Summary of The Society of Thoracic Surgeons Clinical Practice Guideline Development Process

Only guidelines that are written by a Task Force under the Workforce on Evidence Based Surgery (WFEBS) and that follow the STS Clinical Practice Guideline Development ("Guideline") Process will be published as an STS guideline.

STS Guideline Development Process (All activities in each step must be completed before moving onto the next step)	
Step 1 – Guideline Topic Recommendation	
Action	**Responsibility**
Select Guideline Topic for Consideration	WFEBS with staff assistance
Select Task Force Chair (aka, lead author)	WFEBS
Obtain Executive Committee approval on guideline topic	Task Force Chair submits the proposed guideline topic form to staff, who obtain Executive Committee approval
Step 2 – Selecting Task Force Members	
Select Task Force writing group	WFEBS and staff, with special consideration to WFEBS Chair and Task Force Chair suggestions
Formalize joint societal effort (if applicable and if approved by the Executive Committee)	Staff will go through the administrative process of formalizing organizational relationships.
Manage potential conflicts of interest	Task Force members submit disclosure forms for review
Step 3 – Kick-Off Meeting / Call	
Conduct kick-off meeting/call reviewing guideline development process and expectations	Staff-initiated after completion of all activities in steps one and two.
Step 4 – Creating the Guideline	
Submit of PICO question to medical librarian	Staff, with oversight from Task Force Chair
Create evidence tables and evaluation of individual study strength	Staff, to be checked by Task Force members for accuracy and thoroughness
Assign ACC/AHA classifications of strength and level of evidence	Task Force members and staff
Draft guideline	Task Force members and staff, with staff responsible for version control
Step 5 – Approval Process	
Submit for WFEBS approval	Staff and WFEBS
Open 2-week comment period	Staff initiated, with input from interested STS membership
Submit to Quality Research & Patient Safety (QRPS) Council Operating Board for approval	Staff and QRPS Council Operating Board
Submit to Executive Committee for approval	Staff and Executive Committee
Edit document (occurs at every stage of review, if revisions are necessary)	Task Force members and staff, with staff responsible for version control
Step 6 - Publication	
Submit to *The Annals of Thoracic Surgery*	Staff

The Institute of Medicine (IOM) defines a clinical practice guideline as "statements that include recommendations intended to optimize patient care [and] that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." STS guidelines must conform to the National Guideline Clearinghouse's inclusion criteria, which were developed based on the IOM's "Clinical Practice Guidelines We Can Trust." (It should be noted that, unlike IOM guidelines, the STS guidelines are developed without patient participation.)

Choosing Guideline Topics

STS guideline topics may be generated from a variety of sources, including: 1) recommendations from WFEBS members, 2) suggestions from STS members through a "call for topics" in *STS Weekly* or other member communications, 3) outcome trends identified in the STS National Database, and 4) recommendations from STS leadership.

Good guideline topics should be specific, well-explored in the literature, and not overly controversial. Because all

guidelines must be evidence-based, they are unlikely to effectively address ongoing, unsolved controversies in the literature. The WFEBS should review each topic and determine if the topic meets the following criteria:

- A body of science-based evidence of sufficient breadth and depth exists to enable the development of an evidence-based guideline (this does not mean that guideline recommendations must be based solely on randomized controlled trials or level A evidence);
- No other guidelines are available that sufficiently address the topic;
- A high likelihood exists that the guideline will:
  - Serve a significant population of patients;
  - Address a gap in care (i.e., significant variation in management/treatment or poor outcomes);
  - Result in improved quality of care and patient outcomes;
  - Serve patients whom have this condition, will undergo this procedure, or will seek care from the physicians who will be targeted for dissemination of this guideline.

Guideline Topic Approval

After a guideline topic is identified by the WFEBS and before the guideline development process begins, the Task Force Chair is required to complete a Proposed Guideline Form. Staff will submit the form to the STS Executive Committee for review / approval.

Selecting the Task Force Writing Group

Once the guideline topic is approved by the Executive Committee, the WFEBS and Task Force Chairs will begin to create a writing group through a call for participation in *STS Weekly* or other member communication and input from fellow WFEBS members. Ideally the writing group should be made up of experts on the guideline topic, as well as individuals with experience in guideline development, evidence-based medicine/processes, research, preparing systematic reviews, statistics, epidemiology, and/or quality improvement. Task Force members should contribute substantively to the development of the guideline though this contribution can take many forms (i.e., helping to shape the **P**atient **I**ndication **C**omparison **O**utcome (PICO) question, reviewing evidence tables, drafting a section of the guideline, revising drafts, and/or participating actively in Task Force calls).

Joint Societal Effort

With approval of the Executive Committee, Task Force Chairs may choose to partner or collaborate with outside organizations. The parameters of such organizational cooperative efforts are available here. In such a case, STS staff will contact the partnering or collaborating group to make arrangements – no joint societal projects can move forward without confirmation from the partnering organization's staff. Please note that at least half of the members of a Task Force should be STS members.

Conflicts of Interest

The Task Force Chair and a majority of the guideline authors must be free of potential conflicts of interest (COI). Disclosure forms must be submitted by all Task Force members at the beginning of the guideline development process, ***prior to the kick-off call***, and may require updates throughout the guideline development process. Please note that *The Annals of Thoracic Surgery* will require a separate disclosure from all authors at the time of publication.

Task Force applicants are asked to disclose potential COI during the application process using an on-line conflict of interest declaration. STS defines COIs as such:

1. **Financial interest in any amount (e.g., through ownership of stock, stock options, or bonds)**
2. **The receipt of any amount of cash, goods or services within the current 12-month period, e.g., through research grants** (to the extent of research money used for surgeon salary support, but not including travel and other expenses that support a position as Principal Investigator or similar role)**, honoraria, employment, consulting fees, royalties, travel, gifts or any "in-kind" compensation** reflected on any IRS Form 1099 received

3. **Non-remunerative position of influence (e.g.,** as an officer, director, trustee, volunteer leader or public spokesperson of ***a for-profit entity*** (e.g., a pharmaceutical or device manufacturer) ***or a not-for-profit entity*** (e.g., another medical specialty society or a charitable organization) engaged in an area of current or potential interest to STS)

The COI disclosure form will seek additional information regarding the nature of this relationship, including whether financial magnitude is (N/A) Not Applicable, (M1) Under $10, 000 (M2) Between $10,000 and $100,000, or (M3) Over $100,000 (e.g., "Consultant, M2").

The disclosures are reviewed by the WFEBS Chair, Task Force Chair, and STS staff for relevance to the proposed topic and managed accordingly. Individuals deemed by the Steering Committee to have major conflicts based upon the magnitude of the relationship, but whose participation is considered essential to the project may be enlisted as non-voting authors, and cannot participate in the development of clinical recommendations. Authors with minor COI may be asked to recuse from specific recommendations, if necessary.

A table containing writing committee member names and their relevant COI information will be included in the guideline supporting materials on the STS website.

Kick-Off Call
After all activities have been completed in steps one and two, STS staff will initiative an introductory guideline kick-off conference call to begin the guideline development process. This is the most crucial stage of guideline development because, during this call, the PICO question to guide the literature search is crafted, the inclusion/exclusion criteria are developed, and the scope and scale of the guideline are defined. **A strong guideline must have a reproducible methodology that allows others to duplicate the literature search. Any literature that is not captured at this stage cannot be incorporated into the guideline at a later date.**

Systematic Literature Search
The literature search must be systematic and documented. The Task Force is responsible for formulating several search questions in a PICO format and deciding the inclusion and exclusion criteria for selecting relevant publications during the review process. Examples of PICO questions are available online, as are tutorials. STS guidelines are submitted for publication in *The Annals of Thoracic Surgery*, where they are limited to 6500 words and 80 references. Due to these limits, it is essential that the guideline and PICO questions have a narrow focus. *The Annals* publication policy is included at the end of this document.

STS contracts with a library service that will formulate the search strategy and load the results into an Endnote library for dissemination to the writing group. The library service conforms to the IOM's systematic review protocol (Standard 2.6) as detailed here. This ensures that the searches are of high quality and that the search methods are documented and reproducible. The search strategy is posted on the STS website as supporting material for the guideline. If the systematic search does not identify enough published evidence to support writing a guideline, the authors may choose to write a systematic review instead.

The Endnote library produced by a research librarian will be uploaded into the STS guideline software, Indico, for review by guideline authors and STS staff.

Reviewing the Literature and Writing the Guideline Document
Once the results of the literature search are gathered, STS staff will work with the Task Force to develop fields for an evidence table. These can include information about study design (how many patients? What kind of study? How long was follow-up?) and about specific outcome measures (death, stroke, reoperation, etc.). Once the parameters of the table are agreed upon, STS staff will take the lead in drafting an evidence table based on the literature review. Staff will also create additional tables assessing the individual risk of bias of each paper. A different scale or checklist is used for each type of study: A customized checklist for meta-analyses and randomized controlled trials, Newcastle Ottawa for observational studies, and QUADAS-2 for diagnostic studies. While staff will create draft versions of these tables to the best of their abilities, Task Force members are responsible for double-checking the thoroughness and accuracy of the literature review, evidence table, and strength of evidence tables. These tables

will be accessible and modifiable within Indico.

Authors will draft the initial guideline recommendations. STS uses the Table "Classification of Recommendations and Level of Evidence" the suggested phrases for writing recommendations printed on the ACC/AHA table. It is important that the recommendations be actionable and avoid ambiguous or vague language.

To prevent version irregularities, version control between guideline drafts is strictly the responsibility of STS staff.

Consensus

The authors for each section will submit their recommendations. Through a link to an anonymous online poll, all authors can submit their thoughts about each recommendation. After this poll is conducted with at least an 80% response rate, STS staff will arrange for a Task Force phone call to resolve any outstanding issues. A recommendation will be considered to have consensus if both the Class of Recommendation and Level of Evidence have 75% agreement. During the call, the authors will discuss and resolve any differences in Class and Level for each recommendation, and authors may vote up to two more times to reach consensus. Final results from the consensus-building process will be posted on the STS website as supporting material. It is the responsibility of the Task Force chair to help ensure that surgeons with COI/RWI information recuse themselves from voting.

Although consensus likely will be reached on the conference call, in the event of a more enduring conflict, Task Force members will be given the opportunity to register their dissent to specific recommendations. This record will be published as an auxiliary document on the STS website.

Review, Approval and Endorsement Process

1. Once the draft guideline is approved by the Task Force, it will be submitted to the WFEBS for review and comment. In the case of partnering societies, a draft will be forwarded to the organization and circulated according to their processes. All comments must be received within one week.
2. Based on comments received from the WFEBS, the Task Force Chair (working in conjunction with the WFEBS Chair) will modify the document as deemed appropriate*. The Council Operating Board Chair then will determine whether the draft guideline should be reviewed by the Council Operating Board prior to dissemination to the STS membership.
    a. If yes, the document will be forwarded to the Council Operating Board for review and comment. All comments must be received within one week. Based on comments received from the Council Operating Board, the Task Force Chair (working in conjunction with the WFEBS Chair) will modify the document as deemed appropriate.
    b. If no, the revised draft will be posted on www.sts.org for a two week comment period, and a notice will be sent via e- mail to STS members seeking their review and comment. If the guideline is a joint societal effort, a link will also be sent to partnering organizations for comment.
3. Based on comments received in response to the posting, the Task Force Chair (working in conjunction with the WFEBS Chair) will modify the document as deemed appropriate*. Any changes to the evidence and recommendations that are made during the approval process must go back to the author and the WFEBS Chair for review and verification of evidence.
4. The Task Force and WFEBS Chairs forward the document to the Council Operating Board and seek its approval, by an affirmative majority vote, for submission of the document to the Board of Directors** for final STS approval.
5. Final document approval will be issued by the STS Board of Directors**.
6. Once approved, the final document will be submitted to *The Annals of Thoracic Surgery* for publication and posted on www.sts.org.

* The comments will be summarized and provided to the next reviewing body (Council Chair, Council Operating Board or Board of Directors, but not the full membership in step 2b), along with the Task Force and WFEBS Chair responses to them.

**Pursuant to the STS Bylaws, the Executive Committee is authorized to act on behalf of the Board of Directors

during the intervals between Board meetings.

Copyright Release

Task Force members are required to assign copyright ownership for their contributions to the document. Members will be asked to sign a copyright release when the guideline is submitted to *The Annals*.

Guideline Update Policy

In keeping with the National Guideline Clearinghouse requirements, STS has a process for updating guidelines in the STS Clinical Practice Guidelines Series (affixed to the end of this document). The objective of the process is to ensure that all STS clinical practice guidelines are updated at least every five years in order to evaluate the impact of new research on recommendations contained within the original published guideline. A guideline and its recommendations are considered to be still valid if results from post-publication clinical studies do not contradict earlier research results.

Barring any drastic changes to medical consensus, an update involves a new literature search and an addendum tothe prior publication outlining important studies within the field that may or may not make slight changes to levels of evidence and strength of recommendations.

Distribution

Currently guideline distribution includes publication in The Annals of Thoracic Surgery and posting on the STS website. Guidelines will also be available on the Society's iPhone application, downloadable through the iTunes store. All guidelines will be submitted to the National Guideline Clearinghouse, where they will be posted if they meet all inclusion criteria. Partnering or collaborating societies may also distribute guidelines. Guidelines also may be presented in e-learning modules for CME.

STS Process for Updating Clinical Practice Guidelines The Workforce on Evidence Based Surgery

Dr. Charles Bridges, Chair

Background

Clinical practice guidelines, written by members of specialty medical organizations, help healthcare practitioners keep abreast of new techniques, procedures and clinical trial results. Guidelines also are used as evidence driving the development of quality performance measures and appropriateness criteria, which are the backbone of pay-for-performance initiatives. Given the importance of these documents for patient care and the weight guidelines carry for setting policy, it is important that they are based on the most current evidence.

STS clinical practice guidelines are written under the auspices of the Evidence Based Surgery (EBS) Workforce. When the Workforce chooses a guideline topic, a Task Force is formed and clinical evidence, in the form of peer reviewed, published clinical trials, meta-analyses and rarely, case studies, is collected through extensive literature searches. The evidence is evaluated and classified according to the system published by the Joint Task Force for Guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) on line at http://circ.ahajournals.org/manual and in Table 1.[1] The drafted guideline undergoes the STS "Approval process for practice guidelines and other policy documents from the Workforce on Evidence Based Surgery" ("Approval Process"), which includes approval by the full Workforce, an open comment period for STS membership, sign-off by the Quality, Research and Patient Safety Council Operating Board, and approval by the STS Board of Directors or Executive Committee. The Executive Summary of the approved guideline is submitted to *The Annals of Thoracic Surgery* for publication, where it undergoes review by additional external reviewers prior to publication.

The STS guidelines provide treatment recommendations based on the best clinical evidence available at the time of guideline development. It is understood that the recommendations will become outdated as new equipment, techniques and evidence, in the form of new clinical trials, become available. The ACC/AHA process for guideline updates is still evolving, but currently it requires that all guidelines be reviewed for possible update one year after publication. Then, at least one year after the guideline has been reviewed for update, "and/or there is a significant number of the recommendations that need to be revised, or when there is a compelling reason to change the scope or focus of an existing guideline," a revision is undertaken.[1] The National Guidelines Clearinghouse (NGC) (http://www.guidelines.gov) requires that guidelines be updated at least every 5 years. Interestingly, a study by Shekelle et al.[2], using 17 guidelines published by AHRQ between 1990 and 1996 and still in use in 2001, showed that 10% or more of the guidelines were judged to be outdated at 3.6 years, and about half were outdated at 5.8 years.

STS Process Overview

The first STS clinical practice guideline developed under the auspices of the EBS Workforce was published in 2004, and a total of eight have been published as of April 2008. In keeping with ACC/AHA and NGC requirements, the EBS Workforce has developed a clinical practice guideline update policy that will ensure that every guideline has been through the update process no later than 5 years after initial publication. The summary points of the process, shown in Figure 1, are:

1. At one year, and yearly thereafter, the literature is formally surveyed by the entire EBS Workforce and the Chair of the Task Force for a given practice guideline for new clinical trial results, FDA actions, guidelines published by other associations, etc., to determine if changes should be made to the guideline recommendations. If so, a new task force, including some members from the original Task Force and, ideally, at least two new clinical experts, is convened as the "Update Task Force." The revised guideline is

sent through the Approval Process and a revised Executive Summary of the guideline is sent to *The Annals* for publication.

2. At any time, including prior to the yearly review and continuing up until the time the formal update process starts four years after the original publication, the Task Force members who developed the guideline have the responsibility of notifying the Workforce Chair as they become cognizant of developments that might impact the guideline recommendations. If the Workforce Chair determines that revision of the guideline is required, an Update Task Force is convened, the revised guideline goes through the Approval Process and a revised Executive Summary is published, as described above.

3. Starting four years after publication, in preparation for the five-year update requirement of the NGC, STS staff performs a literature search on the guideline topic.

4. Also at 4 years, an Update Task Force, including members from the original Task Force and, ideally, at least two new clinical experts, is convened. Each recommendation in the guideline is reviewed by the Update Task Force to determine if it is still valid, or if new evidence has rendered one or more recommendations invalid. Based on the findings of the Update Task Force, the guideline (a) is deemed "still valid," or (b) is slated for "minor" or "major" revision, or (c) is found to be no longer valid.
    - If the guideline is still valid, the guideline undergoes the Approval Process. A letter is sent to *The Annals of Thoracic Surgery* and the NGC that the guideline has been reviewed and there are no changes.
    - If the guideline requires minor or major revisions, the revisions are made and the guideline undergoes the Approval Process. The revised guideline is posted on the STS Web site. The revised Executive Summary is sent to *The Annals* for publication and to the NGC for posting on its website.
    - If the guideline is judged to be no longer valid, a letter to that effect is sent to *The Annals*, and the guideline will be taken off the STS Web site.

STS Process Details

In the four year period following publication of a guideline, the original Task

1. The guideline needs minor revision (s);
2. The guideline needs major revision (s);
3. The guideline is invalid. The decision to render a guideline invalid is subjective, based on the quality of new evidence and the number of outdated recommendations.

All updated guidelines will go through the Approval Process. If the guideline does not require revision after it undergoes the Approval Process, a letter will be sent to *The Annals of Thoracic Surgery* and the NGC stating that the guideline has been reviewed and there are no changes. Once approved, revised guidelines and their Executive Summaries which were originally published in *The Annals of Thoracic Surgery* again will be submitted to *The Annals* for publication. The revised full-length version of the guideline will be posted on the STS Web site. If the guideline is judged to be no longer valid, and is not revised, that will be noted in a letter to *The Annals*, and the invalid guideline will be taken off of the STS Web site.

References

1. Methodology Manual for ACC/AHA Guideline Writing Committees Methodologies and Policies from the ACC/AHA Task Force on Practice Guidelines, April, 2006.

2. Shekelle PG, Ortiz E, Rhodes S, Morton SC, Eccles MP, Grimshaw JM, and Woolf SH. Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA. 2001;286:1461-1467.

3. Shekelle P, Eccles MP, Grimshaw JM, and Woolf SH. When should clinical guidelines be updated? BMJ. 2001;323:155-157.
4. Rosenfeld RM, and Shiffman RN. Clinical practice guidelines: a manual for developing evidence-based guidelines to facilitate performance measurement and quality improvement. Otolaryngol Head Neck Surg. 2006;135:S1-28.

Approved by the Board of Directors of The Society of Thoracic Surgeons: May 11, 2008

STS Policy on Publication of Clinical Practice Guidelines in *The Annals*

Guidelines for "best" practice for diseases treated by members of The Society of Thoracic Surgeons are developed by the STS Workforce on Evidence Based Surgery. This workforce selects diseases/conditions that merit development of clinical practice guidelines. The purpose of the guidelines is to improve outcomes and enhance patient safety by disseminating current, evidence based knowledge for managing the selected disease.

Advance notice of guideline development. In order to allow planning for publication in *The Annal*s, the Chair of the Workforce on Evidence Based Surgery will inform the Editor whenever a task force is formed to develop a guideline, and will provide an estimated completion date. The guideline must adhere to the formatting requirements described below for publication in *The Annals* (print and electronic).

Frequency of publication. Theoretically there is no limit, but because demand for more clinical practice guidelines is strong, up to one per month is a reasonable, although currently an unattainable goal.

Length and format. The formatting requirements for a guideline submitted for publication in the monthly issue should follow the format for a review article as described in "Information for Authors." The word limit for review articles is **6500** words including abstract, text, figure legends, and references (all words submitted regardless of location). In addition, references are limited to no more than 80. **An executive summary focused on the major conclusions is required and replaces the abstract.** The executive summary does not have a word limit, but is included in the total word count.

Supplement publication of guidelines. Clinical practice guidelines submitted for publication as supplements to the journal are not subject to word or reference limits and will be considered for publication provided that the costs of publication are borne by the STS.

Because of perceived conflicts of interest, industry-sponsored "guidelines" are prohibited.

Electronic publication. Guidelines published in *The Annals* are immediately made available for electronic publication. These articles are open access when posted on CTSNet. Supplemental materials (e.g., additional references, text, tables, figures) incur page costs and are not published on either CTSNet or Science Direct, but are available on the STS website.

Guidelines submitted only for electronic publication on the STS website do not require review by the Editor of *The Annals*, but must be approved for posting by the STS Board of Directors or Executive Committee. No word limits are prescribed.

Approved by the STS Executive Committee: December 8, 2010