

The American Association for Thoracic Surgery/Society of Thoracic Surgeons position statement on developing clinical practice documents



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CLASS OF RECOMMENDATION	LEVEL OF EVIDENCE
Class I Strongly recommended Benefit greatly outweighs risk Alternative treatment is clearly inferior	Level A High quality evidence from multiple randomized controlled trials or meta-analysis
Class IIa Recommended Benefit outweighs risk	Level B Moderate quality evidence from multiple randomized controlled trials or meta-analysis
Class IIb May be recommended Benefit may outweigh risk	Level C Low quality evidence from multiple randomized controlled trials or meta-analysis
Class III No recommendation for or against Benefit and risk are similar	Level D Very low quality evidence from multiple randomized controlled trials or meta-analysis

Class of recommendations and levels of evidence used for clinical practice guidelines.

Central Message

The Guidelines Committee of The American Association for Thoracic Surgery and the Workforce on Evidence Based Surgery of The Society of Thoracic Surgeons jointly developed these definitions to facilitate publication of documents to guide clinical practice in our journals.

Improving patient care and achieving better surgical outcomes are key pillars of The American Association for Thoracic Surgery (AATS) and The Society of Thoracic Surgeons (STS) missions. Both organizations have striven over the years to educate cardiovascular and thoracic surgeons about evidence-based practices through various platforms, including the publication of clinical guidelines and consensus documents in their respective journals. In addition, both the STS and AATS have collaborated with other professional associations on scientific publications setting care standards in a multi-disciplinary context. The demand for clinical practice guidance has increased in recent years because of an exponential increase in medical knowledge driven by the explosion of new technologies for the diagnosis and treatment of disease.

Medical knowledge continues to grow, and by 2020 a doubling of knowledge is estimated to occur in only 73 days,¹ increasing the pressure on physicians, surgeons, and other interested parties to keep pace with the boom in knowledge. In addition, patients and payers have come to expect an evidence-based approach in care delivery. Clinical practice guidelines (CPGs) are an option for knowledge to be processed by content experts and disseminated as efficiently as possible in the form of practical recommendations. Noting the wide disparity in the rigor and quality of the processes behind the development of CPGs, a provision in the Medicare Improvements for Patients and Providers Act of 2008 directed the Institute of Medicine (IOM) to develop standards for CPG developers. This culminated in the 2011 IOM report, *Clinical Practice Guidelines We Can Trust*.²

Useful resources (such as the National Guideline Clearinghouse [<http://www.guideline.gov>]) have emerged to help users identify quality CPGs that adopt many of the principles set forth by the IOM, but compliance with the IOM standards remains difficult,³ and some CPG developers are of the opinion that they are more aspirational and not entirely attainable.⁴

Thus, approaches toward clinical practice documents have taken varying formats, such as those espoused by the IOM,^{2,5,6} the Consensus Guidelines proposed by AATS,⁷ consensus statements from an invited group of experts as has been done on some topics by STS,⁸ position statements,⁹ and white papers.¹⁰

STS and AATS have increasingly adopted many of the IOM principles to ensure rigorous and transparent evaluation of current evidence relating to the timely and appropriate management of cardiovascular and thoracic diseases. This work has been conducted by experts in the field organized and supervised in recent years by the Workforce on Evidence Based Surgery (WFEBs) and the Guidelines Committee (GC) of the STS and AATS, respectively. Both the WFEBs and the GC have followed their respective rules and procedures for the synthesis of evidence to guide clinical practice. These rules and

procedures varied, and the need for modernization, standardization, and a uniform process for developing CPGs was declared a priority by the leadership of both the AATS and STS.

The present project involved a collective effort by the AATS and STS to assemble a joint panel of experts to review the available literature on CPGs and existing organizational policies, establish clear definitions relating to the types of published documents, and set rigorous and practical standards that will ensure consistency and quality of all clinical practice documents published by both organizations. We propose a scientific framework for a reliable and transparent synthesis of evidence-based recommendations in cardiothoracic surgery that will ultimately translate into safe and effective care.

METHODS

The expert panel was composed of participants identified by an initial core group of the chair and immediate past chair of the STS WFEBs (F.B. and J.M., respectively), the coauthors of the AATS GC (L.S. and S.K.), the editor of *The Annals of Thoracic Surgery* (*The Annals*) (G.A.P.), and the editor of *The Journal of Thoracic and Cardiovascular Surgery* (*JTCVS*) (R.W.). The project and composition of the panel were endorsed by the 2 organizations. The draft report written by the chairs of the WFEBs and GC were distributed to the entire expert panel, and comments solicited via frequent conference calls and online communication.

TYPES OF CLINICAL PRACTICE DOCUMENTS: CPGs VERSUS EXPERT CONSENSUS DOCUMENTS VERSUS EXPERT OPINION/WHITE PAPERS

Technically oriented topics relating to the type, extent, and conduct of a surgical intervention are of particular interest to the membership of both organizations. CPGs often address the broader scope of indications and timing of treatment, with less emphasis on technical surgical considerations. AATS and STS clinical practice documents intend to fill this need with the appropriate document type based on the level of evidence available and document development process.

There is broad agreement that CPGs should be based on rigorous evidence. However, high-quality randomized studies are often lacking in the surgical literature. Nevertheless, this lack of randomized studies does not necessarily preclude development of CPGs. Well-designed prospective cohort studies, or large registry studies that compare 2 interventions, can result in useful recommendations.

In the surgical field, much of the published literature is based on single-center, noncomparative case series. Higher-quality evidence may never be obtained in certain areas, but lower-level data and case series may still provide opportunities to optimize outcomes that address important and often common clinical questions. In such scenarios it may be appropriate for the expert panel to use their best judgments to make specific and unambiguous consensus statements designed to reduce poor outcomes. The

consensus of a diverse group of experts can provide enormous value in these areas with little to no comparative evidence, yet unacceptably and unnecessarily high risk of mortality, major morbidity, or resource use persists.

In recognition of the challenges outlined here and the specific needs of the AATS and STS membership, this panel recommends that clinical practice documents be categorized into 3 types: CPGs developed according to core IOM standards with an a priori literature search performed, registration on the www.guidelines.gov Web site, and the inclusion of at least some Level A or B evidence; expert consensus documents (ECDs); and expert opinion/white papers (Figure 1).

The decision on the designation of a document as a CPG or ECD rests with the WFEBs and GC based on whether a systematic review of comparative data can be performed for most clinical questions that make up a particular topic. If a systematic review is not feasible, yet the WFEBs or GC believe that opportunities to correct major gaps in care exist without direct comparative evidence (and the organizations' governing bodies agree), then an ECD is suitable. A low level of evidence is not sufficient on its own to justify development of an ECD. A gap in care and clear clinical question(s) also should be identified.

ECDs result in statements that are considered clinical "suggestions" rather than outright recommendations and are clearly labeled as such. In addition, unlike CPGs, there is no requirement for grading ECDs with the American College of Cardiology (ACC)/American Heart Association (AHA) class of recommendation or level of evidence designation.

An expert opinion/white paper is a document written by field experts and thought leaders on issues related to new procedures, technologies, or health policy for which there are few data and significant uncertainty. These papers are intended to review the literature and identify conflicting opinions and alternative treatment strategies without making recommendations for practice.

Development Process for Clinical Practice Documents (Figure 2)

Identifying a relevant clinical topic. A successful clinical practice document starts with an explicit and well-defined reason relating to the prevention, screening, diagnosis, treatment, or follow-up of a disease or condition. The topic and the associated primary question(s) have to be timely and relevant to contemporary practice. Typically, clinical practice documents focus on topics for which there is significant variation in practice, with disparities in associated outcomes. A CPG, ECD, or white paper may also serve the important purpose of stimulating further research.

Writing committee composition. The writing committee for any STS and/or AATS clinical document should be

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