

## An Appraisal of the Current State of Gastroenterology Practice Guidelines

Over the past 2 decades, clinical practice guidelines have played an increasingly important role in the practice of medicine and in its regulation. During this time, the Institute of Medicine (IOM) has published 2 primers to guide the development process of practice guidelines.<sup>1,2</sup> A guideline, as defined by the IOM, is a “systemically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>1</sup> In most cases, guidelines are perceived as the standard of care and are utilized by physicians in patient care. However, they are also used by insurance and managed care organizations to determine appropriateness of services, level of coverage, and quality-of-care, by lawyers in malpractice cases, and most recently by medical organizations to establish quality metrics for cost-effective care. All of these applications assume that such guidelines are derived from high-quality and up-to-date evidence. However, if guidelines are not reviewed and revised frequently, they can become outdated and inaccurate. Furthermore, the validity of guidelines (perceived or actual) can be undermined by the presence of potential conflicts of interest which may bias recommendations.

Previous analyses of the cardiology, infectious disease, and hepatology practice guidelines have demonstrated that recommendations are frequently based on low quality evidence or expert opinion.<sup>3-5</sup> In these studies, 43.9%–55% of all the recommendations were based on Grade C evidence (expert opinion), while only 12%–22.4% of the recommendations were based on strong Grade A evidence (multiple randomized control trials/meta-analyses).<sup>3-5</sup>

When recommendations use lower-quality evidence, potential conflicts of interest (COI) may have a greater impact on the final recommendations.<sup>6,7</sup> A review of cardiology practice guideline authors found that 87% of the authors had relationships with industry.<sup>6</sup> Additionally, an international survey reviewing the guideline development process noted that 50% of the guideline-issuing bodies did not have any formal process in place to update their guidelines.<sup>8</sup>

Currently, many groups publish gastrointestinal-related guidelines. The 4 main United States gastroenterology and hepatology societies, American Association for the Study of Liver Diseases (AASLD), American Gastroenterological Association (AGA), American College of Gastroenterology (ACG), and the American Society for Gastroenterology Endoscopy (ASGE) all issue clinical practice guidelines. Collectively, these 4 groups have over 160 guidelines published on their respective societal websites,<sup>9-11</sup> freely available to help guide and standardize current practice.

The AASLD, AGA, ACG, and ASGE guidelines range in year of publication from 1996 to 2013. Many of the guidelines are either outdated and contain recommendations that are no longer consistent with current practice, or do not grade the level of evidence used to support their recommendations. When graded, much of the evidence supporting the

recommendations is based on lower quality of evidence. While there have been improvements in the use of evidence grading systems since 2007, multiple different grading methods have been used. By using different systems to grade the evidence, clinicians are forced to evaluate each guideline and understand the evidence grading method used in order to gauge the validity of a recommendation.

To minimize the issue of multiple evidence grading systems, all 4 societies have recently adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system as the standard method through which to assess the evidence and grade the recommendation (Table 1). The GRADE system was first developed in early 2000 and has been adopted by numerous organizations.<sup>12</sup> The GRADE system first assigns a rating to the evidence of high, moderate, low, or very low. The rating is based on the quality of evidence and the likelihood that future evidence may change current practice. The recommendations are then developed by guideline authors who ideally are different from those who graded the evidence. Recommendations are made by balancing the strength of the evidence, the potential outcomes, and patients’ values and preferences. A strong recommendation implies that the current evidence indicates the benefits outweigh the risks, while

**Table 1.** Grade System

Evidence	
High	Any future research is unlikely to change the current estimate of effect
Moderate	Future research is likely to have an impact on the current effect and may change the current estimate
Low	Future research is very likely to have an important impact on the estimate of effect and is likely to change the current estimate
Very Low	Any estimate of effect is very uncertain
Recommendation	
Strong Recommendation	Degree of certainty that the benefits do (or do not) outweigh the risks and burdens.
Weak Recommendation	Degree of certainty is unclear whether the benefits outweigh the risks, or significant uncertainty exists about the magnitude of benefits and risks.

a weak recommendation suggests that the benefits have not been shown to significantly outweigh potential risks. This system attempts to implement an unbiased method of converting the graded evidence into a recommendation. Furthermore, the GRADE system not only simplifies the interpretation of the strength of the recommendation, but it also highlights the areas in need of further research.

Thorough review of the literature and formation of the guideline recommendation process is time consuming and costly. Depending on the amount of literature reviewed, guidelines may take from months to years to develop. The estimated cost to develop a guideline is in the hundreds of thousands of dollars.<sup>2,13</sup> Unfortunately, at publication, some of the evidence evaluated in the guideline may already be outdated. Furthermore, clinical trials remain ongoing with new evidence being added to the literature regularly. Without active reviews and updates, guideline recommendations may quickly become outdated and inaccurate. A study by Shekelle et al in 2001 reviewed the 17 guidelines published by the US Agency for Healthcare Research and Quality (AHRQ) in the 1990s and found that 7 of the guidelines had new evidence necessitating a major update, 6 necessitated minor updates, 3 remained valid, and that for 1 guideline a conclusion could not be reached. After 3.6 years, 10% of the guidelines were no longer valid and after 5.8 years 50% of the guidelines were no longer valid.<sup>14</sup> Based on Shekelle's study, the American College of Physician withdraws all guidelines 5 years after publication or sooner if an updated guideline is developed.<sup>15</sup>

Outdated guidelines have the potential to cause harm. There are numerous examples of outdated gastroenterology guidelines that require updating. For instance, the ACG guideline published in 2001

on hepatic encephalopathy lacks mention of rifaximin.<sup>16</sup> Instead, following the outdated guideline, if a patient was not improving on lactulose, a clinician may opt for neomycin. Similarly, guidelines that are not appropriately updated may lack necessary recommendations like the ASGE guideline from 2009 regarding the management of antithrombotics prior to endoscopic procedures.<sup>17</sup> Since the publication of this guideline, an additional 3 antithrombotic agents (dabigatran etexilate, rivaroxaban, and apixaban) have all been approved.<sup>18</sup> These agents have different mechanisms of action than warfarin and a much shorter onset of action to therapeutic anticoagulation levels. Similarly, the AGA guideline on CT colonography from 2006<sup>19</sup> does not take into account the information from an additional 78 clinical studies regarding CT colonography published since 2006. As medical societies view practice guidelines as one of the key services they provide,<sup>20</sup> the guidelines must be up-to-date and consistent with current practice standards. Furthermore, since guidelines are used by insurance companies to determine levels of care and to formulate quality metrics to assess the quality of the physician's care, outdated guidelines carry multiple risks for patients, physicians, and healthcare organizations. Ideally, a yearly review process should be incorporated in the maintenance of any practice guideline. However, we recognize that this would be challenging for any review group. We would suggest that at least one member of the review panel monitor new literature related to the subject matter annually, and if appropriate, initiate a review process when it appears that new information might change strength of the recommendation. Any changes should be appropriately edited in the practice guideline and older versions removed from the website.

Given their potential impact on clinical practice, guidelines should ideally be based on strong quality evidence. Unfortunately, high-quality evidence is not always available. In these circumstances, recommendations are, by default, based on expert opinion or inferior studies. Instead of placing such recommendations in a practice guideline which may be used by insurance companies or malpractice attorneys, we suggest that recommendations based on weak evidence be formulated in a less strictly worded, "best practice recommendation statement." This would alert clinicians and payers to the fact that strong evidence is lacking and variation in clinical practice is acceptable. Without such stipulation, gastroenterologists may be held accountable for deviating from poorly supported practice guidelines, which are used as the gold standard for appropriate care, by both insurance companies to determine reimbursements and quality indicators, and by attorneys in medical litigation.<sup>21</sup> However, no clinician should be accused of deviating from the accepted standard of care when a weak recommendation is supported by low quality evidence (GRADE system) indicating that further research in the area is likely to significantly impact current practice. Furthermore, a best practice document would highlight areas devoid of evidence where studies are needed to better develop recommendations. Similar to a practice guideline, a thorough review of the literature and timely updates to the document after publication is necessary. Separating out recommendations based on inferior levels of evidence would reinforce the validity of practice guidelines.

Potential COI may also play a role in how practice guidelines are created and received. Mendelson et al<sup>22</sup> noted that both the trust in practice guidelines and their value in setting the standard of care are diminished when guidelines authors have potential COI. Currently, many gastroenterology practice guidelines fail to

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