The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Clinical Practice Guidelines—Anticoagulation During Cardiopulmonary Bypass

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Despite more than a half century of "safe" cardiopulmonary bypass (CPB), the evidence base surrounding the conduct of anticoagulation therapy for CPB has not been organized into a succinct guideline. For this and other reasons, there is enormous practice variability relating to the use and dosing of heparin, monitoring heparin anticoagulation, reversal of anticoagulation, and the use of alternative anticoagulants. To address this and other gaps, The Society of Thoracic Surgeons, the Society of Cardiovascular Anesthesiologists, and the American Society of Extracorporeal Technology developed an Evidence Based Workgroup. This was a group of interdisciplinary professionals gathered to summarize the evidence and create practice recommendations for various aspects of CPB. To date, anticoagulation practices in CPB have not been standardized in accordance with the evidence base. This clinical practice guideline was written with the intent to fill the evidence gap and to establish best practices in anticoagulation therapy for CPB using the available evidence.

To identify relevant evidence, a systematic review was outlined and literature searches were conducted in PubMed using standardized medical subject heading (MeSH) terms from the National Library of Medicine list of search terms. Search dates were inclusive of January 2000 to December 2015. The search yielded 833 abstracts, which were reviewed by two independent reviewers. Once accepted into the full manuscript review stage, two members of the writing group evaluated each of 286 full papers for inclusion eligibility into the guideline document. Ninety-six manuscripts were included in the final review. In addition, 17 manuscripts published before 2000 were included to provide method, context, or additional supporting evidence for the recommendations as these papers were considered sentinel publications.

Members of the writing group wrote and developed recommendations based on review of the articles obtained and achieved more than two thirds agreement on each recommendation. The quality of information for a given recommendation allowed assessment of the level of evidence as recommended by the American College of Cardiology Foundation/American Heart Association Task

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The following clinical practice guidelines (CPGs) were developed before the publication of "The American Association for Thoracic Surgery/Society of Thoracic Surgeons Position Statement on Developing Clinical Practice Documents" (Bakaeen, et al. Ann Thorac Surg 2017;103:1350–6), and thus do not strictly adhere to the development process for CPGs outlined in that document. Nevertheless, these CPGs were the product of a lengthy and rigorous review by a multidisciplinary panel of experts, and approved by the leadership of all three participating societies. All future STS CPGs appearing in *The Annals of Thoracic Surgery* will be developed in accordance with the Position Statement.

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The Appendix and Supplemental Tables can be viewed in the online version of this article [https://doi.org/10.1016/j.athoracsur.2017.09.061] on http://www.annalsthoracicsurgery.org.

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Force on Practice Guidelines. Recommendations were written in the three following areas: (1) heparin dosing and monitoring for initiation and maintenance of CPB; (2) heparin contraindications and heparin alternatives; and (3) reversal of anticoagulation during cardiac operations. It is hoped that this guideline will serve as a resource and will stimulate investigators to conduct more research and to expand on the evidence base on the topic of anticoagulation therapy for CPB.

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The development of cardiopulmonary bypass (CPB) in the 1960s so successfully enabled open heart surgery that rigorous evidence-based clinical trials did not play a part in the initial phases of development [1]. After World War II, clinicians were faced with more and more treatment choices, to the point that uncertainty existed about the "best" options. Indeed, Archie Cochrane recognized the need for a more rigorous approach to give clinicians answers to key questions about patient treatments. Cochrane's efforts eventually led to the formation of the Cochrane Collaboration as a repository of evidence-based summaries to answer important clinical questions [2]. As a result, the modern era expects, and indeed requires, evidence to support surgeons' interventions, preferably in the form of randomized controlled trials (RCTs). During the last 60-plus years since the introduction of clinical CPB as the foundation for performance of cardiac operations, surgeon investigators developed a safe, efficient, and reproducible method of performing highly complex cardiac procedures using CPB. Many advances in CPB are the result of evidence-based RCTs. Others derive from prospective cohort studies and still others, from anecdotal practice or consensus.

Recognizing this large scope of practice and the varied nature of the evidence base to support the use of CPB, the Evidence Based Workforce of The Society of Thoracic Surgeons (STS) undertook a project to develop a series of practice guidelines that reflect the evidence base for the use of CPB in the current era. This effort included a collaboration with the Society of Cardiovascular Anesthesiologists (SCA) and the American Society of ExtraCorporeal Technology (AmSECT) to summarize available evidence in various areas of CPB. A critically important part of CPB is the use of anticoagulation therapy. To date, there are no evidence-based practice guidelines that define the optimal management of anticoagulation during the conduct of CPB. As a result, practice in this area is highly variable and not standardized in accordance with the evidence base to date. Therefore, the STS recognized this deficit and undertook a collaboration with the SCA and AmSECT to address the evidence gap regarding the use of anticoagulation treatment during CPB. This article reviews relevant published information about the use of anticoagulation for the conduct of CPB and provides a synthesis of the available evidence to create a clinical practice guideline. This guideline represents the initial evidence-based approach to the use of anticoagulation in CPB and is the only available comprehensive guideline of its kind. It is the hope of the authors that this guideline will stimulate investigators to amplify and elaborate on the evidence available on this topic.

Abbreviations and Acronyms

ACT	= activated clotting time
AmSECT	= The American Society of Extracorporeal Technology
CPB	= cardiopulmonary bypass
ECT	= ecarin clotting time
ELISA	= enzyme-linked immunosorbent assay
HIPA	= heparin-induced platelet activation
HIT	= heparin-induced thrombocytopenia
MeSH	= medical subject heading
PF4	= platelet factor 4
RCT	= randomized controlled trial
SCA	= The Society of Cardiovascular Anesthesiologists
SRA	= serotonin release assay
STS	= The Society of Thoracic Surgeons

Search Methods

To identify relevant evidence, a systematic review was outlined and literature searches were conducted in PubMed using standardized medical subject heading (MeSH) terms from the National Library of Medicine list of search terms and were inclusive of the dates January 2000 to December 2015. The following terms comprised the standard baseline search terms for topics and were connected with the logical "OR" connector:

- Extracorporeal circulation (MeSH number E04.292 includes extracorporeal membrane oxygenation, left heart bypass, hemofiltration, hemoperfusion, and cardiopulmonary bypass)
- Cardiovascular surgical procedures (MeSH number E04.100 includes off-pump coronary artery bypass graft surgery, coronary artery bypass graft surgery, myocardial revascularization, all valve operations, and all other operations on the heart)
- Pharmacologic actions of anticoagulant drugs (MeSH number D27.505 includes molecular mechanisms, physiologic effects, and therapeutic use of drugs)
- Anticoagulation reversal (MeSH number D12.776 includes protamine sulfate and other protamines and nuclear proteins)

These broad search terms allowed specific topics to be added to the search with the logical "AND" connector and

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