

Financial Conflicts of Interest in Clinical Practice Guidelines: A Systematic Review

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Abstract

Objective: To systematically evaluate the prevalence of disclosed and undisclosed financial conflicts of interest (FCOI) among clinical practice guidelines (CPGs).

Methods: In this systematic review, we ascertained the prevalence and types of FCOI for CPGs from January 1, 1980, to March 3, 2019. The primary outcome was the prevalence of FCOI among authors of CPGs. FCOI disclosures were compared between medical subspecialties and societies producing CPGs.

Results: Among the 37 studies including 14,764 total guideline authors, 45% had at least one FCOI. The prevalence of FCOI per study ranged from 6% to 100%. More authors had FCOI involving general payments (39%) compared with research payments (29%). Oncology, neurology, and gastroenterology had the highest prevalence of FCOI compared with other medical specialties. Among the 8 studies that included the monetary values in US dollars of FCOI, average payments per author ranged from \$578 to \$242,300. Among the 10 studies that included data on undisclosed FCOI, 32% of authors had undisclosed industry payments.

Conclusion: There are numerous FCOI among authors of CPGs, many of which are undisclosed. Our study found a significant difference in FCOI prevalence based on types of FCOI and CPG sponsor society. Additional research is required to quantify the implications of FCOI on clinical judgment and patient care.

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Financial conflicts of interest (FCOI) exist across the spectrum of academia and medicine.¹⁻³ One area that has been evaluated is FCOI in clinical practice guidelines (CPGs). These documents are intended to guide clinicians in decision-making and can be highly influential. There are concerns, however, that FCOI among CPG panel members can introduce bias and jeopardize objectivity.¹

Various approaches have been suggested to mitigate industry influence among CPGs. At a policy level, the National Academy of Medicine in the United States has recommended that guideline chairs be free of FCOI and that authors with FCOI compose less than half of the CPG panel.² In addition, the US government has aimed to make all industry payments to physicians more transparent through the Centers for Medicare & Medicaid Services Open Payments (CMS-OP) database. This database publishes data on payments provided to physicians by pharmaceutical and medical device companies in the United States as part

of the Physician Payments Sunshine Act.³ Some societies, such as the American College of Chest Physicians, use CMS-OP to verify the accuracy of guideline authors' disclosures.⁴

Despite these efforts, a large body of literature suggests that there are substantial FCOI in CPGs.⁵ To summarize and to contextualize the evidence, we conducted a systematic review of studies examining FCOI among CPGs.

METHODS

We registered this systematic review using PROSPERO (CRD42019129060). We aimed to characterize the prevalence of disclosed and undisclosed FCOI among authors of CPGs and to evaluate the impact of FCOI among guideline authors on guideline recommendations.

Search Strategy

We conducted a systematic search in MEDLINE for studies that reported the

prevalence of FCOI among CPGs published between January 1980 and March 2019. The complete search strategy is summarized in the [Supplemental Table](#) (available online at <http://mcpiqjournal.org>). In addition, we hand searched the reference lists of any included studies.

Study Selection

Two authors (S.T., R.K.) independently screened all titles and abstracts for inclusion and a third author (S.C.G.) adjudicated any disagreements. We included studies if they were observational cohort or cross-sectional studies examining the prevalence of FCOI among a subset of CPGs or examining the association of FCOI with guideline recommendations. To determine whether studies examined CPGs, we used the definition of CPG published by the National Academy of Medicine.² We excluded any studies published in a non-English language for which full study details could not be retrieved.

Outcomes

Our primary outcome was the prevalence of FCOI among authors of CPGs in the included studies. We defined conflicts of interest, in keeping with the National Academy of Medicine definition, as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.”² We further categorized payments according to the CMS-OP classification as general payments, such as fees paid for speaking engagements, consulting, travel and accommodation, food and beverage, honoraria, and gifts; research payments for the funding and implementation of research studies, through compensation provided directly to a guideline author or to an author’s institution; and equity, such as investments, ownership stakes, and royalties. When applicable, we separately reported disclosed and undisclosed FCOI. As the majority of studies did not follow these CMS-OP definitions, two authors (S.T., R.K.) independently categorized all payments as general payments, research payments, or equity, and a third author (S.C.G.) resolved any disagreements.

We also reported the monetary value of FCOI in US dollars, separated when possible

ARTICLE HIGHLIGHTS

- Financial conflicts of interest (FCOI) may have an impact on the objectivity of clinical practice guidelines.
- Among the 37 studies included in this systematic review, 45% of the 14,764 guideline authors had an FCOI.
- Authors of oncology, neurology, and gastroenterology guidelines had higher prevalence of FCOI compared with other guidelines. Eight studies included monetary value of FCOI, which ranged from \$578 to \$242,300 per author. Little is known about the direct impact of FCOI on how authors of clinical practice guidelines vote on recommendations during guideline development.

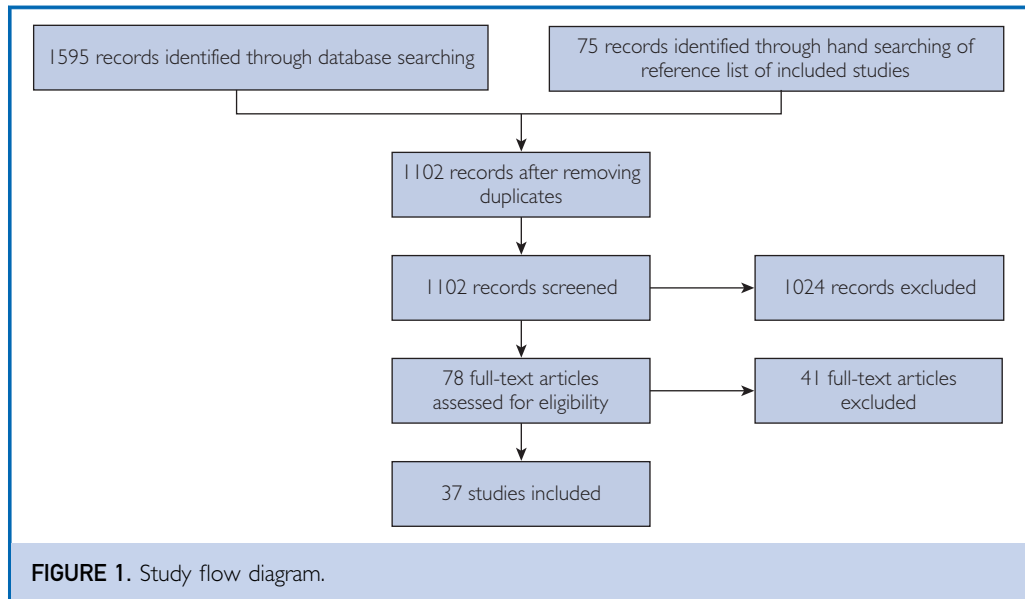
into disclosed and undisclosed payments and general, research, and equity payments.

The secondary outcome was the association between FCOI and guideline recommendations. For this outcome, we included data from studies that assessed a relationship between FCOI and voting on recommendation by guideline members. We did not assess this outcome in studies that provided only FCOI prevalence data as the majority of guidelines do not report individual voting patterns.

Data Extraction and Assessment of Quality

Two authors (S.T., R.K.) independently extracted data using a standardized data collection. For each study, we determined the year of publication, field of medicine, study design, CPG sponsor, clinical focus, prevalence of disclosed and undisclosed FCOI, types of FCOI (general payments, research payments, equity, other), and effect of FCOI on guideline recommendations. A third author (S.C.G.) resolved any disagreements.

We initially aimed to perform a quality assessment of included studies using the National Institutes of Health Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.⁶ We decided, however, not to perform this quality assessment. As all included studies used a descriptive design with no comparison group, we thought that such an assessment would not contribute meaningfully to our ability to discriminate



between studies. Specifically, all studies would have been considered uncontrolled observational studies or case series and thus would be considered level 4 evidence on the basis of the Oxford Centre for Evidence-Based Medicine Levels of Evidence guidelines.⁷

Deviations From Protocol

We included several observational studies that were not strictly cross-sectional and cohort studies. We did this as after initial review of abstracts, we appreciated that several important studies in this field were document reviews that could contribute to the understanding of FCOI in CPGs. In addition, we reported dollar value of FCOI when available. This information provides insight into the magnitude of FCOI.

Data Synthesis

We conducted a qualitative and narrative synthesis across included studies structured around study design, medical specialty, and presence of disclosed and undisclosed FCOI. We also calculated raw prevalence data, reported as the percentage of authors with FCOI among the total number of authors.

For the association between conflict of interest and guideline recommendations, we aimed to summarize the effect of conflicts on

guideline recommendations through a random effects model and by calculating risk ratios (for dichotomous outcomes) and standardized mean differences (for continuous outcomes). We also aimed to assess CPG author characteristics associated with having disclosed and undisclosed FCOI. We did not, however, perform these meta-analyses because of a lack of data in the included studies.

RESULTS

We identified 1595 potentially relevant records through our search strategy, of which 1102 remained after removal of duplicates, and 75 articles through hand searching. We retrieved 78 full-text articles or conference abstracts for review. We excluded 41 articles, which left 37 eligible studies.⁸⁻⁴⁴ Our search flow is outlined in [Figure 1](#).

The 37 included studies were published between 2001 and 2019. The median year of publication was 2015. Twenty-seven studies evaluated guidelines in specific subject areas and 10 evaluated guidelines in general medicine. Twenty-one studies evaluated guidelines published by US-based organizations or housed in US-based databases. Three studies evaluated German guidelines, 2 evaluated Canadian guidelines, and 1 each evaluated Japanese, Australian, and Danish guidelines. The remaining 8 studies included guidelines

TABLE 1. General Characteristics of Included Studies

Characteristic	No. of studies
Year of publication	2001-2005: 2 2006-2010: 3 2011-2015: 13 2016-2019: 20
Country ^a	United States: 21 Germany: 3 Canada: 2 Australia: 1 Denmark: 1 Japan: 1 Multiple countries: 8
Study design	Cross-sectional: 21 Single-group cohort: 9 Systematic search: 6 Document review: 1
Medical specialty	General: 10 Gastroenterology: 5 Cardiology: 4 Psychiatry: 4 Neurology: 2 Oncology: 3 Orthopedic surgery: 2 Other ^b : 7
Guideline authors	Median, 172 (interquartile range, 83-402)

^aCountry of society or organization producing or housing target guidelines.

^bOne guideline each in dermatology, endocrinology, family medicine, interventional specialties, pain medicine, respiratory, and urology.

from more than one country. The studies evaluated a total of 14,764 guideline authors. The number of authors included in each study ranged from 6 to 2495. General characteristics of studies are summarized in Table 1, with study level characteristics available in Table 2.

Identification of Conflicts of Interest

Nineteen studies relied on author declarations of FCOI, either through surveys sent to the authors^{36,41} or through the declaration section of included guidelines or the sponsoring society of the guideline.^{10-16,24,29,31,32,34,37-40,43}

Eleven studies evaluated conflict of interest using the CMS-OP or other national databases.^{8,9,17,18,25-27,30,33,44,45}

Seven studies evaluated conflicts of interest through external searches.^{20-23,28,35,42}

Four of these studies searched through

guideline authors' academic publications in which financial ties with industry were disclosed, US Patent and Trademark Office records that signaled patents pending or awarded for intellectual property in a drug or device whose sales could be affected by guideline recommendations, and disclosures made at peer-reviewed conferences.^{20-22,28}

One study used disclosures from pharmaceutical companies regarding payments made to physicians to identify FCOI.²³ Another report identified guideline authors' FCOI by using Google's search engine, combining each author's name with the name of pharmaceutical companies that produced drugs affected by the guideline and looking through the first 50 search results for reported financial relationships.³⁵ The other study using an external source reviewed FCOI disclosures in guideline authors' academic publications related to the topic of the guideline and in the same time of guideline development.⁴²

Of the 18 studies that used either national databases or external sources, 10 also collected FCOI data from the declaration section of guidelines with the aim of identifying FCOI that were not disclosed by authors.^{8,9,19-22,25,27,35,42}

Prevalence of Conflicts of Interest

Of the 14,764 total authors included in the 37 studies, 45% (n = 6589) had at least one financial conflict of interest. The prevalence of FCOI ranged from 6%⁴⁰ to 100%.²⁰ In total, 22 studies provided data on general payments with a prevalence of 39% (3312/8469). Twenty-one studies provided data on research payments with a prevalence of 29% (1516/5295).

In comparing FCOI prevalence based on method of data collection (ie, author declarations, national databases, external searches), studies that used national databases had the highest prevalence of total payments (53% of authors [1720/3276]). Detailed data prevalence stratified by FCOI identification method is provided in Table 3.

Authors of oncology, neurology, and gastroenterology guidelines had higher FCOI prevalence compared with other medicine subspecialties (Figure 2).

Nine studies included data on monetary value in US dollars. Four studies reported

TABLE 2. Study Characteristics

Study	Year published	Clinical area	Country	Data collection method	No. of included authors
Akl et al ¹¹	2014	Respirology	United States	Author declaration	104
Alhamoud et al ²³	2016	Cardiology	United States	External sources	537
Allan et al ³⁹	2015	Family medicine	Canada	Author declaration	2495
Andreatos et al ⁹	2017	General	United States	National database	1329
Bindslev et al ²⁴	2013	General	Denmark	Author declaration	254
Carlisle et al ²⁵	2018	Urology	United States	National database	54
Checketts et al ²⁷	2017	Dermatology	United States	National database	49
Checketts et al ²⁶	2018	Orthopedic surgery	United States	National database	106
Choudhry et al ⁴¹	2002	General	>1 country	Author declaration	100
Combs et al ³³	2018	Gastroenterology	United States	National database	83
Cosgrove et al ²⁸	2006	Psychiatry	United States	External sources	170
Cosgrove et al ²¹	2009	Psychiatry	United States	External sources	20
Cosgrove et al ²⁰	2013	Psychiatry	United States	External sources	6
Cosgrove et al ²²	2017	Psychiatry	United States	External sources	172
Feuerstein et al ¹²	2013	Gastroenterology	>1 country	Author declaration	113
Feuerstein et al ¹³	2013	Gastroenterology	United States	Author declaration	83
Feuerstein et al ¹⁴	2016	Gastroenterology	>1 country	Author declaration	47
Feuerstein et al ¹⁵	2016	Orthopedic surgery	>1 country	Author declaration	80
Feuerstein et al ¹⁶	2014	Subspecialty interventional fields	United States	Author declaration	697
Grindal et al ¹⁰	2018	Gastroenterology	>1 country	Author declaration	173
Hauser et al ³⁷	2017	Pain medicine	Germany	Author declaration	42
Holloway et al ³⁶	2008	Neurology	United States	Author declaration	351
Jefferson and Pearson ⁴²	2017	Cardiology, gastroenterology	United States	External sources	45
Khan et al ⁸	2018	General	>1 country	National database	160
Langer et al ³⁴	2012	General	Germany	Author declaration	1379
Liu et al ¹⁷	2019	Oncology	United States	National database	542
Mendelson et al ²⁹	2011	Cardiology	United States	Author declaration	651
Mitchell et al ³⁰	2016	Oncology	United States	National database	125
Moynihan et al ¹⁹	2019	General	Australia	National database	402
Neuman et al ³⁵	2011	Cardiology, endocrinology	>1 country	External sources	288
Nifaratos and Pescatore ¹⁸	2019	Neurology	United States	National database	76
Norris et al ³²	2013	Endocrinology	United States	Author declaration	192
Norris et al ³¹	2012	General	United States	Author declaration	731
Papanikolaou et al ⁴⁰	2001	General	>1 country	Author declaration	242
Saito et al ⁴⁴	2019	Oncology	Japan	Author declaration	326
Schott et al ³⁸	2015	General	Germany	Author declaration	2190
Shnier et al ⁴³	2016	General	Canada	External sources	350

median payments per guideline author of \$578 (interquartile range, \$0-\$19,228),²⁵ \$1000 (\$0-\$39,938),³³ \$522 (\$0-\$40,444),⁸ and \$3233 (\$506-\$10,873).⁴⁴ Five studies reported

mean payments of \$67,547 (SD = \$125,751),²³ \$93,537 (\$415,203),²⁶ \$157,777 (\$332,829),²⁷ \$219,557 (no SD data provided),¹⁷ and \$242,300 (no SD data provided).³⁰

TABLE 3. Data Prevalence Stratified by FCOI Identification Method^{a,b}

Prevalence of FCOI	Method used to identify FCOI		
	Group 1 Guideline author declarations	Group 2 Open payment databases	Group 3 External sources
Total	43 (4439/10,250)	53 (1720/3276)	35 (430/1238)
General	32 (2222/6481)	75 (836/1112)	29 (254/876)
Research	29 (860/2938)	42 (465/1119)	15 (191/1238)
Undisclosed	—	37 (729/1936)	9 (46/495)

^aFCOI, financial conflicts of interest.

^bData are presented as percentage (number of authors with FCOI/total number of authors).

Undisclosed Conflicts of Interest

Ten studies included data on undisclosed FCOI for 2431 authors. In addition, 5 studies provided undisclosed payment data on general payments for 539 authors, and 4 reported on undisclosed research payments for 533 authors. The prevalence of FCOI was 32% (775/2431) for total undisclosed FCOI, 36% (195/539) for undisclosed general payments, and 24% (130/533) for undisclosed research payments.

Association Between Conflicts of Interest and Guideline Recommendations

As only 2 studies with heterogeneous methodology reported on an association between FCOI and guideline recommendations, we did not perform a meta-analysis. One study found that in a German clinical guideline committee, when authors with financial or academic conflicts of interest were excluded, there was a change in 1 of 6 evidence-based findings, 0 of 3 guideline consensus statements, and 2 of 23 evidence-based recommendations.³⁷ Another study reported that among National Comprehensive Cancer Network guidelines, there was no association between the prevalence of general or research payments among authors and the percentage of recommendations derived from low-level evidence per guideline.¹⁷

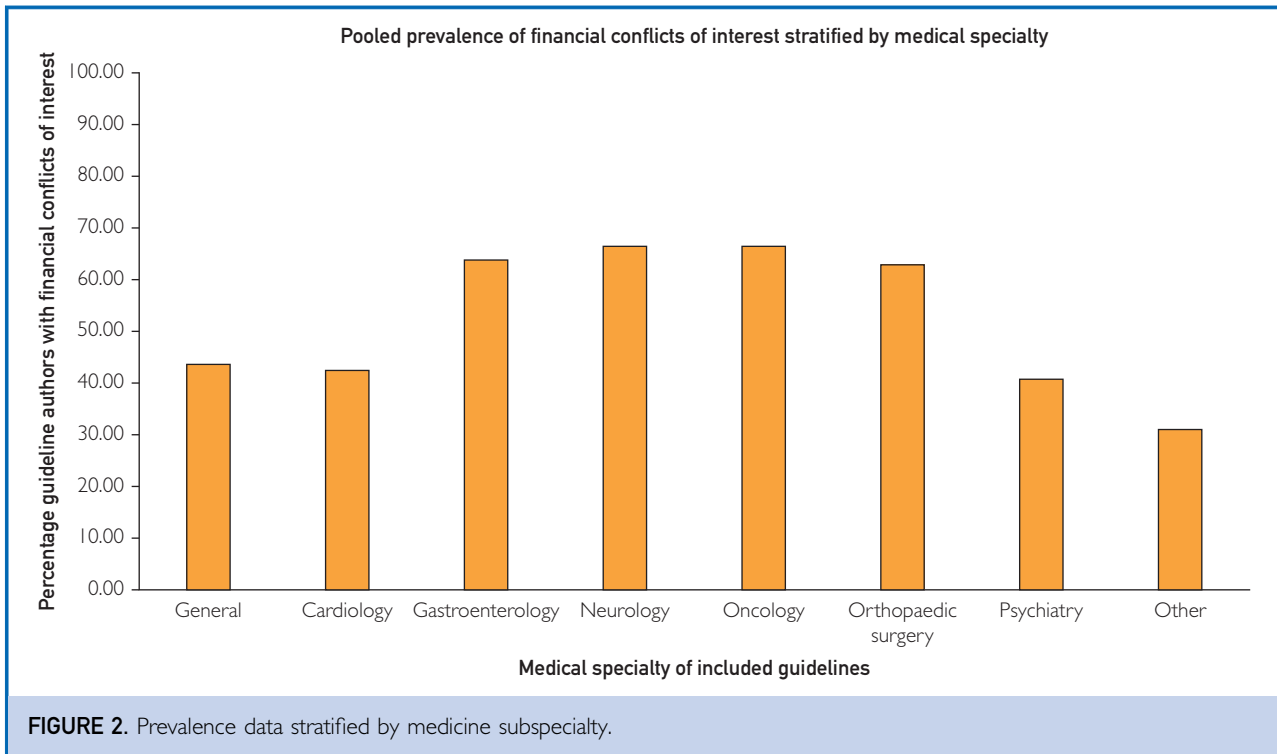
DISCUSSION

Among the 37 studies including 14,764 total guideline authors, 45% had at least one FCOI. In addition, more authors had FCOI involving general payments (39%) compared with research payments (29%). Authors involved in guidelines for oncology, neurology, and

gastroenterology had the highest prevalence of FCOI. Among the 8 studies that included the monetary values in US dollars of FCOI, average payments per author ranged from \$578 to \$242,300. Among the 10 studies that included data on undisclosed FCOI, 32% of authors had undisclosed industry payments.

There has been one previous systematic review examining FCOI among authors of CPGs.⁵ Our study has several strengths compared with this previous review. First, our updated review contains 23 new studies. Second, we performed independent dual data abstraction. This level of rigor is important for this review in particular as the data are heterogeneously collected, analyzed, and reported and thus prone to misinterpretation. Third, we considered differences between studies with respect to methodology and medical subspecialty. Finally, we systematically examined the reporting and prevalence of undisclosed conflicts of interest.

There may be several underlying reasons for the substantial variation in FCOI prevalence between the studies included in this review. The included studies used different data collection methods to identify FCOI. In general, they used 1 of 3 strategies: reporting through CPG author declarations, performing manual searches of external sources, or searching national payment databases for individual authors. Studies that used a national database had the highest prevalence of FCOI as this database lists payments as reported by pharmaceutical and medical device companies rather than by individual authors. A reliance on author declarations may underestimate the prevalence of FCOI as individuals may not recall all their financial interactions



with drug and device companies. In addition, small payments, such as meals, may not even be considered to be a payment by physicians despite evidence that they can influence behaviour.⁴⁶

Studies in certain specialties may be prone to identifying more payments as physicians in these specialties, such as gastroenterology, are more likely to receive industry payments.⁴⁷ Some studies also considered more types of payments compared with others. The studies that included general and research payments, for example, identified more total FCOI compared with studies that included general payments alone. These studies may overestimate the burden of FCOI by combining general and research payments and treating them as equally influential. Previous reports have suggested that research payments are not as likely as general payments to affect behavior.⁴⁸

Our results should be interpreted with caution because of several important limitations of the included studies. First, there was heterogeneity in the definitions of FCOI used and methodology to identify industry payments, which precludes quantitative analysis of the data. Many studies are also inherently

biased because of their descriptive study designs with no comparators. Furthermore, bias may be introduced in the included studies by guideline author declarations because of recall bias and the potential for omission of FCOI. Several studies used external search methods that have no evidence of validity to identify FCOI, such as a search of guideline authors' external publications. In addition, this review itself may be limited by a search of only one database, MEDLINE.

Nevertheless, these data suggest that there are numerous FCOI among authors of CPGs, many of which are undisclosed. Previous studies have shown that industry payments are associated with various outcomes favoring industry sponsors, including more positive findings in research, higher prescription volumes of certain companies' drugs, and poorer methodologic quality.⁴⁹⁻⁵¹ Institutions such as the National Academy of Medicine, World Health Organization, and National Health and Medical Research Council in Australia are increasingly recognizing the influence of for-profit entities on CPGs. For example, the World Health Organization and National Health and Medical Research Council have

published and implemented policies to ensure disclosure and management of FCOI among their panelists and expert committees.^{52,53} In addition, several countries have created databases to systematically track physicians' financial interactions with industry.^{54,55} Using these databases to identify FCOI as opposed to relying on author declarations may yield more accurate data on physician-industry relationships. Journals are also taking a more active role by using external sources to verify guideline authors' disclosed FCOI.⁴ Whereas the impact of these measures is not yet known, increasing efforts to mitigate FCOI may help curb the potential of undue industry influence on clinical guidelines.

CONCLUSION

There are numerous FCOI among authors of CPGs, many of which are undisclosed. We found that the method of assessing FCOI can have an impact on the prevalence. Using national databases populated by pharmaceutical company records may lead to a higher prevalence of FCOI, whereas relying on author declarations may underestimate conflicts. Future research should determine the accuracy and impact of different types of payments (eg, general, research) on authors' voting patterns during CPG development and explore the potential of undisclosed FCOI among guidelines. In addition, researchers should examine the impact of such measures as the implementation of National Academy of Medicine standards on the prevalence of FCOI among CPGs. Finally, additional research is required to quantify the implications of FCOI on clinical judgment and patient care.

SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at <http://mcpiqjournal.org>. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: CMS-OP = Centers for Medicare & Medicaid Services Open Payments; CPG = clinical practice guideline; FCOI = financial conflicts of interest

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