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Evaluation of Industry Relationships Among Authors of Otolaryngology Clinical Practice Guidelines

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IMPORTANCE Financial relationships between physicians and industry have influence on patient care. Therefore, organizations producing clinical practice guidelines (CPGs) must have policies limiting financial conflicts during guideline development.

OBJECTIVES To evaluate payments received by physician authors of otolaryngology CPGs, compare disclosure statements for accuracy, and investigate the extent to which the American Academy of Otolaryngology–Head and Neck Surgery complied with standards for guideline development from the Institute of Medicine (IOM).

DESIGN, SETTING, AND PARTICIPANTS This cross-sectional analysis retrieved CPGs from the American Academy of Otolaryngology–Head and Neck Surgery Foundation that were published or revised from January 1, 2013, through December 31, 2015, by 49 authors. Data were retrieved from December 1 through 31, 2016. Industry payments received by authors were extracted using the Centers for Medicare & Medicaid Services Open Payments database. The values and types of these payments were then evaluated and used to determine whether self-reported disclosure statements were accurate and whether guidelines adhered to applicable IOM standards.

MAIN OUTCOMES AND MEASURES The monetary amounts and types of payments received by physicians who author otolaryngology guidelines and the accuracy of disclosure statements.

RESULTS Of the 49 physicians in this sample, 39 (80%) received an industry payment. Twenty-one authors (43%) accepted more than $1000; 12 (24%), more than $10 000; 7 (14%), more than $50 000; and 2 (4%), more than $100 000. Mean (SD) financial payments amounted to $18 431 ($53 459) per physician. Total reimbursement for all authors was $995 282. Disclosure statements disagreed with the Open Payments database for 3 authors, amounting to approximately $20 000 among them. Of the 3 IOM standards assessed, only 1 was consistently enforced.

CONCLUSIONS AND RELEVANCE Some CPG authors failed to fully disclose all financial conflicts of interest, and most guideline development panels and chairpersons had conflicts. In addition, adherence to IOM standards for guideline development was lacking. This study is relevant to CPG panels authoring recommendations, physicians implementing CPGs to guide patient care, and the organizations establishing policies for guideline development.

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Relationships between clinicians and the pharmaceutical and device industries are prevalent. One nationwide study[1] published in 2017 examined the extent of these relationships and found that, in 1 year, 48% of physicians accepted $2.4 billion in industry-related payments. Although, in some cases, these relationships may lead to improved patient care,[2-4] research suggests that they also foster opportunities for significant financial conflicts of interest (FCOIs). For example, physicians who accepted industry payments were twice as likely to prescribe particular brand name drugs,[4,5] and they may also assess clinical trials more favorably than physicians who did not accept such payments.[5] One study of more than 279 000 physicians across multiple specialties found that industry-sponsored meals, with a mean value of less than $20, were associated with increased rates of prescribing the brand name medication being promoted at significantly higher costs to Medicare beneficiaries.[4] In addition to these issues, FCOIs have the potential to influence development of clinical practice guidelines (CPGs).[6-11]

The Institute of Medicine (IOM) defines CPGs as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".[12(p4)] Clinical practice guidelines set a standard of patient care.[13,14] For this reason, ensuring the integrity of the CPG development process is essential. Because of the need for greater transparency,[15] the Physician Payment Sunshine Act[16] was enacted as part of the Affordable Care Act to provide the public with financial information about physician funding from drug and device companies through Open Payments (https://openpaymentsdata.cms.gov/). Guideline authors are often asked to fully disclose FCOIs; however, evidence suggests that full disclosure is rare.[6] One study examining these disclosure policies found that nearly 50% of CPGs from various specialties cataloged in the National Guideline Clearinghouse did not provide disclosure statements. In addition, nearly half of the CPGs containing disclosures listed authors with industry relationships, and 35% of these authors disclosed an FCOI directly associated with the guideline topic.[6] A similar study investigating professional organizations developing CPGs[17] found that more than half the organizations did not even have an FCOI disclosure policy related to CPGs. The Open Payments database reduces the reliance on authors to self-report FCOIs and supplies the means for an independent evaluation of the extent to which CPG authors have received payments that may compromise CPG development.

Initial research indicates that measures are being taken to reduce FCOIs in otolaryngology[18]; however, the extent of FCOIs pertaining to guideline authors is not as well understood. For example, a 2017 study[1] found that only 2.3% of otolaryngologists as a whole received more than $10 000 in general payments from industry, which is the lowest percentage across all surgical specialties besides obstetrics. Rathi et al[19] found that otolaryngologists received the least amount of nonresearch compensation from industry and had the most restricted ties to industry among all surgical specialties. Another study[18] reported that the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS/F) spent $450 000 to develop CPGs, with an individual guideline costing the foundation anywhere from $100 000 to $120 000. This expense is conservative, considering the IOM per guideline estimate of $200 000 to $800 000.[12] Although preliminary evidence suggests less influence of industry on otolaryngology compared with other surgical subspecialties, further research is needed to determine the nature of industry payments received by CPG authors and to better understand whether policies adopted by the AAO-HNS/F are being effectively implemented. This study will explore the value, frequency, and types of payments received by the authors of AAO-HNS/F CPGs to promote transparent development practices among CPG authors. We also compare disclosure forms from CPGs with Open Payments data to evaluate accuracy of CPG author disclosures. Finally, we apply relevant IOM standards for CPG development, to which the AAO-HNS/F subscribes, to the CPG panels to determine the extent to which these standards were enforced by the AAO-HNS/F.

Key Points

Question What is the extent of potential financial conflicts of interest among physicians who author otolaryngology clinical practice guidelines?

Findings In this cross-sectional analysis of 49 authors of otolaryngology clinical practice guidelines, 39 received industry payments and 3 did not accurately disclose financial relationships. Of the 3 Institute of Medicine standards assessed, only 1 was being enforced.

Meaning Guideline authors received significant industry payments, and most panel members received payments from industry, which raises concern about potential financial conflicts of interest in the otolaryngology guideline development process.

Methods

We performed a cross-sectional analysis to examine the nature of industry payments made to physicians who author otolaryngology CPGs. In developing the methods for this study, we consulted Mitchell et al.[5] This study did not meet the regulatory definition of human subject research as defined in 45 CFR 46.102(d) and (f) of the Department of Health and Human Services[20] and was not subject to institutional review board oversight or the need for informed consent.

One of us (J.X.C.) searched for CPGs from December 1 through 31, 2016, using the AAO-HNS/F website[21] and Agency for Healthcare Research and Quality's National Guideline Clearinghouse.[22] Inclusion criteria required otolaryngology CPGs to be published or revised from January 1, 2013, through December 31, 2016. Also, the CPG needed a list of contributing physicians who were involved with guideline development. The CPGs produced in the United States were included because only physicians practicing in the United States are subject to the Open Payments provision. We used the time frame of 2013 to 2016 because 2013 was the first year that industry payment data were made available, with 2015 data being the

Table 1. Dates for CPG Development and Publication

CPG Title	Included CPG in Present Study	Guideline Work Group Timeline	Publication Date
Otitis Media With Effusion	Yes	Jan to Nov 2015	Feb 2016
Adult Sinusitis	Yes	Mar 2014 to Jan 2015	Apr 2015
Tinnitus	Yes	Nov 2012 to Nov 2013	Oct 2014
Allergic Rhinitis	Yes	Mar 2013 to Mar 2014	Feb 2015
Acute Otitis Externa	Yes	Oct 2012 to Nov 2013	Feb 2014
Evaluation of Neck Mass in Adults	No	Aug 2015 to Aug 2016	Sep 2017
Benign Paroxysmal Positional Vertigo	No	Sep 2015 to Nov 2016	Mar 2017
Cerumen Impaction	No	Apr 2015 to Jun 2016	Jan 2017
Improving Nasal Form and Function After Rhinoplasty	No	Apr 2015 to Aug 2016	Feb 2017
Bell's Palsy	No	Apr 2012 to Feb 2013	Nov 2013
Tympanostomy Tubes in Children	No	Sep 2011 to Sep 2012	Jul 2013
Improving Voice Outcomes after Thyroid Surgery	No	Nov 2011 to Nov 2012	Jun 2013
Sudden Hearing Loss	No	Jul 2010 to Jul 2011	Mar 2012
Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children	No	Nov 2009 to Sep 2010	Jul 2011

Abbreviation: CPG, clinical practice guideline.

most current. For each guideline, we located dates listed for guideline development. According to the AAO-HNS/F financial and intellectual relationship disclosure policy,[23] panel members are required to disclose all conflicts for the previous 3 years. The AAO-HNS/F's code for interactions with companies[24] requires authors to remain conflict free for at least 1 year after publication. The IOM also recommends authors avoid FCOIs in the year after publication.[12] The AAO-HNS/F's code also requires working group members to abstain from speaking about the guideline on behalf of an affected company for 1 year. All collected data fell within this 4-year window recommended by the AAO-HNS/F's Financial and Intellectual Relationship Disclosure Policy, the CPG code, and the IOM standards. The guideline working group timelines and CPG publication dates are listed in **Table 1**.

Guideline authors were identified within each CPG. Physicians' names and affiliations (private or academic) were extracted and copied into an Excel spreadsheet (Microsoft Corp) by one of us (J.X.C.). Names were alphabetized by last name, and duplicates were removed.

One of us (J.X.C.) extracted data by manually entering the physician's first and last name into the Open Payments search engine. In the event of duplication due to common names, authors were confirmed by using middle initials, company, or location. If the search returned no data or the physician name did not match information provided by Open Payments, the physician was considered to have received no industry payments.

After data extraction, each data element was reviewed for accuracy by another of us (J.H.) by reentering each physician's first and last names into Open Payments, selecting the correct physician from the search returns, and verifying payment data. Any discrepancies were flagged and resolved jointly between both investigators. We also entered the names of each author into Dollars for Docs,[25] which provides an accounting of the companies who contributed to individual authors.

Open Payment data are classified according to the following subcategories[26]:

1. General payments include consulting fees, speaking fees, honoraria, gifts, entertainment, food and beverage, travel and lodging, and education.
2. Research payments include payments associated with a research study, such as basic and applied research and product development.
3. Associated research payments include funding for a research project or study for which the physician is named as a principal investigator.
4. Ownership and investment interest in companies describe the actual dollar amount invested and the value of the ownership or investment interest. Records may have 1 or both values associated with them.

Subcategories of reimbursement were classified by year. Means and SDs were calculated by year and by subcategory of reimbursement, and the totals were calculated for each year and subcategory. All calculations were initially performed by one of us (J.X.C.) and independently verified by another of us (J.H.). Excel was used for all calculations.

We used the AAO-HNS/F CPG published disclosure statements for each author to evaluate whether the listed companies were consistent with the companies that reported physician payments. One of us (J.H.) extracted the authors' names, disclosure date, and FCOI information, which included the company's name and conflict type (eg, royalties, research, and consultancy). The investigator next searched author's name in the Open Payments database and recorded payment information. Payment dates were compared with the date of the author's disclosure statement. Only payments received before the disclosure date were included. Food and beverage were not considered to be discrepancies because the AAO-HNS/F CPGs did not include them as an FCOI category.

Last, we evaluated the extent to which the AAO-HNS/F enforced the standards in the IOM's *Clinical Practice Guidelines*

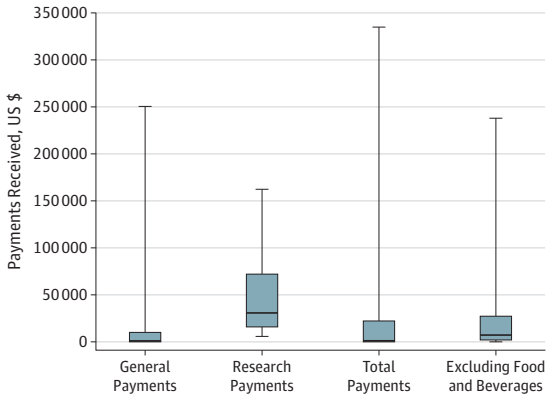
Table 2. Physician Payments by CPG Title

CPG Title (Total No. of Authors per CPG)	No. (%) of Authors			Dates for Which Monetary Data Were Included
	Receiving Payment	Receiving ≥$1000	Receiving ≥$10 000	
Tinnitus (n = 16)	9 (56)	1 (6)	0	Jan 2013 to Dec 2015
Allergic Rhinitis (n = 16)	14 (88)	8 (50)	5 (31)	Jan 2013 to Dec 2015
Otitis Media With Effusion (n = 11)	8 (73)	4 (36)	1 (9)	Jan 2013 to Dec 2015
Adult Sinusitis (n = 9)	6 (66)	4 (44)	3 (33)	Jan 2013 to Dec 2015
Acute Otitis Externa (n = 7)	3 (43)	1 (14)	1 (14)	Jan 2013 to Dec 2015

Abbreviation: CPG, clinical practice guideline.

We Can Trust.[12] As of June 22, 2017, the AAO-HNS/F website stated that "AAO-HNS/F CPGs meet all of the IOM standards for developing a trustworthy clinical practice guideline."[21] Institute of Medicine standards 1 (establishing transparency) and 2 (management of conflict of interest), in particular 2.1 and 2.4, were relevant to this investigation. Standard 1.1 states, "the processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible."[21] Standard 2 is composed of 4 parts, but only 2 are evaluable. Standard 2.1 requires written disclosure of all current and planned interests and activities potentially resulting in an FCOI. Standard 2.4 requires members with an FCOI to be a minority of the guideline group and prohibits chairpersons or assistant chairpersons from having FCOIs. We used Open Payments (using the methods described above), the list of authors, and disclosure statements to evaluate whether these standards were enforced.

Figure 1. Payments Received by American Academy of Otolaryngology–Head and Neck Surgery Foundation Clinical Practice Guideline (CPG) Authors



Data are stratified by payment type. Medians are indicated by the horizontal lines within the boxes; interquartile ranges, box limits; and ranges, error bars.

Results

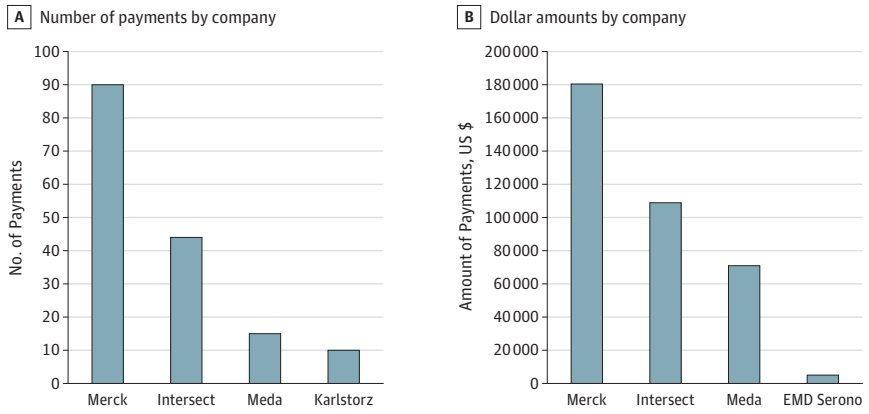
Five CPGs produced by the AAO-HNS/F met inclusion criteria, and 49 CPG authors were included in the final sample, some of whom served on multiple guidelines. Thirty-four authors were from academic institutions, and 15 were in private practice. All CPGs had a greater proportion of authors from academic institutions, including CPGs titled Otitis Media With Effusion (6 of 11 [55%]), Allergic Rhinitis (9 of 16 [56%]), Tinnitus (13 of 16 [81%]), Adult Sinusitis (6 of 9 [67%]), and Acute Otitis Externa (4 of 7 [57%]). Of these, 39 (80%) received at least 1 reported industry payment. Twenty-one CPG authors (43%) accepted more than $1000; 12 (24%), more than $10 000; 7 (14%), more than $50 000; and 2 (4%), more than $100 000. Jointly, the authors received a mean (SD) of $18 431.15 ($53 459) per author. After removing outliers, the adjusted mean for the sample was $7594. The median total of received industry payments was $227 (range, $0-$55 467.18). Total payment disbursed to the 49 physicians from 2013 to 2015 was $995 282.23. On each CPG panel, most authors received payment from industry, including panels for Allergic Rhinitis (14 of 16 [88%]), Otitis Media With Effusion (8 of 11 [73%]), Adult Sinusitis (6 of 9 [67%]), Acute Otitis Externa (4 of 7 [57%]), and Tinnitus (9 of 16 [56%]). Each CPG panel except that for Tinnitus contained at least 1 author accepting $10 000 or more from industry. Among these CPG panels containing authors accepting $10 000 or more, Allergic Rhinitis had 5 (31%), Adult Sinusitis had 3 (33%), Acute Otitis Externa had 1 (14%), and Otitis Media With Effusion had 1 (9%). **Table 2** lists CPG author payments by CPG title.

Figure 1 displays all payment data by category. For general payments, CPG authors who accepted payments received a mean (SD) of $11 910 ($43 024), with a median of $223 (interquartile range, $0-$3125.05). Thirty-six CPG authors (73%) received general payments totaling $643 182.50. Seven CPG authors (14%) received research payments, with a mean (SD) of $50 282 ($55 403) and a total of $351 975. No CPG authors had reported ownership interests.

We also ran a subanalysis for the general payments category, excluding authors who received only food and beverage payments. Furthermore, food and beverage payments were excluded in our analysis for authors receiving multiple types of payments (eg, honoraria, consulting fees, and speaking fees). After exclusions, 22 authors were included in the subanalysis, of whom 18 (82%) accepted more than $1000; 7 (32%), more than $10 000; 2 (9%), more than $50 000; and 1 (5%), more than $100 000. Jointly, the authors received a mean (SD) of $21 393 ($48 780). Total payments disbursed was $599 007.32. Figure 1 displays these data.

Our analysis using Dollars for Docs found that a few companies contributed most of the payments to the authors, including Merck & Co; Intersect ENT, Inc; Meda Pharmaceuticals, Inc; and Acclarent, Inc. Of the 22 authors with conflicts, 9 (41%) received payments from companies whose products directly relate to the guidelines. Four authors (18%) received

Figure 2. Amount of Payments Received by Guideline Authors



Bar graphs represent data for companies contributing payments to authors of the American Academy of Otolaryngology–Head and Neck Surgery Foundation Allergic Rhinitis guideline.

payments from Merck & Co totaling $180 437. All these payments were made to physicians authoring the Allergic Rhinitis CPG. This company manufactures several drugs that can be used to treat allergic rhinitis.[27] Intersect ENT, Inc, contributed $108 893 to 3 (14%) authors developing the Allergic Rhinitis CPG. Meda Pharmaceuticals, Inc, which manufactures several nasal sprays that can be used to treat allergic rhinitis,[28] made payments to 3 authors (14%) of the Allergic Rhinitis CPG totaling $74 464. Acclarent, Inc, which manufactures balloon dilation systems used for the treatment of otitis media,[29] contributed $21 700 to authors developing the Otitis Media With Effusion CPG. **Figure 2** displays the data for companies contributing payments to the authors of the Allergic Rhinitis CPG. Because the Otitis Media With Effusion and Adult Sinusitis CPGs included had 1 company with relevant contributions and the Tinnitus CPG had none, we did not include them in Figure 2.

Next, we evaluated the accuracy of self-reported disclosure statements by authors. Of the 49 disclosure statements, 3 (6%) were discrepant when compared with Open Payments data. Undisclosed amounts per authors ranged from approximately $1000 to $13 000.

Finally, we evaluated the extent to which the AAO-HNS/F enforced IOM standards 1, 2.1, and 2.4.[12] The AAO-HNS/F explicitly and publicly disclosed the funding source of each CPG; therefore, the CPGs were in compliance with standard 1. In accordance with standard 2.1, the AAO-HNS/F requires potential authors to disclose FCOIs and explain how FCOIs could affect CPG development; however (as described above), 3 of the 49 authors (6%) did not disclose FCOIs per IOM standard 2.1. Two authors disclosed some FCOIs but did not include every company from which they received payments as reported in Open Payments. One of these authors had nearly $13 000 in undisclosed payments. Another author did not disclose any FCOIs but received significant industry payments totaling $5198.72. The chairperson and most of the assistant chairpersons for each CPG were reported to have received industry payments; therefore, the guideline development group (GDG) for each guideline assessed was not in compliance with IOM standard 2.4. One guideline author and panel member received $3500 in consulting fees and almost $1700 in travel and lodging payments before the date of disclosure; however, the disclosure reported no FCOIs. Another author and panel member on a separate CPG received nearly $1000 for consulting and speaking fees. The other guideline chairpersons and authors accurately reported FCOIs and received no further industry payments during or immediately after guideline development. Seven of 8 chairpersons and assistant chairpersons (88%) received industry payments. Furthermore, another violation of standard 2.4 was found because members with FCOIs represented more than a minority of the GDG.

Discussion

We examined relationships among otolaryngology CPG authors and industry. Our findings demonstrate the following: (1) more than half of each guideline panel received payments from industry; (2) chairpersons had disclosed FCOIs; (3) disclosure statements did not correlate with Open Payments data; and (4) the AAO-HNS/F lacked compliance with IOM standards. Standards not met included members with FCOIs representing more than a minority of the GDG, chairpersons with FCOIs, and authors not properly disclosing financial relationships. Although the amount paid to the otolaryngologists by industry is not significant when compared with amounts paid to other surgical specialties, data suggest that even small payments and gifts can affect physician decision making.[1,4,30,31] For example, although only a few CPG authors received payments of a disproportionately large amount (only 7 authors [14%] accepted more than $50 000), we found that all 5 guidelines assessed had conflicted panel members, ranging from 56% to 88%. This finding is cause for concern, given that on average three quarters of the GDG voting members have FCOIs potentially affecting decision making. This practice is not in compliance with IOM standard 2.4. However, a lack of adherence is not limited to just our findings, because 1 study[17] found that across multiple specialties, none of the evaluated CPGs were in compliance with IOM standards. CPG development needs improvement, and because otolaryngology is among the specialties with the lowest monetary amounts of FCOIs,[1,19] the field is poised to be a leader in producing CPGs adherent to IOM standards.

We should note that GDGs contained nonphysician voting members, who were not included in the study. We found that

most CPG authors were affiliated with academic institutions. Although academics are more likely to be involved in research, their financial relationships with industry are well established.[32,33] One survey of medical school chairpersons[34] found that almost two-thirds of respondents had ties to industry, with 11% serving on a company board of directors. A similar study[35] from 2015 examined members of the boards of directors for health care companies who were associated with academics (leaders, professors, and trustees). The study showed that of the 442 companies examined, 41% had 1 or more academics as a director. These directors were associated with many prestigious institutions, including 19 of the top 20 National Institutes of Health–funded medical schools and all 17 US News honor roll hospitals. Total annual compensation for these academically associated directors was $54 995 786. The authors concluded that these relationships between industry and nonprofit educational institutions "pose personal, financial, and institutional conflicts of interest beyond that of simple consulting relationships."[35(p1)]

Several different methods for managing financial conflicts among industry and academia have been posited, including disclosure, institutional review, and prohibition of conflict. Although providing accessible information for the public to examine, conflict disclosure alone is not likely to mitigate competing interests that lead to bias. However, institutional review provides academic centers the ability to prohibit individuals from certain activities and decisions in which their competing interest may introduce bias. Many professional societies recommend this approach.[36,37] Pisano et al,[38] who include senior academic leaders and an unpaid board member of a health care company, recommend that leaders at academic institutions be prohibited from holding paid positions with health care companies unless the position is outside the scope of the academic role. Regulation and management of financial conflicts is no small task and will most likely be handled on a case-by-case basis.

Our study also found that for every guideline assessed, each CPG had conflicts in leadership in the chairperson, the assistant chairperson, or both. This finding reveals noncompliance with another tenet of IOM standard 2.4 and raises concern about the independence and transparency of these guidelines. Chairpersons are identified to lead the GDG, with responsibilities that include guiding panel discussions, selecting panel members, and delegating writing assignments.[39] If a GDG chairperson has FCOIs, industry influence could begin to take effect before the panel members are selected. For example, 1 study[40] found that for diabetes and hyperlipidemia alone, half of the guidelines assessed had chairpersons with FCOIs. Therefore, the authors concluded that industry has an influence on guideline recommendations. Furthermore, the AAO-HNS/F's *Clinical Practice Guideline Development Manual* states that each chair is selected by a panel that includes AAO-HNS/F leadership administration.[39] These findings suggest that the panel selecting the chairpersons did not abide by their own policy or the IOM standards in selecting chairpersons with disclosed FCOIs.

In addition to IOM standards, the AAO-HNS/F explicitly describes their FCOI policy in its Code for Interaction with Companies.[24] One key point of this policy requires disclosing all potential FCOIs of GDG members.[24] We found a total of 3 authors (6%) from different guidelines who had disclosures that were discrepant with Open Payments data. One of these authors failed to disclose any FCOI. Although this practice is not in compliance with IOM standards or the AAO-HNS/F's own FCOI policy, compared with all other specialties, this rate of nondisclosure is low. For example, Andreatos et al found that FCOI disclosure among panel members is relatively rare (approximately 10%), concluding that this finding "clearly indicates the need for heightened vigilance in the management and public reporting of potential FCOIs."[15(p5)] The AAO-HNS/F's disclosure policies and practices could become examples for other organizations developing CPGs.

Recommendations

Our findings suggest the need for improvements in FCOI policies among organizations developing CPGs. Evidence indicates that disclosure alone is not sufficient to mitigate panel member bias from influencing recommendations.[41,42] Neuman et al[40] suggest that reducing FCOIs of individual panel members will be more effective to mitigate bias than mere disclosure. We suggest enforcement of the AAO-HNS/F's policy limiting FCOIs to a minority (<50%) of panel members. The AAO-HNS/F might also consider identifying a monetary value that clearly defines what they consider to be an FCOI. For example, the American College of Radiology defines FCOI as "a compensation arrangement (eg, consulting fees, honoraria, and other payments for service) of at least $10 000.00 annually with any entity or individual with which ACR has a transaction or arrangement."[43(p2)] This definition would set clear standards for guideline authors potentially promoting adherence. Although the AAO-HNS/F requires authors to update disclosure information at least annually and when material changes occur,[24] the mechanism for authors to do so seems to be unclear. Implementing a clear mechanism for authors to update their disclosure after guideline publication is an opportunity for improving the guideline development process regarding transparency. Finally, we recommend that the AAO-HNS/F abide by their own policy as well as the IOM standards when selecting GDG chairpersons. We also recommend the addition of a medical ethicist to the review board who would evaluate the FCOI disclosure forms and could then inform the leadership administration which potential guideline members and chairpersons have relevant FCOIs. Implementing these practices would promote selection of a guideline panel that complies with IOM standards and the AAO-HNS/F's own policies.

Limitations

Limitations of this study include possible human error or inaccurate data from the Open Payments site. For example, multiple clinicians could have the same name, leading to potential inaccuracies during data extraction. Some physicians were not retrievable during searches, which could mean that the physician did not receive payments or that parties responsible for reporting payments failed to do so.[44] If the latter is the case, data will be misleading because no record of payment exists. In addition, Open Payments allots a 45-day period to dispute payments reported by the site. This process has proved to be inefficient. Fewer than 5% of physicians reviewed their data during the program's inaugural year[45,46]; therefore, possible errors were not likely to have been rectified. In addition, Open Payments only reports information from US-based physi-

cians; therefore, the generalizations of this study only pertain to the United States.

Conclusions

Authors of otolaryngology CPGs received payments from industry. Our study found that some CPG authors failed to fully disclose all FCOIs, and most guideline development panels and chairpersons were conflicted. We also found a lack of adherence to IOM standards for guideline development. We suggest changes in panel selection, chairperson selection, and the addition of an ethicist to the review board to promote strict compliance with IOM standards. The guideline development process needs to be rectified to ensure credibility of the guidelines produced.

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Study concept and design: All authors.
Acquisition, analysis, or interpretation of data: Horn, Checketts, Vassar.
Drafting of the manuscript: All authors.
Critical revision of the manuscript for important intellectual content: Horn, Checketts, Vassar.
Statistical analysis: Horn, Checketts.
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Invited Commentary

Payments, Conflict of Interest, and Trustworthy Otolaryngology Clinical Practice Guidelines

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Clinical practice guidelines (CPGs) are the cornerstone of the evidence-based practice of otolaryngology–head and neck surgery. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) CPGs are widely distributed, as judged by frequency of downloads, webpage views, and CPG-related sessions at national meetings. Clinical practice guidelines are developed to reduce variation in care and to improve quality. They create debate and even controversy, with concerns expressed about restraints on clinician decision making as well as the medicolegal implications of recommendations. Clinical practice guidelines must be trustworthy, and the Institute of Medicine (IOM) and the Guideline International Network have provided standards for CPGs.[1] A major threat to the creation of trustworthy guidelines is conflict of interest (COI) among the organizations and the committee members who create CPGs.

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Conflict of interest in CPGs has been identified for several decades in guidelines from many medical disciplines. A recent study[2] found that 60% of organizations that produce the CPGs found on the National Guideline Clearinghouse website received funds from a biomedical company, and 38% of guideline committee members had individual financial relationships. Conflict of interest in CPG development includes financial and intellectual conflicts. Financial COI has centered around direct payments and research support, but financial COI may also include professional conflict, by which guideline developers have clinical practices directly affected by the guideline recommendations.[3] Intellectual conflict has been defined by Guyatt et al[4(p739)] as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation." Financial COI is likely to be easier to identify and exclude from guideline development than intellectual COI.

In this issue of *JAMA Otolaryngology–Head & Neck Surgery*, Horn et al[5] used the Open Payments database to identify industry payments to physicians that represent potential COI among members of 5 recent AAO-HNS guideline development groups (GDGs). Thirty-nine of 49 physicians (80%) in these GDGs had received payments, and 12 (24%) had received payments totaling more than $10 000. Three physicians (6%) did not accurately disclose financial COI. Most of the GDG chairpersons for the 5 CPGs received an industry payment as documented in Open Payments. These findings contrast with a prior analysis looking at COI disclosure in AAO-HNS CPGs, in which only 28% of CPG authors self-reported an industry-related COI.[6] Horn et al[5] also used the Dollars for Docs website to identify the sources of financial payments to the AAO-HNS guideline authors. Nine of 22 authors (41%) with conflicts who had received payments (excluding food and beverage payments) received those funds from companies that made products directly related to their guideline topic.

These findings are not unique to otolaryngology CPGs. Checketts et al[7] used the same methodology as Horn et al in their recent report of even more frequent potential COI in dermatology, in which 82% of authors had received some payment, 51% had received more than $10 000, and 45% had inaccurate disclosure of COI. Andreatos et al[8] found that 523 of 1329 guideline authors (39.4%) identified from the National Guideline Clearinghouse website had received more than $5000 from at least 1 health care–associated entity based on Open Payments data. Only 10.7% of these 523 authors accurately disclosed COI.

The study by Horn et al[5] alerts us to include potential COI as part of our critical assessment of guideline recommendations. It is concerning that several AAO-HNS guideline authors received large payments from companies related to their guideline topic and even more troubling that disclosure of conflicts for a few was not accurate. However, the frequency and effect of relevant financial COI in AAO-HNS CPGs remains uncertain. Even if we assume