The American Association for Thoracic Surgery Consensus Guidelines: Reasons and purpose

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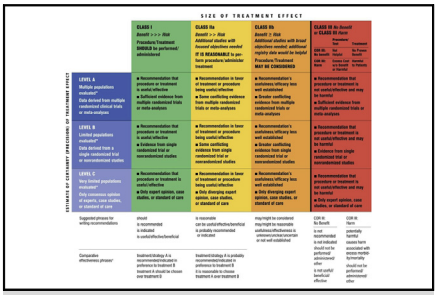
ABSTRACT

The time interval for the doubling of medical knowledge continues to decline. Physicians, patients, administrators, government officials, and payors are struggling to keep up to date with the waves of new information and to integrate the knowledge into new patient treatment protocols, processes, and metrics. Guidelines, Consensus Guidelines, and Consensus Statements, moderated by seasoned content experts, offer one method to rapidly distribute new information in a timely manner and also guide minimal standards of treatment of clinical care pathways as they are developed as part of bundled care programs. These proposed Consensus Guidelines advance The American Association for Thoracic Surgery's mission of leading in cardiothoracic health care, education, innovation, and modeling excellence. (J Thorac Cardiovasc Surg 2016;■:1-5)



AHA/ACC classification of recommendations and level of evidence.

Central Message

The AATS Consensus Guidelines will improve care and advance our mission of leadership, education, innovation, and modeling excellence.

Perspective

The American Association for Thoracic Surgery Consensus Guidelines are intended to provide clinicians with recommendations from experts in the field that are based on the best and latest evidence available. In this way, the Consensus Guidelines will be able to respond rapidly to technologic and practice advances with expert recommendations to improve our patients' care.

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Abbreviations and Acronyms
AATS = The American Association for Thoracic Surgery
AHA/ACC = American College of Cardiology and American Heart Association

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By 2020, medical knowledge will double every 0.2 years.[1]

EVOLUTION OF MEDICAL KNOWLEDGE

During the last century, medical publications have documented revolutionary discoveries. In the early 20th century, publications consisted of either single case reports or small series of patients treated by a new approach, either a medication such as insulin[2] or a surgical procedure such as repair of congenital heart defects on cardiopulmonary bypass.[3] With these early discoveries, there was little doubt concerning the effectiveness of treatment. Insulin injections controlled diabetes, and heart surgery was lifesaving. With time, the literature abounded with reports of series of patients treated by senior experts expounding their personal (successful) experiences with particular treatments. Often, these series may have had conflicts of interest because of bias related to personal experience, particularly when a new device was evaluated. Review articles or book chapters by experts flourished—the latter often read but seldom quoted, although for young surgeons, these reviews continue to be an invaluable educational resource. Later, studies were based on much larger series of patients who were followed up through time, often including comparisons of matched groups.[4] Incremental steps in statistical complexity for determining the veracity of effective treatments became the favored method of analysis and reporting.[5-7] Concurrently, randomized trials of increasing complexity with an a priori structure and carefully planned evaluations of outcomes evolved.[8,9] More often than not, these complex trials raised more questions than answers. Finally, sophisticated meta-analyses of previously reported series, which followed strict guidelines[10] provided further insights into the validity of various treatments.

EXPLOSION OF MEDICAL INFORMATION

Today the explosion of information about medical treatments often leads to contradictory recommendations. For the layperson, internet reviews written by medical reporters who lack insight into medical nuances have become the major source of information about medical advances. Nevertheless, these reviews rapidly disseminate knowledge of new developments. The response in the physician community has been to establish guidelines to aggregate available knowledge and distill the key messages. Guidelines have replaced expert reviews as the documents that establish recommended approaches to medical problems and clinical care pathway development.

GUIDELINES: PUTTING INFORMATION TOGETHER AND FILLING THE GAPS

During the last 30 years, the process of guideline development and the formatting for guideline display have advanced dramatically (Figure 1).[11] The process was initially envisioned to emanate from the collective wisdom of experts in the field, although when John Kirklin convened the first panel on coronary artery bypass operations,[12] he insisted that the process be fundamentally data driven. Through the years, criticism has mounted that guidelines are not sufficiently data driven,[13] so much effort has been expended to critically examine the current literature and synthesize treatment recommendations according to the quality of supporting evidence, including size of treatment effects.[10] These carefully constructed guideline treatises, however, frequently lack critical evidence and the seasoned clinical judgment necessary to interpret available information and recommend therapeutic choices for complex patient populations. Thoracic and cardiovascular surgeons thus must frequently look to senior experts to provide guidance on many of these complex issues. The American Association for Thoracic Surgery (AATS) Consensus Guidelines will attempt to fill this gap.

VALUE AND USE OF GUIDELINES

Previous investigations have determined that expert opinions are vital to proper interpretation of the literature and provision of recommendations, especially when the evidence is unclear. An analysis of the 3271 recommendations in 19 guideline documents issued through 2013 by the American College of Cardiology and American Heart Association (ACC/AHA) Task Force on Clinical Practice Guidelines highlights the need for a consensus among the experts.[11] Although approximately 50% of the recommendations were class I (strongest recommendation), some 50% were informed by a level C quality of evidence (lowest quality). Fewer than 10% were based on a level A quality of evidence. Indeed, of the class I recommendations, only 11% were based on level A evidence and 46% were informed by level C evidence. These results indicate either important gaps in evidence or a failure to find or use existing higher quality evidence,[13,14] resulting in a need for extensive interpretation by content experts. For, as noted

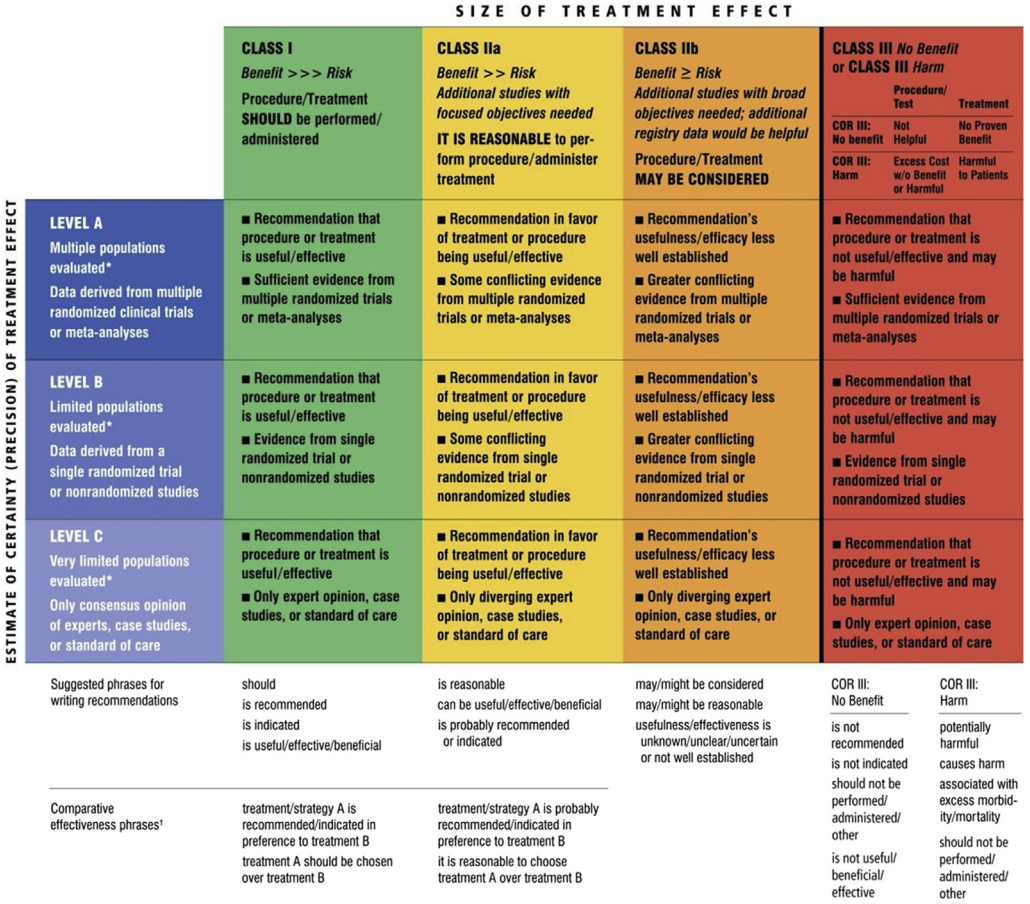

FIGURE 1. American Heart Association and American College of Cardiology Task Force on Clinical Practice Guidelines classification of recommendations and level of evidence.

by the Task Force, ''It is precisely where evidence is lacking or controversial that clinicians need the most guidance.''[11] In addition, two-thirds of the clinicians responding to a recent survey indicated that they used the practice guidelines to guide clinical decisions, even though the quality of available evidence was limited (level C).[11] Recommendations developed by content experts are therefore essential to help clinicians chose among treatment options, particularly when the evidence is limited or incomplete.[13,14] Furthermore, medical leaders are turning to guideline documents to establish care pathways, with the intent of reducing practice variability and cost of care while providing more value to patients.

UNINTENDED CONSEQUENCES OF GUIDELINES

Unfortunately, guidelines are increasingly used by nonphysicians to direct care, ignoring that the recommendations are intended to encourage a dialog between the patient and his or her physician to choose among reasonable alternative treatment options. Government and insurance company reviewers will question testing or surgical treatments, such as for management of valvular heart disease on the basis of symptoms or of an aortic aneurysm on the basis of size, because of their faulty interpretation of the guidelines. Medicolegal cases also frequently refer to published guidelines. Furthermore, the Centers for Medicare and Medicaid Services and insurance companies demand that certain quality metrics, such as patient safety indicators, be met even though these measures may actually cause patient harm. Guidelines, however, allow panels of expert physicians to respond to the imposed, often arbitrary, quality metrics that unreasonably interfere with patient care. For example, after considerable lobbying, the normothermic requirement after cardiac surgery was removed, and the 6 AM glucose level was changed to 16 to 24 hours after surgery completion and then abolished. The consensus of content experts can guide complex treatment decisions, inform patient care pathways, and serve as a minimal standard of care when value-based bundled-care payments are negotiated for disease treatment and management.

CARDIOTHORACIC SURGICAL GUIDELINES

In response to the Institute of Medicine call for more stringent standards for Guidelines,[15] the ACC/AHA Clinical

Practice Guidelines Committee instituted 3 new initiatives: (1) a more rigorous review of the evidence, (2) a more restrictive conflict of interest policy, and (3) a broader consultation with relevant stakeholders, including patients.[11] A survey of clinicians, however identified the additional need to provide rapid expert consensus as the evidence changes, particularly when the level of evidence is inadequate to provide strong guideline recommendations.[16] The committee recommended that the guidelines become ''living'' documents that are rapidly revised and updated to meet the needs of the clinicians.[16] The rapid pace of new clinical evidence in the medical literature means that the extensive review required by the Institute of Medicine standards cannot keep pace with the changing evidence. The ACC/AHA committee states, ''This natural tension between the goals of scientific rigor and clinical need represents an ongoing challenge to CPG [Clinical Practice Guideline] development and requires sound judgment to achieve a delicate, optimal balance.''[16] The AATS will provide important new recommendations that are based on systematic literature review and expert consensus. We will use the term *Consensus Guidelines* for these to distinguish them from the documents developed after more extensive collaborative efforts that meet all of the requirements of the Institute of Medicine standards.

For cardiac and thoracic surgery, these new Consensus Guidelines will provide a rapid response to the latest high-level clinical evidence and the thoughtful consideration of the leading experts in the field. The AATS Consensus Guidelines will provide direction when the evidence is not as clear as we might hope.

We hope that these documents will stimulate further discussion and research, especially with regard to designing and conducting randomized trials that move the field forward and permit development of firmer recommendations. To assist guidelines developers with their structured literature review, we recommend that they follow the checklist provided by Preferred Items for Reporting Systematic Reviews and Meta-Analyses.[17,18]

The goal of the guidelines effort has been to improve patient outcomes; however, the benefits achieved have been difficult to document. Resources such as the American Heart Association's ''Get With the Guidelines'' and ''Mission: Lifeline''[19] and the American College of Cardiology's ''Door to Balloon'' and ''Hospital-to-Home''[20] initiatives have led to improvements in care. The paucity of funding for clinician education and implementation of the science on which guidelines are based, however, coupled with other barriers, hamper the adoption of clinical practice guidelines. One of the goals of the AATS Guidelines Committee will be to review evidence provided by the extensive efforts of other organizations to determine whether their recommendations have contributed to greater compliance and improved patient outcomes.

AATS CONSENSUS GUIDELINES

The AATS Consensus Guidelines will be developed with a systematic review of the literature and input from colleagues in other specialty fields and societies and will strive to establish the accepted standards of treatment, identify best options, and recommend long-term management strategies. An important component of these Consensus Guidelines, however, will be the consensus of experts in the field. The basic structure will include the purpose of the guidelines, background information including other guidelines (such as the well-established ACC/AHA Guidelines), and indications for treatment and investigation, particularly surgical treatments and postoperative intensive care unit and long-term patient management strategies. The Appendix presents the outline for writing the guidelines approved by the AATS president and executive committee and council. We strongly encourage involvement of related experts from other specialties and the support of our sister organizations and societies. For most of the established guidelines and consensus statements, an executive summary is printed in *The Journal of Thoracic and Cardiovascular Surgery*, and a more complete version is available online. The AATS Consensus Guidelines may be shorter, more focused contributions. In addition, the combined wisdom and sage advice of a senior expert will accompany the guidelines as a commentary or editorial. Completed guidelines will also be presented at the annual AATS meeting.

SUMMARY

The AATS Consensus Guidelines are intended to provide clinicians with recommendations from experts in the field that are based on the best and latest information available. In this way, these guidelines will be able to respond rapidly to technologic and practice advances with expert recommendations. Ultimately, we trust that this endeavor will improve our patient care and advance the AATS mission of leadership, education, innovation, and modeling excellence.

Conflict of Interest Statement

L.G.S. reports personal fees from Posthorax. A.M.G. reports personal fees from Medtronic, Edwards Lifesciences, St. Jude Medical, On-X, Abbott, AtriCure, and Clear Catheter. J.S.C. reports personal fees from St. Jude Medical and grants, personal fees, and royalties from Vascutek; he also is a subprincipal investigator for a clinical trial sponsored by Medtronic, has a consulting agreement and is principal investigator for a clinical trial sponsored by WL Gore & Associates, is principal investigator for a clinical trial sponsored by GlaxoSmithKline, and holds a patent, No. W02008157283(A1)-2008-12-24. T.M.S. is a Scientific Advisor for Thrasos Innovation. No other author has a relationship with industry to report. All other authors have nothing to disclose with regard to commercial support.

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Key Word: guidelines

APPENDIX. AATS SURGICAL CONSENSUS GUIDELINES

AUDIENCE

1. Surgeons
2. Physicians
3. Patients

FOCUS

1. Operations
2. Perioperative care

When appropriate, the guideline development group should be multidisciplinary.

DISTINGUISHING FEATURES

1. Focus on *surgical and perioperative* questions
2. *When* to operate/treat
3. *How* to operate/treat; this is the most important contribution
    a. Prescribe the operation/treatment (definitive when possible)
    b. Choose best approach

GENERAL FORMAT

1. Concise
2. Focused systematic review of the best evidence
3. Avoid extensive literature review with hundreds of extraneous references
4. Devise specific ''look'' that identifies these documents as AATS Surgical Consensus Guidelines
5. Follow instructions of Institute of Medicine document on clinical practice guidelines
6. Plan for an Executive Summary of about 3500 words and a longer version with full discussion of recommendations to be an electronic format on the *JTCVS* Web site.
7. If there may be insufficient evidence for a Consensus Guidelines document, consider a Consensus document, but highlight areas where knowledge is lacking and further research would be valuable.
8. Highlight any particular areas where further research is needed to develop better supportive literature.

PRESENTATION

1. Table of contents
2. List of Questions to be addressed
3. Pairings of Questions and Recommendations
    a. Limited number of key Questions and corresponding Recommendations for each set of Consensus Guidelines
    b. Each Question generates a guideline Recommendation
    c. Focus on actual procedures and treatments with somewhat less emphasis on indications, which are covered exhaustively by ACC/AHA or other documents
4. For each Question/Recommendation
    a. Brief overview of the Question
    b. State the Recommendation
        i. Benefits and Harms (Pros and Cons): Clear description of potential benefits and harms of recommendation
        ii. Summary of Relevant Available Evidence
            1. Quality (randomized, controlled trials vs observational studies)
            2. Quantity (numbers studied and completeness)
            3. Consistency
        iii. Expert Clinical Opinion: Explanation of part played by expert clinical opinion
        iv. Controversies and Gaps in Knowledge
    c. Restate Recommendation
        i. Use AHA/ACC Classification of Recommendation and Level of Evidence (COR/LOE)
        ii. Include standard AHA/ACC table (COR/LOE)
        iii. Include flow charts and tables and algorithms
        iv. If possible include a Power Point presentation of key figures for the Web version on *JTCVS*
5. Training considerations (if applicable)
6. Key references leading to recommendations
    a. Limited number of key references informing Guideline Recommendation; there is also a standard list of references at the end of the manuscript
    b. Enables reader to understand most important data behind recommendations

MAINTENANCE AND UPDATING CONSENSUS GUIDELINES

1. Annual review of new evidence related to each Question/Recommendation pair by writing group leader
2. Writing group leader answers this question for Guidelines Committee: *Is there a need to update Consensus Guidelines on the basis of new evidence?*
    a. New evidence identifies superior therapy
    b. New evidence shows that previous recommendation causes harm
    c. New evidence shows that a recommendation can be applied to new populations

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