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GRADE guidelines: 1. Introduction—GRADE evidence profiles and summary of findings tables

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Abstract

This article is the first of a series providing guidance for use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of rating quality of evidence and grading strength of recommendations in systematic reviews, health technology assessments (HTAs), and clinical practice guidelines addressing alternative management options. The GRADE process begins with asking an explicit question, including specification of all important outcomes. After the evidence is collected and summarized, GRADE provides explicit criteria for rating the quality of evidence that include study design, risk of bias, imprecision, inconsistency, indirectness, and magnitude of effect.

Recommendations are characterized as strong or weak (alternative terms conditional or discretionary) according to the quality of the supporting evidence and the balance between desirable and undesirable consequences of the alternative management options. GRADE suggests summarizing evidence in succinct, transparent, and informative summary of findings tables that show the quality of evidence and the magnitude of relative and absolute effects for each important outcome and/or as evidence profiles that provide, in addition, detailed information about the reason for the quality of evidence rating.

Subsequent articles in this series will address GRADE's approach to formulating questions, assessing quality of evidence, and developing recommendations.

Keywords: GRADE; systematic reviews; clinical practice guidelines; health technology assessment; quality of evidence; strength of recommendations

1. Introduction

In this, the first of a series of articles describing the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to rating quality of evidence and grading strength of recommendations, we will briefly summarize what GRADE is, provide an overview of the GRADE process of developing recommendations, and present the endpoint of the GRADE evidence summary: the evidence profile (EP) and the summary of findings

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system has been developed by the GRADE Working Group. The named authors drafted and revised this article. A complete list of contributors to this series can be found on the *Journal of clinical Epidemiology* website.

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Key Points

- Grading of Recommendations Assessment, Development, and Evaluation (GRADE) offers a transparent and structured process for developing and presenting summaries of evidence, including its quality, for systematic reviews and recommendations in health care.
- GRADE provides guideline developers with a comprehensive and transparent framework for carrying out the steps involved in developing recommendations.
- GRADE's use is appropriate and helpful irrespective of the quality of the evidence: whether high or very low.
- Although the GRADE system makes judgments about quality of evidence and strength of recommendations in a systematic and transparent manner, it does not eliminate the inevitable need for judgments.

(SoFs) table. We will provide our perspective on GRADE's limitations and present our plan for this series.

2. What is GRADE?

GRADE offers a system for rating quality of evidence in systematic reviews and guidelines and grading strength of recommendations in guidelines. The system is designed for reviews and guidelines that examine alternative management strategies or interventions, which may include no intervention or current best management. In developing GRADE, we have considered a wide range of clinical questions, including diagnosis, screening, prevention, and therapy. Most of the examples in this series are clinical examples. The GRADE system can, however, also be applied to public health and health systems questions.

GRADE is much more than a rating system. It offers a transparent and structured process for developing and presenting evidence summaries for systematic reviews and guidelines in health care and for carrying out the steps involved in developing recommendations. GRADE specifies an approach to framing questions, choosing outcomes of interest and rating their importance, evaluating the evidence, and incorporating evidence with considerations of values and preferences of patients and society to arrive at recommendations. Furthermore, it provides clinicians and patients with a guide to using those recommendations in clinical practice and policy makers with a guide to their use in health policy.

A common definition of guidelines refers to ''systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'' [1]. This series will describe GRADE's comprehensive approach to guideline development and to other similar guidance documents.

The optimal application of the GRADE approach requires systematic reviews of the impact of alternative management approaches on all patient-important outcomes. In the future, as specialty societies (e.g., American College of Physicians), national guideline developers and HTA agencies (e.g., National Institute for Health and Clinical Excellence), publishers (e.g., BMJ), publications (e.g., UpToDate), and international organizations (e.g., World Health Organization, Cochrane Collaboration) pool resources, high-quality evidence summaries will become increasingly available. As a result, even guideline panels with limited resources charged with generating recommendations for local consumption will be able to use GRADE to produce high-quality guidelines [2].

3. Purpose of this series

This series of articles about GRADE is most useful for three groups: authors of systematic reviews, groups conducting HTAs, and guideline developers. GRADE suggests somewhat different approaches for rating the quality of evidence for systematic reviews and for guidelines. HTA practitioners, depending on their mandate, can decide which approach is more suitable for their goals.

The GRADE approach is applicable irrespective of whether the quality of the relevant evidence is high or very low. Thus, all those who contribute to systematic reviews and HTA, or who participate in guideline panels, are likely to find this series informative. Consumers—and critics—of reviews and guidelines who desire an in-depth understanding of the evidence and recommendations they are using will also find the series of interest.

The series will provide a ''how to'' guide through the process of producing systematic reviews and guidelines, using examples to illustrate the concepts. We will not start with a broad overview of GRADE but rather assume that readers are familiar with the basics. Those who are not familiar may want to begin by reading a brief summary of the approach [3]. Those who want to start with a more detailed overview should examine all the articles in a previously published series describing the GRADE approach [4–9]. Finally, a computer program (GRADEpro) [10] and associated help file [11] that facilitate the development of EPs and SoFs tables provide a complement to this series.

4. The GRADE process—defining the question and collecting evidence

Figure 1 presents a schematic view of GRADE's process for developing recommendations in which unshaded boxes describe steps in the process common to systematic reviews