PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Financial Conflicts of Interest among U.S. Physician Authors of 2020 Clinical Practice Guidelines: A Cross-Sectional Study
AUTHORS	Mooghali, Maryam; Glick, Laura; Ramachandran, Reshma; Ross, Joseph

VERSION 1 – REVIEW

REVIEWER	Murayama, Anju Tohoku University, School of Medicine As a non-financial COI, I have been working on the same theme concerning COI among clinical guideline authors in Japan and the USA.
REVIEW RETURNED	14-Nov-2022

GENERAL COMMENTS	I deeply appreciate the opportunity to review your valuable paper concerning undeclared financial conflicts of interest in clinical guidelines in the USA. I acknowledge that this paper has addressed important topics concerning the COI and trustworthy clinical practice guidelines and added many novel, valuable findings for all of the readers of your paper, users of clinical practice guidelines, and policymakers. However, this study included several large limitations. I recommend the authors should address these limitations before acceptance. My comments were below. Page 4, line 14-18 "Prior studies have demonstrated an association between guideline authors' financial COIs with industry and favorable recommendations for their products.3,4" A recent systematic review published in the BMJ evaluated the association between conflicts of interest in clinical guidelines and favorable recommendations. This study would be also appropriate and helpful to back up your statement and is worth mentioning. (https://www.bmj.com/content/371/bmj.m4234) Page 4, line 18-25 "Therefore full disclosure......" COI declaration is mandated not only due to the favorable recommendations but also due to many historical cases harming patients such as the IDSA lyme guideline, CKD anemia guideline, and sepsis guideline in the USA in 2000s. These cases should be referred here. I think you already know "Guidance for Guideline" by Prof. Steinbrook published in the NEJM in 2007 (https://www.nejm.org/doi/pdf/10.1056/NEJMp068282) introduced several medical scandals concerning COI in guidelines, and your paper should mention these cases in your introduction.

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	Page 4, line 20-21 "the National Academy of Medicine, and the World Health Organization, emphasizing the importance of making transparent potential COIs among panel members who participate in the development of the clinical practice guidelines." The Guidelines International Network also made recommendations for COI management strategies (https://www.acpjournals.org/doi/10.7326/M14-1885?cookieSet=1). This article is also informative and many US societies such as the ASCO and ACP are member organizations of the GIN. Page 4, line 40-42, "numerous studies comparing disclosures by clinical practice guideline authors to those reported to CMS by manufacturers." This sentence needs references. Page 4, line 45-47 "before physicians may have realized that there would be opportunities for external scrutiny of their disclosures.17" Reference 17 is not a study assessing the COI of clinical guidelines, but general surgeons between 2014 and 2017. There will be more appropriate studies for your statement. The research team led by Prof. Matt Vassar conducted many studies for COI in guidelines in the USA and you can find many valuable studies from his team. A study assessing the US dermatology guidelines elucidating that more than 80% of guideline authors received one or more payments was published in 2017. (https://jamanetwork.com/journals/jamadermatology/fullarticle/2657683) I think this study is one appropriate candidate paper for your statement. Page 4, line 49-51 "Accordingly, our objective was to examine the accuracy of disclosed financial COIs among a more contemporary sample of U.S. physician authors of clinical practice guidelines in 2020." Why evaluation of undisclosed FCOIs is important? A sentence or two explaining the rationale in more detail would be valuable to the reader. Page 5, line 15-18 "The study also examined the concordance of COIs self-reported by the guideline authors and those listed for each author with a profile on the CMS Open Payments program database." How did you find the authors' profiles in the Open Payments? Did you search for the name in the Open Payments search webpage (https://openpaymentsdata.cms.gov/), or in the physician profile database (https://openpaymentsdata.cms.gov/dataset/6ed6ae76-2999-49da-b0b2-d7df150ac754)? Page 5, line 36 "For societies with multiple clinical practice guidelines, we chose the one with the largest number of authors" How do you justify this sample selection? For example, societies making many guidelines might have rigorous COI policies for developing guidelines, while societies producing the small number of guidelines might not have policies for guideline development and did not implement their policies to the authors. Therefore this sample selection included a significant bias. I recommend the authors include all or more guidelines published in 2020 and evaluate the society's policy for guideline development and COI management, as well. I know the COI policy evaluation is one research theme, which is different from this study rationale. Therefore, one way to do this would be to make one supplementary document or add references to several previous studies.

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	Page 5, line 49-55 "Authors from outside the United States and those who were not physicians (e.g., PhDs) were excluded from the analysis, as Open Payments, as of 2020 under the Physician Payments Sunshine Act, only required disclosure of payments from industry to U.S. physicians and academic medical centers.21" Did you refer to other COI information for the excluded authors? Many previous studies evaluated underreported COIs by their articles published in the same year or prior to a few years. This method can be employed in your study and if you intended to evaluate the whole prevalence of underreported and undisclosed COIs, you should examine the authors outside the USA as well. A study by Bindslev et al. would be helpful. (https://bmcmedethics.biomedcentral.com/articles/10.1186/1472-6939-14-19) Page 6, line 49 "Data collection from Open Payments was done in May and June 2022." How did you collect the payment data? Was the payment data downloaded manually by the investigators or through automated coding using API or software such as Python or R? Did two investigators separately download the payments from the OPD? If so, did you compare the two data? How did you verify the data? The payment data is the core dataset of your study and needs to be validated. Page 7, line 3-18 "We categorized the status of financial COIs into the following groups: (1) undeclared in the guideline and no payments found on Open Payments (accurate disclosure of no financial COIs), (2) undeclared in the guideline but payments found on Open Payments, (3) disclosure of payments in the guideline and no additional payments found on Open Payments (accurate disclosure of financial COIs), (4) disclosure of payments in the guideline but additional payments found on Open Payments (underreporting), (5) disclosure of payments in the guideline but not all payments were found on Open Payments (overreporting), (6) disclosure of payments in the guidelines, but both additional payments were found and not all disclosed payments were found on Open Payments (underreporting and overreporting)." Have you evaluated your society's COI policy? As several societies such as American Diabetes Association require guideline authors only for the past one year. Therefore, if a guideline author has correctly declared COI for the past year in accordance with the society's policy, but has not declared COI for the past three years, this may be an 'undeclared COI' due to the society's COI policy, rather than an 'undeclared COI' due to author error or author's insincerity. I recommend the authors examine the society COI declaration period, too. Page 7, line 47 "Supplemental Table 1" The authors should include information about societies' COI policies. Supplemental Table 1 was described as "Supplemental Table 4" in the separate supplemental material PDF file. Could you recheck the file again? Page 8, line 10 "Supplemental Table 5" In the Supplemental Material PDF file, this supplemental material 2 was described as "Supplemental Table 5". Is this correct? "Supplemental Table 5" described that the Open Payments profile data was available in 270 (72.8%). What do you mean by this? Do you mean there were 270 authors in the Open Payments? Or 270 authors

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	were eligible for the Open Payments search? Please clarify this Supplemental table. Page 11, line 16 "Table 4" Table 4 should contain the proportion and number of authors receiving each payment. Page 11, line 16 "Table 4" Of the several general payment categories, why have you specifically described food and beverage payments? Food and beverage payments are not required to be declared by the guideline authors in several societies, while consulting, lectures, honoraria, and gifts are generally required to be declared by the authors. Considering the purpose of this study (to assess the accuracy of COI declarations), I think you should more focus on other general payments such as speaking, gifts, and consulting payments which are mandated to declare than food and beverage payments. As numerous studies found that food and beverage payments were associated with increased use of sponsored drugs and increased healthcare costs in physicians, I recommend that the authors show descriptive results of several major general payment categories, not only food and beverage payments. Page 11, line 26 "Supplemental Table 3" How was the order in Supplementary Table 3 determined? In my opinion, it would be easier for readers to understand if they were ordered in descending order by median payment or percentage of undeclared COI. Supplemental Figure 2 There was no supplemental figure 1, but there was "Supplemental Figure 2" in the file. Is this Supp Fig 2 supplemental figure 1? Page 13, line 5 "more than 90% did not completely ......" Maybe I missed the information. How did you calculate this number? Page 13 line 18 "Moreover, for most guidelines, authors with financial COI comprised the majority of the panels." Your study only included US physician authors and did not assess the true prevalence of authors with COIs. Additional analysis including all authors, or reporting the proportion of authors receiving payment relative to the total number of authors, is necessary for this statement. Discussion I have no concerns about the findings of your study describing an undeclared COI in clinical guidelines. However, I believe that your paper could be improved if you could discuss your findings in more detail and link them to previous studies. Furthermore, why do the guidelines issued by some societies, such as the ACP, declare authors' COI more accurately than others? Additionally, COI management strategies for undeclared COIs of each society should be described in your discussion. For example, currently, ASCO's clinical guidelines included the Open Payments Database links of each guideline author (https://ascopubs.org/doi/full/10.1200/JCO.22.01992), while in your study, 14 (87.5%) of ASCO guideline authors incorrectly declared their COIs.

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REVIEWER	Lee, You Kyoung Soonchunhyang University College of Medicine, Department of Laboratory Medicine and Genetics
REVIEW RETURNED	05-Dec-2022

GENERAL COMMENTS	The study included a total of 270 authors, representing 267 unique individuals, in the analysis. The included 20 sample CPGs were published in 2020 in the US. The results were reported in terms of CPG and analyzed in terms of 270 authors. In the case of analysis in terms of CPG, it is considered appropriate to include each data of the three authors in the study. However, they may be regarded as duplicates when analyzed from the perspective of guideline authors. It should be justified in the methods and results sections.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments

1. *Page 4, line 14-18 "Prior studies have demonstrated an association between guideline authors' financial COIs with industry and favorable recommendations for their products.3,4"*

A recent systematic review published in the BMJ evaluated the association between conflicts of interest in clinical guidelines and favorable recommendations. This study would be also appropriate and helpful to back up your statement and is worth mentioning. (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.bmj.com%2Fcontent%2F371%2Fbmj.m4234&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412456431%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=WVhczYDEKFBZW1lyXTSwemcfsaWHv4JlPZ6PGTBJ4RA%3D&reserved=0)
<u>Response</u>: Thank you for this suggestion. This systematic review was added as a citation to the aforementioned sentence (citation 5 in the revised manuscript).

2. *Page 4, line 18-25 "Therefore full disclosure......"*

COI declaration is mandated not only due to the favorable recommendations but also due to many historical cases harming patients such as the IDSA lyme guideline, CKD anemia guideline, and sepsis guideline in the USA in 2000s. These cases should be referred here. I think you already know "Guidance for Guideline" by Prof. Steinbrook published in the NEJM in 2007 (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nejm.org%2Fdoi%2Fpdf%2F10.1056%2FNEJMp068282&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412456431%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YtEI6%2FCglcHzlCoR6E6AAeRc05UnmD6p76UfONiCNOA%3D&reserved=0) introduced several medical scandals concerning COI in guidelines, and your paper should mention these cases in your introduction.
<u>Response</u>: Thank you for this comment. A statement about guideline recommendations influenced by financial COIs being potentially harmful was added to the manuscript, citing the suggested source, as below (the underlined text indicates the revisions):

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"Prior studies have demonstrated an association between guideline authors' financial COIs with industry and favorable recommendations for their products. Moreover, there have been concerns around the harm to patients receiving care based on potentially biased recommendations by guideline authors with financial COIs." **(citation 6 in the revised manuscript)**

3. *Page 4, line 20-21 "the National Academy of Medicine, and the World Health Organization, emphasizing the importance of making transparent potential COIs among panel members who participate in the development of the clinical practice guidelines."*

The Guidelines International Network also made recommendations for COI management strategies (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acpjournals.org%2Fdoi%2F10.7326%2FM14-1885%3FcookieSet%3D1&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa31051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412456431%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2xJa3ZO3tauaOwqC8SCjhLAaVuaK%2BPZKm4b7gJmepAw%3D&reserved=0). This article is also informative and many US societies such as the ASCO and ACP are member organizations of the GIN.

Response: Thank you for this suggestion. The recommendations by the Guidelines International Network are valuable to further support our statement and the sentence was revised to name the organization within the manuscript: "Therefore, full disclosure of financial COIs has been mandated by several medical professional societies issuing guidelines, the Guidelines International Network, the National Academy of Medicine, and the World Health Organization, emphasizing the importance of making transparent potential COIs among panel members who participate in the development of the clinical practice guidelines."

4. *Page 4, line 40-42, "numerous studies comparing disclosures by clinical practice guideline authors to those reported to CMS by manufacturers.*

This sentence needs references.

Response: Thank you for this comment and we apologize for the oversight. Several references were added to support the statement (citation 10 and 15 in the revised manuscript).

5. *Page 4, line 45-47 "before physicians may have realized that there would be opportunities for external scrutiny of their disclosures.17"*

Reference 17 is not a study assessing the COI of clinical guidelines, but general surgeons between 2014 and 2017. There will be more appropriate studies for your statement. The research team led by Prof. Matt Vassar conducted many studies for COI in guidelines in the USA and you can find many valuable studies from his team. A study assessing the US dermatology guidelines elucidating that more than 80% of guideline authors received one or more payments was published in 2017. (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fjamanetwork.com%2Fjournals%2Fjamadermatology%2Ffullarticle%2F2657683&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412456431%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=je120YcQGVxIrO1mkGJxhVbd0F4quoFU8FSI6B5i0%2FE%3D&reserved=0) I think this study is one appropriate candidate paper for your statement.

Response: Thank you for this comment. A more appropriate reference, as suggested, was added (citation 22 in the revised manuscript).

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6. *Page 4, line 49-51 "Accordingly, our objective was to examine the accuracy of disclosed financial COIs among a more contemporary sample of U.S. physician authors of clinical practice guidelines in 2020."*

Why evaluation of undisclosed FCOIs is important? A sentence or two explaining the rationale in more detail would be valuable to the reader.
Response: Thank you for this comment. Within the first and second paragraph of the Introduction, we discuss the importance of existence and disclosure of financial COIs. Further explanation of the impact of undisclosed financial COIs (underlined) has also been added in response to this comment.
"Prior studies have demonstrated an association between guideline authors' financial COIs with industry and favorable recommendations for their products. Moreover, there have been concerns around the potential harm to patients receiving care based on biased recommendations by guideline authors with financial COI. Therefore, full disclosure of financial COIs has been mandated by several medical professional societies issuing guidelines, the Guidelines International Network, the National Academy of Medicine, and the World Health Organization, emphasizing the importance of making transparent potential COIs among panel members who participate in the development of the clinical practice guidelines.

Despite increased requirements for guideline authors to have limited COIs and to fully disclose COIs when present, studies have shown high rates of financial relationships among guideline panel members, many of which are undisclosed or underreported...
Inaccurate disclosure of financial COI could undermine the integrity of clinical practice guidelines and diminish physician and patient confidence in their recommendations. Accordingly, our objective was to examine the accuracy of disclosed financial COIs among a more contemporary sample of U.S. physician authors of clinical practice guidelines in 2020."

7. *Page 5, line 15-18 "The study also examined the concordance of COIs self-reported by the guideline authors and those listed for each author with a profile on the CMS Open Payments program database."*

How did you find the authors' profiles in the Open Payments? Did you search for the name in the Open Payments search webpage (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fopenpaymentsdata.cms.gov%2F&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412456431%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=bJ%2Bne20xYJDrk8vNT7Uk%2FwR8ve3%2FC3hXjTFqU3trj%2F4%3D&reserved=0), or in the physician profile database (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fopenpaymentsdata.cms.gov%2Fdataset%2F6ed6ae76-2999-49da-b0b2-d7df150ac754&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412612680%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=rmfmiOXqvj%2F93VEMJEMTx0kZOAt%2BMcUXCkCN%2Fd%2Bd6Fc%3D&reserved=0)?
Response: Thank you for this comment. We used the first link, as described in the following sentence of the Methods: "Financial COIs were determined using the publicly available guideline materials and the Open Payments program database.**" (citation 23 in the revised manuscript)**

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8. *Page 5, line 36 "For societies with multiple clinical practice guidelines, we chose the one with the largest number of authors"*

How do you justify this sample selection? For example, societies making many guidelines might have rigorous COI policies for developing guidelines, while societies producing the small number of guidelines might not have policies for guideline development and did not implement their policies to the authors. Therefore, this sample selection included a significant bias.
I recommend the authors include all or more guidelines published in 2020 and evaluate the society's policy for guideline development and COI management, as well. I know the COI policy evaluation is one research theme, which is different from this study rationale. Therefore, one way to do this would be to make one supplementary document or add references to several previous studies.
Response: Thank you for this comment. Please find below the number of published guidelines in 2020 for each professional society that issued any eligible clinical practice guideline in 2020. With the exception of ASCO, which issued 12 guidelines in 2020, every other organization issued 5 or fewer, and 13 of the 20 (65%) issued 3 or fewer. While we appreciate the Reviewer's suggestion to expand our study to all guidelines issued by professional societies in 2020, that would not be feasible for our team at this time, as it would essentially triple the size of our study. Fortunately, as demonstrated in the table, there is no clear relationship between the number of guidelines a society issued in 2020 and the accuracy of the financial COI disclosures we studied and reported in our original manuscript. For that reason, we have retained the study as originally designed, but would point out the text of the limitations section that addresses this issue:
"First, although we included an eligible guideline from all the CMSS members, it was not feasible to include all the guidelines published by CMSS in 2020. Among those with multiple guidelines, we selected the ones with the largest number of authors to have an appropriate sample."

Medical professional society	Number of guidelines in 2020	Accurate financial COI disclosure	Inaccurate financial COI disclosure
American Academy of Allergy, Asthma & Immunology (AAAAI)	2	2 (13.3%)	13 (86.7%)
American Academy of Dermatology (AAD)	1	5 (16.1%)	26 (83.9%)
American Academy of Family Physicians (AAFP)	1	4 (66.7%)	2 (33.3%)
American Academy of Neurology (AAN)	2	6 (35.3%)	11 (64.7%)
American College of Cardiology (ACC)	3	4 (26.7%)	11 (73.3%)
American College of Emergency Physicians (ACEP)	2	4 (57.1%)	3 (42.9%)
American College of Physicians (ACP)	3	3 (75.0%)	1 (25.0%)
American College of Rheumatology (ACR)	3	8 (33.3%)	16 (66.7%)
American Gastroenterological Association (AGA)	4	4 (57.1%)	3 (42.9%)
American Society of Anesthesiologists (ASA)	1	4 (66.7%)	2 (33.3%)
American Society of Clinical Oncology (ASCO)	12	2 (12.5%)	14 (87.5%)
American Society of Colon and Rectal Surgeons (ACSRS)	3	0 (0.0%)	10 (100.0%)
American Society of Hematology (ASH)	4	1 (7.1%)	13 (92.9%)
American Society for Radiation Oncology (ASTRO)	3	2 (14.3%)	12 (85.7%)
American Society for Reproductive Medicine (ASRM)	2	2 (15.4%)	11 (84.6%)
American Thoracic Society (ATS)	4	5 (50.0%)	5 (50.0%)

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American Urological Association (AUA)	4	1 (7.1%)	13 (92.9%)
Infectious Diseases Society of America (IDSA)	4	4 (40.0%)	6 (60.0%)
Society of Critical Care Medicine (SCCM)	2	11 (44.0%)	14 (56.0%)
Society for Vascular Surgery (SVS)	5	0 (0.0%)	12 (100.0%)

9. *Page 5, line 49-55 "Authors from outside the United States and those who were not physicians (e.g., PhDs) were excluded from the analysis, as Open Payments, as of 2020 under the Physician Payments Sunshine Act, only required disclosure of payments from industry to U.S. physicians and academic medical centers.21"*

Did you refer to other COI information for the excluded authors? Many previous studies evaluated underreported COIs by their articles published in the same year or prior to a few years. This method can be employed in your study and if you intended to evaluate the whole prevalence of underreported and undisclosed COIs, you should examine the authors outside the USA as well. A study by Bindslev et al. would be helpful. (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbmcmedethics.biomedcentral.com%2Farticles%2F10.1186%2F1472-6939-14-19&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412612680%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=t%2Bi07Bk73kKXIj0jb9dLv2XvAa3d8sL7AlxPd0f57f4%3D&reserved=0)

Response: Thank you for this suggestion. The purpose of our approach was to compare the disclosure against systematically collected and validated information in a reliable dataset, which is only possible by using Open Payments. Open Payments is a regularly updated dataset where drug and medical device companies (reporting entities) are required by law to report payments to physicians to CMS annually, and the data are validated by recipients before being made public. We believe that reviewing prior publications or using other datasets will cause inconsistencies and potential bias in the collected data and so have not adopted this suggested change.

10. *Page 6, line 49 "Data collection from Open Payments was done in May and June 2022."*

How did you collect the payment data? Was the payment data downloaded manually by the investigators or through automated coding using API or software such as Python or R? Did two investigators separately download the payments from the OPD? If so, did you compare the two data? How did you verify the data? The payment data is the core dataset of your study and needs to be validated.

Response: Thank you for this comment. The payment data was downloaded manually, and 25% of the data was validated by a second author. The manuscript has been revised to better clarify this process (Methods, page 8): "Data collection from Open Payments was done manually in May and June 2022, of which 25% were validated by a second investigator; any disagreements were resolved by consensus or through the input of a third investigator."

11. *Page 7, line 3-18 "We categorized the status of financial COIs into the following groups: (1) undeclared in the guideline and no payments found on Open Payments (accurate disclosure of no financial COIs), (2) undeclared in the guideline but payments found on Open Payments, (3) disclosure of payments in the guideline and no additional payments found on Open Payments (accurate disclosure of financial COIs), (4) disclosure of payments in the guideline but additional payments found on*

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Open Payments (underreporting), (5) disclosure of payments in the guideline but not all payments were found on Open Payments (overreporting), (6) disclosure of payments in the guidelines, but both additional payments were found and not all disclosed payments were found on Open Payments (underreporting and overreporting)."

Have you evaluated your society's COI policy? As several societies such as American Diabetes Association require guideline authors only for the past one year. Therefore, if a guideline author has correctly declared COI for the past year in accordance with the society's policy, but has not declared COI for the past three years, this may be an 'undeclared COI' due to the society's COI policy, rather than an 'undeclared COI' due to author error or author's insincerity.
I recommend the authors examine the society COI declaration period, too.
Response: Thank you for this comment. Despite the differences in the societies' policies, in alignment with the International Committee of Medical Journal Editors' (ICMJE) recommended timespan, we aimed to take a uniform approach and consider disclosures in the past 3 years for all guidelines. However, based on the reviewer's recommendation, we collected more information about each society's disclosure policy in 2020. We also compared the number (%) of authors with undisclosed/underreported COI based on the past 36 months with those based on the timespan specified by societies' policies for each society (when a reporting period different from the past 36 months was specified). Importantly, of the 20 professional societies included in our analysis, 7 (35%) specified reporting financial disclosures for the past 12 months, 7 (35%) for the past 24 months, 4 (20%) for the past 36 months, and 2 (10%) did not specify a reporting period (Updated Supplemental Table 1). When financial COI disclosures were examined only for the period specified by the professional society, the proportion of authors with undisclosed/underreported COIs remained high (160 of 270 [59.3%]). We have added this information to the revised manuscript, first explaining the approach as a Sensitivity Analysis in the Methods, then reporting the results of the Sensitivity Analysis in the Results, and finally as a limitation in the Discussion:

"In alignment with the ICMJE's recommended timespan, this study aimed to take a uniform approach and examine COI disclosures in the past 3 years for all eligible guidelines' authors. However, we also conducted a sensitivity analysis to identify the numbers and proportion of authors with undisclosed or underreported COI based on each society's disclosure policy in 2020."

"Of the 20 professional societies included in our analysis, 7 (35.0%) specified reporting financial disclosures for the past 12 months, 7 (35.0%) for the past 24 months, 4 (20.0%) for the past 36 months, and 2 (10.0%) did not specify a reporting period. When financial COI disclosures were examined only for the period specified by the professional society, the proportion of authors with undisclosed or underreported COIs remained high (160 of 270 [59.3%])."

"Moreover, although the required timespan for disclosing financial COI by the societies varied between 12 to 36 months, our analysis was based on the past 36 months, according to the ICMJE's recommendation. When accounting for the mandated disclosure timespan by each society, the portion of authors with undisclosed or underreported COI remained substantially high."

Supplemental Table 1 - 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

Medical professional society	Number of guidelines in	Selected Guideline Randomly Selected for Study	Total number of	Number of U.S.-based	COI disclosure policy by society i	Number(%*) of authors with	Number(%*) of authors with

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	2020		listed authors	physicians listed authors	n 2020	undisclosed / underreported COI based on the past 36 months	undisclosed / underreported COI based on timespan specified by societies' policies
American Academy of Allergy, Asthma & Immunology (AAAAI)	2	Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis	17	15	Not specified	12 (80.0%)	12 (80.0%)
American Academy of Dermatology (AAD)	1	Joint American Academy of Dermatology - National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies	34	31	12 months	23 (74.2%)	20 (64.5%)
American Academy of Family Physicians (AAFP)	1	Nonpharmacologic and Pharmacologic Management of Acute Pain From Non–Low Back, Musculoskeletal Injuries in Adults: A Clinical Guideline From the American College of Physicians and American Academy of Family Physicians	6	6	36 months	2 (33.3%)	2 (33.3%)
American Academy of Neurology (AAN)	2	Practice Guideline: Treatment for Insomnia and Disordered Sleep Behavior in Children and Adolescents with Autism Spectrum Disorder	26	17	24 months	10 (58.8%)	9 (52.9%)
American College of Cardiology (ACC)	3	2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients with	19	15	12 months	11 (73.3%)	8 (53.3%)

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		Hypertrophic Cardiomyopathy					
American College of Emergency Physicians (ACEP)	2	Clinical Policy: Critical Issues Related to Opioids in Adult Patients Presenting to the Emergency Department	7	7	24 months	2 (28.6%)	2 (28.6%)
American College of Physicians (ACP)	3	Testosterone Treatment in Adult Men With Age-Related Low Testosterone: A Clinical Guideline From the American College of Physicians	5	4	36 months	1 (25.0%)	1 (25.0%)
American College of Rheumatolog y (ACR)	3	2020 American College of Rheumatology Guidelines for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases	36	24	24 months	15 (62.5%)	14 (58.3%)
American Gastroentero logical Association (AGA)	4	AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia	7	7	12 months	3 (42.9%)	2 (28.6%)
American Society of Anesthesiolo gists (ASA)	1	Practice Guidelines for Central Venous Access 2020: An Updated Report by the American Society of Anesthesiologists Task Force on Central Venous Access	7	6	Not specified	2 (33.3%)	2 (33.3%)
American Society of Clinical Oncology (ASCO)	12	Metastatic Pancreatic Cancer: ASCO Guideline Update	19	16	24 months	14 (87.5%)	14 (87.5%)
American Society of Colon and Rectal Surgeons (ACSRS)	3	The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Surgical Management of Crohn's Disease	10	10	36 months	10 (100.0%)	10 (100.0%)
American Society of Hematology (ASH)	4	American Society of Hematology 2020 guidelines for treating newly	23	14	24 months	11 (78.6%)	10 (71.4%)

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		diagnosed acute myeloid leukemia in older adults					
American Society for Radiation Oncology (ASTRO)	3	Radiation Therapy for Small Cell Lung Cancer: An ASTRO Clinical Practice Guideline	17	14	12 months	12 (85.7%)	7 (50.0%)
American Society for Reproductive Medicine (ASRM)	2	Evidence-based treatments for couples with unexplained infertility: a guideline	15	13	12 months	11 (84.6%)	8 (61.5%)
American Thoracic Society (ATS)	4	Initiating Pharmacologic Treatment in Tobacco-Dependent Adults: An Official American Thoracic Society Clinical Practice Guideline	30	10	36 months	5 (50.0%)	5 (50.0%)
American Urological Association (AUA)	4	Microhematuria: AUA/SUFU Guideline	15	14	24 months	12 (85.5%)	12 (85.5%)
Infectious Diseases Society of America (IDSA)	4	Clinical Practice Guidelines by the IDSA: 2020 Guideline on the Diagnosis and Management of Babesiosis	14	10	24 months	4 (40.0%)	2 (20.0%)
Society of Critical Care Medicine (SCCM)	2	Surviving Sepsis Campaign International Guidelines for Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children	51	25	12 months	12 (48.0%)	8 (32.0%)
Society for Vascular Surgery (SVS)	5	Society for Vascular Surgery (SVS) and Society of Thoracic Surgeons (STS) reporting standards for type B aortic dissections	13	12	12 months	12 (100.0%)	12 (100.0%)
Total			**371**	**270**		**184 (68.1%)**	**160 (59.3%)**

12. Page 7, line 47 "Supplemental Table 1"

The authors should include information about societies' COI policies. Supplemental Table 1 was described as "Supplemental Table 4" in the separate supplemental material PDF file. Could you recheck the file again?

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Response: Information about societies' COI policies was added to Supplemental Table 1 (please see above). Thank you for noting the issue with the Table caption. There was a formatting error when submitting the files. The caption was corrected to "Supplemental Table 1".

13. *Page 8, line 10 "Supplemental Table 5"*

In the Supplemental Material PDF file, this supplemental material 2 was described as "Supplemental Table 5". Is this correct?
"Supplemental Table 5" described that the Open Payments profile data was available in 270 (72.8%). What do you mean by this? Do you mean there were 270 authors in the Open Payments? Or 270 authors were eligible for the Open Payments search? Please clarify this Supplemental table.
Response: Thank you for noting the issue with the Table caption. There was a formatting error when submitting the files. The caption was corrected to "Supplemental Table 2".
Open Payments only includes payments for healthcare providers, including physicians, physician assistants, and advanced practice nurses who are based in the U.S. We searched all the 371 guideline authors on Open Payments, but did not find profiles of individuals who were non-physicians (e.g., PhDs) and/or were not based in the U.S. This led to the final sample of 270 authors for our study.

14. *Page 11, line 16 "Table 4"*

Table 4 should contain the proportion and number of authors receiving each payment.
Response: Thank you for this comment. A column was added to present the proportion and number of authors who have received each payment.

15. *Page 11, line 16 "Table 4"*

Of the several general payment categories, why have you specifically described food and beverage payments?
Food and beverage payments are not required to be declared by the guideline authors in several societies, while consulting, lectures, honoraria, and gifts are generally required to be declared by the authors.
Considering the purpose of this study (to assess the accuracy of COI declarations), I think you should more focus on other general payments such as speaking, gifts, and consulting payments which are mandated to declare than food and beverage payments. As numerous studies found that food and beverage payments were associated with increased use of sponsored drugs and increased healthcare costs in physicians, I recommend that the authors show descriptive results of several major general payment categories, not only food and beverage payments.
Response: Thank you for this comment. We agree with the point that disclosure of food and beverage has less importance compared to disclosure of other components of general payments. We separated food and beverage payments from other general payment categories since studies have shown that physicians found food and beverage payments "less worrisome" compared with other types of payments, and physicians may not remember receiving payments for such items. We added further explanation to the Discussion section: "Although a large proportion of the monetary value of financial COIs was associated with research activities through institutions, we found that authors were more likely to have undisclosed or underreported COIs for direct payments. Since physicians may not be aware of or remember receiving payments for food and beverage, we separated food and beverage payments from other general payments categories and found that around 95% of general payments fees were associated with costs such as consulting, honoraria, royalty or license, education, gifts, and travel and lodging."

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Consistent with prior analyses, our study showed that the values of food and beverage payments were relatively small. The total value of undisclosed general payments was $3,769,344, of which only $195,191 (5.2%) were related to food and beverage. Thus, a significant portion of general payments fees was associated with other categories, such as consulting, honoraria, royalty or license, education, gifts, and travel and lodging. Evaluating each of the general payments categories could be overwhelming for readers and may not add sufficient value to this study's findings since it is not clear whether categories have different influences on physicians' recommendations.

16. *Page 11, line 26 "Supplemental Table 3"*

How was the order in Supplementary Table 3 determined?
In my opinion, it would be easier for readers to understand if they were ordered in descending order by median payment or percentage of undeclared COI.
Response: Thank you for this comment. Guidelines are ordered alphabetically, consistent with Table 3 and Supplemental Table 1.

17. *Supplemental Figure 2*

There was no supplemental figure 1, but there was "Supplemental Figure 2" in the file. Is this Supp Fig 2 supplemental figure 1?
Response: Thank you for noting the issue with the Figure caption. There was a formatting error when submitting the files. The caption was corrected to "Supplemental Figure 1"

18. *Page 13, line 5 "more than 90% did not completely ......"*

Maybe I missed the information. How did you calculate this number?
Response: We apologize for not being clear in the manuscript text. This number was calculated by dividing 184 (authors with undisclosed or underreported COIs) by 199 (authors who have received payments from industry based on Open Payments database), as demonstrated in Fig 1 (184/199=92.5%).
Therefore, 199 authors had financial COIs listed on the database, of which 184 did not disclose all or underreported some of their financial COIs.
More details on the 184 authors:

- **101: Undeclared in the guideline but payments found on Open Payments**
- **23: Disclosure of payments in the guideline but additional payments found on Open Payments (underreporting)**
- **60: Disclosure of payments in the guidelines, but both additional payments were found and not all disclosed payments were found on Open Payments (underreporting and overreporting)**

19. *Page 13 line 18 "Moreover, for most guidelines, authors with financial COI comprised the majority of the panels."*

Your study only included US physician authors and did not assess the true prevalence of authors with COIs. Additional analysis including all authors, or reporting the proportion of authors receiving payment relative to the total number of authors, is necessary for this statement.
Response: Thank you for this comment. As demonstrated in the table below, in 14 (70%) guidelines, authors with financial COI comprised the majority of U.S physician

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members of the panels. If we want to consider all the guideline authors, we are certain that in at least 10 (50%) guidelines, authors with financial COI comprised the majority of the panels. The sentence was changed to "Moreover, for at least half of the guidelines, authors with financial COI comprised the majority of the panels."

Medical Professional Society	Total number of listed authors	Number of U.S.-based physicians listed authors	Number of authors with identified COI	% Authors with identified COI - of total number of listed authors)	% Authors with identified COI - of U.S.-based physicians listed authors
American Academy of Allergy, Asthma & Immunology	17	15	13	76%	87%
American Academy of Dermatology	34	31	26	76%	84%
American Academy of Family Physicians	6	6	2	33%	33%
American Academy of Neurology	26	17	12	46%	71%
American College of Cardiology	19	15	11	58%	73%
American College of Emergency Physicians	7	7	2	29%	29%
American College of Physicians	5	4	1	20%	25%
American College of Rheumatology	36	24	16	44%	67%
American Gastroenterological Association	7	7	3	43%	43%
American Society of Anesthesiologists	7	6	2	29%	33%
American Society of Clinical Oncology	19	16	14	74%	88%
American Society of Colon and Rectal Surgeons	10	10	10	100%	100%
American Society of Hematology	23	14	13	57%	93%
American Society for Radiation Oncology	17	14	12	71%	86%
American Society for Reproductive Medicine	15	13	11	73%	85%
American Thoracic Society	30	10	6	20%	60%
American Urological	15	14	13	87%	93%

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Association					
Infectious Diseases Society of America	14	10	5	36%	50%
Society of Critical Care Medicine	51	25	15	29%	60%
Society for Vascular Surgery	13	12	12	92%	100%

20. *Discussion*

I have no concerns about the findings of your study describing an undeclared COI in clinical guidelines. However, I believe that your paper could be improved if you could discuss your findings in more detail and link them to previous studies. Furthermore, why do the guidelines issued by some societies, such as the ACP, declare authors' COI more accurately than others?

Response: Thank you for this comment and we appreciate the Reviewer's favorable comments. In our originally submitted manuscript, we had discussed our findings in detail and linked them to previous literature in several instances in the Discussion. In response to this comment, we have added more discussion points about types of payments and guideline policies.

" … consistent with prior research, our analysis identified a majority of 2020 guidelines within our sample had panel chairs with COI, all of which inaccurately disclosed their COI. Moreover, for at least half of the guidelines, authors with financial COI comprised the majority of the panels. Consistent with the literature, our study demonstrates that even among more contemporary guideline panels, when professional organizations had the opportunity to scrutinize financial COIs among physicians who were being considered for panel membership, financial COIs were common and remained inaccurately disclosed. As previous studies have shown, financial COIs create a risk that professional judgments or actions may be unduly influenced by secondary interests. Thus, our findings raise concerns about the quality, reliability, and integrity of guidelines commonly used in the U.S."

To the Reviewer's point about the ACP, we did not explore reasons why certain societies had more accurate COI disclosure among their panel members compared to others. Conducting a deeper investigation of each COI disclosure policy would be a valuable topic of research for future studies.

21. *Additionally, COI management strategies for undeclared COIs of each society should be described in your discussion. For example, currently, ASCO's clinical guidelines included the Open Payments Database links of each guideline author (https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fascopubs.org%2Fdoi%2Ffull%2F10.1200%2FJCO.22.01992&data=05%7C01%7Cmaryam.mooghali%40yale.edu%7C44fa371051d14505de8008dad84b96a0%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C0%7C638060116412612680%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=j5XFKXVBmNpMsw6WD3V%2Fhog68s0Xt1xOk%2FdHVUU4smk%3D&reserved=0), while in your study, 14 (87.5%) of ASCO guideline authors incorrectly declared their COIs.*

Response: Thank you for this suggestion. In the Discussion of this paper, we aimed to recommend several suggestions for improving the overall COI disclosure in U.S. guidelines, rather than each particular society. It is certainly interesting that although ASCO's guidelines provide links to the Open Payments database, there was a high rate of inaccuracy of disclosed financial COIs among panel members. We have discussed this matter in the manuscript as below:

"Our study showed that although medical professional societies, such as the American Society of Clinical Oncology (ASCO), have provided links to individual guideline authors' entries within the Open Payments database, comparisons of self-reported disclosure and

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what is reported on Open Payments may persist without oversight from the medical professional societies. Therefore, medical professional societies should evaluate the completeness of COI disclosure by comparing the self-reported COIs with data available on Open Payments. Thereafter, all COIs that potentially affect guideline development should be managed appropriately."

It would be useful for future studies to identify the strength and limitations of COI disclosure policies for each CMSS society.

Reviewer 1 Comments

1. *The study included a total of 270 authors, representing 267 unique individuals, in the analysis. The included 20 sample CPGs were published in 2020 in the US.*

The results were reported in terms of CPG and analyzed in terms of 270 authors. In the case of analysis in terms of CPG, it is considered appropriate to include each data of the three authors in the study. However, they may be regarded as duplicates when analyzed from the perspective of guideline authors. It should be justified in the methods and results sections.
Response: Thank you for this comment. Justification was added in both the "Methods" and "Result" sections: "We evaluated duplicate authors across guidelines independently since authors were responsible for disclosing their financial COI in each guideline and had independent opportunities to disclose their COI."

"Thus, 270 authors, representing 267 unique individuals, who had profiles on the Open Payments database, were included in the analysis; 3 individuals were listed as authors of two guidelines. Duplicate authors across the guidelines were examined independently."

VERSION 2 – REVIEW

REVIEWER	Murayama, Anju Tohoku University, School of Medicine As a non financial conflict of interest, I have conducted several research projects concerning the financial conflicts of interest in Japanese and the US clinical guidelines.
REVIEW RETURNED	26-Dec-2022

GENERAL COMMENTS	The authors significantly improved their manuscript and appropriately addressed all of my comments. I appreciate the opportunity to review this and excellent manuscript. I have no concerns about this study.

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