

# Development of Evidence-based Recommendations: Implications for Preparing Expert Consensus Statements

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## INTRODUCTION

In the past decades, the introduction of evidence-based medicine has prompted a paradigm shift in clinical practice. One of the important progress is involving health-care professionals in making informed decisions according to recommendations from evidence-based practice guidelines or other guidance documents (e.g., expert consensus statements) published by national and international authorities (e.g., the National Institute for Health and Care Excellence [NICE]; World Health Organization [WHO]) as well as professional bodies.

Historically, guidelines are produced by consensus development methods, such as the Delphi process, nominal group technique, or consensus development conference.<sup>[1]</sup> With growing emphasis in using transparent, evidence-based approach, there has been wide agreement that those traditional consensus-based guidelines are likely less robust than evidence-based guidelines. In 2011, the Institute of Medicine (IOM), following the 1990 definition, revised clinical practice guidelines as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”.<sup>[2]</sup> This updated definition highlights the role of rigorous systematic reviews in developing trustworthy, evidence-based clinical practice guidelines.

However, the emphasis of adequate evidence base for developing clinical practice guidelines is sometimes faced with challenges in areas where available evidence is often limited. In such situations, professional societies often develop expert consensus guidance to aid clinicians in decision-making. Such expert consensus statements (alternatively called

consensus reports, task force position papers, or position statements) typically summarize the opinions of an expert panel on a particular topic that is narrower and more focused than that of a clinical guideline. These expert consensus statements often contain comprehensive, up-to-date information relevant to the topics and are summarized by a panel of clinical experts. However, the methods of developing these consensus statements are often not reported clearly, and thus, one cannot be certain how the evidence has been collected or assessed. For example, the recent “World Heart Federation Expert Consensus Statement on Antiplatelet Therapy in East Asian Patients with acute coronary syndrome (ACS) or Undergoing percutaneous coronary intervention (PCI)” summarized latest development and study data on the use of antiplatelet in the East Asian populations with ACS or for whom PCI is performed.<sup>[3]</sup> The document is written by an expert panel of a wide array of experiences and knowledge, and yet, the methodology of summarizing the evidence cited in this statement remains unreported.

Nevertheless, expert consensus statements can be developed by incorporating findings from rigorous systematic reviews of available evidence using the same transparent and explicit methods as those for clinical practice guidelines. When this approach is used, the expert consensus statements become evidence-based, which reflect recommendations that take

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into consideration of the best available evidence, patient values and preferences, resources, and clinical expertise, thus ensuring better delivery of care. Even if the evidence base might remain suboptimal, the recommendations might also better assist stakeholders with decision-making and highlight knowledge gaps for future research.

## DEVELOPMENT PROCESS OF EVIDENCE-BASED EXPERT CONSENSUS STATEMENTS

The development process of evidence-based expert consensus statements can be summarized into the following five steps: (1) topic selection; (2) expert group composition; (3) systematic review of evidence; (4) formulation of recommendations or suggestions; (5) peer review.<sup>[4]</sup> The rationale of topic selection for evidence-based expert consensus statements differs slightly from that for guidelines since consensus statements focus on areas that are more specific with narrower scopes. Topics might be commissioned by professional societies when new research evidence emerges (e.g., when new interventions are introduced, when new study data of existing interventions are published) or when urgent advice is needed. In addition, during the development process of clinical practice guidelines, questions for which the body of evidence is found to be insufficient for translation into recommendations are viable expert consensus statement topics.

Once the scope and topics are determined, an expert consensus development group, ideally including all relevant stakeholders, such as representatives from relevant professional societies, allied health professionals, patient/consumer representatives, and methodologists, is formulated. For consensus statements, where the topics are derived from clinical practice guidelines, the involvement of members from the corresponding clinical guideline development groups is also desirable. Conflict of interests should be explicitly declared in any case.

The expert consensus statement development group then assesses the statement topics and translates them into key research questions based on the PICO framework, including the components of the study population (P), targeted interventions (I), desired comparators (C), and outcomes of interest (O). Using the PICO framework, methodologists conduct systematic reviews employing a comprehensive literature search strategy to identify all relevant evidence, including existing guidelines, systematic reviews, and meta-analyses, as well as primary studies. However, a hierarchical search approach might be employed, meaning that primary studies might not be necessary if high-quality, up-to-date systematic reviews are identified and assessed to be applicable for use. Critical appraisal of the methodological quality of evidence is performed using the appropriate assessment tools (e.g., the Appraisal of Guidelines, Research and Evaluation [AGREE]-II tool for guidelines;<sup>[5]</sup> the Assessment of Multiple Systematic Reviews [AMSTAR] tool for systematic reviews;<sup>[6]</sup> the Cochrane Collaboration's tool for assessing risk of bias for randomized controlled

trials [RCTs]).<sup>[7]</sup> Evidence might be synthesized as meta-analyses and evidence tables where appropriate. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach is a system for rating the quality of evidence and GRADE summary of findings' tables, and evidence profiles are useful tools to support the formulation of consensus statement recommendations.<sup>[8]</sup>

Notably, the approaches to developing consensus statement recommendations differ by professional societies. For instance, the 2014 Heart Rhythm Society (HRS) Expert Consensus Statement on the Diagnosis and Management of Arrhythmias Associated with Cardiac Sarcoidosis follows the American College of Cardiology (ACC)/American Heart Association (AHA) Classification of Recommendation and Level of Evidence grading scheme for developing recommendations.<sup>[9]</sup> Since cardiac sarcoidosis is a rare condition, no randomized (Level A) or nonrandomized studies (Level B) are available, and thus, all recommendations of this consensus statement are given Level C of evidence (based on expert opinion, case studies). By comparison, recommendations of the 2014 HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-defibrillator Therapy in Patients Who are not Included or not Well Represented in Clinical Trials are derived from subgroup analysis of randomized studies, registries, and retrospective studies, and no levels of evidence are provided.<sup>[10]</sup> Another useful example to demonstrate the process of developing recommendations in consensus statements is the 2014 American College of Chest Physicians (CHEST) Consensus Statement of Care of the Critically Ill and Injured during Pandemics and Disasters.<sup>[11]</sup> CHEST employs the GRADE approach in grading guidance recommendations.<sup>[4]</sup> However, the evidence base for the field of disaster medicine is naturally small and systematic reviews conducted for this consensus statement indicated that there was limited information to formulate evidence-based recommendations. Instead, a modified Delphi consensus process was used to develop suggestions from identified observational studies in combination with expert opinion.

## CURRENT CHALLENGES AND FUTURE PERSPECTIVES

The development process of the ACC expert consensus statements generally takes 12–18 months.<sup>[12]</sup> Since evidence base of expert consensus statements is rapidly evolving, the long development time poses a risk of outdated research findings and irrelevant recommendations when the statements are published. The speed at which evidence and recommendations are made available for implementation is thus crucial. A streamlined production of new or updated evidence-based expert consensus statements, rapid expert consensus statements, is a potential solution. To streamline the development process, a narrow and focused topic with a minimal number of clinical questions should be defined by a multidisciplinary consensus statement development group, and rapid reviews concerning the selected questions should subsequently be developed. These reviews are

evidence synthesis products employing modified systematic review methods, such as updating the literature search of previous systematic reviews and presenting a descriptive summary of data instead of meta-analyses.<sup>[13]</sup> In comparison to traditional systematic reviews that can take up to 2 years to be produced, rapid reviews can be completed between 3 weeks and 6 months.<sup>[14]</sup>

The sheer volume of evidence and recommendations is proving to be a challenge for busy clinicians, who are expected to apply them to practice. For effective patient care, timely production of guidance documents that incorporate current evidence and presents only the essential information of the most relevance and interest to stakeholders is much needed. The new concept of rigorous, rapid expert consensus statements as a concise and efficient clinical decision-making tool to meet the demands of stakeholders brings us to a new paradigm of evidence-based medicine.

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