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Financial Conflicts of Interest among U.S. Physician Authors of 2020 Clinical Practice Guidelines: A Cross-Sectional Study

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3 **Financial Conflicts of Interest among U.S. Physician Authors of**
4 **2020 Clinical Practice Guidelines: A Cross-Sectional Study**
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What is already known on this topic

- Clinical practice guidelines are commonly used by physicians and influence patient care decisions
- Financial conflicts of interest among authors of clinical practice guidelines could compromise their integrity

What this study adds

- Financial conflicts of interest are common among U.S. physician authors of clinical practice guidelines and often are not disclosed or disclosed inaccurately
- Although a significant proportion of the monetary value of industry payments received from guideline authors was associated with research activities through institutions, authors were more likely to have undisclosed or underreported COIs for direct payments

Strength and limitations of this study

- Our study included a wide range of contemporary clinical practice guidelines from different professional societies, enhancing relevance and generalizability.
- We were limited to characterizing disclosures only for U.S. physicians.
- We only considered financial COIs with the pharmaceutical and medical device industry.

ABSTRACT

Objective To evaluate the prevalence and accuracy of industry-related financial conflict of interest (COI) disclosures among U.S. physician guideline authors

Design Cross-sectional study

Setting Clinical practice guidelines published by the Council of Medical Specialty Societies in 2020

Participants U.S. physician guideline authors

Main outcome measures Financial COI disclosures, both self-reported and determined using Open Payments data

Results Among 270 U.S. physician authors of 20 clinical practice guidelines, 101 (37.4%) disclosed industry-related financial COIs, whereas 199 (73.7%) were found to have received payments from industry when accounting for payments disclosed through Open Payments. The median payments received by authors during the 3-year period was \$27,451 (interquartile range [IQR], \$1,385-\$254,677). Comparing authors' self-disclosures with Open Payments, 72 (26.7%) of the authors accurately disclosed their financial COIs, including 68 (25.2%) accurately disclosing no financial COIs and 4 (1.5%) accurately disclosing a financial COI. In contrast, 101 (37.4%) disclosed no financial COIs and were found to have received payments from industry, 23 (8.5%) disclosed a financial COI but had underreported payments received from industry, 14 (5.2%) disclosed a financial COI but had overreported payments received from industry, and 60 (22.2%) disclosed a financial COI but were found to have both underreported and overreported payments received from industry. We found that inaccurate COI disclosure was more frequent among professors compared to non-professors (81.9% vs. 63.5%; $p<0.001$) and among males compared to females (77.7% vs 64.8%; $p=0.02$). The accuracy of disclosures also varied among medical professional societies ($p<0.001$).

Conclusions Financial relationships with industry are common among U.S. physician authors of clinical practice guidelines and are often not accurately disclosed. To ensure high-quality guidelines and unbiased recommendations, more effort is needed to minimize existing COIs and improve disclosure accuracy among panel members.

INTRODUCTION

Clinical practice guidelines are commonly used by clinicians to inform patient care decisions. The National Academy of Medicine (formerly called the Institute of Medicine) has defined conflict of interest (COI) as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” and have the potential to undermine guidelines’ quality, reliability, and integrity, resulting in harm to patients, healthcare professionals, and the healthcare systems.^{1,2} Prior studies have demonstrated an association between guideline authors’ financial COIs with industry and favorable recommendations for their products.^{3,4} Therefore, full disclosure of financial COIs has been mandated by several medical professional societies issuing guidelines, 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.^{2,5,6}

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.⁷⁻¹¹ A recent systematic review of nearly 15,000 guideline authors found that 45% reported a financial COI,⁷ however, 32% of authors had undisclosed financial relationships with the industry.⁷ In 2014, data representing payments from industry to U.S.-based physicians was first made available through the Centers for Medicare and Medicaid Services (CMS) Open Payments program, enabling numerous studies comparing disclosures by clinical practice guideline authors to those reported to CMS by manufacturers. However, many of these were conducted for guidelines issued by a single professional society or very soon after the Open Payments program went into effect,^{7,12-16} before physicians may have realized that there would be opportunities for external scrutiny of their disclosures.¹⁷

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. We hypothesized that with the availability of the Open Payments database, most guideline authors would disclose their COIs accurately and expected modest differences in the disclosure of

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3 financial COIs among medical professional societies. We also evaluated the scope and nature of
4 the payments received by U.S. physician guideline authors.
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8 **METHODS**

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10 This cross-sectional study examined the prevalence and monetary value of financial COIs
11 for authors of guidelines published in 2020 that were issued by any eligible member organization
12 of the Council of Medical Specialty Societies (CMSS). The study also examined the concordance
13 of COIs self-reported by the guideline authors and those listed for each author with a profile on
14 the CMS Open Payments program database. Financial COIs were determined using the publicly
15 available guideline materials and the Open Payments program database.¹⁸ Since publicly
16 available nonclinical datasets were used, informed consent and institutional review board
17 approval were not required. Patients or the public were not involved in the design, or conduct,
18 or reporting, or dissemination plans of our research. Findings were reported according to the
19 STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines.¹⁹
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30 **Sample**

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32 We identified one guideline from each of the medical professional societies that were
33 member organizations of the CMSS in 2020.²⁰ For societies with multiple clinical practice
34 guidelines, we chose the one with the largest number of authors. We included guidelines that
35 were authored by multiple societies if all were members of the CMSS. We excluded systematic
36 review documents that were not endorsed by the associated society as official guidelines. For all
37 authors, we recorded the name, gender, degree, academic rank, country of practice, and whether
38 they were panel chairs of eligible guidelines. We determined the rank (as of 2020) and gender of
39 each author using their academic profile webpages. If the gender or associated pronoun was not
40 available on the institution profile page, we used Google searches to identify gender and matched
41 them with available profile photos. Authors from outside the United States and those who were
42 not physicians (e.g., PhDs) were excluded from the analysis, as Open Payments, as of 2020 under
43 the Physician Payments Sunshine Act, only required disclosure of payments from industry to U.S.
44 physicians and academic medical centers.²¹
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Main Outcome measure

We searched the main documents and supplementary files for each guideline and collected the industry-related declared financial COIs (collected by MM and LG). Financial disclosures related to payments from foundations, medical professional societies, academic institutions, and governmental entities were excluded. Industry payments over the prior three years were determined from the Open Payments database (in alignment with the International Committee of Medical Journal Editors' (ICMJE) recommended timespan for disclosing any potential COIs).²² To facilitate data collection, we collected information on all payments from January 1, 2017 to December 31, 2019 for all guidelines accepted for publication before January 2020 or published before March 2020. For the remaining guidelines, we collected information on all payments over the three-year period before acceptance for publication. If the acceptance date was not available, we assumed that the guideline was accepted three months before the publication date.

Financial COIs were defined as any payments received by a guideline author from pharmaceutical or medical device companies. The payments included research funding and general payments, as categorized by CMS.²³ Research funding could be paid either directly to the recipient ("Research Payment") or through a research institution or entity where the recipient was a principal investigator ("Associated Research Funding"). General payments covered fees for non-research activities such as consulting, honoraria, royalty or license, education, gifts, travel and lodging, and food and beverage. Ownership and investment interest of authors were excluded.²⁴ We categorized payments as either "Direct Payment", including general payments and direct research payments, and "Associated Research Funding", which were received through a research organization. Data collection from Open Payments was done in May and June 2022.

For each guideline author, we first confirmed their identity by matching their name, specialty, and practice location reported on their Open Payment profile with their information in the guidelines. Next, we compared the data collected from Open Payments with authors' self-disclosed COIs. If the source of payment found on Open Payments matched with the declared COI, that payment was considered as a disclosed COI. Otherwise, it was recorded as an undisclosed COI. Total COIs were calculated by adding the disclosed and undisclosed COIs.

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).

Patient and Public Involvement

None

Statistical Analysis

We reported the prevalence and accuracy of disclosure of financial COIs, as well as the types and amounts of compensation received by all guideline authors. We also examined whether there were any associations between the accuracy of COI disclosure with gender, rank, role as panel chair, and medical professional society. We analyzed the differences between each group by using a two-sided, chi-squared test. A p -value <0.05 was considered statistically significant. Data were recorded and categorized in Microsoft Excel software, 2018 (Microsoft Corp). We used JMP Pro, Version 16.2 (SAS Institute Inc) for conducting the chi-squared tests.

RESULTS

Sample characteristics

A total of 20 guidelines were included in our study, listed in Supplemental Table 1. All guidelines were issued by a medical professional society with a COI policy for panel members, and all the guidelines provided an opportunity for authors to publicly disclose their financial COIs. The median number of guideline authors was 16 (interquartile range [IQR], 9-24). A total of 371 individuals were listed as authors of the 20 guidelines, of which 101 (27.2%) were based outside

the U.S and/or did not have an MD/DO/MBBS degree. Thus, 270 authors, representing 267 unique individuals, were included in the analysis; 3 individuals were listed as authors of two guidelines. Of the 270 authors included in the analysis, 177 (65.6%) were male, 144 (53.3%) were of the professor rank, and 22 (8.1%) were panel chairs. Additional characteristics of total 371 authors and the 270 included authors are summarized in Supplemental Table 2 and Table 1, respectively.

Table 1- Characteristics of U.S. Physician Authors of 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

| Characteristics | N (%) (n=270) |
|------------------------|------------------|
| Gender | |
| • Male | 177 (65.6%) |
| • Female | 90 (33.3%) |
| • Unclear | 3 (1.1%) |
| Rank | |
| • Professor | 144 (53.3%) |
| • Associate Professor | 65 (24.1%) |
| • Assistant Professor | 34 (12.6%) |
| • Other / Not Reported | 27 (10.0%) |
| Panel Chair | |
| • Yes | 22 (8.1%) |
| • No / Not reported | 248 (91.9%) |

Prevalence of financial COIs

Of the 270 panel members, 101 (37.4%) declared financial COIs and 169 (62.6%) did not declare any financial COIs. However, when accounting for disclosures listed on Open Payments, 199 (73.7%) were found to have received payments from industry. Authors with COI comprised the minority of the panel for only 5 (25.0%) guidelines. Among the 22 panel chairs, 7 (31.8%) declared financial COIs. However, when accounting for disclosures listed on Open Payments, 18 (81.8%) had financial COIs, none of which disclosed their COI accurately.

Comparing authors' self-disclosures with Open Payments, 72 (26.7%) of the authors accurately disclosed their financial COIs, including 68 (25.2%) accurately disclosing no financial COIs and 4 (1.5%) accurately disclosing a financial COI. In contrast, 101 (37.4%) disclosed no financial COIs and were found to have received payments from industry, 23 (8.5%) disclosed a

financial COI but had underreported all payments received from industry, 14 (5.2%) disclosed a financial COI but had overreported payments received from industry, and 60 (22.2%) disclosed a financial COI but were found to have both underreported and overreported payments received from industry (Table 2).

Table 2 – Financial Conflict of Interest Disclosures among U.S. Physician Authors of 2020 Clinical Practice Guidelines

| | N (%) (n=270) |
|---|------------------|
| Undeclared in the guideline and no payments found on Open Payments (accurate disclosure of no financial COIs) | 68 (25.2%) |
| Undeclared in the guideline but payments found on Open Payments | 101 (37.4%) |
| Disclosure of payments in the guideline and no additional payments found on Open Payments (accurate disclosure of financial COIs) | 4 (1.5%) |
| Disclosure of payments in the guideline but additional payments found on Open Payments (underreporting) | 23 (8.5%) |
| Disclosure of payments in the guideline but not all payments were found on Open Payments (overreporting) | 14 (5.2%) |
| 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) | 60 (22.2%) |

Abbreviations: COI = conflict of interest.

Conflict of interest by authors' characteristics and societies

Inaccurate disclosures of financial COIs were more common by professors compared with non-professors or those with unavailable rank (81.9% vs. 63.5%; $p < 0.001$) and by male authors compared with female authors (77.7% vs. 64.8%; $p = 0.02$). Furthermore, the accuracy of COIs reported among the medical professional societies statistically differed ($p < 0.001$), as the American Society of Colon and Rectal Surgeons (ACRS) and Society for Vascular Surgery (SVS) had the highest inaccuracy rates (100%), whereas the American College of Physicians (ACP) had the lowest inaccuracy rate (25.0%). We found no statistically significant difference in the accuracy of COIs reported among panel chairs compared with other panel members (Table 3).

Table 3 - Accuracy of Financial Conflict of Interest Disclosures among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Author and Guideline Characteristics

| | Accurate financial COI disclosure | Inaccurate financial COI disclosure | P-value |
|--|-----------------------------------|-------------------------------------|---------|
| Gender | | | |
| • Male | 40 (22.3%) | 139 (77.7%) | 0.02 |
| • Female | 32 (35.2%) | 59 (64.8%) | |
| Rank | | | |
| • Professor | 26 (18.1%) | 118 (81.9%) | <0.001 |
| • Non-professor / Not reported | 46 (36.5%) | 80 (63.5%) | |
| Role as a Panel Chair | | | |
| • Yes | 4 (18.2%) | 18 (81.8%) | 0.35 |
| • No / Not reported | 68 (27.4%) | 180 (72.6%) | |
| Medical Professional Societies | | | |
| • American Academy of Allergy, Asthma & Immunology (AAAAI) | 2 (13.3%) | 13 (86.7%) | <0.001 |
| • American Academy of Dermatology (AAD) | 5 (16.1%) | 26 (83.9%) | |
| • American Academy of Neurology (AAN) | 6 (35.3%) | 11 (64.7%) | |
| • American College of Cardiology (ACC) | 4 (26.7%) | 11 (73.3%) | |
| • American College of Emergency Physicians (ACEP) | 4 (57.1%) | 3 (42.9%) | |
| • American College of Physicians (ACP) | 3 (75.0%) | 1 (25.0%) | |
| • American College of Rheumatology (ACR) | 8 (33.3%) | 16 (66.7%) | |
| • American Gastroenterological Association (AGA) | 4 (57.1%) | 3 (42.9%) | |
| • American Society of Anesthesiologists (ASA) | 4 (66.7%) | 2 (33.3%) | |
| • American Society of Clinical Oncology (ASCO) | 2 (12.5%) | 14 (87.5%) | |
| • American Society of Colon and Rectal Surgeons (ACRS) | 0 (0.0%) | 10 (100.0%) | |
| • American Society of Hematology (ASH) | 1 (7.1%) | 13 (92.9%) | |
| • American Society for Radiation Oncology (ASTRO) | 2 (14.3%) | 12 (85.7%) | |
| • American Society for Reproductive Medicine (ASRM) | 2 (15.4%) | 11 (84.6%) | |
| • American Thoracic Society (ATS) | 5 (50.0%) | 5 (50.0%) | |
| • American Urological Association (AUA) | 1 (7.1%) | 13 (92.9%) | |
| • Infectious Diseases Society of America (IDSA) | 4 (40.0%) | 6 (60.0%) | |
| • American Academy of Family Physicians (AAFP) | 4 (66.7%) | 2 (33.3%) | |
| • Society of Critical Care Medicine (SCCM) | 11 (44.0%) | 14 (56.0%) | |
| • Society for Vascular Surgery (SVS) | 0 (0.0%) | 12 (100.0%) | |

Abbreviations: COI = conflict of interest.

Authors with identified COIs on Open Payments

Based on the search conducted on Open Payments, 199 authors had financial COIs listed on the database, with the median 3-year payments of \$27,451 (IQR, \$1,385-\$254,677). The values of total and undisclosed COIs were \$98,716,681 and \$23,976,655, respectively. Over 80% of COIs were received as Associated Research Funding (median \$154 [IQR, \$0-\$212,932]), and the median value of general payments and research payments received directly by physicians were \$5,487 (IQR, \$344-\$48,834) and \$0 (\$0-\$770), respectively (Table 4).

Table 4 – Monetary Value of Financial Conflict of Interests among U.S. Physician Authors of 2020 Clinical Practice Guidelines

| | Median (IQR) | Total (%) |
|--|----------------------------------|-------------------------|
| Total COIs (All categories) | \$ 27,451 (\$1,385-\$254,677) | \$98,716,681 |
| • Total Direct Payments | \$6,336 (\$667-\$57,484) | \$18,936,416 (19.2%) |
| ○ General payments | \$5,487 (\$344-\$48,834) | \$16,087,973 (16.3%) |
| ▪ Food & beverage | \$487 (\$92-\$2,062) | \$461,698 (0.5%) |
| ▪ Others* | \$ 5000 (\$0-\$46,232) | \$15,626,275 (15.8%) |
| ○ Direct research payment | \$0 (\$0-\$770) | \$2,851,194 (2.9%) |
| • Associated Research Funding | \$154 (\$0-\$212,932) | \$79,780,264 (80.8%) |
| Disclosed COIs (All categories) | \$ 0 (\$0-\$121,305) | \$74,740,026 (75.7%) |
| • Total Direct Payments | \$0 (\$0-\$22,310) | \$14,971,881 (20%) |
| ○ General payments | \$0 (\$0-\$17,298) | \$12,318,629 (16.5%) |
| ▪ Food & beverage | \$0 (\$0-\$313) | \$266,507 (0.4%) |
| ▪ Others* | \$0 (\$0-\$17,076) | \$12,052,122 (16.1%) |
| ○ Direct research payment | \$0 (\$0-\$0) | \$2,653,252 (3.5%) |
| • Associated Research Funding | \$0 (\$0-\$66,026) | \$59,768,145 (80.0%) |
| Undisclosed COIs (All categories) | \$ 4,178 (\$227-\$62,564) | \$23,976,655 (24.3%) |
| • Total Direct Payments | \$ 1,153 (\$113-\$9,902) | \$3,964,536 (16.5%) |

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|-------------------------------|-------------------------|-------------------------|
| ○ General payments | \$992 (\$60-\$8,509) | \$3,769,344 (15.7%) |
| ▪ Food & beverage | \$191 (\$20-\$988) | \$195,191 (0.8%) |
| ▪ Others* | \$ 268 (\$0-\$6,810) | \$3,574,153 (14.9%) |
| ○ Direct research payment | \$0 (\$0-\$0) | \$197,942 (0.8%) |
| ● Associated Research Funding | \$0 (\$0-\$35,416) | \$20,012,119 (83.5%) |

* Other general payment includes consulting, honoraria, royalty or license, education, gifts, and travel and lodging.

Abbreviations: COI = conflict of interest; IQR = interquartile range

Among all medical professional societies, the guideline panel members of the American Academy of Dermatology had the highest general payments received (mean [IQR], \$70,727 [\$3,945-\$544,211]), while panel members from the American Society of Anesthesiologists received the lowest general payments (mean [IQR], \$62 [\$58-\$65]). More details about the identified COI by medical professional societies are reported in Supplemental Table 3.

While 15 (7.5%) authors with financial COIs on Open Payments disclosed all received payments, 108 (54.3%) did not disclose any payments (Supplemental Figure 1). Among the authors with undisclosed or underreported COIs (n=184), 58.7% of authors' nondisclosures were for Direct Payments (4.9% general payments only, 53.8% combination of general payments and direct research payments), 5.4% for Associated Research Funding, and 35.9% for a combination of Direct payments and Associated Research funding (List of figures:

Figure 1 – Types of Financial Conflict of Interest Under- and Undisclosed among U.S. Physician Authors of 2020 Clinical Practice Guidelines

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DISCUSSION

In our cross-sectional study of 2020 clinical practice guidelines that compared self-reported financial COIs with payments from industry reported to CMS through the Open Payments program, we found that financial COIs are common among U.S. physician guideline

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3 panel members and are often not disclosed accurately. Although the majority of guideline
4 authors had financial relationships with industry, more than 90% did not completely disclose all
5 financial COIs. These findings raise concerns about potential bias in the treatment
6 recommendations developed by key medical professional societies in the United States.
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10 The National Academy of Medicine recommends guideline panel chairs and co-chairs to
11 not have any conflicts, and that only a minority of guideline authors should have a financial COI.²
12 However, consistent with prior research¹¹, our analysis identified a majority of 2020 guidelines
13 within our sample had panel chairs with COI, all of which inaccurately disclosed their COI.
14 Moreover, for most guidelines, authors with financial COI comprised the majority of the panels.
15 Our study demonstrates that even among more contemporary guideline panels, when
16 professional organizations had the opportunity to scrutinize financial COIs among physicians who
17 were being considered for panel membership, financial COIs were common and remain
18 inaccurately disclosed. Because financial COIs create a risk that professional judgments or actions
19 may be unduly influenced by secondary interests, our findings raise concerns about guidelines'
20 quality, reliability, and integrity.
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31 Although a large proportion of the monetary value of financial COIs were associated with
32 research activities through institutions, we found that authors were more likely to have
33 undisclosed or underreported COIs for direct payments. Considering that direct payments could
34 potentially have a greater impact on panel members' decisions, more attention should be paid
35 to such COIs. Certain medical professional societies also had higher rates of COIs, inaccurate
36 disclosures, and greater values of payments received from the industry among their panel
37 members, thus necessitating more rigorous action to be taken by those societies, perhaps with
38 oversight from CMSS. Disclosure, assessment, and management of COIs is a process that requires
39 consideration throughout the guideline development, particularly since relationships may
40 change. Utilizing specific structured disclosure forms with closed-ended questions may improve
41 the accuracy of COI disclosure.⁹ These forms should inquire about both active and inactive
42 relationships with the industry ahead of the process of guideline development to ensure
43 compliance with National Academy of Medicine recommendations. Additional detailed questions
44 can further clarify the relevancy and extent of those financial relationships. Moreover, medical
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3 professional societies should evaluate the completeness of COI disclosure by comparing the self-
4 reported COIs with data available on Open Payments. Thereafter, all COIs that potentially affect
5 guideline development should be managed appropriately.
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9 This study had certain limitations. First, although we included an eligible guideline from
10 all the CMSS members, it was not feasible to include all the guidelines published by CMSS in 2020.
11 Among those with multiple guidelines, we selected the ones with the largest number of authors
12 to have an appropriate sample. Also, we included only physicians based in the U.S since other
13 guideline authors would not have profiles on the Open Payments database. Second, data
14 available on Open Payments, although frequently updated and verified by payment recipients,
15 does not contain all the payments received and may not be fully accurate.²⁵ Third, we attempted
16 to characterize all payments from industry to physicians reported through the Open Payments
17 program in the three years prior to guideline publication, in alignment with ICMJE disclosure
18 requirements.²² However, our look back may be imprecise because exact dates for guidelines'
19 convening, which may have taken months to more than a year to finalize, and for guidelines' first
20 submission to a journal for consideration, were not consistently available. Lastly, we only
21 considered the pharmaceutical and medical device industry-related financial COIs. Although
22 other financial COIs and other types of COIs could influence the quality of clinical practice
23 guidelines, Open Payments only records industry payments and does not contain data related to
24 other COIs. Despite these limitations, our study included a wide range of contemporary clinical
25 practice guidelines from different societies, making the findings more generalizable than those
26 of similar studies.
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44 **CONCLUSION**

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46 Financial COIs among U.S. physician authors of clinical practice guidelines are common
47 and are often not disclosed accurately. Given the importance of clinical practice guidelines in
48 both providing care to patients and guiding future research in medicine, these guidelines should
49 be as accurate and unbiased as possible. The substantial COIs that exist among guideline authors
50 and the inconsistencies between payments reported by industry and COI self-reported within the
51 guidelines emphasized the need for implementing greater oversight and additional policies for
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3 disclosing and managing COIs in medical professional societies producing clinical practice
4 guidelines to ensure their quality, reliability, and integrity.
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Ethics statements

Ethical approval: Not required. Publicly available nonclinical datasets were used.

Contributorship statement

MM, LG and JSR conceived of and designed the study. MM and LG collected the data. MM led the data analysis and drafted the first version of the manuscript. All authors reviewed and interpreted the data, read the manuscript and provided critical feedback for important intellectual content. JSR provided supervision. All authors approved the submission of the current version of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Competing interests

Drs. Mooghali, Ramachandran, and Ross currently receive research support through Yale University from Arnold Ventures. Dr. Ramachandran currently receives research support through Yale Law School from the Stavros Niarchos Foundation for a project focused on public R&D and manufacturing for enabling equitable access to medical technologies. She also serves as a consultant to the ReAct-Action on Antibiotic Resistance Strategic Policy Program based out of Johns Hopkins Bloomberg School of Public Health, which is funded by the Swedish International Development and Cooperation Agency (Sida). Dr. Ross currently receives research support through Yale University from Johnson and Johnson to develop methods of clinical trial data sharing, from the Medical Device Innovation Consortium as part of the National Evaluation System for Health Technology (NEST), from the Food and Drug Administration for the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938), from the Agency for Healthcare Research and Quality (R01HS022882), and from the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) (R01HS025164, R01HL144644); in addition, Dr. Ross is an expert witness at the request of Relator's attorneys, the Greene Law Firm, in a qui tam suit alleging violations of the False Claims Act and Anti-Kickback Statute against Biogen Inc.

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Data Sharing statement

Relevant data are available on reasonable request from the corresponding author.

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List of figures:

Figure 1 – Types of Financial Conflict of Interest Under- and Undisclosed among U.S. Physician Authors of 2020 Clinical Practice Guidelines

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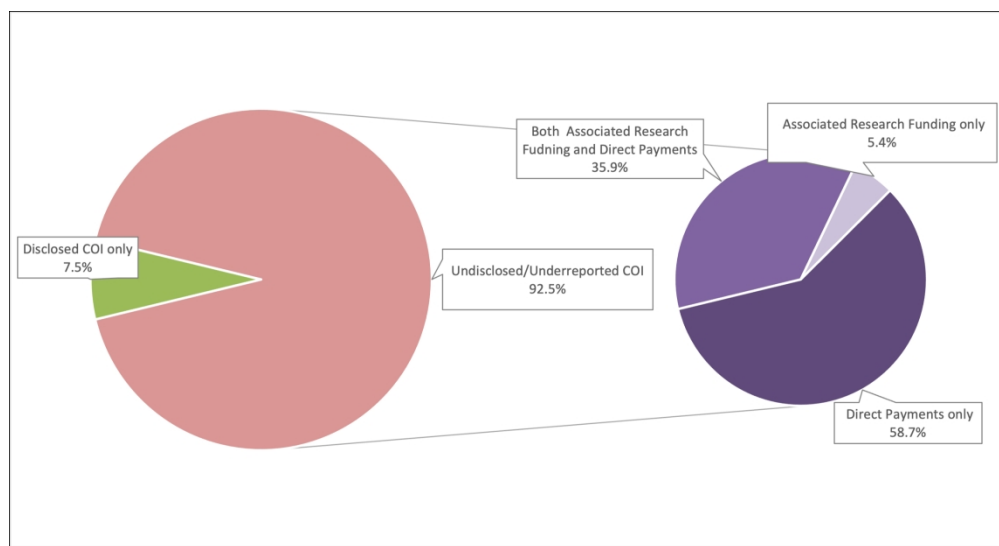


Figure 1 – Types of Financial Conflict of Interest Under- and Undisclosed among U.S. Physician Authors of 2020 Clinical Practice Guidelines

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List of Supplemental Tables and Figures

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Supplemental Figure 1 - Conflict of Interest Among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Proportions of Undisclosed/Total Conflict of Interest

Supplemental Table 4 - 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

| Medical Professional Society | Guideline | Total number of listed authors | Number of U.S.-based physicians listed authors |
|--|---|--------------------------------|--|
| American Academy of Allergy, Asthma & Immunology | Anaphylaxis: 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis ¹ | 17 | 15 |
| American Academy of Dermatology | Joint American Academy of Dermatology - National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies ² | 34 | 31 |
| American Academy of Neurology | Practice Guideline: Treatment for Insomnia and Disordered Sleep Behavior in Children and Adolescents with Autism Spectrum Disorder ³ | 26 | 17 |
| American College of Cardiology | 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy ⁴ | 19 | 15 |
| American College of Emergency Physicians | Clinical Policy: Critical Issues Related to Opioids in Adult Patients Presenting to the Emergency Department ⁵ | 7 | 7 |
| American College of Physicians | Testosterone Treatment in Adult Men With Age-Related Low Testosterone: A Clinical Guideline From the American College of Physicians ⁶ | 5 | 4 |
| American College of Rheumatology | 2020 American College of Rheumatology Guidelines for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases ⁷ | 36 | 24 |
| American Gastroenterological Association | AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia ⁸ | 7 | 7 |
| American Society of Anesthesiologists | Practice Guidelines for Central Venous Access 2020: An Updated Report by the American Society of Anesthesiologists Task Force on Central Venous Access ⁹ | 7 | 6 |
| American Society of Clinical Oncology | Metastatic Pancreatic Cancer: ASCO Guideline Update ¹⁰ | 19 | 16 |
| American Society of Colon and Rectal Surgeons | The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Surgical Management of Crohn's Disease ¹¹ | 10 | 10 |
| American Society of Hematology | American Society of Hematology 2020 guidelines for treating newly diagnosed acute myeloid leukemia in older adults ¹² | 23 | 14 |

| | | | |
|--|---|----|----|
| American Society for Radiation Oncology | Radiation Therapy for Small Cell Lung Cancer: An ASTRO Clinical Practice Guideline ¹³ | 17 | 14 |
| American Society for Reproductive Medicine | Evidence-based treatments for couples with unexplained infertility: a guideline ¹⁴ | 15 | 13 |
| American Thoracic Society | Initiating Pharmacologic Treatment in Tobacco-Dependent Adults: An Official American Thoracic Society Clinical Practice Guideline ¹⁵ | 30 | 10 |
| American Urological Association | Microhematuria: AUA/SUFU Guideline ¹⁶ | 15 | 14 |
| Infectious Diseases Society of America | Clinical Practice Guidelines by the IDSA: 2020 Guideline on the Diagnosis and Management of Babesiosis ¹⁷ | 14 | 10 |
| American Academy of Family Physicians | 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 ¹⁸ | 6 | 6 |
| Society of Critical Care Medicine | Surviving Sepsis Campaign International Guidelines for Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children ¹⁹ | 51 | 25 |
| Society for Vascular Surgery | Society for Vascular Surgery (SVS) and Society of Thoracic Surgeons (STS) reporting standards for type B aortic dissections ²⁰ | 13 | 12 |

Supplemental Table 5 - Characteristics of Guideline Authors of 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

| Characteristics | N (%) (n=371) |
|---|------------------|
| Gender | |
| • Male | 221 (59.6%) |
| • Female | 145 (39.1%) |
| • Unclear | 5 (1.3%) |
| Rank | |
| • Professor | 174 (46.9%) |
| • Associate Professor | 87 (23.5%) |
| • Assistant Professor | 44 (11.9%) |
| • Other / Not Reported | 66 (17.8%) |
| Location | |
| • United States | 309 (83.3%) |
| • Canada (No profile on Open Payments) | 28 (7.5%) |
| • Other Countries (No profile on Open Payments) | 34 (9.2%) |
| Degree | |
| • MD/DO/MBBS | 318 (85.7%) |
| • Non-MD/DO/MBBS | 53 (14.3%) |
| Profile on Open Payments | |
| • No available profile - Excluded from the analysis | 101 (27.2%) |
| • Available Profile - Included in the analysis | 270 (72.8%) |
| Conflict of Interest declared in the guideline | |
| • Authors who declared industry-related COIs in the guidelines | 129 (34.8%) |
| • Authors who did NOT declare any industry-related COIs in the guidelines | 242 (65.2%) |

Abbreviations: COI = conflict of interest; DO = Doctor of Osteopathic Medicine; MBBS = Bachelor of Medicine, Bachelor of Surgery; MD = Doctor of Medicine.

Supplemental Table 6 - Financial Conflict of Interests among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Medical Professional Societies

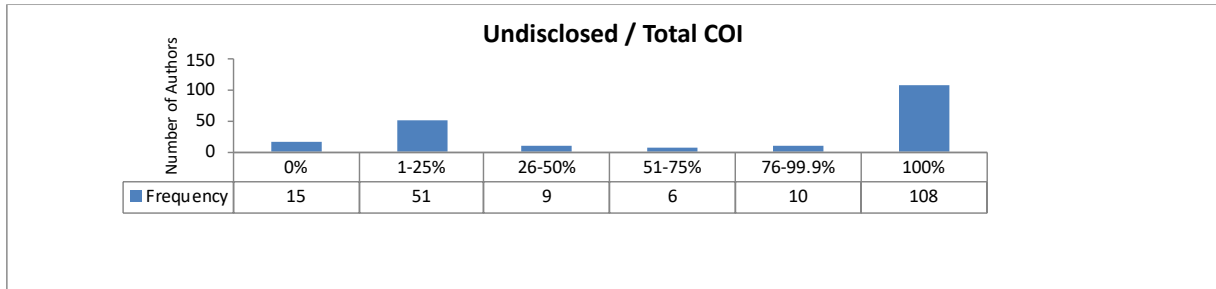
| Medical Professional Society | Number of Included Authors | Number of authors with COI (%) | General payments received, Mean (IQR) | Direct research payments received, Mean (IQR) | Associated research funding received, Mean (IQR) |
|--|----------------------------|--------------------------------|---------------------------------------|---|--|
| American Academy of Allergy, Asthma & Immunology | 15 | 13 (86.7%) | \$32,119 (\$4,933-\$68,247) | \$0 (\$0-\$2,403) | \$2,500 (0-\$72,166) |
| American Academy of Dermatology | 31 | 26 (83.9%) | \$70,727 (\$3,945-\$544,211) | \$19,333 (\$0-\$47,124) | \$140,916 (\$0-\$1,735,916) |
| American Academy of Neurology | 17 | 12 (70.6%) | \$1,128 (\$176-\$6,002) | \$0 (\$0-\$0) | \$0 (\$0-\$11,836) |
| American College of Cardiology | 15 | 11 (73.3%) | \$439 (\$60-\$11,982) | \$0 (\$0-\$0) | \$0 (\$0-\$114,716) |
| American College of Emergency Physicians | 7 | 2 (28.6%) | \$533 (\$280-\$787) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American College of Physicians | 4 | 1 (25.0%) | \$239 (\$239-\$239) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American College of Rheumatology | 24 | 16 (66.7%) | \$3,180 (\$91-\$34,226) | \$0 (\$0-\$1,097) | \$25,423 (\$0-\$221,056) |
| American Gastroenterological Association | 7 | 3 (42.9%) | \$188 (\$118-\$315) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Society of Anesthesiologists | 6 | 2 (33.3%) | \$62 (\$58-\$65) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Society of Clinical Oncology | 16 | 14 (87.5%) | \$20,332 (\$2,126-\$49,587) | \$1,315 (\$0-\$4,213) | \$588,530 (\$203,102-\$2,730,253) |
| American Society of Colon and Rectal Surgeons | 10 | 10 (100.0%) | \$18,990 (\$12,137-\$69,903) | \$0 (\$0-\$0) | \$266 (\$0-\$30,962) |
| American Society of Hematology | 14 | 13 (92.9%) | \$11,239 (\$1,286-\$133,932) | \$1,221 (\$0-\$27,779) | \$477,734 (\$222,642-\$803,713) |
| American Society for Radiation Oncology | 14 | 12 (85.7%) | \$6,190 (\$2,248-\$35,673) | \$0 (\$0-\$0) | \$0 (\$0-\$74,438) |
| American Society for Reproductive Medicine | 13 | 11 (84.6%) | \$834 (\$54-\$5,444) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Thoracic Society | 10 | 6 (60.0%) | \$445 (\$249-\$11,657) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Urological Association | 14 | 13 (92.9%) | \$8,853 (\$1,120-\$28,184) | \$0 (\$0-\$0) | \$0 (\$0-\$10,000) |

| | | | | | |
|--|----|----------------|---------------------------------|------------------|---------------------------------|
| Infectious Diseases Society of America | 10 | 5 (50.0%) | \$133 (\$70-\$12,757) | \$0 (\$0-\$0) | \$0 (\$0-\$36,825) |
| American Academy of Family Physicians | 6 | 2 (33.3%) | \$2,482 (\$1,372-\$3,539) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| Society of Critical Care Medicine | 25 | 15 (60.0%) | \$291 (\$6 - \$3,637) | \$0 (\$0-\$0) | \$0 (\$0-\$6,917) |
| Society for Vascular Surgery | 12 | 12 (100.0%) | \$28,714 (\$18,066-\$85,445) | \$0 (\$0-\$0) | \$54,800 (\$6,155-\$350,983) |

Abbreviations: COI = conflict of interest; IQR = interquartile range.

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Supplemental Figure 2 – Conflict of Interest Among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Proportions of Undisclosed/Total Conflict of Interest



Abbreviations: COI = conflict of interest.

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

| Section/Topic | Item # | Recommendation | Reported on page # |
|---------------------------|--------|--|--------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract | 1, 3 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 3 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any pre-specified hypotheses | 4, 5 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants | 5 |
| | | (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case | N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6, 7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 5, 6 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 5, 6 |
| Study size | 10 | Explain how the study size was arrived at | 5 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6, 7 |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 7 |
| | | (b) Describe any methods used to examine subgroups and interactions | N/A |
| | | (c) Explain how missing data were addressed | N/A |
| | | (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed | 5 |

| | | | |
|--------------------------|-----|--|--------|
| | | <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy | |
| | | (e) Describe any sensitivity analyses | N/A |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 7 |
| | | (b) Give reasons for non-participation at each stage | N/A |
| | | (c) Consider use of a flow diagram | N/A |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 7, 8 |
| | | (b) Indicate number of participants with missing data for each variable of interest | 7 |
| | | (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) | N/A |
| Outcome data | 15* | <i>Cohort study</i> —Report numbers of outcome events or summary measures over time | N/A |
| | | <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure | N/A |
| | | <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures | 7 |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 7-11 |
| | | (b) Report category boundaries when continuous variables were categorized | N/A |
| | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | N/A |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 12 |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 12, 13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 14 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 14 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 14 |
| Other information | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 15 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Financial Conflicts of Interest among U.S. Physician Authors of 2020 Clinical Practice Guidelines: A Cross-Sectional Study

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3 **Financial Conflicts of Interest among U.S. Physician Authors of**
4 **2020 Clinical Practice Guidelines: A Cross-Sectional Study**
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ABSTRACT

Objective To evaluate the prevalence and accuracy of industry-related financial conflict of interest (COI) disclosures among U.S. physician guideline authors

Design Cross-sectional study

Setting Clinical practice guidelines published by the Council of Medical Specialty Societies in 2020

Participants U.S. physician guideline authors

Main outcome measures Financial COI disclosures, both self-reported and determined using Open Payments data

Results Among 270 U.S. physician authors of 20 clinical practice guidelines, 101 (37.4%) disclosed industry-related financial COIs, whereas 199 (73.7%) were found to have received payments from industry when accounting for payments disclosed through Open Payments. The median payments received by authors during the 3-year period was \$27,451 (interquartile range [IQR], \$1,385-\$254,677). Comparing authors' self-disclosures with Open Payments, 72 (26.7%) of the authors accurately disclosed their financial COIs, including 68 (25.2%) accurately disclosing no financial COIs and 4 (1.5%) accurately disclosing a financial COI. In contrast, 101 (37.4%) disclosed no financial COIs and were found to have received payments from industry, 23 (8.5%) disclosed a financial COI but had underreported payments received from industry, 14 (5.2%) disclosed a financial COI but had overreported payments received from industry, and 60 (22.2%) disclosed a financial COI but were found to have both underreported and overreported payments received from industry. We found that inaccurate COI disclosure was more frequent among professors compared to non-professors (81.9% vs. 63.5%; $p < 0.001$) and among males compared to females (77.7% vs 64.8%; $p = 0.02$). The accuracy of disclosures also varied among medical professional societies ($p < 0.001$).

Conclusions Financial relationships with industry are common among U.S. physician authors of clinical practice guidelines and are often not accurately disclosed. To ensure high-quality guidelines and unbiased recommendations, more effort is needed to minimize existing COIs and improve disclosure accuracy among panel members.

Strength and limitations of this study

- Our study included a wide range of contemporary clinical practice guidelines from different professional societies, enhancing relevance and generalizability.
- We were limited to characterizing disclosures only for U.S. physicians.
- We only considered financial COIs with the pharmaceutical and medical device industry.

For peer review only

INTRODUCTION

Clinical practice guidelines are commonly used by clinicians to inform patient care decisions. The National Academy of Medicine (formerly called the Institute of Medicine) has defined conflict of interest (COI) as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” and have the potential to undermine guidelines’ quality, reliability, and integrity, resulting in harm to patients, healthcare professionals, and the healthcare systems.^[1,2] Prior studies have demonstrated an association between guideline authors’ financial COIs with industry and favorable recommendations for their products.^[3-5] Moreover, there have been concerns around the harm to patients receiving care based on potentially biased recommendations by guideline authors with financial COIs.^[6] 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.^[2,7-9]

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.^[10-14] A recent systematic review of nearly 15,000 guideline authors found that 45% reported a financial COI,^[10] however, 32% of authors had undisclosed financial relationships with the industry.^[10] In 2014, data representing payments from industry to U.S.-based physicians was first made available through the Centers for Medicare and Medicaid Services (CMS) Open Payments program, enabling numerous studies comparing disclosures by clinical practice guideline authors to those reported to CMS by manufacturers.^[10,15] However, many of these were conducted for guidelines issued by a single professional society or very soon after the Open Payments program went into effect,^[10,16-20] before physicians may have realized that there would be opportunities for external scrutiny of their disclosures.^[21,22]

Inaccurate disclosure of financial COI could undermine the integrity of clinical practice guidelines and diminish physician and patient confidence in their recommendations.

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3 Accordingly, our objective was to examine the accuracy of disclosed financial COIs among a more
4 contemporary sample of U.S. physician authors of clinical practice guidelines in 2020. We
5 hypothesized that with the availability of the Open Payments database, most guideline authors
6 would disclose their COIs accurately and expected modest differences in the disclosure of
7 financial COIs among medical professional societies. We also evaluated the scope and nature of
8 the payments received by U.S. physician guideline authors.
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16 **METHODS**

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18 This cross-sectional study examined the prevalence and monetary value of financial COIs
19 for authors of guidelines published in 2020 that were issued by any eligible member organization
20 of the Council of Medical Specialty Societies (CMSS). The study also examined the concordance
21 of COIs self-reported by the guideline authors and those listed for each author with a profile on
22 the CMS Open Payments program database. Financial COIs were determined using the publicly
23 available guideline materials and the Open Payments program database.^[23] Since publicly
24 available nonclinical datasets were used, informed consent and institutional review board
25 approval were not required. Patients or the public were not involved in the design, or conduct,
26 or reporting, or dissemination plans of our research. Findings were reported according to the
27 STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines.^[24]
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38 **Sample**

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40 We identified one guideline from each of the medical professional societies that were
41 member organizations of the CMSS in 2020.^[25] For societies with multiple clinical practice
42 guidelines, we chose the one with the largest number of authors. We included guidelines that
43 were authored by multiple societies if all were members of the CMSS. We excluded systematic
44 review documents that were not endorsed by the associated society as official guidelines. For all
45 authors, we recorded the name, gender, degree, academic rank, country of practice, and whether
46 they were panel chairs of eligible guidelines. We evaluated duplicate authors across guidelines
47 independently since authors were responsible for disclosing their financial COI in each guideline
48 and had independent opportunities to disclose their COI. We determined the rank (as of 2020)
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3 and gender of each author using their academic profile webpages. If the gender or associated
4 pronoun was not available on the institution profile page, we used Google searches to identify
5 gender and matched them with available profile photos. Authors from outside the United States
6 and those who were not physicians (e.g., PhDs) were excluded from the analysis, as Open
7 Payments, as of 2020 under the Physician Payments Sunshine Act, only required disclosure of
8 payments from industry to U.S. physicians and academic medical centers.^[26]
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16 **Main Outcome measure**

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18 We searched the main documents and supplementary files for each guideline and
19 collected the industry-related declared financial COIs (collected by MM and LG). Financial
20 disclosures related to payments from foundations, medical professional societies, academic
21 institutions, and governmental entities were excluded. Industry payments over the prior three
22 years were determined from the Open Payments database (in alignment with the International
23 Committee of Medical Journal Editors' (ICMJE) recommended timespan for disclosing any
24 potential COIs).^[27] To facilitate data collection, we collected information on all payments from
25 January 1, 2017 to December 31, 2019 for all guidelines accepted for publication before January
26 2020 or published before March 2020. For the remaining guidelines, we collected information on
27 all payments over the three-year period before acceptance for publication. If the acceptance date
28 was not available, we assumed that the guideline was accepted three months before the
29 publication date.
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40 Financial COIs were defined as any payments received by a guideline author from
41 pharmaceutical or medical device companies. The payments included research funding and
42 general payments, as categorized by CMS.^[28] Research funding could be paid either directly to
43 the recipient ("Research Payment") or through a research institution or entity where the
44 recipient was a principal investigator ("Associated Research Funding"). General payments
45 covered fees for non-research activities such as consulting, honoraria, royalty or license,
46 education, gifts, travel and lodging, and food and beverage. Ownership and investment interest
47 of authors were excluded.^[29] We categorized payments as either "Direct Payment", including
48 general payments and direct research payments, and "Associated Research Funding", which
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3 were received through a research organization. Data collection from Open Payments was done
4 manually in May and June 2022, of which 25% were validated by a second investigator; any
5 disagreements were resolved by consensus or through the input of a third investigator.
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9 For each guideline author, we first confirmed their identity by matching their name,
10 specialty, and practice location reported on their Open Payment profile with their information in
11 the guidelines. Next, we compared the data collected from Open Payments with authors' self-
12 disclosed COIs. If the source of payment found on Open Payments matched with the declared
13 COI, that payment was considered as a disclosed COI. Otherwise, it was recorded as an
14 undisclosed COI. Total COIs were calculated by adding the disclosed and undisclosed COIs.
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19 We categorized the status of financial COIs into the following groups: (1) undeclared in
20 the guideline and no payments found on Open Payments (accurate disclosure of no financial
21 COIs), (2) undeclared in the guideline but payments found on Open Payments, (3) disclosure of
22 payments in the guideline and no additional payments found on Open Payments (accurate
23 disclosure of financial COIs), (4) disclosure of payments in the guideline but additional payments
24 found on Open Payments (underreporting), (5) disclosure of payments in the guideline but not
25 all payments were found on Open Payments (overreporting), (6) disclosure of payments in the
26 guidelines, but both additional payments were found and not all disclosed payments were found
27 on Open Payments (underreporting and overreporting).
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38 **Patient and Public Involvement**

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43 **Statistical Analysis**

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45 We reported the prevalence and accuracy of disclosure of financial COIs, as well as the
46 types and amounts of compensation received by all guideline authors. We also examined
47 whether there were any associations between the accuracy of COI disclosure with gender, rank,
48 role as panel chair, and medical professional society. We analyzed the differences between each
49 group by using a two-sided, chi-squared test. A p-value<0.05 was considered statistically
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3 significant. Data were recorded and categorized in Microsoft Excel software, 2018 (Microsoft
4 Corp). We used JMP Pro, Version 16.2 (SAS Institute Inc) for conducting the chi-squared tests.
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8 **Sensitivity analysis**

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

20 **Sample characteristics**

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22 A total of 20 guidelines were included in our study, listed in Supplemental Table 1. All
23 guidelines were issued by a medical professional society with a COI policy for panel members,
24 and all the guidelines provided an opportunity for authors to publicly disclose their financial COIs.
25 The median number of guideline authors was 16 (interquartile range [IQR], 9-24). A total of 371
26 individuals were listed as authors of the 20 guidelines, of which 101 (27.2%) were based outside
27 the U.S and/or did not have an MD/DO/MBBS degree. Thus, 270 authors, representing 267
28 unique individuals, who had profiles on the Open Payments database, were included in the
29 analysis; 3 individuals were listed as authors of two guidelines. Duplicate authors across the
30 guidelines were examined independently. Of the 270 authors included in the analysis, 177
31 (65.6%) were male, 144 (53.3%) were of the professor rank, and 22 (8.1%) were panel chairs.
32 Additional characteristics of total 371 authors and the 270 included authors are summarized in
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Table 1- Characteristics of U.S. Physician Authors of 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

| Characteristics | N (%) (n=270) |
|------------------------|------------------|
| Gender | |
| • Male | 177 (65.6%) |
| • Female | 90 (33.3%) |
| • Unclear | 3 (1.1%) |
| Rank | |
| • Professor | 144 (53.3%) |
| • Associate Professor | 65 (24.1%) |
| • Assistant Professor | 34 (12.6%) |
| • Other / Not Reported | 27 (10.0%) |
| Panel Chair | |
| • Yes | 22 (8.1%) |
| • No / Not reported | 248 (91.9%) |

Prevalence of financial COIs

Of the 270 panel members, 101 (37.4%) declared financial COIs and 169 (62.6%) did not declare any financial COIs. However, when accounting for disclosures listed on Open Payments, 199 (73.7%) were found to have received payments from industry. Authors with COI comprised the minority of the panel for only 5 (25.0%) guidelines. Among the 22 panel chairs, 7 (31.8%) declared financial COIs. However, when accounting for disclosures listed on Open Payments, 18 (81.8%) had financial COIs, none of which disclosed their COI accurately.

Comparing authors' self-disclosures with Open Payments, 72 (26.7%) of the authors accurately disclosed their financial COIs, including 68 (25.2%) accurately disclosing no financial COIs and 4 (1.5%) accurately disclosing a financial COI. In contrast, 101 (37.4%) disclosed no financial COIs and were found to have received payments from industry, 23 (8.5%) disclosed a financial COI but had underreported all payments received from industry, 14 (5.2%) disclosed a financial COI but had overreported payments received from industry, and 60 (22.2%) disclosed a financial COI but were found to have both underreported and overreported payments received from industry (

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3 Table 2).
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Table 2 – Financial Conflict of Interest Disclosures among U.S. Physician Authors of 2020 Clinical Practice Guidelines

| | N (%) (n=270) |
|---|------------------|
| Undeclared in the guideline and no payments found on Open Payments (accurate disclosure of no financial COIs) | 68 (25.2%) |
| Undeclared in the guideline but payments found on Open Payments | 101 (37.4%) |
| Disclosure of payments in the guideline and no additional payments found on Open Payments (accurate disclosure of financial COIs) | 4 (1.5%) |
| Disclosure of payments in the guideline but additional payments found on Open Payments (underreporting) | 23 (8.5%) |
| Disclosure of payments in the guideline but not all payments were found on Open Payments (overreporting) | 14 (5.2%) |
| 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) | 60 (22.2%) |

Abbreviations: COI = conflict of interest.

Conflict of interest by authors' characteristics and societies

Inaccurate disclosures of financial COIs were more common by professors compared with non-professors or those with unavailable rank (81.9% vs. 63.5%; $p < 0.001$) and by male authors compared with female authors (77.7% vs. 64.8%; $p = 0.02$). Furthermore, the accuracy of COIs reported among the medical professional societies statistically differed ($p < 0.001$), as the American Society of Colon and Rectal Surgeons (ACRS) and Society for Vascular Surgery (SVS) had the highest inaccuracy rates (100%), whereas the American College of Physicians (ACP) had the lowest inaccuracy rate (25.0%). We found no statistically significant difference in the accuracy of COIs reported among panel chairs compared with other panel members (Table 3).

Table 3 - Accuracy of Financial Conflict of Interest Disclosures among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Author and Guideline Characteristics

| | Accurate financial COI disclosure | Inaccurate financial COI disclosure | P-value |
|--|-----------------------------------|-------------------------------------|---------|
| Gender | | | |
| • Male | 40 (22.3%) | 139 (77.7%) | 0.02 |
| • Female | 32 (35.2%) | 59 (64.8%) | |
| Rank | | | |
| • Professor | 26 (18.1%) | 118 (81.9%) | <0.001 |
| • Non-professor / Not reported | 46 (36.5%) | 80 (63.5%) | |
| Role as a Panel Chair | | | |
| • Yes | 4 (18.2%) | 18 (81.8%) | 0.35 |
| • No / Not reported | 68 (27.4%) | 180 (72.6%) | |
| Medical Professional Societies | | | |
| • American Academy of Allergy, Asthma & Immunology (AAAAI) | 2 (13.3%) | 13 (86.7%) | <0.001 |
| • American Academy of Dermatology (AAD) | 5 (16.1%) | 26 (83.9%) | |
| • American Academy of Family Physicians (AAFP) | 4 (66.7%) | 2 (33.3%) | |
| • American Academy of Neurology (AAN) | 6 (35.3%) | 11 (64.7%) | |
| • American College of Cardiology (ACC) | 4 (26.7%) | 11 (73.3%) | |
| • American College of Emergency Physicians (ACEP) | 4 (57.1%) | 3 (42.9%) | |
| • American College of Physicians (ACP) | 3 (75.0%) | 1 (25.0%) | |
| • American College of Rheumatology (ACR) | 8 (33.3%) | 16 (66.7%) | |
| • American Gastroenterological Association (AGA) | 4 (57.1%) | 3 (42.9%) | |
| • American Society of Anesthesiologists (ASA) | 4 (66.7%) | 2 (33.3%) | |
| • American Society of Clinical Oncology (ASCO) | 2 (12.5%) | 14 (87.5%) | |
| • American Society of Colon and Rectal Surgeons (ACRS) | 0 (0.0%) | 10 (100.0%) | |
| • American Society of Hematology (ASH) | 1 (7.1%) | 13 (92.9%) | |
| • American Society for Radiation Oncology (ASTRO) | 2 (14.3%) | 12 (85.7%) | |
| • American Society for Reproductive Medicine (ASRM) | 2 (15.4%) | 11 (84.6%) | |
| • American Thoracic Society (ATS) | 5 (50.0%) | 5 (50.0%) | |
| • American Urological Association (AUA) | 1 (7.1%) | 13 (92.9%) | |
| • Infectious Diseases Society of America (IDSA) | 4 (40.0%) | 6 (60.0%) | |
| • Society of Critical Care Medicine (SCCM) | 11 (44.0%) | 14 (56.0%) | |
| • Society for Vascular Surgery (SVS) | 0 (0.0%) | 12 (100.0%) | |

Abbreviations: COI = conflict of interest.

Authors with identified COIs on Open Payments

Based on the search conducted on Open Payments, 199 authors had financial COIs listed on the database, with the median 3-year payments of \$27,451 (IQR, \$1,385-\$254,677). The values of total and undisclosed COIs were \$98,716,681 and \$23,976,655, respectively. Over 80% of COIs were received as Associated Research Funding (median \$154 [IQR, \$0-\$212,932]), and the median value of general payments and research payments received directly by physicians were \$5,487 (IQR, \$344-\$48,834) and \$0 (\$0-\$770), respectively (Table 4).

Table 4 – Monetary Value of Financial Conflict of Interests among U.S. Physician Authors of 2020 Clinical Practice Guidelines

| | Median (IQR) | Total (%) | N (%) of Authors Receiving Payments |
|--|----------------------------------|-------------------------|-------------------------------------|
| Total COIs (All categories) | \$ 27,451 (\$1,385-\$254,677) | \$98,716,681 | 199 (73.7%) |
| • Total Direct Payments | \$6,336 (\$667-\$57,484) | \$18,936,416 (19.2%) | 193 (71.5%) |
| ○ General payments | \$5,487 (\$344-\$48,834) | \$16,087,973 (16.3%) | 193 (71.5%) |
| ▪ Food & beverage | \$487 (\$92-\$2,062) | \$461,698 (0.5%) | 184 (68.1%) |
| ▪ Others* | \$ 5000 (\$0-\$46,232) | \$15,626,275 (15.8%) | 129 (47.8%) |
| ○ Direct research payment | \$0 (\$0-\$770) | \$2,851,194 (2.9%) | 52 (19.3%) |
| • Associated Research Funding | \$154 (\$0-\$212,932) | \$79,780,264 (80.8%) | 101 (37.4%) |
| Disclosed COIs (All categories) | \$ 0 (\$0-\$121,305) | \$74,740,026 (75.7%) | 91 (33.7%) |
| • Total Direct Payments | \$0 (\$0-\$22,310) | \$14,971,881 (20%) | 82 (30.4%) |
| ○ General payments | \$0 (\$0-\$17,298) | \$12,318,629 (16.5%) | 78 (28.9%) |
| ▪ Food & beverage | \$0 (\$0-\$313) | \$266,507 (0.4%) | 69 (25.6%) |
| ▪ Others* | \$0 (\$0-\$17,076) | \$12,052,122 (16.1%) | 64 (23.7%) |
| ○ Direct research payment | \$0 (\$0-\$0) | \$2,653,252 (3.5%) | 44 (16.3%) |
| • Associated Research Funding | \$0 (\$0-\$66,026) | \$59,768,145 (80.0%) | 58 (21.5%) |
| Undisclosed COIs (All categories) | \$ 4,178 (\$227-\$62,564) | \$23,976,655 (24.3%) | 185 (68.5%) |

| | | | |
|-------------------------------|-----------------------------|-------------------------|----------------|
| • Total Direct Payments | \$ 1,153 (\$113-\$9,902) | \$3,964,536 (16.5%) | 175 (64.8%) |
| ○ General payments | \$992 (\$60-\$8,509) | \$3,769,344 (15.7%) | 175 (64.8%) |
| ▪ Food & beverage | \$191 (\$20-\$988) | \$195,191 (0.8%) | 164 (60.7%) |
| ▪ Others* | \$ 268 (\$0-\$6,810) | \$3,574,153 (14.9%) | 96 (35.6%) |
| ○ Direct research payment | \$0 (\$0-\$0) | \$197,942 (0.8%) | 13 (4.8%) |
| • Associated Research Funding | \$0 (\$0-\$35,416) | \$20,012,119 (83.5%) | 76 (28.1%) |

* Other general payment includes consulting, honoraria, royalty or license, education, gifts, and travel and lodging.

Abbreviations: COI = conflict of interest; IQR = interquartile range

Among all medical professional societies, the guideline panel members of the American Academy of Dermatology had the highest general payments received (mean [IQR], \$70,727 [\$3,945-\$544,211]), while panel members from the American Society of Anesthesiologists received the lowest general payments (mean [IQR], \$62 [\$58-\$65]). More details about the identified COI by medical professional societies are reported in Supplemental Table 3.

While 15 (7.5%) authors with financial COIs on Open Payments disclosed all received payments, 108 (54.3%) did not disclose any payments (Supplemental Figure 1). Among the authors with undisclosed or underreported COIs (n=184), 58.7% of authors' nondisclosures were for Direct Payments (4.9% general payments only, 53.8% combination of general payments and direct research payments), 5.4% for Associated Research Funding, and 35.9% for a combination of Direct payments and Associated Research funding (Figure 1).

Sensitivity analysis

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%]).

DISCUSSION

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In our cross-sectional study of 2020 clinical practice guidelines that compared self-reported financial COIs with payments from industry reported to CMS through the Open Payments program, we found that financial COIs are common among U.S. physician guideline panel members and are often not disclosed accurately. Although the majority of guideline authors had financial relationships with industry, more than 90% did not completely disclose all financial COIs. These findings raise concerns about potential bias in the treatment recommendations developed by key medical professional societies in the United States.

The National Academy of Medicine recommends guideline panel chairs and co-chairs to not have any conflicts, and that only a minority of guideline authors should have a financial COI.^[2] However, consistent with prior research^[14], 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,^[10] 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,^[3-5] 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.

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. Considering that these direct payments could potentially have a greater impact on panel members' decisions, more attention should be paid to such COIs. Certain medical professional societies also had higher rates of COIs, inaccurate disclosures, and greater values of payments received from the industry among their panel members, thus

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3 necessitating more rigorous action to be taken by those societies, perhaps with oversight from
4 CMSS. Disclosure, assessment, and management of COIs is a process that requires consideration
5 throughout the guideline development, particularly since relationships may change. Utilizing
6 specific structured disclosure forms with closed-ended questions may improve the accuracy of
7 COI disclosure.^[12] These forms should inquire about both active and inactive relationships with
8 the industry ahead of the process of guideline development to ensure compliance with National
9 Academy of Medicine recommendations. Additional detailed questions can further clarify the
10 relevancy and extent of those financial relationships. Our study showed that although medical
11 professional societies, such as American Society of Clinical Oncology (ASCO), have provided links
12 to individual guideline authors' entries within the Open Payments database, comparisons of self-
13 reported disclosure and what is reported on Open Payments may persist without oversights from
14 the medical professional societies. Therefore, medical professional societies should evaluate the
15 completeness of COI disclosure by comparing the self-reported COIs with data available on Open
16 Payments. Thereafter, all COIs that potentially affect guideline development should be managed
17 appropriately.

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31 This study had certain limitations. First, although we included an eligible guideline from
32 all the CMSS members, it was not feasible to include all the guidelines published by CMSS in 2020.
33 Among those with multiple guidelines, we selected the ones with the largest number of authors
34 to have an appropriate sample. Also, we included only physicians based in the U.S. since other
35 guideline authors would not have profiles on the Open Payments database. Second, data
36 available on Open Payments, although frequently updated and verified by payment recipients,
37 does not contain all the payments received and may not be fully accurate.^[30] Third, we attempted
38 to characterize all payments from industry to physicians reported through the Open Payments
39 program in the three years prior to guideline publication, in alignment with ICMJE disclosure
40 requirements.^[27] However, our look back may be imprecise because exact dates for guidelines'
41 convening, which may have taken months to more than a year to finalize, and for guidelines' first
42 submission to a journal for consideration, were not consistently available. Moreover, although
43 the required timespan for disclosing financial COI by the societies varied between 12 to 36
44 months, our analysis was based on the past 36 months, according to the ICMJE's

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3 recommendation. When accounting for the mandated disclosure timespan by each society, the
4 portion of authors with undisclosed or underreported COI remained substantially high. Lastly, we
5 only considered the pharmaceutical and medical device industry-related financial COIs. Although
6 other financial COIs and other types of COIs could influence the quality of clinical practice
7 guidelines, Open Payments only records industry payments and does not contain data related to
8 other COIs. Despite these limitations, our study included a wide range of contemporary clinical
9 practice guidelines from different societies, making the findings more generalizable than those
10 of similar studies.
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20 **CONCLUSION**

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22 Financial COIs among U.S. physician authors of clinical practice guidelines are common
23 and are often not disclosed accurately. Given the importance of clinical practice guidelines in
24 both providing care to patients and guiding future research in medicine, these guidelines should
25 be as accurate and unbiased as possible. The substantial COIs that exist among guideline authors
26 and the inconsistencies between payments reported by industry and COI self-reported within the
27 guidelines emphasized the need for implementing greater oversight and additional policies for
28 disclosing and managing COIs in medical professional societies producing clinical practice
29 guidelines to ensure their quality, reliability, and integrity.
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Ethics statements

Ethical approval: Not required. Publicly available nonclinical datasets were used.

Contributorship statement

MM, LG and JSR conceived of and designed the study. MM and LG collected the data. MM led the data analysis and drafted the first version of the manuscript. MM, LG, RR, and JSR reviewed and interpreted the data, read the manuscript, and provided critical feedback for important intellectual content. JSR provided supervision. MM, LG, RR, and JSR approved the submission of the current version of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Competing interests

Drs. Mooghali, Ramachandran, and Ross currently receive research support through Yale University from Arnold Ventures. Dr. Ramachandran currently receives research support through Yale Law School from the Stavros Niarchos Foundation for a project focused on public R&D and manufacturing for enabling equitable access to medical technologies. She also serves as a consultant to the ReAct-Action on Antibiotic Resistance Strategic Policy Program based out of Johns Hopkins Bloomberg School of Public Health, which is funded by the Swedish International Development and Cooperation Agency (Sida). Dr. Ross currently receives research support through Yale University from Johnson and Johnson to develop methods of clinical trial data sharing, from the Medical Device Innovation Consortium as part of the National Evaluation System for Health Technology (NEST), from the Food and Drug Administration for the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938), from the Agency for Healthcare Research and Quality (R01HS022882), and from the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) (R01HS025164, R01HL144644); in addition, Dr. Ross is an expert witness at the request of Relator's attorneys, the Greene Law Firm, in a qui tam suit alleging violations of the False Claims Act and Anti-Kickback Statute against Biogen Inc.

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Data Sharing statement

Relevant data are available on reasonable request from the corresponding author.

For peer review only

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List of figures:

Figure 1 – Types of Financial Conflict of Interest Under- and Undisclosed among U.S. Physician Authors of 2020 Clinical Practice Guidelines

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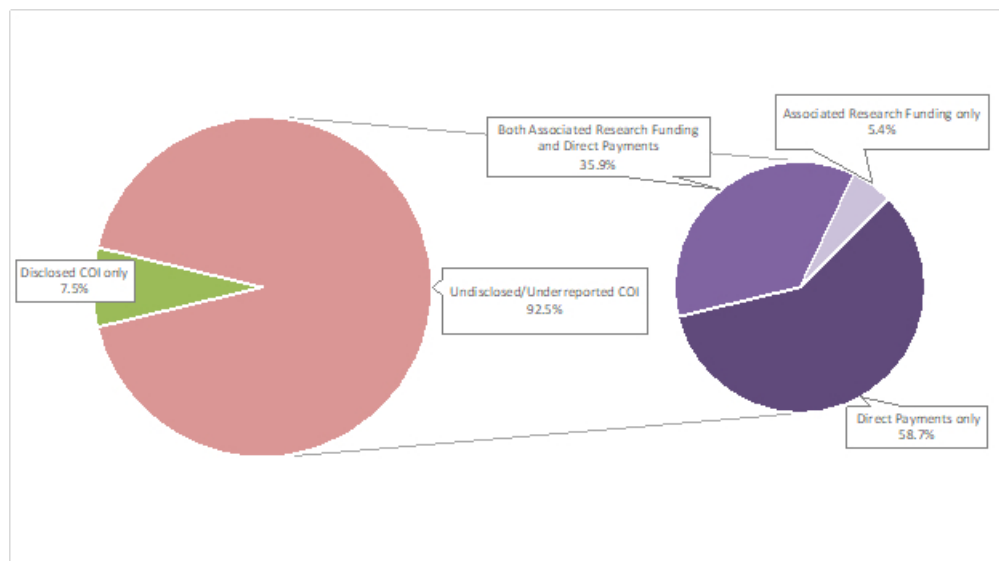


Figure 1 – Types of Financial Conflict of Interest Under- and Undisclosed among U.S. Physician Authors of 2020 Clinical Practice Guidelines

417x231mm (38 x 38 DPI)

List of Supplemental Tables and Figures

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Supplemental Figure 1 – Conflict of Interest Among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Proportions of Undisclosed/Total Conflict of Interest

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

| Medical professional society | Number of guidelines in 2020 | Selected Guideline for Study | Total number of listed authors | Number of U.S.-based physicians listed authors | COI disclosure policy by society in 2020 | Number (%*) of authors with undisclosed / underreported COI based on the past 36 months | Number (%*) of authors with 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 ¹ | 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 ² | 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 ¹⁸ | 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 ³ | 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 Hypertrophic Cardiomyopathy ⁴ | 19 | 15 | 12 months | 11 (73.3%) | 8 (53.3%) |

| | | | | | | | |
|--|----|---|----|----|---------------|-------------|-------------|
| American College of Emergency Physicians (ACEP) | 2 | Clinical Policy: Critical Issues Related to Opioids in Adult Patients Presenting to the Emergency Department ⁵ | 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 ⁶ | 5 | 4 | 36 months | 1 (25.0%) | 1 (25.0%) |
| American College of Rheumatology (ACR) | 3 | 2020 American College of Rheumatology Guidelines for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases ⁷ | 36 | 24 | 24 months | 15 (62.5%) | 14 (58.3%) |
| American Gastroenterological Association (AGA) | 4 | AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia ⁸ | 7 | 7 | 12 months | 3 (42.9%) | 2 (28.6%) |
| American Society of Anesthesiologists (ASA) | 1 | Practice Guidelines for Central Venous Access 2020: An Updated Report by the American Society of Anesthesiologists Task Force on Central Venous Access ⁹ | 7 | 6 | Not specified | 2 (33.3%) | 2 (33.3%) |
| American Society of Clinical Oncology (ASCO) | 12 | Metastatic Pancreatic Cancer: ASCO Guideline Update ¹⁰ | 19 | 16 | 24 months | 14 (87.5%) | 14 (87.5%) |
| American Society of Colon and Rectal Surgeons (ACRS) | 3 | The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Surgical Management of Crohn's Disease ¹¹ | 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 diagnosed acute myeloid leukemia in older adults ¹² | 23 | 14 | 24 months | 11 (78.6%) | 10 (71.4%) |
| American Society for Radiation Oncology (ASTRO) | 3 | Radiation Therapy for Small Cell Lung Cancer: An ASTRO Clinical Practice Guideline ¹³ | 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 ¹⁴ | 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 ¹⁵ | 30 | 10 | 36 months | 5 (50.0%) | 5 (50.0%) |
| American Urological Association (AUA) | 4 | Microhematuria: AUA/SUFU Guideline ¹⁶ | 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 ¹⁷ | 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 ¹⁹ | 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 ²⁰ | 13 | 12 | 12 months | 12 (100.0%) | 12 (100.0%) |
| Total | | | 371 | 270 | | 184 (68.1%) | 160 (59.3%) |

Supplemental Table 2 - Characteristics of Guideline Authors of 2020 Clinical Practice Guidelines published by the Council of Medical Specialty Societies

| Characteristics | N (%) (n=371) |
|---|------------------|
| Gender | |
| • Male | 221 (59.6%) |
| • Female | 145 (39.1%) |
| • Unclear | 5 (1.3%) |
| Rank | |
| • Professor | 174 (46.9%) |
| • Associate Professor | 87 (23.5%) |
| • Assistant Professor | 44 (11.9%) |
| • Other / Not Reported | 66 (17.8%) |
| Location | |
| • United States | 309 (83.3%) |
| • Canada (No profile on Open Payments) | 28 (7.5%) |
| • Other Countries (No profile on Open Payments) | 34 (9.2%) |
| Degree | |
| • MD/DO/MBBS | 318 (85.7%) |
| • Non-MD/DO/MBBS | 53 (14.3%) |
| Profile on Open Payments | |
| • No available profile - Excluded from the analysis | 101 (27.2%) |
| • Available Profile - Included in the analysis | 270 (72.8%) |
| Conflict of Interest declared in the guideline | |
| • Authors who declared industry-related COIs in the guidelines | 129 (34.8%) |
| • Authors who did NOT declare any industry-related COIs in the guidelines | 242 (65.2%) |

Abbreviations: COI = conflict of interest; DO = Doctor of Osteopathic Medicine; MBBS = Bachelor of Medicine, Bachelor of Surgery; MD = Doctor of Medicine.

Supplemental Table 3 - Financial Conflict of Interests among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Medical Professional Societies

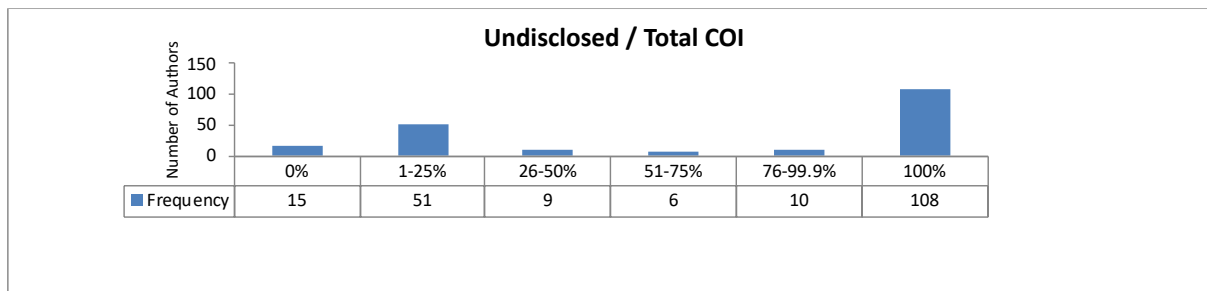
| Medical Professional Society | Number of Included Authors | Number of authors with COI (%) | General payments received, Mean (IQR) | Direct research payments received, Mean (IQR) | Associated research funding received, Mean (IQR) |
|--|----------------------------|--------------------------------|---------------------------------------|---|--|
| American Academy of Allergy, Asthma & Immunology | 15 | 13 (86.7%) | \$32,119 (\$4,933-\$68,247) | \$0 (\$0-\$2,403) | \$2,500 (0-\$72,166) |
| American Academy of Dermatology | 31 | 26 (83.9%) | \$70,727 (\$3,945-\$544,211) | \$19,333 (\$0-\$47,124) | \$140,916 (\$0-\$1,735,916) |
| American Academy of Family Physicians | 6 | 2 (33.3%) | \$2,482 (\$1,372-\$3,539) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Academy of Neurology | 17 | 12 (70.6%) | \$1,128 (\$176-\$6,002) | \$0 (\$0-\$0) | \$0 (\$0-\$11,836) |
| American College of Cardiology | 15 | 11 (73.3%) | \$439 (\$60-\$11,982) | \$0 (\$0-\$0) | \$0 (\$0-\$114,716) |
| American College of Emergency Physicians | 7 | 2 (28.6%) | \$533 (\$280-\$787) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American College of Physicians | 4 | 1 (25.0%) | \$239 (\$239-\$239) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American College of Rheumatology | 24 | 16 (66.7%) | \$3,180 (\$91-\$34,226) | \$0 (\$0-\$1,097) | \$25,423 (\$0-\$221,056) |
| American Gastroenterological Association | 7 | 3 (42.9%) | \$188 (\$118-\$315) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Society of Anesthesiologists | 6 | 2 (33.3%) | \$62 (\$58-\$65) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Society of Clinical Oncology | 16 | 14 (87.5%) | \$20,332 (\$2,126-\$49,587) | \$1,315 (\$0-\$4,213) | \$588,530 (\$203,102-\$2,730,253) |
| American Society of Colon and Rectal Surgeons | 10 | 10 (100.0%) | \$18,990 (\$12,137-\$69,903) | \$0 (\$0-\$0) | \$266 (\$0-\$30,962) |
| American Society of Hematology | 14 | 13 (92.9%) | \$11,239 (\$1,286-\$133,932) | \$1,221 (\$0-\$27,779) | \$477,734 (\$222,642-\$803,713) |
| American Society for Radiation Oncology | 14 | 12 (85.7%) | \$6,190 (\$2,248-\$35,673) | \$0 (\$0-\$0) | \$0 (\$0-\$74,438) |
| American Society for Reproductive Medicine | 13 | 11 (84.6%) | \$834 (\$54-\$5,444) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |
| American Thoracic Society | 10 | 6 (60.0%) | \$445 (\$249-\$11,657) | \$0 (\$0-\$0) | \$0 (\$0-\$0) |

| | | | | | |
|--|----|----------------|---------------------------------|------------------|---------------------------------|
| American Urological Association | 14 | 13 (92.9%) | \$8,853 (\$1,120-\$28,184) | \$0 (\$0-\$0) | \$0 (\$0-\$10,000) |
| Infectious Diseases Society of America | 10 | 5 (50.0%) | \$133 (\$70-\$12,757) | \$0 (\$0-\$0) | \$0 (\$0-\$36,825) |
| Society of Critical Care Medicine | 25 | 15 (60.0%) | \$291 (\$6 - \$3,637) | \$0 (\$0-\$0) | \$0 (\$0-\$6,917) |
| Society for Vascular Surgery | 12 | 12 (100.0%) | \$28,714 (\$18,066-\$85,445) | \$0 (\$0-\$0) | \$54,800 (\$6,155-\$350,983) |

Abbreviations: COI = conflict of interest; IQR = interquartile range.

For peer review only

Supplemental Figure 1 – Conflict of Interest Among U.S. Physician Authors of 2020 Clinical Practice Guidelines, Stratified by Proportions of Undisclosed/Total Conflict of Interest



Abbreviations: COI = conflict of interest.

For peer review only

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

| Section/Topic | Item # | Recommendation | Reported on page # |
|---------------------------|--------|--|--------------------|
| Title and abstract | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract | 1, 2 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any pre-specified hypotheses | 4, 5 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants | 5 |
| | | (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case | N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6, 7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 5, 6 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 5-8 |
| Study size | 10 | Explain how the study size was arrived at | 5 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6, 7 |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 7, 8 |
| | | (b) Describe any methods used to examine subgroups and interactions | N/A |
| | | (c) Explain how missing data were addressed | N/A |
| | | (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed | 5 |

| | | | |
|--------------------------|-----|--|--------|
| | | <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy | |
| | | (e) Describe any sensitivity analyses | 8 |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 7 |
| | | (b) Give reasons for non-participation at each stage | N/A |
| | | (c) Consider use of a flow diagram | N/A |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 8, 9 |
| | | (b) Indicate number of participants with missing data for each variable of interest | 8 |
| | | (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) | N/A |
| Outcome data | 15* | <i>Cohort study</i> —Report numbers of outcome events or summary measures over time | N/A |
| | | <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure | N/A |
| | | <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures | 8-10 |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 8-13 |
| | | (b) Report category boundaries when continuous variables were categorized | N/A |
| | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | N/A |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 13 |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 14 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 15, 16 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 16 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 16 |
| Other information | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 18 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.