American Academy of Otolaryngology–Head and Neck Surgery Foundation Clinical Practice Guideline Development Process

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The recent article “Evaluation of Industry Relationships Among Authors of Otolaryngology Clinical Practice Guidelines,” by Horn et al.,¹ published in the January 2018 issue of *JAMA Otolaryngology–Head and Neck Surgery*, presents a simplistic and limited view of the creation and maintenance of clinical practice guidelines (CPGs). By focusing only on conflict of interest and related potential bias, the authors do a disservice to the process as a whole.

The American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) has developed CPGs for over a decade. It maintains a stringent policy to limit bias and unmanageable conflicts in all committee activities, including the CPG Task Force, and it is committed to enforcing its policies in this area. At the start of every meeting, all participants are asked to declare any new conflicts, financial and nonfinancial, that have occurred since the preceding meeting. Prior to the publication of this article, in September 2017, AAO-HNSF president Gavin Setzen, MD, charged the Ethics Committee to review the entire subject of conflict of interest and bias across the AAO-HNSF and to present a report to the Board of Directors. Dr Setzen also commissioned an Industry Relations Task Force to review the subject matter from that perspective.

The AAO-HNSF recognizes its responsibility to help define “quality” care for disease processes in which it has expertise. It is important to remember, however, that AAO-HNSF quality products (CPGs, clinical consensus statements, and position statements) are used by multiple specialists treating these patients. The development of these valuable products relies on both assessment of current literature and clinical expertise. By necessity, it is essential that conflicts be managed since they cannot be totally avoided. The AAO-HNSF does an excellent job of managing potential bias in its quality products and stands by them as valuable contributions to the practice of medicine. It is clear that there is not a process in existence that cannot be improved, and the AAO-HNSF is constantly striving to do so.

In 2006, the AAO-HNSF publicly presented its process with the publication of the CPG development manual.² Now in its third edition, the manual outlines a transparent process for CPG development, including the management of conflict of interest within the guideline development group (GDG) and the CPG leadership. The chair and GDG members must determine if the conflict of interest should result in a recusal from discussion, recusal from voting on any key action statement (or statements), or dismissal from the workgroup entirely. As cited in Dr Tunkel’s personal commentary “Payments, Conflict of Interest, and Trustworthy Otolaryngology Clinical Practice Guidelines,”³ the AAO-HNSF CPGs include narrative for each recommendation that clarifies differences of opinions expressed by the GDG members.

External organizations have recognized the reliability, validity, and transparency of the AAO-HNSF CPG development process. The AAO-HNSF CPG development manual was cited by the Institute of Medicine throughout its report on the development of trustworthy guidelines.⁴ CPGs developed by the AAO-HNSF also meet the criteria for inclusion in the Agency for Healthcare Research and Quality National Guideline Clearinghouse, which has posted to its website all published AAO-HNSF CPGs.⁵ The National Guideline Clearinghouse has performed a NEATS assessment (National Guideline Clearinghouse Extent Adherence to Trustworthy Standards) on 3 AAO-HNSF CPGs: cerumen impaction,⁶ benign paroxysmal positional vertigo,⁷ and rhinoplasty.⁸ The NEATS assessment includes an evaluation of the management of conflict of interest (Institute of Medicine standard 2.2), and all 3 CPGs are noted as

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excellent in its Agency for Healthcare Research and Quality guideline summary.

In their article, Horn et al reported that they “evaluated the accuracy of self-reported disclosure statements,” comparing the statements with open payments—the reporting of benefits >$10 to clinicians, their spouses, or their children. A 2016 analysis of the Open Payments program revealed that much of the compensation was for clinical expertise and consultation; approximately 2% of all reported payments related to ownership or investment. As identified by Horn et al, otolaryngologists fell in the low end of the payment spectrum overall and received the lowest payment overall for surgical specialties. Questions regarding the accuracy of the Open Payments data have been reported, with a 2014 estimate suggesting that ≥30% of data collected may be inaccurate.10,11 In a 2015 market research survey, almost one-third of physicians had no awareness of the Open Payments website, and of those who were aware, approximately 30% reported that they were incorrectly attributed payments.12

As pointed out by Dr Tunkel’s accompanying commentary, most experts associated with CPG development are likely to have intellectual and financial conflicts of interest. In addition, Horn et al failed to discuss that a good proportion of the literature utilized in the production of CPGs was initially written by authors with significant conflicts and that bias may exist in that foundational literature.1

Developing trustworthy guidelines takes a major commitment to quality and is extremely resource intensive. However, the AAO-HNSF realized over a decade ago that such contributions can have multiple benefits to not only our members but other clinicians who treat otolaryngic conditions. The AAO-HNSF process for managing the development, dissemination, implementation, and ongoing update of its CPGs has been recognized as best practice. As evident through these updates, the AAO-HNSF continues to assess and refine its processes, including the management of conflicts of interest in CPGs. The AAO-HNSF is committed to the development and dissemination of accurate, impactful, and unbiased CPGs that will provide best evidence for the delivery of quality care to patients with otolaryngic conditions.

**Author Contributions**

James C. Denneny III, author; Jean Brereton, author; Lisa Satterfield, author.

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**References**