, evidence shows that nonfinancial interests may question the impartiality of systematic reviews and negatively affect the equitable allocation of health resources in grant funding procedures [11]. Furthermore, some argue that by overlooking nonfinancial COI, this discourages exploration of the inter-relationship between financial and nonfinancial COI and impedes the development of policies and strategies for collecting and managing all types of COI [8]. In addition to this perspective of COI affecting individuals, others have highlighted how COI may be embedded within institutions and social structures [12]. For example, decision-making processes can be established which privilege commercial interests in a way that undermines health, as occurred by the embedding of impact assessments within the European Commission at the instigation of British American tobacco and other industries [13]. Although both of these aspects of COI are important, our focus in this article is on the former.

An important concern is that COI may be present among the evidence base which guideline developers draw upon and this may lead to recommendations being distorted to favour a secondary interest (e.g., study funding) [14,15]. In recent years, COI disclosure policies have become a routine part of scientific research [16]. The International Committee of Medical Journal Editors (ICMJE) guideline recommends that authors should disclose the study's funding source and any financial ties to industry, for example, pharmaceutical or tobacco companies [17]. In addition, COI among guideline developers may act as a potential source of bias in the development of public health recommendations and clinical and public health guidelines [14,15]. There is recognition that managing COI among guideline developers is a requirement of trustworthy guidelines and recommendations; however, the identification and management of COI remains challenging [18]. Although COI among the evidence base are important, our focus in this article is on COI among guideline developers.

The tobacco industry has historically undermined public health policies and has a long history of selectively reporting industry-favorable results [19]. To address the global tobacco epidemic, the World Health Organization (WHO) developed the Framework Convention on Tobacco Control, with Article 5.3 of this focusing on limiting the tobacco industries' influence on public health policy [20]. There is concern among the scientific community that the e-cigarette industry may similarly hide COI and report-biased results [21], noting that these are often the same corporate entities [21]. The production and dissemination of COI can apply across many industries: the tobacco industry archetypically but may also apply to the pharmaceutical and alcohol industry [22]. Even within public health topics, different industries may have different interests and positions, with some authors noting this in relation to tobacco and e-cigarette companies [23].

Electronic cigarettes (e-cigarettes, also known as Electronic Nicotine Delivery Systems or ENDS) are an important case study to understand the management of COI during the guideline development process due to the range of vested interests. A range of regulatory approaches towards e-cigarette products has been pursued across the globe from being completely prohibited (e.g., Singapore) to being regulated as consumer products (e.g., United Kingdom and Spain), tobacco products (e.g., Malta), or medicinal devices (e.g., Finland) [24,25]. The management of COI during the guideline development process might impact upon the regulatory approaches that are pursued.

This study investigates how public health bodies across four jurisdictions collect and manage COI during the development of e-cigarette public health recommendations.

2. Methods

2.1. Selection of study jurisdictions

We purposively selected four jurisdictions, WHO, United Kingdom (Scotland, England, Wales, and Northern Ireland), Australia, and United States. These jurisdictions were chosen due to their different e-cigarette regulatory frameworks and their relative importance for setting the agenda on policy recommendations for tobacco control and e-cigarettes [26]. Studies have shown that the United Kingdom has pursued a 'harm reduction' approach towards e-cigarettes, proposing that smokers should be encouraged to switch to e-cigarettes [24,25]. In contrast, the WHO Australia, and United States have pursued a 'precautionary' approach, arguing that smokers should be encouraged to quit smoking and not switch to e-cigarettes [25,27].

After identifying specific public health bodies which produced public health recommendations, we systematically identified published e-cigarette public health recommendations they had produced (Appendix A). Public health recommendation documents can be characterized as documents that contain recommendation(s) for health practice, public health, or health policy [28]. It is generally agreed that the process for developing public health recommendations should be transparent and lead to impartial decisions that improve health, based on the best available evidence [29].

2.2. Identification of conflicts of interest policies

We searched the websites of included public health bodies for documents that described the processes for managing COI in the guideline development process (manuals, handbooks, methodology articles, and webpages). We aimed to include documents that addressed COI in guideline development and that provided data on information required for disclosure of financial and nonfinancial relationships and processes for collecting and managing COI. We called a document detailing this information a ''COI policy''.

If a COI policy was not publicly available via website search, the public health body was contacted by e-mail and asked to provide any details on the processes for managing COI.

2.2.1. Coding and analysis

We coded the COI policies based on standards and recommendations proposed by the Institute of Medicine (IOM) [1,30] and ICMJE [17] (Appendix B provides a full list of the COI policy coding framework). M.S. conducted all of the coding, with 40% double-coded by K.S. Following the initial coding, we conducted a thematic analysis, making comparisons across documents and jurisdictions using NVivo 12 for data management.

2.3. Expert interviews

2.3.1. Sampling of experts

Expert interviews were chosen to gain insights into the processes for managing COI during the development of e-cigarette recommendations. We used a purposive sampling approach and identified experts from the author and/or contributor lists of the public health bodies' e-cigarette recommendation documents (detailed in Appendix A) and snowball sampling. Snowball sampling therefore allowed both authors and contributors (who may not have been authors but still closely involved) to be included in the sample of experts. In addition, participants were asked to recommend additional respondents from their knowledge of the field and involvement in the decision-making process. To provide an overview of the e-cigarette debate and an insight into the development process, we included academics, policymakers, and methodologists (i.e., people with expertise in applying evidence to produce recommendations).

To ensure anonymity, the names and identifying details of the study participants are not reported.

2.3.2. Data collection

Potential participants were approached by e-mail and provided with an information sheet. Interested participants were contacted by M.S. to arrange the interview. Before the interview, participants completed a consent form. All interviews were conducted by M.S.

Initially, interview schedules were developed based on the Grading of Recommendations Assessment, Development and Evaluation Evidence to Decision Framework [31]. For example, participants were asked about topics that are influential and important to consider during the development of recommendations, such as how COI were managed during the development process, how the recommendations would impact health equity, and how evidence is translated into recommendations. Following this, schedules were further developed by adding in topics relating to COI in the evidence base and the role of evidence. These were then tailored to two different interview schedules: academics (Appendix C) and policymakers and methodologists (Appendix D).

Interviews lasted between 34 minutes and 84 minutes (median 53 minutes). All interviews were audio-recorded and transcribed verbatim. Reflective field notes were made immediately after the interview, to assist with analysis.

2.3.3. Coding and analysis

Framework method is a systematic approach that identifies commonalities and differences in qualitative data, defines relationships, and builds conclusions [32]. Transcripts were coded based on the Grading of Recommendations Assessment, Development and Evaluation Evidence to Decision Framework [31], supplemented by inductive codes (Appendix E provides coding framework). M.S. led the

analysis with 30% double-coded by S.V.K. and K.S. Following the initial coding, we conducted a thematic analysis, making comparisons across documents and jurisdictions and pay attention to contradictory data.

2.4. Comparison across two data sources

The data were synthesized by merging the COI policies and expert interview analysis NVivo projects together and a large data synthesis framework was produced (Appendix F). Descriptive summaries of the data were generated, which allowed for cross-comparisons to be made between the sources.

3. Results

Five of the 10 public health bodies had a formal COI policy, either publicly available or provided on request (Appendix G).

Of the 40 potential participants identified and contacted for this study, 15 (one from WHO, four from United Kingdom, five from Australia, and five from the United States) participated in interviews (eight academics, five policymakers, and two methodologists) in 2020. All participants authored/contributed to at least one of the public health bodies' e-cigarette recommendation documents (Appendix A).

3.1. Conflicts of interest policies

There are subtle differences between the public health bodies' definitions of the term 'conflict of interest' (Table 1). American Public Health Association talks explicitly about the potential gain and National Health and Medical Research Council (NHMRC) discusses direct and indirect interest [39,37]. Whereas others include a broader definition (e.g., the WHO talks more generally about judgement being impaired or influenced [33]).

"There are lots of organizations including WHO that have banned people who work for tobacco companies from participating in the World Conference on Tobacco or Health and that they themselves (WHO) do not associate with industry, especially the tobacco industry. Article 5.3 is and has always got to be prime" (Academic, United States).

One participant discussed institutional COI and how this was reported within their associated public health body's reports. It is worth highlighting that the public health body that this participant worked with did not have a publicly available COI policy."Wherever we [public health body] get money from 'and people can make their own decisions' and we make very explicit in our reports that we [public health body] have no links to industry, including any vaping or tobacco manufacturers" (Policymaker, United Kingdom).

3.2. Disclosure of conflicts of interest

Details on the types of information required varied across the public health bodies' COI policies (Appendix H). The five public health bodies that had a formal COI policy collected details on financial COI and there was consistency in their categorization (e.g., paid employment and stocks/shares) [33–39]. Among those that included details on nonfinancial COI (WHO, NHMRC, National Institute

Table 1. Definition of conflict of interest by public health body

Jurisdiction	Public health body	Definition of the term conflict of interest
International	WHO [33]	"A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" [30]. "Any interest declared by an expert that may affect or reasonably be perceived to affect the expert's objectivity and independence in providing advice to WHO" [[33], p.57].
United Kingdom	National Institute for Health and Care Excellence [34,35]	"A conflict of interest arises when the judgement of someone involved in the work of NICE may be compromised, by the financial or other considerations set out in this policy" [[35], p.4].
	Public Health Wales [36]	"A set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold" [[36], p.7].
Australia	National Health and Medical Research Council [37,38]	"Interests are any direct or indirect pecuniary or nonpecuniary interest" [[37], p.4].
United States	American Public Health Association [39]	"Conflict of interest or bias means any financial interest or potential for gain that (1) could impair the individual's objectivity or (2) could create an unfair competitive advantage for the individual or for the individual's business partner(s), employer, spouse or partner, ancestors, children, grandchildren, great grandchildren, siblings (whether by whole or half-blood), and the spouses of children, grandchildren, and great grandchildren" [[39], p.2].

for Health and Care Excellence, and Public Health Wales [PHW]), there was broad agreement on what this constitutes (e.g., member of a committee or organization) [33−38]. The American Public Health Association did not provide details on nonfinancial COI, in keeping with their definition (Table 1) [39].

Interview participants generally agreed on the importance of disclosing COI.

"I definitely think that in the report it (COI) should be fully disclosed. The audience should be made aware about it" (Academic, United States).

When asked about the types of COI required to be disclosed (e.g., financial), participants stated that there should be full disclosure, whether these be financial or personal, by those involved in the development of recommendations. In doing so, this could help prevent the under-reporting of COI and potential influence that may occur.

"To limit the scope for introducing bias to simply to where you have a connection, financial connection to tobacco industry or vaping industry or whatever, is pretty reductive. Actually, there are lots of influences on people's lives that would influence how they view research or how they wish to see the world and they are all kinds of COI" (Academic, United Kingdom).

There was a substantial difference in the time for disclosure (Appendix H), NHMRC required only potential interests within the last 3 months, whereas National Institute for Health and Care Excellence, PHW, and American Public Health Association required disclosure of potential COI within the last 12 months and WHO did not specify a time frame [33−39]. Participants highlighted that such variations can negatively impact the reporting process:

"There are potential pitfalls with declaration and that depends on what is expected in terms of the time frame and this can result in under-reporting conflicts of interest" (Methodologist, International).

3.3. Process for collecting and managing conflicts of interest

There is variation in the format and process for disclosure and the management of COI (Appendix I). Most interview participants discussed that they were required to fill out a form disclosing any COI before their involvement in the development process. However, one participant stated that when declaring COI with their public health body there was no written process but "a verbal declaration at the beginning of every meeting about conflicts of interest" (Academic, United Kingdom). It is worth highlighting that the public health body that this participant worked with did not have a publicly available COI policy.

Although COI disclosure has become a common practice, participants argued that there is a blurring of what is acceptable which has resulted in partial or hidden COI in disclosures, particularly concerning the tobacco/vaping industry.

"There are partial declarations of interest, so you will get people saying, I have done work for [vaping company] but they would not say [vaping company] is actually a tobacco industry body" (Academic, Australia).

Although one participant stated that, in their experience, those involved in developing recommendations are not "in any way, shape or form conflicted" (Policymaker, Australia), others reported that no action was taken when COI were declared.

"[Conflicted individuals] were not prevented from taking part in the [development] process; they just had to declare their conflicts of interest" (Academic, Australia).

This statement was not consistent with the COI policy of the public health body that this participant was associated. Based on further discussion, the participant reported that the COI were not considered during the development process. Nonetheless, the most common approach discussed by participants was to limit the involvement of conflicted individuals, so that conflicted individuals were only allowed to participate in certain stages of the development process and excused from others.

"There are different ways for managing conflicts. Most commonly, you can ask those who are conflicted (e.g., declare a financial conflict) to participate in the discussion of or maybe the interpretation of the evidence as opposed to voting on what the recommendation should be. This is our approach. It is a kind of limited involvement and limited to the discussion and giving an opinion on the evidence, providing an insight into the evidence but not making judgement about how to interpret this evidence and how to develop a recommendation accordingly" (Methodologist, International).

Exclusion of individuals with specific relationships was mentioned only by PHW and this related to direct or indirect financial incentives, restrictions on hospitality, and money/gifts rewards or incentives [36]. When asked about the exclusion of individuals with specific relationships, participants often discussed industry relationships (e.g., pharmaceutical, tobacco, and vaping industries). We found there to be three different approaches to handling industry COI. Most participants stated that any industry COI was excluded from the development process.

"The most important one is that they (public health bodies and organizations) ask is have you received money or had any involvement with industry, particularly tobacco, or any other industry that might have an interest in one side of the argument" (Academic, Australia).

However, one participant stated that the public health body they worked with did not always exclude individuals who declared industry COI.

"Conflicted work and individuals do not lack credibility automatically but you take a very careful look to see if they are being influenced" (Policymaker, United States).

One participant explained that the public health body they worked with took a completely different approach to managing COI, stating that "the quality of the study and

credibility of the scientists over-rides any perception of a conflict of interest'' (Policymaker, United States). However, it was not further made clear how this 'credibility' was defined.

Although processes are in place to increase the transparency of COI disclosure, overall participants lamented the ''appalling lack of transparency in terms of conflicts of interest'' (Academic, Australia). Despite disclosure of COI becoming more accepted within the scientific and policy communities, policies are open to interpretation and participants argued that this is ''not a perfect system'' (Policymaker, United States).

4. Discussion

Our study shows that there is a general agreement about the importance of disclosing COI. However, public health bodies across four jurisdictions vary in their approach to collecting and managing COI, with some not describing their COI policy publicly at all, even in relation to tobacco control. Furthermore, definition of the term 'conflict of interest' varies. Variation in how COI are defined illustrates that there are different understandings of what a COI entails. As such, important details could be excluded from disclosures. For example, there is agreement relating to the definition and management of financial COI; however, there is debate surrounding the relevance of nonfinancial COI, which was reflected in the definitions of COI by the public health bodies in this study. Participants in the study were in agreement that nonfinancial COI of those involved in the development process should be included in COI policies and involvement of those with conflicts should be restricted. This is in line with research showing that nonfinancial COI can influence study results and clinical recommendations [40]. Under less stringent COI definitions, conflicted individuals could be involved in the public health recommendation development process and influence subsequent recommendations. Our analysis demonstrated there to be varied approaches to handling COI, ranging from total exclusion of conflicted individuals, limited involvement, which is consistent with IOM standards, to simply declaring COI but being able to continue participating in the development process. In some cases, limiting a conflicted individual's involvement implies that although they are not permitted to feed into determining the evidence drawn upon, they are permitted to be involved in its interpretation. Given the potential for unconscious bias, it is perhaps questionable that COI cease to be important at this stage of guideline development. Previous research (such as [41−43]) has examined the various approaches to managing COI and has shown that limited involvement or exclusion of conflicted individuals is the most common approach. Furthermore, several studies [41,43] have discussed a more nuanced approach where the management is on an individual basis and is dependent on the conflict and context.

Occasionally, participants who were involved in the guideline development process for Australian and US public health bodies, where precautionary approaches to e-cigarettes were adopted, described less restrictive COI policies than other jurisdictions in the study, including those who adopted harm reduction approaches to e-cigarettes. The variation in COI policies was discussed by participants who ultimately argued that the current processes for collecting and managing COI are insufficient and that all COI should be disclosed.

Previous studies (including 28, 43, 44, 45, and 46) have examined the presence and management of COI in the development process, finding there to be high rates of COI among those involved. Eccles et al. [28] gave an insight into how they believe COI should be managed during guideline development, arguing that those involved should disclose all potential COI, consistent with the views of our study participants. Guyatt et al. [44], Mendelson et al. [45], Qaseem and Wilt [46], and Traversy et al. [43] examined the COI management process in specific guidelines and suggest that explicit processes can be used by guideline development panels to declare COI and mitigate their effects (such as limited involvement). In addition, they argue the disclosure should include all past and current potential COI and if COI are identified those individuals should abstain from discussion of recommendations, similar to many of the participants in our study. However, only half of the public health bodies in our study detailed a COI policy and research by Norris et al. [14] similarly found that only 46% of the 37 surveyed organizations had a COI policy directly related to healthcare guidelines. This suggests that the absence of COI policies could result in the under-reporting of COI by individuals involved in the development process [14]. Even a decade after Guyatt et al.'s [44] research, which offered a potential solution by developing a strategy to resolve the tension between incorporating the expertise and knowledge of conflicted guideline developers, we are still seeing research highlighting a lack of an agreed process for collecting and managing COI.

Guideline developers should consider how to balance the competing goals of incorporating diverse knowledge and expertise into the guideline process while minimizing the potential influence of COI [47]. Using a standard for collecting COI (e.g., ICMJE) may support transparency and trustworthiness in recommendations produced. Therefore, we recommend that public health bodies should ensure that their processes for collecting and managing COI are publicly available, as this will improve the transparency and trustworthiness of the recommendations produced and also of the public health body themselves.

The collection and management of COI remains challenging and future research could examine how individual COI (both financial and nonfinancial) declared by those

involved in the development process and institutional COI impacts decision-making, assessment of the certainty of evidence, the inclusion of specific studies (such as those that declare COI or industry funding/sponsorship), and the translation of evidence into recommendations. This is important for understanding how COI relates to the evidence used in policy recommendations.

The management of COI in the field of tobacco control, particularly e-cigarettes, is of importance given the misinformation and deception by the tobacco industry, which historically undermined public health policies (e.g., in the 1970s, the tobacco industry downplayed the harms associated with second-hand smoke) [21]. Public health bodies have the opportunity to acknowledge and address the potential implications of tobacco and/or e-cigarette−associated COI and address these in their COI policies. Although previous studies have demonstrated variability in handling COI within guidelines [42,48], our findings show that this still occurs and even in relation to tobacco control—the topic where most evidence of industry influence on decision-making exists—is noteworthy. The management of COI of those involved in developing public health recommendations is only one part of the issue; COI within the evidence that is drawn upon in the development process also need to be managed [49]. In addition, contextual factors are important to consider when examining the possible reasons for diversity in e-cigarette regulatory approaches, which also warrants further investigation.

The development of public health recommendations is a complex issue with numerous factors impacting on the approaches ultimately taken including types of COI—individual and institutional and COI within evidence itself and various other contextual factors.

Our study has several strengths. We systematically identified publicly available COI policies and transparently coded the COI policies based on standards by ICMJE [17] and IOM [1,30]. By combining multiple data sources, the data are woven together to promote a greater understanding of the processes for collecting and managing COI during the guideline development process. However, some limitations should be noted. First, the results are based on studying a single topic (e-cigarettes) in a specific international context and therefore we excluded public health bodies that deal with other public health topics. Second, we are limited by the public health bodies' available COI policies. It is possible that we may have missed policies relating to organizational relationships. However, we contacted public health bodies directly if their COI policy was not available on their website. By not providing details of the policy, it could be argued that this impacts the transparency of the process as no such policy can be demonstrated. However, participants discussed having to declare COI, even when the public health body did not have a publicly available COI policy. Third, the findings from this research rely on the perceptions of a limited number of key experts per jurisdiction. Although the experts were selected due to their knowledge of the development process and the e-cigarette debate, their views may not comprehensively or accurately describe the public health development process in their jurisdictions.

5. Conclusion

COI represent a potential threat to the trustworthiness, credibility, and utility of public health recommendations. It is concerning that some public health bodies either do not have or are unable to share their COI policy. The variation in COI policies can result in the incomplete reporting of potential COI and divergent declarations across public health bodies. There is a lack of transparency in the process, which could translate into a decrease in trust and credibility of recommendations produced. Guideline developers should consider how to balance the competing goals of incorporating diverse knowledge and expertise into guidelines while minimizing the potential influence of COI. Ultimately, public health bodies should have a well-defined and robust process to assess and manage COI.

CRediT authorship contribution statement

Marissa J. Smith: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing − original draft, Visualization. **S. Vittal Katikireddi:** Conceptualization, Writing − review & editing, Supervision. **Shona Hilton:** Conceptualization, Writing − review & editing, Supervision. **Kathryn Skivington:** Conceptualization, Validation, Writing − review & editing, Supervision.

Appendix A

Supplementary Data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2022.09.006.

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