

# Methodologists and context experts disagreed regarding managing conflicts of interest of clinical practice guidelines panels

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## Abstract

**Objective:** A new strategy to manage conflicts of interests (COIs) of a clinical guideline's panelists gives primary responsibility to a methodologist, puts equal emphasis on intellectual and financial COIs, and excludes panelists with primary conflicts from drafting or voting on recommendations. We explored the views of the methodologists and content experts regarding the new strategy.

**Study Design and Setting:** Before the guidelines chapter panels initiated their work, we conducted semi-structured personal interviews with the methodologists and the lead content experts. We analyzed the data qualitatively.

**Results:** Twenty-four panelists participated. The methodologists thought that the new strategy increased their responsibility and authority. The lead content experts perceived their role label as unfair and reflecting a demotion. Whereas methodologists were concerned about potential conflicts with content experts, the lead content experts were uncomfortable with the “extra surveillance” by the methodologists. Whereas methodologists believed that the changes ensure more rigorous evidence-based guidelines, some lead content experts were worried that methodologists' lack of content expertise and content expert attrition could hurt the quality of the guidelines.

**Conclusions:** The methodologists and lead content experts were uneasy regarding their counterpart's role. They disagreed about the potential effect of the new strategy on the quality of the guideline. © 2012 Elsevier Inc. All rights reserved.

**Keywords:** Conflicts of interest; Practice guidelines; Quality; Content expert; Methodologist; Interview

## 1. Background

Up until now, most clinical practice guidelines have relied largely on content experts to generate recommendations [1]. Most of these experts have built their expertise through participating in and often leading the major studies that inform guidelines. Consequently, they are likely to be conflicted both financially and intellectually relative to recommendations they are asked to develop [2]. Although

most conflicted experts may develop recommendations consistent with an objective, dispassionate, and unencumbered view of the evidence, some may not [3]. As a result reliance on conflicted experts threatens guideline quality and credibility [4].

Critics have expressed skepticism about current approaches to dealing with conflict of interest (COI) in guideline development, which rely mainly on declaration of financial ties [1,4–6]. In a recent report, the Institute of Medicine (IOM) recommended the general exclusion of individuals with COI from guideline panels [7]. However, others have argued that unique insights into clinical context and evidence that only experts can offer mandate their participation [8].

The executive committee of the American College of Chest Physicians (ACCP) ninth edition of the Antithrombotic guidelines (AT9) has developed a strategy designed to use experts' experience and insight while ensuring that financial and intellectual conflicts do not influence recommendations [8]. The three main elements of the strategy

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**What is new?****Key finding:**

- A new strategy to manage conflicts of interests (COIs) of a clinical guideline's panelists and giving primary responsibility to methodologists made the content experts discontent with the change in power structure.

**What this adds to what was known?**

- Whereas methodologists believed that the strategy will ensure more rigorous evidence-based guidelines, content experts were worried that methodologists' lack of content expertise and content expert attrition could hurt the quality of the guidelines.

**Implications:**

- Professional organizations considering new COI strategies should be aware of the potential discontent and frustration of content experts from any shift of power.

are the following: (1) giving primary responsibility for each chapter to a methodologist; (2) placing equal emphasis on intellectual and financial conflict; (3) and allowing only panel members without important conflicts to be involved in the development of the recommendation. Please refer to **Box 1** for further details about AT9 structure and process, **Box 2** for the definitions of financial and intellectual COI, and **Box 3** for a detailed description of the strategy.

Understanding the reactions of methodologists and content experts to the new process is important to assess its acceptability and feasibility. The objective of this study was to compare the initial views of the chapter methodologists (called editors) and lead content experts (called deputy editors) participating in the ACCP AT guidelines regarding the elements of the new strategy.

## 2. Methods

### 2.1. Study design

The study consisted of semi-structured personal interviews with note taking, conducted either in person or over the phone. The interviewer (E.A.A.) structured the interview around the following issues: giving the primary responsibility for each chapter to a methodologist, emphasizing intellectual COI, and placing restrictions on panelists with primary conflicts. We completed data collection in the summer of 2009 before the guidelines chapter panels initiated their work and had the chance to experience the new strategy.

### Box 1 Det ails about the AT9 structure and process

- AT9 included a number of background chapters not providing graded recommendations and 15 chapters focusing on the different indications of anticoagulation and providing graded recommendations.
- Rating the quality of evidence and grading of recommendations followed the GRADE methodological framework [10].
- The membership of each chapter providing graded recommendations included a methodologist (the chapter editor), a lead content expert (the chapter deputy editor), a frontline clinician, a resource use consultant, and a number of content experts.
- Methodologists were chosen based on methodological training, familiarity with the GRADE process of rating quality of evidence and grading strength of recommendations, and a lack of COIs. Lead content experts are chosen based on content expertise, methodological training, and prior performance.
- The methodologist was in charge of summarizing the evidence in the form of evidence profiles, preparing the first draft of the recommendations, and ensuring that COIs do not materially affect the presentation of the evidence or the recommendations.
- The chapter methodologist was ultimately responsible for the quality and integrity of the chapter and for the timely meeting of all deadlines.
- Otherwise, the methodologist and the lead content expert worked together on the different steps of the process (e.g., drafting the questions that the recommendations addressed, searching for and identifying relevant literature, summarizing the evidence or reviewing summaries prepared by other panel members).
- The methodologist and the lead content expert negotiated specific responsibilities and the order of authorship (which was based on the amount of contribution).

*Abbreviations:* AT9, ninth edition of the Antithrombotic guidelines; GRADE, the Grading of Recommendations Assessment, Development and Evaluation; COI, conflict of interest.

### 2.2. Participants

Participants consisted of the methodologist and the lead content expert of each of the 15 chapters to issue graded recommendations in the ACCP AT9 guidelines. They received a detailed explanation of the COI strategy in person during the first planning meeting for the guideline project as well in a written document. The Institutional Review Board of the State University of New York at Buffalo approved the study.

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