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Financial conflicts of interest among US physician authors of 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 US physician guideline authors.

Design Cross-sectional study.

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

Participants US physician guideline authors.

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

Results Among 270 US 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 US$27 451 (IQR, US$1385–US$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 under-reported payments received from industry, 14 (5.2%) disclosed a financial COI but had over-reported payments received from industry and 60 (22.2%) disclosed a financial COI but were found to have both under-reported and over-reported payments received from industry. We found that inaccurate COI disclosure was more frequent among professors compared with non-professors (81.9% vs 63.5%; p<0.001) and among males compared with 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 US 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 minimise existing COIs and improve disclosure accuracy among panel members.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our study included a wide range of contemporary clinical practice guidelines from different professional societies, enhancing relevance and generalisability.
⇒ We were limited to characterising disclosures only for US physicians.
⇒ We only considered financial conflicts of interest with the pharmaceutical and medical device industry.

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 favourable 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 WHO, emphasising 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 under-reported.[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 US-based physicians was first made available through the Centers for Medicare and Medicaid Services (CMS) Open Payments programme, 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 programme went into effect,[10 16–20] before physicians may have realised 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. Accordingly, our objective was to examine the accuracy of disclosed financial COIs among a more contemporary sample of US physician authors of clinical practice guidelines in 2020. We hypothesised 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 financial COIs among medical professional societies. We also evaluated the scope and nature of the payments received by US physician guideline authors.

METHODS

This cross-sectional study examined the prevalence and monetary value of financial COIs for authors of guidelines published in 2020 that were issued by any eligible member organisation of the Council of Medical Specialty Societies (CMSS). The study also examined the concordance of COIs self-reported by the guideline authors and those listed for each author with a profile on the CMS Open Payments programme database. Financial COIs were determined using the publicly available guideline materials and the Open Payments programme database.[23] Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research. Findings were reported according to the Strengthening the Reporting of Observational studies in Epidemiology guidelines.[24]

Sample

We identified one guideline from each of the medical professional societies that were member organisations of the CMSS in 2020.[25] For societies with multiple clinical practice guidelines, we chose the one with the largest number of authors. We included guidelines that were authored by multiple societies, if all were members of the CMSS. We excluded systematic review documents that were not endorsed by the associated society as official guidelines. For all authors, we recorded the name, gender, degree, academic rank, country of practice and whether they were panel chairs of eligible guidelines. We evaluated duplicate authors across guidelines independently since authors were responsible for disclosing their financial COI in each guideline and had independent opportunities to disclose their COI. We determined the rank (as of 2020) and gender of each author using their academic profile webpages. If the gender or associated pronoun was not available on the institution profile page, we used Google searches to identify gender and matched them with available profile photos. Authors from outside the USA and those who were not physicians (eg, PhDs) were excluded from the analysis, as Open Payments, as of 2020 under the Physician Payments Sunshine Act, only required disclosure of payments from industry to US physicians and academic medical centres.[26]

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 3 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).[27] To facilitate data collection, we collected information on all payments from 1 January 2017 to 31 December 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 3-year period before acceptance for publication. If the acceptance date was not available, we assumed that the guideline was accepted 3 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 categorised by CMS.[28] 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.[29] We categorised payments as either 'Direct Payment', including general payments and direct research payments, and 'Associated Research Funding', which were received through a research organisation. Data collection from Open Payments was done manually in May and June 2022, of which 25% were validated by a second investigator; any disagreements were resolved by consensus or through the input of a third investigator.

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 categorised 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 (under-reporting), (5) disclosure of payments in the guideline but not all payments were found on Open Payments (over-reporting), (6) disclosure of payments in the guidelines, but both additional payments were found and not all disclosed payments were found on Open Payments (under-reporting and over-reporting).

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 analysed the differences between each group by using a two-sided, χ^2 test. A p value<0.05 was considered statistically significant. Data were recorded and categorised in Microsoft Excel software, 2018 (Microsoft Corp). We used JMP Pro, V.16.2 (SAS Institute) for conducting the χ^2 tests.

Sensitivity analysis

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

RESULTS

Sample characteristics

A total of 20 guidelines were included in our study, listed in online 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 (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 US and/or did not have an MD/DO/MBBS degree. Thus, 270 authors, representing 267 unique individuals, who had profiles on the Open Payments database, were included in the analysis; 3 individuals were listed as authors of 2 guidelines. Duplicate authors across the guidelines were examined independently. 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 summarised in online supplemental table 2 and table 1, respectively.

Table 1 Characteristics of US 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 under-reported payments received from industry, 14 (5.2%) disclosed a financial COI but had over-reported payments received from industry and

Table 2 Financial conflict of interest disclosures among US 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 (under-reporting)	23 (8.5%)
Disclosure of payments in the guideline but not all payments were found on Open Payments (over-reporting)	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 (under-reporting and over-reporting)	60 (22.2%)

COI, conflicts of interest.

60 (22.2%) disclosed a financial COI but were found to have both under-reported and over-reported payments received from industry (table 2).

COI 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 and Society for Vascular Surgery had the highest inaccuracy rates (100%), whereas the American College of Physicians 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).

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 US$27 451 (IQR, US$1385–US$254 677). The values of total and undisclosed COIs were US$98 716 681 and US$23 976 655, respectively. Over 80% of COIs were received as associated research funding (median US$154 (IQR, US$0–US$212 932)), and the median value of general payments and research payments received directly by physicians were US$5487 (IQR, US$344–US$48 834) and US$0 (US$0–US$770), respectively (table 4).

Among all medical professional societies, the guideline panel members of the American Academy of Dermatology had the highest general payments received (mean (IQR), US$70 727 (US$3945–US$544 211)), while panel members from the American Society of Anesthesiologists received the lowest general payments (mean (IQR), US$62 (US$58–US$65)). More details about the identified COI by medical professional societies are reported in online supplemental table 3.

While 15 (7.5%) authors with financial COIs on Open Payments disclosed all received payments, 108 (54.3%) did

Table 3 Accuracy of financial conflict of interest disclosures among US 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	2 (13.3%)	13 (86.7%)	<0.001
American Academy of Dermatology	5 (16.1%)	26 (83.9%)	
American Academy of Family Physicians	4 (66.7%)	2 (33.3%)	
American Academy of Neurology	6 (35.3%)	11 (64.7%)	
American College of Cardiology	4 (26.7%)	11 (73.3%)	
American College of Emergency Physicians	4 (57.1%)	3 (42.9%)	
American College of Physicians	3 (75.0%)	1 (25.0%)	
American College of Rheumatology	8 (33.3%)	16 (66.7%)	
American Gastroenterological Association	4 (57.1%)	3 (42.9%)	
American Society of Anesthesiologists	4 (66.7%)	2 (33.3%)	
American Society of Clinical Oncology	2 (12.5%)	14 (87.5%)	
American Society of Colon and Rectal Surgeons	0 (0.0%)	10 (100.0%)	
American Society of Hematology	1 (7.1%)	13 (92.9%)	
American Society for Radiation Oncology	2 (14.3%)	12 (85.7%)	
American Society for Reproductive Medicine	2 (15.4%)	11 (84.6%)	
American Thoracic Society	5 (50.0%)	5 (50.0%)	
American Urological Association	1 (7.1%)	13 (92.9%)	
Infectious Diseases Society of America	4 (40.0%)	6 (60.0%)	
Society of Critical Care Medicine	11 (44.0%)	14 (56.0%)	
Society for Vascular Surgery	0 (0.0%)	12 (100.0%)	

COI, conflict of interest.

Table 4 Monetary value of financial conflict of interests among US physician authors of 2020 clinical practice guidelines

	Median (IQR)	Total (%)	Authors receiving payments, N (%)
Total COIs (all categories)	US$27 451 (US$1385–US$254 677)	US$98 716 681	199 (73.7%)
Total Direct Payments	US$6336 (US$667–US$57 484)	US$18 936 416 (19.2%)	193 (71.5%)
General payments	US$5487 (US$344–US$48 834)	US$16 087 973 (16.3%)	193 (71.5%)
Food and beverage	US$487 (US$92–US$2062)	US$461 698 (0.5%)	184 (68.1%)
Others*	US$5000 (US$0–US$46 232)	US$15 626 275 (15.8%)	129 (47.8%)
Direct research payment	US$0 (US$0–US$770)	US$2 851 194 (2.9%)	52 (19.3%)
Associated research funding	US$154 (US$0–US$212 932)	US$79 780 264 (80.8%)	101 (37.4%)
Disclosed COIs (all categories)	US$0 (US$0–US$121 305)	US$74 740 026 (75.7%)	91 (33.7%)
Total Direct Payments	US$0 (US$0–US$22 310)	US$14 971 881 (20%)	82 (30.4%)
General payments	US$0 (US$0–US$17 298)	US$12 318 629 (16.5%)	78 (28.9%)
Food and beverage	US$0 (US$0–US$313)	US$266 507 (0.4%)	69 (25.6%)
Others*	US$0 (US$0–US$17 076)	US$12 052 122 (16.1%)	64 (23.7%)
Direct research payment	US$0 (US$0–US$0)	US$2 653 252 (3.5%)	44 (16.3%)
Associated research funding	US$0 (US$0–US$66 026)	US$59 768 145 (80.0%)	58 (21.5%)
Undisclosed COIs (all categories)	US$4178 (US$227–US$62 564)	US$23 976 655 (24.3%)	185 (68.5%)
Total Direct Payments	US$1153 (US$113–US$9902)	US$3 964 536 (16.5%)	175 (64.8%)
General payments	US$992 (US$60–US$8509)	US$3 769 344 (15.7%)	175 (64.8%)
Food and beverage	US$191 (US$20–US$988)	US$195 191 (0.8%)	164 (60.7%)
Others*	US$268 (US$0–US$6810)	US$3 574 153 (14.9%)	96 (35.6%)
Direct research payment	US$0 (US$0–US$0)	US$197 942 (0.8%)	13 (4.8%)
Associated research funding	US$0 (US$0–US$35 416)	US$20 012 119 (83.5%)	76 (28.1%)

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

not disclose any payments (online supplemental figure 1). Among the authors with undisclosed or under-reported COIs (n=184), 58.7% of authors' non-disclosures 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

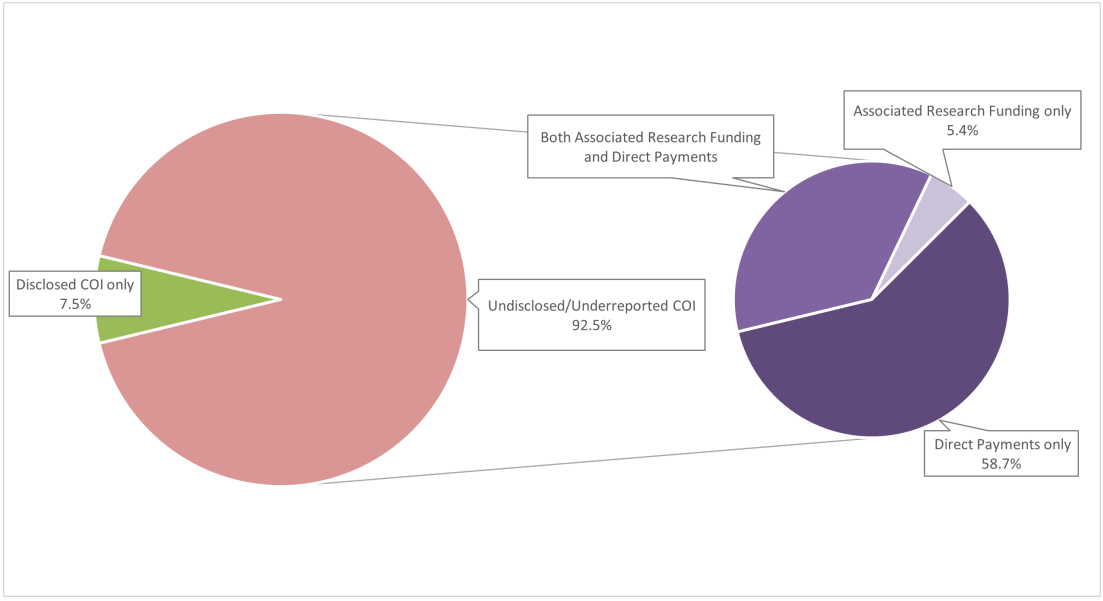

Figure 1 Types of financial conflict of interest (COI) under-reported or undisclosed among US physician authors of 2020 clinical practice guidelines.

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 under-reported COIs remained high (160 of 270 (59.3%)).

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 programme, we found that financial COIs are common among US 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 USA.

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 that 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 organisations had the opportunity to scrutinise 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 USA.

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 under-reported 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 necessitating more rigorous action to be taken by those societies, perhaps with oversight from CMSS. Disclosure, assessment and management of COIs is a process that requires consideration throughout the guideline development, particularly since relationships may change. Using specific structured disclosure forms with closed-ended questions may improve the accuracy of COI disclosure.[12] These forms should inquire about both active and inactive relationships with the industry ahead of the process of guideline development to ensure compliance with National Academy of Medicine recommendations. Additional detailed questions can further clarify the relevancy and

extent of those financial relationships. Our study showed that although medical professional societies, such as the *American Society of Clinical Oncology*, have provided links to individual guideline authors' entries within the Open Payments database, comparisons of self-reported disclosure and what is reported on Open Payments may persist without oversights from the medical professional societies. Therefore, medical professional societies should evaluate the completeness of COI disclosure by comparing the self-reported COIs with data available on Open Payments. Thereafter, all COIs that potentially affect guideline development should be managed appropriately.

This study had certain limitations. First, although we included an eligible guideline from all the CMSS members, it was not feasible to include all the guidelines published by CMSS in 2020. Among those with multiple guidelines, we selected the ones with the largest number of authors to have an appropriate sample. Also, we included only physicians based in the USA since other guideline authors would not have profiles on the Open Payments database. Second, data available on Open Payments, although frequently updated and verified by payment recipients, does not contain all the payments received and may not be fully accurate.[30] Third, we attempted to characterise all payments from industry to physicians reported through the Open Payments programme in the 3 years prior to guideline publication, in alignment with ICMJE disclosure requirements.[27] However, our look back may be imprecise because exact dates for guidelines' convening, which may have taken months to more than a year to finalise, and for guidelines' first submission to a journal for consideration, were not consistently available. Moreover, although the required timespan for disclosing financial COI by the societies varied between 12 and 36 months, our analysis was based on the past 36 months, according to the ICMJE's recommendation. When accounting for the mandated disclosure timespan by each society, the portion of authors with undisclosed or under-reported COI remained substantially high. Lastly, we only considered the pharmaceutical and medical device industry-related financial COIs. Although other financial COIs and other types of COIs could influence the quality of clinical practice guidelines, Open Payments only records industry payments and does not contain data related to other COIs. Despite these limitations, our study included a wide range of contemporary clinical practice guidelines from different societies, making the findings more generalisable than those of similar studies.

CONCLUSION

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

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Contributors 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. MM accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Competing interests MM, RR and JSR currently receive research support through Yale University from Arnold Ventures. RR 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). JSR 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, from the Food and Drug Administration for the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation 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 (R01HS025164, R01HL144644); in addition, JSR 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.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Since publicly available non-clinical datasets were used, informed consent and institutional review board approval were not required.

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