

# Methodology for Antithrombotic and Thrombolytic Therapy Guideline Development\*

## American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition)

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The American College of Chest Physicians (ACCP) invited a panel of experts, researchers, information scientists, and guideline methodologists to develop the eighth edition of ACCP evidence-based guidelines on antithrombotic and thrombolytic therapy. The process began with guideline authors specifying the population, intervention and alternative, and outcomes for each clinical question and defined criteria for eligible articles, including methodologic criteria, for each recommendation. The McMaster University Evidence-Based Practice Center, in collaboration with the guideline authors and methodologists, developed strategies and executed systematic searches for evidence. The resulting guidelines are organized in chapters that present a clear link between the evidence and the resulting recommendations. The panel identified questions in which resource allocation issues were particularly important and obtained input from consultants with expertise in economic analysis for these issues. Authors paid careful attention to the quality of underlying evidence and the balance between risks and benefits, both reflected in grades of recommendations. For recommendations that are particularly sensitive to underlying values and preferences, the panel made explicit the values underlying the recommendations. Thus, the process of making recommendations for the ACCP guidelines included explicit definition of questions, transparent eligibility criteria for including studies, comprehensive searches and methodologic assessment of studies, and specification of values and preferences and resource implications underlying recommendations where particularly relevant. In combination with our previous practice of grading recommendations according to their strength and the methodologic quality of the supporting studies, these methods establish our guideline methodology as evidence based. (CHEST 2008; 133:113S–122S)

**Key words:** evidence-based medicine; grade; guideline development; guidelines; quality of evidence; recommendations

**Abbreviations:** ACCP = American College of Chest Physicians; EPC = evidence-based practice center; HSP = Health Science Policy; LMWH = low-molecular-weight heparin; RCT = randomized controlled trial; tPA = tissue plasminogen activator

The methodology for the Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition) built on the innovations of prior conferences. As with other iterations, the changing evidence base in the field of antithrombotic and thrombolytic research led to many updated and new recommendations. To further improve the quality of these guidelines, we have made additional

changes to the methodology. Evidence-based approaches to guideline development include acknowledgment of factors other than evidence that inevitably influence recommendations—values and preferences. For the first time, we involved consultants whose role was to focus on patient value and preference issues. We also implemented recommendations of a recent American College of Chest Physicians (ACCP) task force on integrating resource allocation in guideline develop-

ment by restricting resource expenditure consideration to a small number of recommendations for which they were particularly relevant.<sup>1</sup> To accomplish this task, we involved experts in economic analysis in developing these recommendations.<sup>1,2</sup> In addition, for this iteration of the guidelines, we collaborated with the McMaster University Evidence-Based Practice Center (EPC) [Hamilton, ON, Canada], one of the 13 North American EPCs.

To maintain transparency of the guideline development, we followed explicit rules for managing conflicts of interest. Before participating on the panel, all participants submitted conflict-of-interest statements that were reviewed by the ACCP Health Science and Policy (HSP) Committee. Participants' potential conflicts are listed prominently in the front section of the guideline document.<sup>3</sup> The panelists updated their conflict-of-interest disclosures again before the final conference and before publication. These disclosures are published with the guidelines and posted on the *CHEST* journal Web site ([www.chestjournal.org](http://www.chestjournal.org)).

The development of evidence-based guidelines includes explicitly defining the question that the guideline or recommendation is addressing; formulating eligibility criteria for evidence to be considered; conducting a comprehensive search for evidence; evaluating study quality; summarizing the studies; balancing the benefits and downsides of the alternative management strategies; and, finally, acknowledging values and preferences underlying the recommendations, including considerations on expenditures.<sup>4-6</sup> This process ends with a recommendation for action and a grading of that recommendation according to the balance of desirable effects (benefits), undesirable effects (harms, burden, and resource expenditures), and the quality of the evidence. We followed the methodology for grading the quality of evidence and strength of recommendations that the ACCP codified during a recent ACCP task force meeting. The grading system adopted was a modification from that developed by the Grading

of Recommendations Assessment, Development and Evaluation Working Group.<sup>7-9</sup> This article describes the methodology for guideline development for the *Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition)*. Figure 1 summarizes this process.

## GUIDELINE DEVELOPMENT FOR THE EIGHTH ACCP CONFERENCE ON ANTITHROMBOTIC AND THROMBOLYTIC THERAPY

### *Panel Selection Process*

The criteria for panel selection were an established track record in the relevant clinical or research area, international and gender representation, prior involvement with the ACCP Conference on Antithrombotic and Thrombolytic Therapy, and absence of conflicts of interest that could not be resolved. The senior editors suggested individual chapter chairs as well as chapter members. Chapter chairs also made suggestions for the inclusion of chapter members. All panel members were approved by the ACCP HSP Committee after review of their curriculum vitae.

### *Defining the Clinical Question*

Developing a clinical practice guideline should begin with specifying a clinical question that defines the relevant population, alternative management strategies (comparison), and outcomes.<sup>10</sup> For the current ACCP guidelines, authors defined one question for each recommendation or set of recommendations. Readers can find these questions in the corresponding table of each chapter containing practice recommendations.

### *Presentation of Evidence and Recommendations*

To provide a transparent, explicit link among questions, evidence, and recommendations, the section numbering in each chapter corresponds to numbers in the corresponding table in the chapters, which specifies the patients, interventions, and outcomes; the section numbering also corresponds to the numbering of the recommendations themselves.

### *Process of Searching for Evidence*

Defining the clinical question provided the framework for formulating eligibility criteria that guided the search for relevant evidence. In specifying eligibility criteria, authors identified not only patients, interventions, and outcomes, but also methodologic criteria. For many recommendations, authors re-

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