
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. A major threat to the creation of trustworthy guidelines is conflict of interest (COI) among the organizations and the committee members who create CPGs. Conflict of interest in CPGs has been identified for several decades in guidelines from many medical disciplines. A recent study 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. Intellectual conflict has been defined by Guyatt et al 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 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 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. Horn et al 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 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. Andreotas et al 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 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
the accuracy of the Open Payments database, the database does not show the relevance of reported financial payments to the subject of a given CPG. What does a small general payment on the Open Payments database really mean? It is concerning that 25% of the guideline committee members received more than $10,000 from industry but the median total financial payment to AAO-HNS guideline developers was $227. The AAO-HNS GDGs include nonphysician members who develop, write, and vote on the recommendations. These members, who are not in the Open Payments database, were excluded from the analysis in this study. Inclusion of these members or authors likely would reduce the percentage of committee members with conflict.

Clinical practice guidelines could be developed by a group with few members with potential COI, perhaps by using fewer academic physicians. Guideline development in otolaryngology is a volunteer task. Academic physicians are more likely than nonacademics to serve on GDGs, because guideline development and publication contribute to portfolios for academic advancement. The AAO-HNS recruits GDG members through recommendations of the topic-relevant committees and sections with a preponderance of academics. The need for content experts and clinicians familiar with the processes of literature assessment and guideline development further emphasizes the academic sector. However, academic physicians are also more likely to have intellectual and financial COI.

Guideline development groups should contain a variety of stakeholders, including clinicians who are the target audience, critical thinkers who can analyze the available evidence, content experts who are familiar with the evidence and the variations in clinical practice, and patient representatives. Chairpersons of GDGs should be without COI and have skills in gaining consensus in the GDG. Conflict of interest should be disclosed and managed throughout the process, although disclosure of financial COI may not identify intellectual conflicts. Future COI disclosure forms could be tailored to provide context to the CPG topic and, thus, provide more thorough disclosure and identification of COI. Disclosure of COI alone is insufficient. Conflicts of interest should be managed and likelihood of bias should be minimized by selecting guideline group leaders without COI, including methodologists without conflicts, minimizing the number of GDG members with conflict, and recusing conflicted members from discussion or votes on recommendations relevant to the specific conflict. Well-intentioned efforts to avoid COI should not eliminate the participation of stakeholders, because diverse stakeholders create a relevant guideline that truly integrates the best available evidence with clinical experience and patient preferences.

Development of AAO-HNS CPGs aims at compliance with IOM standards, but the findings by Horn et al emphasize the need to do more. Compliance with all 8 IOM standards for trustworthiness is unlikely for any CPG. The AAO-HNS CPGs are created using a well-defined, published process with methods to disclose, minimize, and manage COI. The CPG process is transparent. Guideline development groups composed of diverse stakeholders use high-quality systematic reviews as evidence to articulate actionable recommendations. Each guideline details evidence quality and recommendation strength, and the draft is reviewed by peers, the public, and journal reviewers before publication. The readers of AAO-HNS CPGs should not only look at the disclosures of the authors, but should also study the action statement profiles in which value judgements and any differences of opinions are detailed for each recommendation.

Open Payments, Dollars for Docs, and similar resources take COI disclosure beyond self-report. Our patients can and should assess bias in guideline recommendations. In An American Sick- ness: How Healthcare Became Big Business and How You Can Take It Back, Elisabeth Rosenthal, MD, warns, “The specialists who make money from procedures create the guidelines for when and how often they should be performed.” Even the appearance of bias in a high-quality guideline reduces acceptance and implementation. Although CPGs help clinicians “translate best evidence into best practice,” these guidelines serve our patients by leveling the asymmetry of knowledge between patients and clinicians. Our CPGs must be trusted by clinicians and patients as we balance the need for stakeholder participation with our goal to minimize COI.

REFERENCES