

Systematic Analysis Underlying the Quality of the Scientific Evidence and Conflicts of Interest in Interventional Medicine Subspecialty Guidelines

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Abstract

Objective: To determine the validity of guidelines published by interventional medical societies.

Methods: We reviewed the interventional medicine subspecialty society websites of the American Association for Bronchology and Interventional Pulmonology (AABIP), American Society of Diagnostic and Interventional Nephrology (ASDIN), American Society for Gastrointestinal Endoscopy (ASGE), and Society for Cardiovascular Angiography and Interventions (SCAI) as of November 15, 2012, for published interventional guidelines. The study was performed between November 15, 2012, and January 1, 2013. The AABIP did not publish guidelines, so American Thoracic Society and American College of Chest Physicians guidelines were reviewed. All the guidelines were reviewed for graded levels of evidence, methods used to grade the evidence, and disclosures of conflicts of interest (COIs).

Results: Of 153 interventional guidelines evaluated, 4 were duplicates. Forty-six percent of guidelines (69 of 149) graded the quality of evidence using 7 different methods. The ASGE graded 71% of guidelines (46 of 65) compared with 29% (23 of 78) by the SCAI and 0 by the ASDIN (n=4) and the pulmonary societies (n=2). Of the 3425 recommendations reviewed, 11% (n=364) were supported by level A, 42% (n=1432) by level B, and 48% (n=1629) by level C. The mean age of the guidelines was 5.2 years. Additionally, 62% of the guidelines (92 of 149) failed to comment on COIs; when disclosed, 91% of guidelines (52 of 57) reported COIs. In total, 1827 COIs were reported by 45% of the authors (317 of 697), averaging 5.8 COIs per author.

Conclusion: Most of the interventional guidelines failed to grade the evidence. When present, most guidelines used lower-quality evidence. Furthermore, most guidelines failed to disclose COIs. When commented on, numerous COIs were present. Future guidelines should clearly state the quality of evidence, use a standard grading system, be transparent regarding potential biases, and provide frequent updates.

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For editorial
comment, see
page 5

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Since 1990, the Institute of Medicine (IOM) has published 2 primers to guide the practice guideline development process.^{1,2} The IOM defines a guideline as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”^{1(p.2)} Guidelines are meant to create a succinct roadmap for the diagnosis and treatment of medical conditions by analyzing and summarizing the increasingly abundant medical literature. These guidelines have an effect on physicians and clinical practice and are also used by government organizations, insurance companies, and malpractices attorneys.¹ Guidelines are used as a

means to establish a standard of care. This standard of care assumes that the guidelines are fundamentally sound and supply the framework for providing exceptional care. However, a guideline’s validity is rooted in its development process.^{3,4} Limitations occur when the evidence to support recommendations is lacking and recommendations are based solely on expert opinion. This becomes more worrisome when the authors have underlying conflicts of interest (COIs) that could bias recommendations.^{2,5-8} Furthermore, the cost and time required to develop and maintain guidelines may hinder their adequate updating, resulting in outdated recommendations.^{2,6}

Previous studies have reported that guidelines frequently base their recommendations on lower-quality evidence.⁹⁻¹¹ Similarly, a random sampling of guidelines on the National Guideline Clearinghouse found poor compliance with IOM standards.¹² Previous studies have also noted issues regarding COIs in practice guidelines, finding that most authors of the cardiology guidelines had multiple COIs.¹³

The primary goal of practice guidelines is to improve the safety and quality of care. One area that poses a relatively high risk of harm is procedures performed in internal medicine and its subspecialties. The medicine subspecialties of cardiology, gastroenterology, nephrology, and pulmonology all have interventional-specific societies. Many of these societies have developed intervention-specific guidelines to inform and standardize their society's procedure practices. Given the risks associated with interventional procedures, it is important that these guidelines are based on strong evidence.

We, therefore, performed a systematic review of medicine subspecialty interventional guidelines published on the professional websites of the American Society for Gastrointestinal Endoscopy (ASGE), the American Association of Bronchology and Interventional Pulmonology (AABIP), the American Society of Diagnostic and Interventional Nephrology (ASDIN), and the Society for Cardiovascular Angiography and Interventions (SCAI). The goal was to evaluate the quality of the evidence cited in formulating the recommendations, review the methods used to grade the evidence, assess potential COIs, and highlight opportunities for improvement.

METHODS

Guidelines

We reviewed the societal websites of the ASGE (<http://www.asge.org/publications/publications.aspx?id=352>), the AABIP (<http://www.aabronchology.org>), the SCAI (<http://www.scai.org/Publications/Guidelines.aspx>), and the ASDIN (<http://asdin.org/displaycommon.cfm?an=1&subarticlenbr=62>) as of November 15, 2012, for published interventional guidelines. The AABIP did not publish any interventional pulmonary guidelines. Therefore, the guidelines of the 2 main pulmonary societies, the American College of Chest Physicians (<http://journal.publications.chestnet.org/ss/guidelines.aspx>)

and the American Thoracic Society (<http://www.thoracic.org/statements>), were reviewed for any interventional-specific guidelines. The study was performed between November 15, 2012, and January 1, 2013. The websites were evaluated for interventional guidelines and if present were reviewed for grading of evidence.

Each guideline was reviewed to determine whether any grading system was used to assess the level of evidence for the recommendations. If a grading system was used, the level of evidence supporting the recommendations was evaluated. The layouts of the guidelines were assessed for consistency and easily identifiable recommendations. The age of the guidelines and any comments regarding planned updates to the current guidelines were also evaluated in the guideline document and on the societal website. The guidelines were examined individually, in aggregate by society, and between societies.

Levels of Evidence

The societies used multiple systems when grading the level of evidence. To standardize the reporting of the level of evidence, when possible, we merged the grading systems into the standard ABC grading system that has been used by multiple societies^{9,11}: grade A, randomized controlled trials/meta-analyses; grade B, single randomized controlled/nonrandomized trials; and grade C, expert opinion/case studies/standard of care. [Supplemental Table 1](#) (available online at <http://www.mayoclinicproceedings.org>) describes the methods used to standardize the grading systems.

Conflicts of Interest

All the guidelines were reviewed for any comments regarding COIs. We determined whether a disclosure was made noting COIs, a comment was made that no COIs were present, or there was no specific mention of COIs. If a COI was present, the guideline was further analyzed to calculate the number of authors with COIs, the number of COIs for the first author, and the number of COIs recorded per author. Conflicts of interest were subdivided into research awards/grants and others, including advisory board, speaker's bureau, consulting, industry-sponsored continuing medical education activities, and expert witnesses. Government and nonprofit-based research awards and volunteer

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