

The GRADE System for Rating Clinical Guidelines

Brian P. Kavanagh^{1,2,3*}

¹ Departments of Critical Care Medicine and Anesthesia, Hospital for Sick Children, Toronto, Canada, ² Program in Physiology and Experimental Medicine, The Research Institute, Hospital for Sick Children, Toronto, Canada, ³ Departments of Anesthesia, Medicine & Physiology, University of Toronto, Toronto, Canada

Introduction

Professional medical groups commonly issue clinical practice guidelines. Such guidelines are traditionally the result of consensus conferences or expert panels and represent attempts to synthesize—from the best available evidence and expertise—practical guidance on the best possible care. Beyond issuing a guideline, many organizations have felt the need to provide a grading of each guideline's quality, thereby conveying to the reader a sense of the confidence that might be placed in it. This article addresses only the grading of guidelines, not their use or development.

The idea that evidence in the medical literature should be graded was initially proposed in publications from McMaster University [1–3], with the idea of categorizing individual studies into grades of reliability ranging from randomized controlled trials (most reliable) to case reports with expert opinion (least reliable). Grading of guidelines followed, but this has been beset with problems. To give one example, a guideline by Ferraris and colleagues gave the use of aprotinin during high-risk cardiac surgery a “high-grade” recommendation [4], but this intervention was subsequently shown to increase mortality [5].

The pursuit of better approaches to grading guidelines has resulted in GRADE (Grades of Recommendation Assessment, Development and Evaluation), introduced in 2004 [6]. GRADE has been adopted “unchanged or with only minor modifications” by national and international professional medical societies, health-related branches of government, health care regulatory bodies, and UpToDate, an on-line medical resource that is accessed by trainees and physicians in most US academic medical centers (Box 1) [7,8].

The developers of the GRADE system emphasized consistency in the rating of

guidelines, as well as a wish to incorporate, and distinguish between, the “strength” of each guideline and the “quality” of the underlying studies (i.e., evidence) upon which it is based. Yet there is a central paradox: while GRADE has evolved through the evidence-based medicine movement, there is no evidence that GRADE itself is reliable.

Are Different Guidelines Externally Consistent?

GRADE is one of several different systems for grading clinical evidence and creating clinical practice guidelines based on this underlying evidence. How do these systems compare with each other?

Adkins and colleagues, from the GRADE Working Group, compared six different systems (Box 2) [9]. Twelve assessors independently evaluated each system on the basis of 12 criteria to assess the “sensitivity” (overall usefulness) of the different approaches. There was poor agreement between them. In the absence of a proven gold standard, such disagreement signals concern about the inherent validity of any of these grading systems. Commenting on this lack of agreement, the authors wrote that a new system—GRADE—could overcome the problems [9].

But the example of the Surviving Sepsis Campaign (SSC), an important attempt to produce guidelines to improve the care of patients with sepsis or septic shock, suggests that GRADE has not overcome these problems (see Boxes 3 and 4) [10–11]. The endorsement of the SSC by many influential organizations underscores its importance [10–11]. Nonetheless, the SSC illustrates some of the important difficulties with grading in

general and with the GRADE system in particular. There are three reasons why I focus here on the SSC. First, sepsis encompasses all medical and surgical specialties, accounts for over 500,000 emergency visits per year in North America alone [12], and when accompanied by shock has a mortality of over 50% [13]. Second, the SSC may have significant impact: some believe that incorporating the SSC guidelines could save up to 100,000 lives in an 18-mo interval [14]. Third, the SSC is the best known source of advice on managing sepsis and all of its recommendations carry a grading. Finally, because the SSC published two documents 4 y apart (in 2004 and 2008 [10–11]), it presents a unique opportunity to compare interval changes. I focus only on grading (Boxes 3 and 4), not on the controversies surrounding the SSC [15], and I do not express support for—or criticism of—any of its recommendations.

Is GRADE Internally Consistent?

Inter-rater agreement of GRADE. In 2005, the GRADE working group—all experts who themselves developed the GRADE system—published a pilot study of the system [16]. The study found that the kappa value (i.e., the inter-rater agreement beyond chance) for 12 judgments about the quality of evidence was very low (mean $\kappa = 0.27$; $\kappa < 0$ for four judgments). The authors stated that “with discussion” they were able to considerably improve their system, but provided no supportive data. Furthermore, the presentation of GRADE that had been published a year earlier in 2004 contains neither assessment of reliability, agreement, nor proof of usefulness [6].

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* E-mail: brian.kavanagh@sickkids.ca

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