

**The Society  
of Thoracic  
Surgeons**

# **STS Health Policy Compendium**

*Created: January 2014*

The Society of Thoracic Surgeons  
Washington Office  
20 F St. NW, Suite 310 C  
Washington, DC 20001  
**T:** 202-787-1230 **E:** [advocacy@sts.org](mailto:advocacy@sts.org)

# About STS

Founded in 1964, The Society of Thoracic Surgeons is an international not-for-profit organization representing more than 7,500 cardiothoracic surgeons, researchers, and other health care professionals who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society's mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The STS National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. The STS National Database has four components—the Adult Cardiac Surgery Database (ACSD), the General Thoracic Surgery Database (GTSD), the Congenital Heart Surgery Database (CHSD), and the Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs) Database. Anesthesiology participation also is available within the ACSD and CHSD.

As a national leader in health care transparency and accountability, STS believes the public has a right to know the quality of surgical outcomes. To further this goal, the Society has established the STS Public Reporting initiative, which allows participants in the ACSD, CHSD, and GTSD to voluntarily publicly report their surgical outcomes.

STS also has partnered with the American College of Cardiology to create the STS/ACC TVT Registry™, a data repository developed to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. The Registry, which launched in December 2011, has since added mitral valve procedures. To date, approximately 600 sites have entered more than 195,00 patient records.

In 2011, the Society launched the STS Research Center, which seeks to capitalize on the value of the STS National Database and other resources to provide scientific evidence and support cutting-edge research that ultimately helps cardiothoracic surgeons, government, industry, and other interested parties improve surgical outcomes and the quality of patient care.

# CONTENTS

About STS	1
<hr/>	
Comparative Effectiveness Research	3
<hr/>	
Overview	3
STS and CER	4
STS Position on CER/PCOR Policy	5
Coverage with Evidence Development and Parallel Review of Medical Devices	9
<hr/>	
Overview	9
STS and CED/Parallel Review	10
STS Position on CED/Parallel Review Policy	10
Healthcare Associated Infections	13
<hr/>	
Overview	13
STS and HAI	13
STS Position on HAI Policy	14
Graduate Medical Education	16
<hr/>	
Overview	16
STS and GME	17
STS Position on GME Policy	19
Medical Liability Reform	21
<hr/>	
Overview	21
STS and MLR	23
STS Position on MLR Policy	23
Patient Advocacy – Lung Cancer Screening	25
<hr/>	
Overview	25
STS and Lung Cancer Screening	27
STS Position on Lung Cancer Screening	28
Physician Medicare Payments and the Sustainable Growth Rate	30
<hr/>	
Overview	30
STS and Quality Innovation	30
STS Position on Medicare Payment Policy	32
Tobacco and Nicotine	36
<hr/>	
Overview	36
STS and Tobacco	38
STS Position on Tobacco Policy	39
Appendix A: TAVR NCD Highlights	42
Appendix B: Adult Cardiac Surgery Checklist	43
Appendix C: General Thoracic Surgery Checklist	44
Appendix D: Congenital Heart Surgery Checklist	45
Appendix E: Metrics for Assessing the Performance of Medical Liability Reforms	46

# Comparative Effectiveness Research

## Overview

Comparative effectiveness, while still the province of the Agency for Healthcare Research and Quality (AHRQ), has been the object of considerable attention from policy-makers over the past few years. Efforts at health reform pre-dating the 2010 legislation attempted to define and promote comparative effectiveness research (CER) as a cost-saving, quality enhancement tool of policy-makers and healthcare providers alike.

AHRQ defines CER as research “to inform health-care (sic) decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care (sic).” AHRQ states that “there are two ways that this evidence is found:

- Researchers look at all of the available evidence about the benefits and harms of each choice for different groups of people from existing clinical trials, clinical studies, and other research. These are called research reviews, because they are systematic reviews of existing evidence.
- Researchers conduct studies that generate new evidence of effectiveness or comparative effectiveness of a test, treatment, procedure, or health-care (sic) service.<sup>1</sup>

Further, AHRQ states that CER, “requires the development, expansion, and use of a variety of data sources and methods to conduct timely and relevant research.”<sup>2</sup>

Created under the American Recovery and Reinvestment Act of 2009, the Federal Coordinating Council for Comparative Effectiveness Research (the Council) was established to foster optimum coordination of CER conducted or supported by Federal departments and agencies. The Council was also tasked with providing a report to Congress and the President containing information describing current Federal activities on comparative effectiveness research and recommendations for such research provided for under the act. In that report, the Council states that Comparative effectiveness differs from efficacy research because it is ultimately applicable to real world needs and other decisions faced by patient, clinicians, and other decision makers.”

The Council defined CER as:

The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.

This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.<sup>3</sup>

In the Affordable Care Act, Congress took a different approach to CER, attempting to solidify the link between CER and patient-centered care, by creating the Patient-Centered Outcomes Research Institute (PCORI). The PCORI board has defined Patient-Centered Outcomes Research (PCOR) in the following terms<sup>4</sup>:

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions such as:

- “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
- “What are my options and what are the potential benefits and harms of those options?”
- “What can I do to improve the outcomes that are most important to me?”
- “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives

## STS and CER

### STS / ACC ASCERT Study

Funded by the National Heart Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH), the ASCERT (American College of Cardiology Foundation-The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies) study was designed to examine the comparative long-term effectiveness of Coronary Artery Bypass Graft (CABG) and percutaneous coronary intervention (PCI) revascularization strategies in real world populations, including specific subgroups of patients such as those with diabetes, low ejection fractions, chronic lung disease, and renal dysfunction. The study uses data from STS Database and ACC registry along with CMS Medicare Provider Analysis and Review (MEDPAR) data. The total number of patients used in these analyses is an order of magnitude greater than in all previous randomized control trials combined. Comparative analyses were performed using propensity score and inverse probability weighting approaches.<sup>5,6</sup>

STS views the ASCERT study as a paradigm for a comparative effectiveness research enterprise based on linked clinical and administrative data. Clinically robust, broadly generalizable data from thousands of patients, linked with longitudinal outcomes from claims data, could quickly and cost-effectively answer a broad range of questions that will arise in the coming years of healthcare reform. At least in the cardiovascular world, the necessary data are available now. The results of these studies will be a unique source of information for patients and their providers about the potential

long-term results of different treatments in specific subgroups.

## STS/ACC TVT Registry

The TVT Registry™ is a benchmarking tool developed to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. Created by The Society of Thoracic Surgeons and the American College of Cardiology (ACC), the TVT Registry is designed to monitor the safety and efficacy of this new procedure for the treatment of aortic stenosis<sup>7</sup>.

Employing a first-of-its-kind transcatheter heart valve technology, TAVR provides a new treatment option for patients who are considered to be inoperable for conventional aortic valve replacement surgery. Through the capture and reporting of patient demographics, procedure details, and facility and physician information, the TVT Registry provides a data repository capable of delivering insight into clinical practice patterns and patient outcomes. Additionally, the TVT Registry has been approved by the Centers for Medicare and Medicaid Services (CMS) to meet the registry requirement outlined in the Medicare National Coverage Decision on TAVR.

The TVT Registry Measures:

- Patient demographics, provider and facility characteristics;
- History/risk factors, cardiac status and detailed health status;
- Well-defined indications for the procedure;
- Pre, intra and post-procedure data points and adverse event rates; and
- Outcomes at 30 days and one year.

Backed by the registry expertise of the ACC's NCDR® and the STS National Database, the TVT Registry serves as the main repository for clinical data related to TAVR and is positioned to incorporate future catheter-based procedures. A powerful data source, the registry allows the cardiovascular profession to monitor important safety information, detect infrequent complications and build the robust clinical research infrastructure necessary to advance the science surrounding the TAVR procedure. In this capacity, it will serve as a tool for conducting research in areas of comparative effectiveness, cost effectiveness and appropriate use criteria. Analysis of these data will allow the cardiovascular profession and medical community to understand how this new technology will be deployed throughout the U.S., and what impact it will have on patient outcomes as it becomes more prevalent. Data from the TVT Registry will assist the medical device industry and the FDA in surveillance of the quality, safety and efficacy of new medical devices.

## STS Position on CER/PCOR Policy

### General Priorities and Parameters

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence readily available to physicians and patients when they need it most about which treatments work best for which patients. We believe that federal agencies should target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, fostering the delivery of patient-centered care, and producing substantial benefit to the health care system as a whole.

All aspects of the CER process, including priority setting, must be transparent and include a set of mechanisms to support physician engagement and participation. STS also believes that initial priority areas of CER/PCOR should focus on high volume, high cost delivery models, modalities, and other health services which evidence significant variation in practice. In terms of methodology and study design, we appreciate that the PCORI board has included long-term and short-term assessments as PCOR should not be limited to new treatments. While we agree that the Board should establish a diverse portfolio of priorities, we believe that the national PCOR priorities should, at a minimum, address the prevention, management, and treatment of preventable disease which collectively

represent a major cost-driver in today's health care system. Areas in need of further study and research include cardiovascular, endocrinology and metabolic disorders (including diabetes), and nutrition (including obesity). There is a wide range of available research on prevention, nutrition, and obesity interventions with little clarity about which is most effective. We feel that research related to high-cost, preventable diseases will produce the most immediate and useful results.

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and system-wide. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients is necessary, as are other clinical interventions, technologies, and pharmaceutical remedies. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, we support the inclusion of racial and ethnic health disparities—and health disparities more generally—as a CER/PCOR priority area.

STS believes that the most effective way to study the complete “typical clinical population” is to utilize two powerful infrastructure mechanisms, registries and clinical data networks that not only produce research findings, but play a key role in priority-setting as well as uptake and adoption of findings in a rapid cycle. Clinical data registries allow health care stakeholders to more clearly observe patterns of care and the effectiveness of various interventions over time. In addition, because clinical registries can be designed to collect population demographics including race/ethnicity, gender, geographic location, socio-economic status, and other factors, they are a useful tool for addressing healthcare disparities as well.

Methodologically speaking, data from randomized controlled studies may not be ideal and are not always feasible to obtain, especially for surgical procedures and rare diseases. Effective CER/PCOR will require opportunities to incorporate data from alternative sources, such as clinical registries. Registries allow health care professionals to identify clinical research priorities in real-time, to generate and test hypotheses, and to develop clinical guidelines in a very rapid cycle. The development and use of registries also align with the Institute of Medicine's current effort to promote a “learning healthcare system”—a system that delivers the best care every time, and to learn and improve with each care experience.<sup>8</sup>

## **Defining CER/PCOR**

STS supports a broad definition of CER/PCOR that involves a comparison of different modalities, including health delivery models, to manage a specific health problem, condition, or disease. Besides the more typical areas of research, such as pharmaceuticals, medical devices and diagnostics, CER/PCOR should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes.

We understand that the mandate for PCORI is to focus on patient outcomes. We appreciate that the PCOR definition covers a broad range of categories from preventive, diagnostic, therapeutic, or health delivery system interventions.

## **Clinical Registries**

Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER/PCOR. We encourage federal support for clinical registry infrastructure creation and expansion. Utilizing, replicating, expanding, or integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on “real life” conditions where care delivery settings vary, patients may have numerous co-morbidities, and the patient populations are diverse. In turn, the clinical registries are not identical and may, to a greater or lesser extent, be able to promote a learning health care environment. Thus, evaluating the relative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building the CER/PCOR infrastructure and capacity, in part, upon registries

and clinical data networks will leverage CER/PCOR resources and boost the capacity of the system as a whole to learn and adapt in real-time.

STS is eager to participate in efforts to demonstrate the utility of clinical registries to develop an infrastructure to accelerate CER/PCOR and methodological research. We look forward to opportunities to assist federal agencies in this regard. CER/PCOR has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, may help address escalating health care costs. We look forward to working closely interested agencies to ensure that physicians remain engaged, enthusiastic, and involved stakeholders in this complex and very important process. We believe that CER/PCOR can help physicians, in collaboration with patients and families, to provide right care at the right time.

To facilitate scaling of this model across other healthcare sectors, we would advocate

- Incentives for hospitals to participate in registries and for specialties to develop new registries where needed;
- Technical support to facilitate the development of new clinical registries by professional organizations;
- Data element standardization across registries;
- Clarification of federal privacy regulations regarding the submission of unique patient identifiers required for linking across registries; and
- Facilitation of the often cumbersome “one-off” approach to acquisition and use of MEDPAR data through RESDAC.

## Regulatory Obstacles

There is significant regional variability in Institutional Review Board (IRB) requirements. In some instances, contribution of data to a national registry has been considered a quality reporting initiative and therefore IRB- exempt. At the other extreme, a significant number of IRBs have treated registry participation like a research effort, requiring the added burden of individual patient consents and standard research protections. While this presents an obstacle in terms of current registry projects, it is also a problem that individual physicians and hospitals will face with increasing frequency as they are held accountable for numerous private sector and ACA- authorized quality reporting requirements, many of which will necessitate the inclusion of patient-reported outcomes. Without some sort of governmental clarification indicating that registry reporting and data collection related to CER/PCOR are considered IRB-exempt quality reporting activities and do not require consent, this added regulatory burden will severely inhibit our ability to generate CER/PCOR data on the scale that will be required to support clinical decision-making at the point of care.

## CER and Patient Demographics

Finally, CER/PCOR should be designed, communicated, and used in ways that recognize variation in individual patients’ needs, circumstances, preferences, and responses to particular therapies, rather than encouraging one- size-fits-all solutions based on population averages. Similarly, CER/PCOR should support personalized medicine and the ability of physicians to tailor treatments to the needs of individual patients based on genetic information and other factors including patient preference, evidence-based, shared decision-making, and appropriateness of use criteria.

CER/PCOR has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, may help address escalating health care costs.

*Approved: January 27, 2013 (STS Board of Directors)*

<sup>1</sup> AHRQ. (n.d.). *Agency for Healthcare Research and Quality*. Retrieved 11 2013, from What is comparative effectiveness research: <http://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/>

<sup>2</sup> Ibid



<sup>3</sup> Effectiveness, F. C. (2009, June 30). Report to the President and the Congress. Retrieved November 2013, from

[http://www.tuftsctsi.org/~media/Files/CTSI/Library%20Files/FCC%20for%20CER%20Rpt%20to%20Pres%20and%20Congress\\_063009.ashx](http://www.tuftsctsi.org/~media/Files/CTSI/Library%20Files/FCC%20for%20CER%20Rpt%20to%20Pres%20and%20Congress_063009.ashx)

<sup>4</sup> PCORI. (2012, March 5). Patient-Centered Outcomes Research Instituted. Retrieved November 26, 2013, from Patient-Centered Outcomes Research:

<http://www.pcori.org/research-we-support/pcor/>

<sup>5</sup> Shahian, D., O'Brien, S., Sheng, S., Grover, F., Mayer, J., Jacobs, J., Edwards, F. (2012). Predictors of long-term survival after coronary artery bypass grafting: Results from the Society of Thoracic Surgeons Adult Cardiac Surgery Database (the ASCERT study). *Circulation*, 1491- 500.

<sup>6</sup> Klein, L. W., Edwards, F. H., DeLong, E. R., Ritzenthaler, L., Dangas, G. D., & Weintraub, W. S. (2010). ASCERT: The American College of Cardiology Foundation The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies. *The Journal of the American College of Cardiology Cardiovascular Interventions*, 124-126. Retrieved from <http://interventions.onlinejacc.org/cgi/content/full/3/1/124>

<sup>7</sup> <https://www.ncdr.com/TVT/Home/Default.aspx>

<sup>8</sup> Institute of Medicine. (2012, September 6). Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. Retrieved 2012, from IOM.edu:

<http://www.iom.edu/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>

# Coverage with Evidence Development and Parallel Review of Medical Devices

## Overview

### Coverage with Evidence Development

Coverage with Evidence Development (CED) is an evolving policy employed by the Centers for Medicare and Medicaid Services (CMS) that conditions national coverage of a novel item or service under Medicare Part A or B on additional data collection. Data collection requirements may include establishing a registry or conducting or participating in a clinical trial.

On May 16 2012, CMS held a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on evidentiary characteristics for coverage with evidence development (CED). This meeting followed CMS' earlier solicitation for public comments on its 2006 CED guidance document. CMS accepted public comments to inform changes to the existing CED policy. CMS' 2006 guidance on the use of CED indicated that this coverage tool would be used infrequently; however, recent coverage decisions suggest that CMS is beginning to use CED more frequently than expected.

Overall, the MEDCAC discussion favored frequent use of CED in CMS coverage decisions, under specific circumstances, and called on CMS to more clearly define evidentiary thresholds and criteria for applying CED. CMS released a draft, updated CED guidance document in November, 2012.<sup>1</sup>

### Parallel Review

The Food and Drug Administration (FDA) and the CMS have established a pilot program for concurrent review of certain FDA premarket review submissions for medical devices and CMS national coverage determinations. By reducing the interval between FDA marketing approval and Medical coverage, this process will facilitate the development of innovative products and shorten the time it takes to bring these important products to patients.

During its pilot phase, the agencies will offer to perform parallel review for up to five innovative devices per year. Appropriate candidates for the parallel review pilot are medical devices that meet one of the following criteria:

- New technologies for which the sponsor/requester has a pre-investigational device exemption (IDE) or an approved IDE application designation;
- New technologies that would require an original or supplemental application for premarket approval (PMA) or a petition for de novo review; or
- New technologies that fall within the scope of a Part A or Part B Medicare benefit category and are not subject to a national coverage decision (NCD)<sup>2</sup>.

The pilot program is voluntary and will not change the existing, separate and distinct review standards for FDA device approval and CMS coverage determination. It is only available for medical device technologies that meet the above criteria.

Although it was approved and accepted for coverage outside of the Parallel Review Pilot, the Edwards Sapien Transcatheter Aortic Valve Replacement (TAVR) device, may be considered one of the pioneers of parallel review. In the CMS Blog, Acting CMS Administrator Marilyn Tavenner touted the NCD for TAVR as

The result of an unprecedented level of collaboration between CMS, the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the American College of Cardiology, the Society of Thoracic Surgeons and Edwards Lifesciences, this proposed National Coverage Determination continues CMS' commitment to cross-agency collaboration and ensuring patients have access to the latest and best medical technology.<sup>3</sup>

## STS and CED/Parallel Review

- September 22, 2011: STS and the American College of Cardiology (ACC) initiated a request on, for a NCD on TAVR that would tie coverage to hospital and provider participation in a prospective, national, audited registry that consecutively enrolls TAVR patients, accepts all manufactured devices, follows patient outcomes for at least one year, and complies with relevant patient privacy protections.
- November 2, 2011: FDA approved Edwards Life Sciences Sapien device, the first TAVR device approved for use in the United States. FDA directed Edwards to "continue to evaluate the outcomes with the Sapien THV through a national Transcatheter Valve Therapy (TVT) registry."
- December 1, 2011: The STS/ACC TVT Registry was jointly developed to track real-world outcomes related to TAVR.
- May 1, 2012: CMS published a groundbreaking National Coverage Determination (NCD) that allows for Medicare CED for transcatheter aortic valve replacement (TAVR) using a national registry.<sup>4</sup>

The STS National Database has earned the Society a place at the leading edge of meaningful health care policy that helps to improve quality while improving efficiency in the delivery of care. Clinical registries are a proven resource to assist in both the FDA's efforts to approve new medical technology and CMS's mission to bring new medical treatments to beneficiaries more quickly. To that end, the Society has strongly supported CMS's use of CED. The Society believes the collection of additional information may be useful in determining that a treatment is reasonable and necessary while also serving to validate the safety and effectiveness of the treatment in question. Additionally, CED may better ensure that appropriate beneficiaries have earlier access to new medical technologies and services.

Throughout the TAVR approval and coverage determination processes, STS sent a strong message that the health care community – and the physician community in particular – has the ability and the responsibility to play an active role in the CED process.

## STS Position on CED/Parallel Review Policy

STS supports the development and use of data collection systems to ensure that patients, providers, and decision-makers, like CMS, can make decisions based on the best available clinical evidence. To that end, we strongly support CMS' use of CED. We believe that the collection of additional information may be useful in determining that a treatment is reasonable and necessary while also serving to ensure the safety of those receiving the treatment in question. Additionally, we believe that CED may better ensure that beneficiaries have appropriate access to new medical technologies and services at an earlier stage in their development.

We believe that the health care community, and the physician community in particular, has the ability and the responsibility to play an active role in the CED process. We believe CED/Parallel Review policy should encourage the following three principles:

1. Coordination among relevant stakeholders;
2. Early discussions among the agency and relevant stakeholders so as to allow sufficient time for ensuring appropriate application, design, and implementation of

- CED/Parallel Review;
3. Flexibility of the CED/Parallel Review data collection mechanism to adjust the inputs and outputs based on new developments.

## **Key Principle 1: Coordination among relevant stakeholders**

It is crucial that any CED/Parallel Review effort permits collaboration and generates buy-in from relevant stakeholders, including professional societies, government agencies, and industry. Some current activities fail to ensure complementary and collaborative activities between healthcare stakeholder segments. As such, many manufacturers of similar products in the same class often design their studies differently or collect disparate evidence. Further, different government agencies often have dissimilar evidentiary needs, forcing stakeholders to generate significant, varied data for different stakeholders.

STS believes that CED/Parallel Review policy can and should encourage integration and collaboration among different stakeholders. Given that many interventions are unproven from a real world perspective, CED/Parallel Review can be used to help all stakeholders to understand how new technologies work in patients. This can be accomplished by supporting the integration of clinical and administrative data which allows for real time clinical analyses and feedback to stakeholders. Protocol should be designed to enhance the ability for partnerships among industry members to better align development and data collection efforts and to meet the needs of regulators and payors.

STS' experience with the TVT Registry demonstrates that this model may be an effective platform to support collaboration and meet the needs of varied stakeholders. The TVT Registry relies on the integration of clinical and administrative data (e.g., it can be linked to CMS MEDPAR information) to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. The Registry tracks relevant outcomes, which allows stakeholders to use the information to enhance evidence-based shared decision-making with patients and caregivers. Standardized definition and data endpoints in the registry reduce redundancy, decrease unnecessary duplication, and increase important standardization in evidence development efforts. The TVT Registry model allows the varied needs of stakeholders to be addressed but does not "blend" or change different agencies' requirements (and thereby compromise the level or quality of evidence needed by one particular entity). The TVT Registry supports coordination among manufacturers on data collection efforts and has the potential to support the joint evidentiary needs of both CMS and FDA in light of the recently established parallel review initiative.

## **Key Principle 2: Early discussions among stakeholders**

Given the limited statutory timeframes of issuing a NCD, it is important to start the CED/Parallel Review discussion early to ensure sufficient time to setup the mechanism to capture the appropriate data elements and engage relevant stakeholders. In fact, going through a more robust and thorough process for designing CED may have addressed previous CED implementation challenges.

During the TAVR effort, STS and ACC initiated conversations with CMS, FDA, and other relevant stakeholders early to ensure upfront agreement on the components and structure of the TVT Registry. Lessons learned from STS/ACC's experience developing the TVT Registry suggest that CED/Parallel Review policy decisions can be successful if federal agencies facilitate early discussions among relevant stakeholders so as to allow sufficient time for ensuring appropriate application, design, and implementation of CED/Parallel Review.

## **Key Principle 3: Flexibility of the data collection mechanism**

The CED/Parallel Review process must be adaptable and able to evolve in order to respond the changing evidentiary and technology landscape, which may introduce new or different indications, outcomes, and subpopulations, among others. Data collection should be useable to identify anomalies, target the causes of adverse events, or identify the reason for changes in outcomes. Once

a medical specific issues/problem or population is identified, the data collection activities should be able to be adjusted to better capture specific types of information if early results suggest a need to focus on a specific outcome, population, etc. There are endless research questions that can be asked about a given device or product. Registries provide a pragmatic way to get the answers to all of those questions and registry data collection crosses agency boundaries providing a tangible asset to address a number of regulatory pathways

STS' experience with the TVT Registry suggests that data collection through a registry allows for the necessary flexibility and can evolve alongside the changing environment. The TVT Registry is able to target specific areas for clinical practice improvements, reflect actual practice patterns, assess national and regional averages, and support quality improvement.

*Approved January 27, 2013 (STS Board of Directors)*

<sup>1</sup> CMS. (2012, December). CMS.gov. Retrieved 2012, from Draft Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development in the context of coverage decisions: <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23>

<sup>2</sup> FDA. (2013, November). FDA.gov. Retrieved from FDA-CMS Parallel Review: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm>

<sup>3</sup> Tavenner, M. (2012, February 2). CMS Blog. Retrieved August 24, 2012, from CMS.gov: <http://blog.cms.gov/2012/02/02/better-coordination-leading-to-swifter-medicare-coverage-and-access/>

<sup>4</sup> See Appendix A

# Healthcare Associated Infections

## Overview

STS is intent on helping to reduce the incidence of healthcare associated infections and conditions in cardiothoracic surgery when possible, and has spent many years of collecting data through participant feedback, working toward this goal. Many hospital or healthcare-associated conditions are not always avoidable despite the adherence to evidence-based guidelines. For example, in 2009 mediastinitis was known to occur in 0.6 percent of coronary artery bypass graft (CABG) patients, but this does not mean that it is a 100 percent preventable condition. In obese patients with diabetes, the rate of this complication is estimated to be 10 times higher. We are unaware of any large studies that have reported a “zero” mediastinitis rate. Through the use of the STS National Cardiac Database, well-recognized risk factors for mediastinitis have been identified and reported (e.g. diabetes mellitus, obesity, etc.).

## Hospital Acquired Conditions

Since October 1, 2008, an inpatient hospital discharge is not assigned to a higher paying Medicare Severity Diagnosis-Related Group (MS-DRG) if a selected hospital-acquired condition (HAC) were not present on admission (POA). That is, the case will be paid as though the secondary diagnosis was not present. The selected HACs are among those that CMS determines: (1) are high cost, high volume, or both; (2) would result in the assignment of a case to a DRG that was a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

## HAI Data and Data Inventory

There is a significant need to reconcile differences among different data sources with respect to the type of data collected from each source and the ability of researchers to paint a thorough picture of the circumstances surrounding HAI. For example, signals detected through the Centers for Disease Control and Prevention (CDC) may not allow researchers to control for extraneous circumstances and comorbidities. For that reason, STS is working with a variety of stakeholders to align CDC nomenclature with clinical conditions to allow for more realistic signal detection that will allow for risk-adjusted HAI observations.

## STS and HAI

STS has long lead the way in patient safety and quality enhancement efforts through our ongoing, innovative work with the STS National Database – a long-standing, trail-blazing quality improvement tool. We believe that any payment methodology associated with hospital or health care-acquired infections should include risk adjustment. Payment that considers non-risk adjusted HAI as a factor will have a negative impact on care as physicians become more concerned about treating high-risk patients.

## Public Reporting

STS believes that the public has a right to know and understand the quality of surgical outcomes and sees public reporting as an ethical responsibility of the specialty. Our public reporting initiative is the culmination of many STS efforts. STS volunteer leaders have worked tirelessly to develop a mechanism whereby Database participants can voluntarily report their STS coronary artery bypass grafting (CABG) composite star ratings (overall and component domains).

STS has long recognized the importance of taking a leadership role in developing fair and meaningful reporting structures. Evaluations of quality based solely on administrative or claims data would be incomplete even in the best of situations, misleading and possibly inaccurate in the worst. STS methodology ensures that 11 individual components of clinical care are addressed, including mortality and morbidity rates and adherence to NQF-endorsed measures of quality<sup>1,2,3</sup>.

As part of its commitment to public reporting, STS has partnered with Consumers Union (CU), publishers of Consumer Reports, which now presents the 2009 STS CABG composite star ratings on the health section of its website. This STS Public Reporting Online Website complements the CU initiative and goes further in presenting hospital-level reports and using data going back to 2008<sup>4</sup>.

## Patient Safety Checklists

STS disseminates Patient Safety Checklists in each of the main areas of cardiothoracic surgery to its members:

- Adult Cardiac Surgery<sup>5</sup>
- General Thoracic Surgery<sup>6</sup>
- Congenital Heart Surgery<sup>7</sup>

## STS Position on HAI Policy

STS is concerned that the combination of unrealistic expectations and negative incentives may adversely influence physicians faced with providing care to those patients at higher risk. For example, we are troubled with the manner in which the current HAC payment policy has been implemented and how it will be incorporated into the Hospital Value Based Purchasing Program (VBP). STS does not believe that punitive payment mechanisms are the most appropriate or effective methods to reduce complications. In fact, we fear that the lack of risk adjustment combined with a punitive-payment approach may negatively impact patient care. Adverse consequences could include improper coding changes and limited patient access to care for patients who are most likely to have or acquire these complications.

STS agrees with only those approaches outlined in the National Action Plan to Prevent Healthcare Associated Infections (the Action Plan) (Department of Health and Human Services, 2012) that support reductions in hospital or health care-acquired infections through measurement, feedback, and focused systems efforts at improvement. As such, we are willing to work with all HAI stakeholders to develop appropriate risk-adjustment models for mediastinitis, clostridium difficile infections, ventilator-associated pneumonia, and other infections or conditions that can occur with cardiothoracic surgery.

STS supports implementation of Sec. 3008 of the Affordable Care Act, which modifies the current HAC payment policy by requiring the Secretary of HHS to employ an appropriate risk adjustment methodology so that hospitals are not unfairly punished for health care-acquired conditions that are not always avoidable. To that point, we note that the Action Plan calls for considerable, continuing research into the epidemiology of various HAI. Until the epidemiology of a particular condition is fully understood, it stands to reason that it is next to impossible to fully prevent it. Further, if we know that patients with certain characteristics and/or comorbidities are prone to particular HAI, complete elimination of that HAI may be impossible even with the most intense prevention efforts. While we share this lofty goal, and will continue to strive toward that end, we feel that payment policy should be appropriately risk-adjusted so as not to unfairly punish those who are already treating the sickest among us.

*Approved: January 27, 2013 (STS Board of Directors)*

- <sup>1</sup> Shahian, D. M. (2011). Public Reporting of Cardiac Surgery Performance:. *Ann Thorac Surg*, 92, S1. Retrieved from [http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformanceIntro\\_090611.pdf](http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformanceIntro_090611.pdf)
- <sup>2</sup> Shahian, D. M. (2011). Public Reporting of Cardiac Surgery Performance:. *Ann Thorac Surg*, 92, S2-S11. Retrieved from [http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformance\\_HistoryRationaleConsequences\\_090611.pdf](http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformance_HistoryRationaleConsequences_090611.pdf)
- <sup>3</sup> Shahian, D. M. (2011). Public Reporting of Cardiac Surgery Performance: Part 2 Implementation. *Ann Thorac Surg*, 92, S12-S23. Retrieved from [http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformance\\_Implementation\\_090611.pdf](http://www.sts.org/sites/default/files/documents/PublicReportingofCardiacSurgeryPerformance_Implementation_090611.pdf)
- <sup>4</sup> The business of healing hearts. (2011, September). *Consumer Reports*, pp. 26-36.
- <sup>5</sup> See Appendix B
- <sup>6</sup> See Appendix C
- <sup>7</sup> See Appendix D



# Graduate Medical Education

## Overview

### Funding Basics of Graduate Medical Education (GME)

Medicare is the single largest payer supporting Graduate Medical Education (GME) in the United States. Medicare spent approximately \$10 billion in 2012 on GME payments,<sup>1</sup> making up approximately two thirds of all funding. Additional sources of GME funding include Medicaid, patient care revenues, private payers, Veterans Affairs/Department of Defense, Health Resources and Services Administration (for children's hospitals) and other state and federal programs. Medicare GME funding is divided into two areas: Direct Graduate Medical Education (DGME) and Indirect Graduate Medical Education (IGME).

#### DGME Payments

DGME includes costs that are directly related to educating residents/fellows (trainees):

- Trainee and faculty salaries, benefits, and administrative expenses
- Other overhead costs

Basic Payment Formula: DGME payments are calculated using on a base period, per-resident amount (PRA) multiplied by the number of full-time equivalent (FTE) trainees the hospital staffed in the base period (i.e., 1 resident *working in patient care activities* full-time in one hospital = 1.0 FTE). The base period and PRA are typically based on the hospital's cost reporting period beginning in FY 1984 and the PRA is indexed for inflation each year. This is then multiplied by the hospital's ratio of Medicare inpatient days to total days to arrive at the DGME payment amount the hospital will receive from Medicare.

$$(PRA \times FTE) \times (Medicare \text{ inpatient days} / \text{total days}) = Medicare \text{ DGME } \$ \text{ Per Trainee}$$

$$\text{Example, Resident: } (\$85,000 \times 1.0) \times (212 / 365) = \$49,369.86$$

$$\text{Example, Fellow: } (\$85,000 \times 0.5) \times (212 / 365) = \$24,684.93$$

Trainees in their initial residency period (IRP) are counted as 1.0 FTE. Trainees who pursue training beyond the IRP or decide to retrain in another specialty are counted as 0.5 FTE. IRP examples include:

- General surgery = 5 years
- Internal Medicine = 3 years
- Obstetrics and gynecology = 4 years

Since cardiothoracic surgery trainees in traditional programs have already completed their general surgery residency and their IRP of five years, they are counted as 0.5 FTE for Medicare DGME payments. 6-year integrated program trainees will have 5 years at 1.0 FTE and one year at 0.5 FTE.

#### IGME Payments

IGME includes compensation to teaching hospitals for higher inpatient operating costs associated with residency programs:

- Lower productivity

- Standby capacity
- Increased patient complexity (above MS-DRG payments)

Basic Payment Formula: IGME payments are calculated as a percentage add-on to the hospital's Medicare per-case MS-DRG payments based on an intern and resident-to-bed ratio (IRB). The IRB is multiplied by a regional multiplier to calculate the IGME MS-DRG percentage increase.

The Medicare multiplier since 2003 has been 1.35 and basically amounts to a 5.5% increase to MS-DRG payments for 10% increase in the IRB.

$$\text{Multiplier} \times ((1 + \text{IRB})^{0.405} - 1) = \text{IGME \%} \text{ Example: } 1.35 \times ((1 + 0.215)^{0.405} - 1) = 11\%$$

*Example of impact on MS-DRG Payment*

*MS-DRG 236; Coronary Bypass w/o Cardiac Catheterization w/o MCC= \$21,240.74\**

*Example: \$21,240.74 x (1.11) = \$23,577.22*

*Increased payment of \$2,336.48 per case*

*\*Based on 2012 IPPS Medicare National rate*

## STS and GME

In the coming decades, the United States will face a projected shortage of both primary care and specialist physicians, including cardiothoracic surgeons. Robust, data-driven forecasting of physician supply and demand from a recent report by the American Association of Medical Colleges (AAMC) identified a projected physician shortfall of 40,800 to 104,900 physicians by 2030.<sup>2</sup> Analyses commissioned at the state-level overwhelmingly support this conclusion, with thirty three states identifying current or future physician shortages—including a shortfall of at least 1,500 cardiothoracic surgeons by 2025.<sup>3</sup>

Critics of such forecasts point to the U.S. health care system's increasing utilization of advanced practice registered nurses (APRNs) and physician assistants (PAs), and the identification of further efficiencies in primary-care settings as means of mitigating predicted shortages.<sup>4</sup> However, the AAMC's report accounted for the increasing supply of APRNs and PAs in their predictions, as well as changes in payment and delivery systems such as accountable care organizations and retail clinics. Despite controlling for these factors, a shortage of 7,300 to 43,100 primary care physicians is forecasted. Moreover, significant shortfalls are predicted amongst surgical specialties whose services are not well addressed by mid-level providers. The AAMC report predicts a shortage of between 19,800 and 29,000 surgeons by 2030.

The physician shortage is driven by many factors, including: an aging population and the retirement of senior physicians; an outdated cap on resident positions; a geographic maldistribution of specialists; and the ever-increasing technological proficiencies necessary to be competitive in the field. Unfortunately, shortages will disproportionately impact vulnerable and underserved populations. These groups include the approximately twenty percent of Americans who live in rural or inner-city locations that are designated as health professional shortage areas (HPSA).<sup>5</sup> Since Medicare accounts for the vast majority of GME funding, its policies have a massive impact on the system and are an important place to start when looking for ways to address the shortage.

Growing concern regarding the projected shortage of surgeons of all specialties was evident in the American College of Surgeons' 2017 Policy and Position Paper on GME Reform.<sup>6</sup> One factor causing considerable concern is that older physicians are retiring alongside the aging patient

population.

According to the latest AAMC workforce report, as of 2015 there were just 4,485 active cardiothoracic surgeons nationwide, which equated to 1 cardiothoracic surgeon per 71,665 people (increased from 62,577 people in a 2008 report). At the same time, fifty seven percent of active cardiothoracic surgeons are older than fifty five years. Among senior surgeons, forty four percent plan to retire between the age of sixty six and seventy years of age, escalating the shortage.<sup>7</sup> And even as the physician supply decreases, the patient demand increases: Baby Boomers are reaching older adulthood. The Medicare population is expected to grow from fifty four million Americans in 2015 to over eighty million beneficiaries by 2030.<sup>8</sup> Many researches have raised serious concerns about the dire consequences of a shortage of cardiothoracic surgeons tasked with caring for a growing Medicare-eligible population.<sup>9</sup> Cardiovascular disease accounts for more than one-third of the deaths in the U.S., and the Medicare population is at the highest risk. Older patients will suffer disproportionately if the projected shortage of surgeons is not addressed.

Another major factor that exacerbates the shortage as older physicians retire is the federal cap on residency positions, established by Congress in the Balanced Budget Act of 1997. Congress capped the number of residency positions that Medicare would support at the number of residents who were training in a given teaching hospital as of December 31, 1996.<sup>10</sup> Any new trainee position created after this twenty-year-old cap is not federally funded. Because of the cap, the number of thoracic surgery training programs has remained fairly constant since the late 1990's, with sixty nine traditional thoracic surgery residency programs (general surgery residency followed by thoracic surgery residency training) and twenty seven integrated thoracic surgery residency programs (general surgery training and thoracic surgery training combined into a six year program.)

In contrast, medical schools increased enrollment by twenty five percent between 2002 and 2015 in an attempt to address the projected physician shortage.<sup>11</sup> As the number of medical school graduates increases and the number of GME training programs remains stagnant, there will soon be a shortage of GME training opportunities for newly graduated physicians across all medical specialties. According to the latest report of the Accreditation Council for Graduate Medical Education, the goal of increasing medical school enrollment was achieved; enrollment is projected to have grown by thirty percent since 2002 by 2018, an increase of 4,946 students.<sup>12</sup> Yet because Congress limited the number of residents that can receive DGME funding, hospitals have no incentive to increase graduate medical education programs or start new programs.

The Affordable Care Act (ACA) of 2010 attempted to address these physician workforce issues by including a provision, effective for portions of cost reporting periods occurring on or after July 1, 2011, which redistributed DGME and IGME payments for trainee FTE's from hospitals that had fewer residents than their caps. CMS was to take sixty five percent of the DGME and IGME residency slots that went unused by a hospital for the past three years and redistribute them according to certain criteria. Seventy percent of the redistributions were to go to hospitals with resident-to-population ratios in the lowest quartile, and thirty percent to hospitals in health professional shortage areas (HPSA). On August 15, 2011, CMS posted a list of hospitals that would be either losing or gaining residency slots from their cap. Fifty eight hospitals received an increase in their caps while 276 hospitals saw reductions in their caps. In addition, the ACA called for training positions from hospitals that closed on or after March 28, 2008 to be redistributed to other hospitals. Prior to this provision, DGME and IGME payments allocated to hospital systems that closed were not redistributed and simply vanished. These reforms were a positive step, but have not solved the larger problem caused by the outdated caps.

Failure to increase federal funding for GME will prevent current thoracic surgery residency programs from expanding training opportunities and new programs from being created. Given the facts of population growth and aging, an increase in federal funding for GME is essential to address workforce shortages and access limitations in the future. Ensuring an adequate workforce, including the supply of skilled surgical specialists, will be crucial to successful health care reform implementation.

Projected manpower shortages in the thoracic surgical workforce are also compounded by a geographic maldistribution of physicians: some areas have more than enough cardiothoracic surgeons, while others have none. While this is well recognized in the area of primary care, there are data on the surgical fields as well. The best documented information is in General Surgery. An Institute of Medicine (IOM) Report noted that the current GME program does not produce adequate numbers of physicians prepared to work in needed specialties or geographic areas, and has failed to train and encourage physicians to practice in the community-based settings where most Americans seek care.<sup>13</sup> Furthermore, since a significant percentage of graduates of GME programs enter clinical practice in close proximity to their final program, the specialty mix and geographic location of GME programs are essential considerations to resolve the maldistribution of practicing physicians. Addressing inadequate physician distribution at the GME level is likely to have effects that are long lasting and less disruptive to existing physician practices than other options. This strategy requires a coordinated plan for identifying long- term physician workforce needs.

As all of these trends play out, the employment market is expanding. Cardiothoracic surgery is diversifying because of new advancements in mechanical circulatory support devices, endovascular aortic approaches, and percutaneous cardiac valves, to name a few growth areas. In a 2014 Thoracic Surgery Practice and Access Task Force Survey commissioned by STS, most respondents reported that it had been less than 3 years since their practices hired a new surgeon, which is similar to the findings of prior surveys. In a shift from previous surveys, however, respondents reported planning to hire at least 1 new surgeon in the next year.<sup>14</sup> In this new market for cardiothoracic surgeons, recruits must have “special skills.” These requirements have increased the training time to 9 years or more for forty percent of cardiothoracic surgeons. Lacking federal support, surgeons have disparate access to new training techniques depending on where they are located.

## STS Position on GME Policy

STS is pursuing the following professional and public policy options that may help address the looming cardiothoracic surgeon shortage and better distribute graduate medical education funding.

- To keep pace with increased medical school enrollment and patient demand, the federal government must increase the number of full time equivalent residents for which hospitals receive funding by lifting the caps. Medicare must continue supporting training costs by supporting at least a 15 percent increase in GME positions, allowing teaching hospitals to prepare another 4,000 physicians a year to meet the needs of a growing and aging population. STS has endorsed HR 2267/S 1301, the Resident Physician Shortage Reduction Act, as a step in the right direction towards this goal.
- There is no reliable funding mechanism to address physician and other health care professional development. It is critical to provide reliable funding, subject to periodic reassessment, which ensures a stable and thoughtful distribution in alignment with the changing needs of the nation.
- Some areas of the US face much more severe shortages than others, whereas a system that best serves all Americans should accurately reflect current and future health care needs. It is crucial to investigate geographical and economic factors that lead to the selection of cardiothoracic residency positions by applicants. It may be necessary to redistribute residency positions within cardiothoracic surgery programs.

Several pilot programs, such as the one undertaken by Utah, provide valuable lessons in ensuring that residents are located where they are needed. The Utah Medical Education

Commission (UMEC) applied for and received a waiver from CMS to distribute DGME funding based on the needs of various specialties as demonstrated by workforce surveys. During the project, FTE positions increased by thirty seven percent, including forty five positions outside the waiver that were “the result of the teaching hospitals within the consortium restructuring and reallocating their own GME resources based on UMEC’s recommendations.”<sup>15</sup> This program demonstrated the effectiveness of using data and public policy to redistribute funding and thus, surgeons.

Other options that incentivize surgeons to practice in underserved areas include loan deference and/or forgiveness programs, and immigration assistance for foreign-born surgeons. These types of policy solutions reduce the economic barriers for medical professionals to choose work in underserved areas.

- As teaching hospitals increasingly rely on new technologies to train the next generation of surgeons, Congress should pass legislation supporting the development of medical simulation technologies that augment training. Medical simulation clinical skills training allows physicians to train and improve techniques without any risk or harm, resulting in reduced errors and improved outcomes for patients while ultimately reducing costs. Some states currently provide grants for this purpose; federal funding would ensure that all residents benefit.

*Approved: January 2018 (STS Board of Directors)*

<sup>1</sup> "HEALTH CARE WORKFORCE Federal Investments in Training and the Availability of Data for Workforce Projections." US Senate HELP Committee. April 9, 2014. <https://www.help.senate.gov/imo/media/doc/Kohn.pdf>.

<sup>2</sup> "2017 Update: The Complexities of Physician Supply and Demand: Projections from 2015 to 2030." AAMC Projections. February 28, 2017. [https://aamc-black.global.ssl.fastly.net/production/media/filer\\_public/a5/c3/a5c3d565-14ec-48fb-974b-99fafaeeeb00/aamc\\_projections\\_update\\_2017.pdf](https://aamc-black.global.ssl.fastly.net/production/media/filer_public/a5/c3/a5c3d565-14ec-48fb-974b-99fafaeeeb00/aamc_projections_update_2017.pdf).

<sup>3</sup> "Recent Studies and Reports on Physician Shortages in the US." Center for Workforce Studies, Association of American Medical Colleges. October 2012. <https://www.aamc.org/download/100598/data/>.

<sup>4</sup> Gudbranson, E; Glickman, A; Emanuel, EJ. "Reassessing the Data on Whether a Physician Shortage Exists." The JAMA Network. May 16, 2017. <http://jamanetwork.com/journals/jama/article-abstract/2613209>

<sup>5</sup> HPSAs are designations that indicate health care provider shortages in primary, dental, or mental health care. There is currently no federal data on cardiothoracic surgery shortage areas.

<sup>6</sup> "ACS Policy & Position Paper on GME Reform." American College of Surgeons. January 2017.

[https://www.facs.org/-/media/files/advocacy/workforce/2017\\_ahp\\_gmepaperappendixprimer.ashx](https://www.facs.org/-/media/files/advocacy/workforce/2017_ahp_gmepaperappendixprimer.ashx)

<sup>7</sup> Ikonmidis, J. S. "The Society of Thoracic Surgeons Thoracic Surgery Practice and Access Task Force: 2014 Workforce Report." US National Library of Medicine. September 13, 2016. <https://www.ncbi.nlm.nih.gov/labs/articles/27637287/>

<sup>8</sup> "Report to the Congress: Medicare and the Health Care Delivery System" MedPAC.gov. 2015. <http://www.medpac.gov/docs/default-source/reports/chapter-2-the-next-generation-of-medicare-beneficiaries-june-2015-report.pdf?sfvrsn=0>

<sup>9</sup> Grover, Atul; Orłowski, Janis; Erikson, Cles. "The Nation's Physician Workforce and Future Challenges." Improving U.S. Healthcare Symposium. THE AMERICAN JOURNAL OF THE MEDICAL SCIENCES, 2016.

<https://www.aamc.org/download/452922/data/thenationsphysicianworkforceandfuturechallenges.pdf>

<sup>10</sup> Iglehart, John K. "The Residency Mismatch." THE NEW ENGLAND JOURNAL OF MEDICINE. July 25, 2013. <http://www.nejm.org/doi/pdf/10.1056/NEJMp1306445>.

<sup>11</sup> "Nation's Medical Schools Increase Enrollment by 25 Percent Since 2002." AAMC. May 5<sup>th</sup>, 2016.

[https://www.aamc.org/newsroom/newsreleases/459956/enrollment\\_survey\\_05052016.html](https://www.aamc.org/newsroom/newsreleases/459956/enrollment_survey_05052016.html)

<sup>12</sup> "Number of Accredited Programs Academic Year 2017-2018." August 31, 2017. ACGME

<https://apps.acgme.org/ads/Public/Reports/ReportRun?ReportId=3&CurrentYear=2017&AcademicYearId=2017>

<sup>13</sup> "Graduate Medical Education That Meets the Nation's Health Needs." The Institute of Medicine Report on GME. July 29, 2014.

<http://www.nationalacademies.org/hmd/Reports/2014/Graduate-Medical-Education-That-Meets-the-Nations-Health-Needs.aspx>

<sup>14</sup> Ikonmidis, 2016.

<sup>15</sup> ACS Policy & Position Paper on GME Reform.

# Medical Liability Reform

## Overview

### Medical Liability Reform Objectives

Meaningful and effective medical liability reform has the goal of improving patient care and outcomes by eliminating preventable errors, and saving money by decreasing incidence of defensive medicine.

### Analysis of Reform Policy

The following summarizes some of the more typical medical liability reform policies and assesses them against care-related and liability metrics which are described in Appendix E.

Effects of proposed medical liability reforms <sup>1</sup>		
Proposed reform	Description	Effects (see Appendix E)
<b>Caps on damages</b>	Limit amount of awards for non-economic losses or punitive damages	Reduces some defensive practices Mostly improves physician supply <sup>2</sup> Reduces indemnity payments Constrain growth of insurance premiums Limited or equivocal evidence on claims frequency or care quality
<b>Statute of limitation and repose</b>	Limit the amount of time a patient has to file a claim	Associated with modestly lower premiums No effect on indemnity payments Limited or equivocal evidence on defensive medicine, physician supply, quality of care, claims frequency, and overhead costs
<b>Pretrial screening panels</b>	Expert panels review cases to determine merit	May reduce defensive practices No effect on indemnity costs, claims, or premiums Limited or equivocal evidence on physician supply and quality of care
<b>Certificate-of-merit requirement</b>	Requires an affidavit from a medical expert affirming merit	Limited or equivocal effect on defensive medicine, physician supply, indemnity costs, overhead costs, claims frequency and premiums
<b>Limit on attorneys' fees</b>	Limits amount of plaintiff's attorney may charge as a contingency fee	No effect on indemnity costs, claims frequency, premiums, or physician supply Limited or equivocal evidence on defensive practices and quality of care
<b>Joint and several liability "fair share rule"</b>	When multiple defendants exist, liability is limited to the percentage of fault allocated to that defendant	No effect on indemnity costs, premiums, overhead costs, or physician supply Limited or equivocal evidence on defensive medicine, quality of care, and claims frequency

<b>Collateral-source rule</b>	Allows deduction of an award if injured patient has received compensation from another source	No effect on defensive medicine, physician supply, quality of care, indemnity costs, claims frequency, premiums, or overhead costs
<b>Periodic payment</b>	Allows awards to be made over a period of time rather than a lump sum	No effect on physician supply or indemnity costs Limited or equivocal effect on defensive medicine, quality of care, claims frequency, premiums, and overhead costs

Per the table above, many of the reform proposals have “limited” or “no effect” on the metrics in Appendix E. This clearly demonstrates the difficulty of developing meaningful medical liability reform policy that improves patient care and outcomes, and decreases incidence of defensive medicine. As a result, policy-makers have begun to explore other ways to implement meaningful reform.

## Federal Demonstration Grants

The Affordable Care Act (ACA)<sup>3</sup> contained a provision authorizing \$50 million in demonstration grant money to states for the development, implementation, and evaluation of alternatives to current tort litigation. All demonstrations must allow for the resolution of disputes and promote the reduction of health care errors by encouraging collection and analysis of patient safety data. Although authorized, ACA tort reform demonstration programs have not been awarded any money to proceed.

Prior to the enactment of the Affordable Care Act, President Obama directed the Secretary of Health and Human Services, Kathleen Sebelius, to launch medical liability planning grants and demonstration projects through the Agency for Healthcare Resources and Quality (AHRQ) to help States and health care systems test models that meet the following goals:

- Put patient safety first and work to reduce preventable injuries;
- Foster better communication between doctors and their patients;
- Ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits;
- And reduce liability premiums.
- \$23 million in grant funding was awarded under this program. AHRQ released the first annual report on these demonstrations in February, 2012, entitled *Medical Liability Reform and Patient Safety Initiative Progress Reports*.<sup>23</sup>

Some of the alternative reform proposals that have been tested as a part of these efforts, among other initiatives, are described below:

Alternative Medical Liability Reform Proposals	
Proposed reform	Description
<b>Full disclosure programs/ disclosure and offer</b>	Insurer and insured institution proactively disclose adverse outcomes, investigate, apologize, and compensate
<b>Health court</b>	Specialist judge and committee hears all malpractice cases
<b>Binding alternative dispute resolution</b>	Providers and patients submit disputes to a third party instead of a court
<b>Guidelines protection “safe harbor”</b>	Physicians practicing within established guidelines would be presumed to be non-negligent
<b>Enterprise liability</b>	Organizations bear some of the liability for malpractice
<b>No fault</b>	Administrative body replaces court, grants awards without seeking to prove fault
<b>Adverse event prevention</b>	Targets improvements in communication about potential adverse outcomes and focuses on attempts to reduce adverse events from happening



## STS and MLR

### **HR 5 (112th Congress):**

STS endorsed medical liability reform legislation introduced in the 112th Congress. Introduced by Representatives Phil Gingrey, MD (R-GA) and David Scott (D-GA) in the House and Sens. Roy Blunt (R-MO) and Mark Kirk (R-IL) in the Senate, the bills would have capped non-economic compensatory damages at \$250,000, established a statute of limitations for filing medical malpractice suits, and limited attorneys' fees in health care lawsuits.

### **HR 1473 (113th Congress):**

In the 113th Congress, Rep. Phil Gingrey introduced the Standard of Care Protection Act, which would protect physicians from new liability exposure resulting national care and practice standards put in place by the Affordable Care Act. The legislation would also disallow these new provisions from preempting states' existing liability laws.

This bill has been folded into the larger SGR repeal package put forth by the House Ways & Means Committee. STS has weighed in on the larger SGR package and continues to work towards passage of broad Medicare physician payment reform.

### **ACS MLR summit:**

In October, 2012, the American College of Surgeons hosted a Medical Liability Reform Summit with a wide range of MLR stakeholders in attendance. Participants heard presentations and took part in discussions of a wide array of topics including, alternative dispute resolution, arbitrators and mediators, risk management, health courts and safe harbors.

## STS Position on MLR Policy

Our country's inability to protect physicians from frivolous law suits while also maintaining patients' rights to seek redress for legitimate grievances has had a deleterious effect on STS members' ability to provide appropriate care. The prevalence of excessive tort claims against providers limits physicians' ability to provide needed health care services, affects the cardiothoracic surgical workforce as increasing numbers of medical students choose careers in fields with lower liability insurance costs, makes the practice of defensive medicine and the erosion of patient-centered care far more prevalent, and drives up the cost of health care nationwide. STS supports reforms of medical malpractice laws to help lower the costs and reduce incidence of defensive medicine throughout the health care system, while ensuring that patients injured by true malpractice are compensated fairly for their losses.

### **Demonstration Program Proposal**

Quality measurement and data on clinical risk should be used to reduce lawsuits and the cost of liability insurance, and to restore balance to the justice system. Setting standards aligned with best practices identified by specialty societies with simultaneous quality and outcomes assessment is the best way to institute meaningful medical liability reform. STS advocates for the testing of such models, perhaps under the demonstration programs described above.

STS is well-equipped to develop specialty-specific benchmarks and best practices. STS established the STS National Database 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. The Database includes quality performance measures in all three sub-



specialties of surgery; adult cardiac, general thoracic, and congenital. Many of these measures have been approved or are being considered for approval by NQF. By collecting outcomes data for submission to the STS National Database, surgeons are committing to improving the quality of care that their patients receive. Since its inception, more than 100 publications have been derived from Database outcomes and have significantly advanced knowledge in cardiothoracic surgery. In addition, in the interest of transparency, STS Public Reporting Online enables Database participants to voluntarily report to the public their coronary bypass surgery performance.

The STS National Database also serves as the backbone of the STS Risk Calculator. This tool allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity<sup>4</sup>. As a part of the medical liability reform mode, the STS Risk Calculator could be used to facilitate patient informed consent.

Despite the utility of these tools, we would caution that tort-reform should not be implemented in a way that is overly burdensome to specialty societies in general. Further, the creation of specialty-specific, clinical guidelines while being extremely useful in establishing a baseline for the “standard of care,” must be sufficiently specific in their intent such that poor clinical practices or judgments which may happen to meet minimum standards are not, necessarily, considered justifiable. Practice guidelines exist to “guide” physicians in the majority of clinical scenarios, but guidelines do not replace the time-honored physician judgment and should never be used in such a way that would make a physician vulnerable to malpractice litigation because (s)he thoughtfully deviated from the exact elements of the guideline and exercised the appropriate clinical judgment on an individual case. It is this recognition of the occasional patients with unique clinical features that warrant deviation from established “guidelines” and is the hallmark of a competent physician. This must never be used as a means to ensnare the physician for failure to strictly adhere to the exact elements of a clinical guideline.

## Additional Concerns

STS and its members across the country are also prepared to engage in a number of other medical liability reform efforts to move med malpractice out of the jurisdiction of the civil court system to a process that will rationally take into consideration the tenets of practice excellence. Any future reform must have stakeholder buy-in and representation. For example, having a relevant specialist empaneled on a health court or pretrial screening panels is absolutely essential. In addition, STS deems as particularly counterproductive and reprehensible the practice by plaintiff attorneys of using “expert witnesses” who have no specialty training relevant to the malpractice event under review other than a general medical degree. Without specialty training and familiarity with specific issues germane to the litigation, these individuals cannot be viewed as expert. STS proposes that any medical liability reform legislation include strict guidelines as to who/what constitutes an “expert” witness.

We will continue to actively monitor and participate in the alternative medical liability reform models described above.

*Approved: January 2014 (STS Board of Directors)*

<sup>1</sup> Metzler, I., & Meara, J. (2012, January). Medical Liability Reform: Evidence for legislative and alternative approaches. *Bulletin of the American College of Surgeons*, 97(1), 7.

<sup>2</sup> Further research may be required to determine if caps on damages has a more significant impact on certain medical specialties – those that have high malpractice premiums or high rates of lawsuits – above others.

<sup>3</sup> Public Law 111-148: Patient Protection and Affordable Care Act of 2010. (124 Stat. 1009; Date: 3/23/10). [www.ahrq.gov/qual/liability/medliabrep/htm](http://www.ahrq.gov/qual/liability/medliabrep/htm)

<sup>4</sup> <http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models/risk-calculator>

# Patient Advocacy – Lung Cancer Screening

## Overview

In November 2010, the National Lung Cancer Screening Trial (NLST) -- the largest and most expensive cancer randomized controlled trial ever conducted by the National Cancer Institute (NCI) -- provided conclusive evidence that CT screening can diagnose lung cancer at its earliest, most curable stage and significantly reduce deaths. Lung cancer is the leading cause of all cancer deaths, taking more lives each year than breast, prostate, colon and pancreatic cancers combined. Each year, 160,000 lives are lost to lung cancer, and only 16.6 percent of people diagnosed with lung cancer will live 5 years or longer.<sup>1,2</sup> Without screening, the majority of lung cancers will continue to be diagnosed at a late stage, when treatment options are extremely expensive and ultimately futile in almost all cases. Currently lung cancer is the leading cause of cancer costs under Medicare by every economic metric. Screening will shift the time of diagnosis to a younger, commercially insured population at early stage when treatments are far more successful and half the cost of late stage treatments.

The NLST randomized more than 53,000 patients to screening with low-dose computed tomography (LDCT) versus chest x-ray, and, in October 2010, the NLST was halted due to a 20% mortality reduction identified in the study population (LDCT).<sup>3</sup> According to STS President, Doug Wood, "A 20% mortality reduction is, by far, the most profound finding that benefits our patients at risk for lung cancer, overshadowing improvements in surgical care, new chemotherapy drugs, and evolution in radiation combined." As a result of the study, the National Comprehensive Cancer Network (NCCN) published a new guideline supporting lung cancer screening in October 2011.<sup>4</sup>

## USPSTF

On December 31, 2013, The U.S. Preventive Services Task Force (USPSTF) released a recommendation for using low-dose computed tomography (CT) screening for lung cancer among patients at high risk, endorsing a "B" Grade for the screening protocol.<sup>5</sup> The panel's recommendations for screening include current and former smokers age 55–80 years, who have a smoking history equivalent to a pack a day for 30 years or two packs a day for 20 years. The recommendation for screening also includes those who have quit within the past 15 years.

USPSTF Grade Definitions <sup>6</sup>		
Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

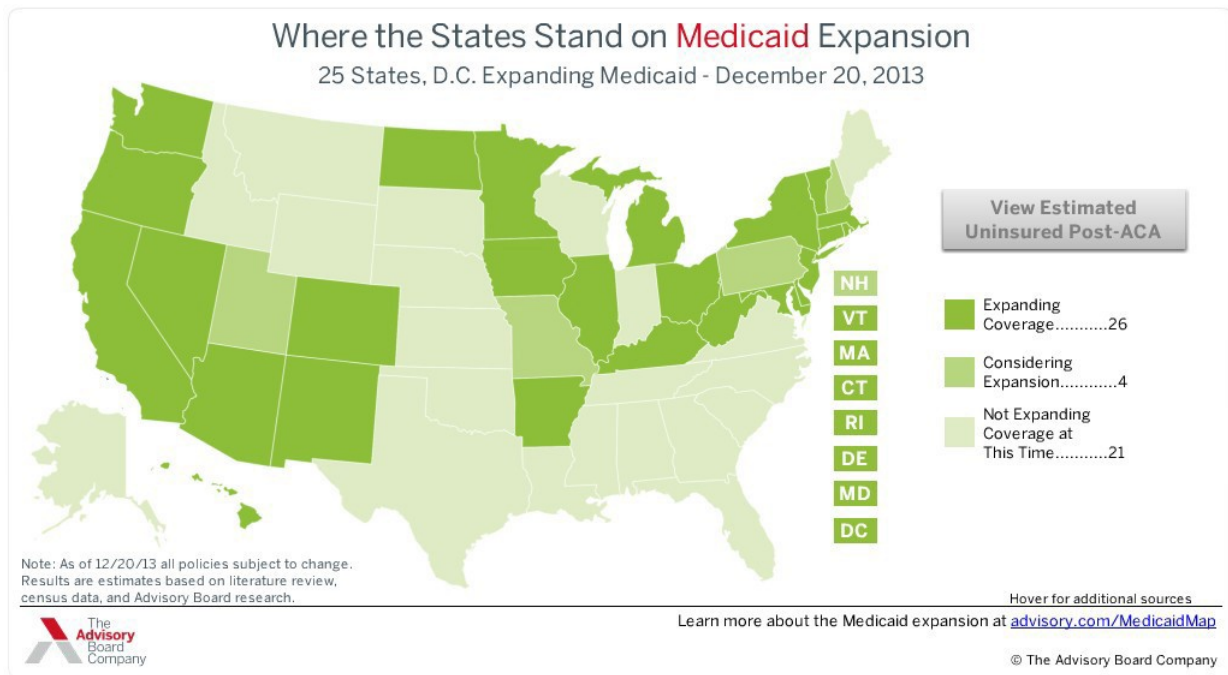
## Medicare

In 2014, Medicare is expected to publish a National Coverage Determination providing some Medicare beneficiaries access to lung cancer screening with no cost sharing.<sup>7</sup>

## Medicaid

Under the Affordable Care Act (ACA), states that elect to cover, without beneficiary cost sharing, all services graded level A or B by the USPSTF and approved vaccines and their administration, as recommended by the Advisory Committee in Immunization Practices (ACIP), will receive a one percent federal medical assistance percentage (FMAP) increase for expenditures related to those services. States may still opt to cover these services with cost-sharing between the patient and Medicaid under the existing Medicaid program. Medicaid alternative benefit plans, also referred to as Medicaid expansion under the ACA, must provide these services without cost-sharing to all applicable beneficiaries. Under the Medicaid expansion, states will receive additional federal funding for agreeing to cover adults who are less than or equal to 133 percent of the federal poverty level.<sup>8</sup>

As of September, 2013, only five states, California, Nevada, New Hampshire, New Jersey, and New York had opted to cover preventive services with no beneficiary cost-sharing, thereby making them eligible for a one percent FMAP increase for those services.<sup>9</sup> States that have approved the Medicaid expansion as of November, 2013 are shown in the map below.



10

## Private Insurance / Health Insurance Exchange

Effective September 23, 2010, all new group and individual health insurance plans must cover preventive services that have received a A or B grade from the USPSTF and immunizations recommended by the ACIP and other services for which there is supporting scientific evidence and which are recommended by the Department of Health and Human Services. New health plans must provide these services without applying deductibles or coinsurance if the services are provided in-network. Out-of-network services are eligible for cost-sharing. This requirement does not apply to health plans that have been requested to be “grandfathered” from new health benefit requirements. Plans must begin covering lung cancer screening as recommended by USPSTF by January 2015.

## STS and Lung Cancer Screening

### Research Advocacy

STS has supported several lung cancer policy initiatives, including the Lung Cancer Mortality Reduction Act. This bipartisan legislation, introduced in the 112th Congress, called for a multifaceted plan to address all aspects of lung cancer. Through a series of legislative compromises, language from the legislation was combined with the Pancreatic Cancer Research & Education Act to form the Recalcitrant Cancer Act of 2012, which was passed by Congress and signed into law in January 2013 as part of the National Defense Authorization Act of 2013.<sup>11</sup> The Act directs the National Cancer Institute (NCI) to convene a working group and establish a scientific framework for recalcitrant cancers. Recalcitrant cancers, such as lung cancer, are defined as types of cancers that have a 5-year relative survival rate of less than 20% and are estimated to cause at least 30,000 deaths annually. NCI must submit the framework to Congress by July 2014.

### Screening Guidelines Endorsement

In December, 2012, the STS Executive Committee adopted a Clinical Statement on the Role of the Surgeon and Surgical Issues Relating to Computed Tomography Screening Programs for Lung Cancer.<sup>12</sup>

## USPSTF Recommendation Advocacy and Endorsement

On July 30, 2013 the USPSTF posted its final evidence report and draft recommendation statement on screening for lung cancer, followed by a final recommendation issues on December 31, 2013. The Task Force provided a grade B draft recommendation supporting screening people “who are at high risk for lung cancer with annual low- dose CT scans, which can prevent a substantial number of lung cancer-related deaths.”

Prior to the July, 2013 recommendation, STS members reached out to their members of Congress and HHS Secretary, Kathleen Sebelius to try to expedite the USPSTF review. STS members noted that, absent a recommendation from the USPSTF more than two and a half years after the scientific validation of lung cancer screening by the NLST, the USPSTF’s delay in making its recommendation was a de facto denial of coverage.

STS also provided a comment letter in support of the B rating from USPSTF on lung cancer screening. In the letter, STS recommended that the USPSTF broaden the scope of lung cancer risk factors beyond smoking and age.

## STS Position on Lung Cancer Screening

STS agrees with the B rating from the U.S. Preventive Services Task Force that assures access to screening for patients at risk for lung cancer, as well as the language recommending screening for a group of high-risk patients. These recommendations provide clear guidance to physicians and other providers about the benefits, as well as potential harms, of LDCT screening, and even more importantly, empower patients to ask questions about screening with their physicians. The Task Force has been pragmatic in noting that the benefits may not exceed the potential harms in each individual patient, even in the group at high risk for cancer, stating “Shared decision making is important for persons within the population for whom screening is recommended. The benefit of screening varies with risk because persons who are at higher risk because of smoking history or other risk factors are more likely to benefit.” STS has long been a proponent of patient education, empowerment, and shared decision-making as evidenced by guidelines for the treatment of ischemic heart disease and recent participation in the Choosing Wisely™ campaign led by the American Board of Internal Medicine Foundation.

However, STS is concerned by the apparent decision by the USPSTF to disregard preexisting data about additional risk factors for lung cancer beyond smoking and age. The USPSTF should not have limited the consideration of all risk factors relevant for the development of lung cancer when one is making recommendations for screening policy. Studies have identified environmental, genetic, and other diagnoses as independent risk factors for lung cancer, often synergistic in combination with smoking. As a clinical trial the National Lung Screening Trial (NLST) limited its research question to patients based on age and smoking history only. Although this is an understandable limitation to allow conduct of a well-defined clinical trial, it should not limit the consideration of all risk factors relevant for the development of lung cancer when one is making recommendations for screening policy. It is naive and unrealistic to imply that lung cancer risk is limited to age and smoking history only.

The National Comprehensive Cancer Network recognized this and suggested that independent risk factors should be calculated in risk assessment for persons to be considered for lung cancer

screening. Asbestos and radon exposure, family history, history of certain previous cancers, COPD, and pulmonary fibrosis are examples of relevant patient history that should be factored into recommendations for lung cancer screening.

Although the data is softer than the randomized trial data from the NLST, STS has strongly recommended that USPSTF consider broadening their inclusion criteria for screening to include patients with less cigarette exposure if combined with additional independent risk factors for the development of lung cancer, similar to that proposed by the broad panel of experts convened by the NCCN. We will continue to advocate that for screening for patients with these additional risk factors be included as an essential health benefit.

STS will continue to advocate that all federal and private health plans cover lung cancer screening. Specifically, STS will be working with other stakeholder groups to ensure proper coverage of lung cancer screening for Medicare beneficiaries.

*Approved: January 2014 (STS Board of Directors)*

<sup>1</sup> <http://www.cdc.gov/cancer/lung/statistics/>

<sup>2</sup> <http://seer.cancer.gov/statfacts/html/lungb.html>

<sup>3</sup> <http://www.cancer.gov/clinicaltrials/noteworthy-trials/nlst/nlstataglance/nlst-at-a-glance>

<sup>4</sup> [http://www.lungcanceralliance.org/assets/docs/news/NCCN%20Screening%20Guidelines%2010\\_11.pdf](http://www.lungcanceralliance.org/assets/docs/news/NCCN%20Screening%20Guidelines%2010_11.pdf)

<sup>5</sup> <http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.htm>

<sup>6</sup> <http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm#post>

<sup>7</sup> <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>

<sup>8</sup> <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-13-002.pdf>

<sup>9</sup> [http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/affordable\\_care\\_act\\_update\\_sept2013.pdf](http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/affordable_care_act_update_sept2013.pdf)

<sup>10</sup> <http://www.advisory.com/daily-briefing/resources/primers/medicaidmap>

<sup>11</sup> <http://www.gpo.gov/fdsys/pkg/BILLS-112hr4310enr/pdf/BILLS-112hr4310enr.pdf>

<sup>12</sup> <http://www.sts.org/sites/default/files/documents/pdf/guidelines/LungScreeningClinicalStatement.pdf>

# Physician Medicare Payments and the Sustainable Growth Rate

## Overview

The Medicare Sustainable Growth Rate is the conversion factor used by CMS to determine physician payments for services provided to Medicare Part B (outpatient) beneficiaries. Enacted under the Balanced Budget Act of 1997, the SGR-based formula was adopted to control spending growth by pegging physician reimbursements to growth in GDP. Beginning in 2002 and each subsequent year the SGR-based payment system has been scheduled to impose a cut to physician pay. Congress has voted 12 times to stave off impending reductions to Medicare payments.

Each time Congress passes a temporary patch, a permanent solution becomes more expensive and unlikely. The continued delay in replacing the SGR has escalated the cost of permanent payment reform from \$48 billion in 2005 to more than \$300 billion today. In Fiscal Year (FY) 2013, according to the FY 2013 Physician Fee Schedule, physicians were scheduled to receive a 27.4% cut in pay in addition to a probable 2% sequestration of all federal outlays mandated under the Budget Control Act of 2011.

Many attribute the rising cost of healthcare to the current Medicare payment methodology that rewards physicians for the quantity of services they provide rather than the quality of care the patients receive. If Congress is to act to repeal the current payment formula, they will need to identify a quality-based payment mechanism to stand in its place or at the very minimum must establish a payment system that avoids penalizing physician specialties that develop and disseminate changes in practice patterns that reduce the volume of services provided while maintaining the same or better quality. As a leader in the provision of evidence-based quality healthcare, STS stands at the forefront of this ongoing conversation.

## STS and Quality Innovation

### Quality and Outcome Measures

STS has an extensive quality program that includes development of National Quality Forum- (NQF) endorsed quality measures and inclusion in CMS's Physician Quality Reporting System (PQRS). STS has developed composite, outcome, process and structure measures focused in the three subspecialty areas of Adult Cardiac Surgery, Congenital Heart Surgery and General Thoracic Surgery. STS National Database participants can voluntarily elect to have STS send their data from the Adult Cardiac Surgery Database directly to CMS's PQRS. The STS Adult Cardiac Database has been successfully used as the platform for statewide quality improvement initiatives in Michigan (Share, et al., 2011) and Virginia (Speir, Rich, Crosby, & Fonner, Jr., 2009), and to increase the use of arterial grafts and beta-blockers in a multi-state initiative (Ferguson Jr., et al., 2003).

In the interests of transparency, the Society has also established STS Public Reporting Online<sup>1</sup> the publishing of Coronary Artery Bypass Graft (CABG) composite quality ratings from STS Adult Cardiac Surgery Database participants who have volunteered to participate. Launched in January 2011, STS received consent from 226 database participants to report their information through STS Public Reporting Online. Today, overall composite star ratings as well as their component ratings are listed on the STS website for 386 Database participants. These ratings were recently published in Consumer Reports as a consumers' guide on how heart surgeons "perform (The business of healing hearts, 2011)."



## Evidence-Based Guidelines

The Society of Thoracic Surgeons Workforce on Evidence Based Surgery has developed evidence-based guidelines to provide practical assistance to STS membership. Thorough research of each guideline topic is completed through an exhaustive review of clinical information. The conclusions and recommendations are based on a review of scientific evidence published in the medical literature.

STS Clinical Practice Guidelines are intended to assist physicians and other health care providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. STS has developed clinical guidelines on areas such as pre- and post- surgical antibiotic management, blood conservation, managing atrial fibrillation and surgical management of endocarditis.

## Patient Registries

Tools such as the STS National Database can be utilized to track, monitor, and assess clinical improvement by physicians. To this end, the STS National Database plays an essential role in several initiatives aimed at improving health care quality.

In early 2012, CMS contracted with STS to develop measures that reflect quality of care for patients undergoing CABG. Specifically, STS will use its robust database to develop a hospital-level all-cause risk-adjusted readmission measure for CABG.

Additionally, the STS National Database plays a valuable role in many regional quality improvement programs. In the Virginia Cardiac Surgery Quality Initiative (VCSQI) Unsolicited Demonstration Project, which is a voluntary consortium of 17 hospitals and 13 cardiac surgical practices providing open-heart surgery in the Commonwealth of Virginia, participants utilize the STS National Database to identify quality improvement opportunities and patient outcomes. The work of the VCSQI has gone beyond quality improvement to include cost containment in cardiac surgery and its work has been highlighted in numerous Congressional testimonies over the past several years (Rich, Jeffrey on behalf of STS, October 7, 2005), (Rich, Measuring Physician Quality and Efficiency of Care for Medicare Beneficiaries, March 15, 2005), (Rich, Medicare Physician Payment: How to Build a Payment System the Provides Quality, Efficient Care for Medicare Beneficiaries, July 27, 2006), (Mayer Jr, MD, 2009), (STS, February, 2012).

As described previously, the STS National Database is the information platform for the Michigan STS initiative which involves all institutions and surgeons in Michigan and has led to the adoption of higher quality surgical practices such as the use of arterial bypass conduits during coronary artery bypass operations. The Northern New England Cardiovascular Study Group has used similar methods over many years to improve the mortality rates for patients undergoing coronary artery bypass surgery and to completely eliminate the inter-institutional variation in outcomes that was present initially.

STS actively engages in the creation of quality performance measures many of which have been endorsed by the National Quality Forum. Some of the Society's measures have also been approved for inclusion in the PQRS, allowing STS National Database participants who participate in PQRS to qualify for incentive payments by satisfactorily reporting on the approved quality measures under the existing program.

Non-Medicare payers have readily recognized that the utilization of quality performance measures generated from comprehensive clinical registries that offer alternatives to standard fee for service reimbursement. By linking overall payments, or supplemental payment to routine reimbursement, to clinical outcomes that have exceeded accepted benchmarks derived from recognized clinical databases, non-Medicare payers have established legal incentives to surgical providers who have achieved clinical improvement to cardiac surgical care at decreased cost by reduction of mortality and morbidity. This is exemplified by the pay for performance agreement with the cardiac surgery practices that were members of the VCSQI and Anthem that was in effect from 2006 to 2011.



Clinical and process metrics were generated and mutually agreed upon, derived from STS performance measures, and endorsed by the National Quality Forum. Weighted scores were derived from such metrics and augmented payments to contracted rates, ranging between 3 percent and 8 percent, were then added to the payments of surgical care depending upon the extent to which these metrics were achieved. This resulted in an overall improvement in care with associated decrease in costs by those providers who exceeded established quality standards. Importantly, the Michigan initiative has also received major funding through a grant from Michigan Blue Cross.

From 2006 to the present, STS has partnered with WellPoint, one of the largest private health plans, to provide performance information from hospitals and medical groups that agreed to share their data from the Society's Adult Cardiac Surgery Database of nationally accepted outcomes measures for adult cardiothoracic surgical procedures.

STS provides WellPoint with a series of reports on the quality performance of hospitals and cardiothoracic surgeon groups in certain states served by WellPoint health plans. The reports highlight participant performance on approximately 15 performance measures that have been endorsed by the National Quality Forum. These measures represent the first national voluntary consensus measures for cardiac surgical care, and include use of beta blockers before and after surgery, as well as infection and mortality rates. WellPoint has incorporated performance on these quality measures into its pay-for-performance and quality improvement programs, including the Quality-In-Sights: Hospital Incentive Program. The Society also provides information on quality performance to United Healthcare, which incorporates STS's quality metrics into their quality recognition program. Periodically, STS has provided quality performance information to Blue Cross Blue Shield related to its Blue Distinction Quality Recognition Program.

Finally, employing a first-of-its-kind transcatheter heart valve technology, TAVR provides a new treatment option for patients who are considered to be inoperable for conventional aortic valve replacement surgery. Through the capture and reporting of patient demographics, procedure details, and facility and physician information, the TVT Registry provides a data repository capable of delivering insight into clinical practice patterns and patient outcomes. According to a recent National Coverage Determination, the TVT Registry will likely play a pivotal role in CMS' coverage with evidence development of TAVR.

## STS Position on Medicare Payment Policy

STS believes that an alternative payment methodology should align incentives along specialty or disease process lines at the regional or national level. This type of payment system would foster and incentivize physicians to act as members of a profession and fulfill their professional responsibilities to collaborate and share knowledge and practices with their peers (Mayer Jr, MD, 2009). There are several alternatives to current Medicare physician and hospital payment mechanisms which could advance these goals, including specialty-specific conversion factors for physician payment and global payments to hospitals and physicians for specified procedures such as isolated coronary bypass procedures

STS believes that the most powerful and reliable method to affect physician practice is to engage physicians in the collection of outcomes data on the services that they provide, and to provide meaningful, risk-adjusted feedback that allows them to compare these outcomes to those of their peers. We believe that the reimbursement system should promote physician practices that exemplify the profession's responsibilities to not only improve the quality of the care that is given to patients but also to wisely allocate societal healthcare resources. We also believe that responsible professional organizations provide important database and educational resources that can provide the infrastructure to support the needed improvements in physician practice and resource utilization.

Any modernization of the physician payment system should ensure that individual medical specialties can—and have incentive to—control the growth rate of their services and payments by identifying the most effective and appropriate treatment for the patient. At the very least, specialties should not be penalized if their quality and value improvement activities result in a lower Medicare utilization and expenditures (Alhassani, Chandra, & Chernew, Sources of the SGR "Hole", 2012). As the STS National Database and registries of other specialties have demonstrated, feedback of credible, risk-adjusted outcomes data encourages physicians to change their practice patterns to achieve better outcomes, more efficient care delivery, and thereby, increased patient value. The following should be included in any Medicare physician payment reform initiatives:

- Mandate and incentivize the development and utilization of clinical data registries;
- Require the Centers for Medicare and Medicaid Services (CMS) and other payers to make administrative (cost and claims) data available to registries for use in their analyses so that resource utilization becomes an outcome variable to be assessed in the same manner as traditional clinical outcomes such as mortality or complication rates;
- Address barriers imposed by federal and state privacy regulations;
- Allow physicians to share the savings generated by their quality improvement efforts and consider providing economic incentives and disincentives at higher level than the individual physician or practice; and
- Utilize registries and other resources to generate comparative effectiveness research.
- Consider significant changes to reimbursement systems for both hospitals and physicians that promote wise use of resources and improved clinical outcomes

STS believes that meaningful quality measures and rewards for physician performance cannot be applied simply to administrative data reported by hospitals and physicians (Bufalino VJ, 2011). While administrative data provides information on longitudinal medical treatment and resource utilization across settings of care and by various physicians, its clinical accuracy has been shown to be sub-optimal (Shahian & Normand, Comparison of "risk-adjusted" hospital outcomes, 2008), and it excludes pertinent information on patient risk factors, disease severity, or clinical outcomes. This critical information is only found in clinical datasets where there is input of clinical data by clinicians. It is only by linking administrative and clinical data that we can appropriately and accurately assess whether physicians are improving patient outcomes.

## **Registry-Based Reform**

STS urges the policy-makers to consider quality incentive programs that encourage the coordination of Medicare claims data with existing registries to enhance patient monitoring and physician performance, and improve quality. Without linking the administrative data collected by health plans with the clinical information reported by clinicians, patients cannot be effectively monitored. By using linked longitudinal registries, physicians can more broadly monitor patients for readmissions or care transitions. Similarly, longitudinal patient histories allow physicians to assess the success of cardiothoracic interventions. The successful linking of the STS database with CMS administrative data in Virginia, for example, has led to a clinical/financial tool that brings quality improvement and cost containment to reality through a focus on reductions in costly complications and the redesign of care delivery models that promote high quality efficient care.

## **Public Reporting and Patient Involvement**

It is important that patients have access to high-quality, high-value healthcare services. Through STS Public Reporting Online and incorporation of STS quality measures in other ranking programs, STS has led the way towards increasing transparency and access to value-based care. STS encourages patients to utilize these tools in seeking out cardiothoracic surgery services.

STS believes that patients will seek high-value healthcare services if they are provided with access to accurate, vetted physician and hospital performance measurements or ratings. The STS Public Reporting Online program allows patients to review provider scores based on a "star" system derived from quality measures reported to the STS National Database (The business of healing hearts, 2011).

The U.S. News and World Report utilized the STS Congenital Heart Surgery Database in their ranking calculations for the Best Children's Hospitals of 2011–2012 (Olmsted, et al., 2011). Hospitals reporting congenital heart program data to the Database earned additional points for quality improvement activities. We believe that including endorsed measures and quality programs in these publicly available ranking programs is beneficial to both providers and patients. However, we strongly urge that any performance information must be appropriately risk-adjusted and weighted and we believe that clinical registries such as the STS Databases offer the most valid and reliable mechanisms for risk-adjustment. We also believe that there should be mechanisms in place to allow for physician appeal of the ratings prior to public release.

## Care Coordination

STS believes that quality improvement initiatives such as Accountable Care Organizations (ACOs) have the potential to improve the quality of patient care and patient outcomes. However, the final ACO rule released by CMS mandates that participating ACOs must comply with 33 quality measures, none of which are relevant to cardiothoracic (CT) surgery. Measures used in any payment delivery model must include items for specialists, such as CT surgeons, to encourage their participation. Moreover, the final ACO rule does not require registry-based reporting, such as that in the STS National Database.

STS supports the use of payment systems that align incentives not only between physicians and hospitals, but also among physicians of the same or related specialties. Bundled payment, such as the previously mentioned VCSQI and the CMS Acute Care Episode (ACE) demo, are appropriate alternatives to the current fee-for-service environment. Utilizing STS data, both programs were shown to be associated with improved quality and patient outcomes when physician payment is bundled with the hospital. By bundling payments, Medicare can align payment with quality and efficiency based on the patient's disease or condition.

## Regulatory Relief

As stated previously, the lack of access to Medicare cost and utilization data for physician claims is a roadblock in the path towards understanding care delivery and the impact of medical and surgical interventions. We believe that important first steps have been taken in opening the Medicare claims files to collaborating investigators from STS and the American College of Cardiology in the NIH funded ASCERT comparative effectiveness trial on coronary artery disease treatments recently reported in the New England Journal of Medicine and in the Annals of Thoracic Surgery (Weintraub, et al., 2012) (Shahian, et al., 2012). We urge the Committee to eliminate any barriers that prevent CMS from sharing this data with approved registries and databases. Physicians, hospitals, payers and patients could all benefit if registries could access and merge this data with administrative claims to study trends and ultimately improve the quality of interventions (Jacobs, et al., Successful linking of the Society of Thoracic Surgeons adult cardiac surgery database to Centers for Medicare and Medicaid Services Medicare data, 2010).

In addition, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the Social Security Death Master File (SSDMF). There are continuing efforts to restrict access to the SSDMF further so as to protect those listed in the file from identity theft. As expressed in a recent letter to Social Security Commissioner, "linking clinical registries to the SSDMF allows for the verification of 'life status' of patients who otherwise would be lost for follow up after their treatment. Research based on this information helps physicians to provide information to today's patients and families to help them with decision making. Outcomes data gives patients confidence in their medical interventions and demonstrates to patients and their families the durability and long-term benefits of medical procedures (Jacobs, et al., Successful linking of the Society of Thoracic Surgeons database to social security data to examine survival after cardiac operations, 2011) (The Society of Thoracic Surgeons, et. al.)." We look forward to working with Congress to find a solution to this problem that protects those listed in the SSDMF and their families from fraud while allowing legitimate users continued access to this important resource.

We also encourage Congress to consider the effects of certain regulations that impose restrictions on potential gainsharing programs among providers. STS has commented to CMS on Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center (The Society of Thoracic Surgeons).

In addition, the current and upcoming reporting programs will greatly impact the amount of time and attention physicians can dedicate to their patients. These programs include the value-based modifier, penalties under the electronic prescribing (e-prescribing) program, PQRS and EHR incentive program. We have recently joined over 90 other specialty and state medical societies to urge CMS to re-evaluate the penalty timelines associated with these programs and examine the administrative and financial burdens and intersection of these various federal regulatory programs. The combined implementation of these programs, along with preparations for transition to the ICD-10 coding system in 2014, may cause confusion and burden for physician practices.

While these programs are designed to improve quality, the design and implementation schedules place an administrative burden on physicians and their practices. Our hope is that these programs can be streamlined to work in concert with each other rather than creating repetitive work for physicians and their staff.

As the facility setting is the primary setting for care delivered by cardiothoracic surgeons, our members influence both physician and hospital reimbursements and revenues. Cardiothoracic surgeons need to be involved not only in discussions regarding Medicare physician payment systems, but also hospital payment systems. While cardiothoracic surgeons are not primary care physicians and to this point in time have not been the lead physicians performing care coordination services and chronic condition management, our members do have a significant influence over costs and value in the healthcare system. Any changes to physician and hospital payment systems should be those that effectively and adequately value both primary care and specialty services.

Finally, we hope that Congress will use payment reform as an opportunity to address the issue of medical liability. Our inability to protect physicians from frivolous law suits while maintaining patients' rights to seek redress for legitimate grievances has had a deleterious effect on our ability to provide appropriate care. In addition to limiting physicians' ability to provide needed health care services, our current system is affecting the cardiothoracic surgical workforce as increasing numbers of medical students choose careers in fields with lower liability insurance costs.

*Approved: January 27, 2013 (STS Board of Directors)*

<sup>1</sup> <http://www.sts.org/quality-research-patient-safety/sts-public-reporting-online>

# Tobacco and Nicotine

## Overview

### Death & Disease

Tobacco exposure is the leading preventable cause of death and disease in the United States (U.S.). Worldwide, tobacco use causes more than seven million deaths per year.<sup>1</sup> In the US alone, cigarette smoking is responsible for more than 480,000 deaths per year, including over 41,000 deaths resulting from secondhand smoke exposure. Tobacco therefore causes one in five deaths in the US annually, or 1,300 deaths every day.<sup>2</sup> In addition, more than 16 million Americans live with a disease caused by smoking. Smoking causes cancer, cardiovascular disease (CVD), stroke, diabetes, and lung diseases like chronic obstructive pulmonary disease (COPD), which includes emphysema and chronic bronchitis.<sup>3</sup>

Fourteen percent of all U.S. adults, or 34.3 million people, smoked cigarettes in 2017, a record low<sup>4</sup>. Smoking rates are different in various populations. For example, 15.8% of men smoke as compared to 12.2% of women. In the U.S., people living below the poverty level and people with lower levels of educational attainment have higher rates of cigarette smoking than the general population.<sup>5</sup> Smoking rates are higher among certain racial and ethnic groups, such as those identifying as mixed-race (20.6%) and American Indian/Alaska Native (24%).<sup>6</sup>

### Advertising & Subsidies

The tobacco industry heavily promotes this highly addictive substance. Tobacco companies spent \$9.36 billion on advertising and promotion of tobacco products in 2017. This amounts to more than \$25 million spent every day.<sup>7</sup> Price discounts to retailers account for 71.7% of all cigarette marketing or about \$6.19 billion. These are discounts paid to reduce the price of cigarettes to consumers, thus subsidizing their use. Tobacco companies target advertising towards low-income and minority communities, and researchers have found a higher density of tobacco retailers in low-income neighborhoods.<sup>8</sup> In comparison to the money spent on tobacco advertising, the U.S. Office of Smoking and Health (OSH), the lead federal agency for comprehensive tobacco prevention and cessation, had a budget of just \$210 million in 2019.<sup>9</sup>

Tobacco companies must also spend money on youth smoking prevention ads after a 2006 ruling in a court case brought by the U.S. Justice Department required them to do so. Altria, a spinoff from Phillip Morris, one of the world's largest tobacco producers, said in its 2016 annual filing that it expected actions related to the order to cost \$31 million.<sup>10</sup> However, groups like the Campaign for Tobacco-Free Kids have criticized these campaigns as intentionally ineffective. Studies have shown that the tobacco industry's anti-smoking ads can make smoking *more* appealing to kids by describing smoking as an 'adult choice,'<sup>11</sup> instead of focusing on the health risks of tobacco use.

The total economic cost of smoking in the U.S. alone is more than \$300 billion a year, including nearly \$170 billion in direct medical care for adults,<sup>12</sup> and more than \$156 billion in lost productivity due to premature death and exposure to secondhand smoke.<sup>13</sup> These costs could be reduced by preventing people from initiating smoking and helping current smokers quit. Unfortunately, nearly 2000 young people under the age of 18 smoke their first cigarette every day<sup>14</sup> - which is particularly concerning because 9 out of 10 adult cigarette smokers first try smoking by age 18.<sup>15</sup>

### Youth Nicotine Use & E-cigarettes

Cigarette smoking rates among U.S. youth declined over the last two decades and the cigarette smoking rate among teenagers is at a historic low.<sup>16</sup> However, the overall youth rate of nicotine use has remained unchanged thanks to the advent of electronic cigarettes (e-cigarettes). E-cigarettes are electronic devices that heat a liquid and produce an aerosol. They come in many shapes and sizes, but most have a battery,

a heating element, and a place to hold a liquid. Some e-cigarettes look like regular cigarettes or pipes, while others look like USB flash drives or pens. E-cigarettes are known by many different names, such as “e-cigs,” “e-hookahs,” “vapes,” and “electronic nicotine delivery systems (ENDS).” Using an e-cigarette is sometimes called “vaping” or “JUULing,” after the most popular brand of e-cigarettes in the U.S., JUUL.<sup>17</sup> One JUUL “pod,” or cartridge of nicotine liquid, contains as much nicotine as a pack of cigarettes. However, 63% percent of JUUL users aged 15-24 did not know that this product always contains nicotine.<sup>18</sup>

E-cigarette use among U.S. middle and high school students increased 900% during 2011-2015, before declining briefly during 2015-2017. E-cigarette use then increased 78% among high school students during 2018. 20.8% of all high school students used e-cigarettes in 2018. Frequent use (more than 20 days in the past 30 days) of e-cigarettes increased from 20 percent in 2017 to 28 percent in 2018 among high school e-cigarette users.<sup>19</sup> Following national smoking trends, more male high school students used e-cigarettes than female students. By race/ethnicity in 2018, e-cigarettes were the most commonly used product among all racial/ethnic groups except black high school students, among whom cigars were the most commonly reported product.<sup>20</sup>

Adolescents' nervous systems are particularly vulnerable to the addictive properties of nicotine, the primary habit-forming chemical contained within tobacco products.<sup>21</sup> Nicotine exposure can cause mood disorders and permanent lowering of impulse control in young people by changing the way synapses are formed in the brain.<sup>22</sup> Epidemiological data suggests this neurochemical vulnerability has grim consequences for public health in the U.S. - 75% of teenage smokers continue into adulthood.<sup>23</sup> In addition, using e-cigarettes has been found to increase the likelihood of smoking cigarettes among young people: U.S. youth are four times more likely to try cigarettes if they previously used e-cigarettes.<sup>24</sup>

E-cigarettes have been marketed as a less harmful alternative to cigarettes and as a cessation device for current adult smokers, even though they have not been authorized by the Food and Drug Administration (FDA) as such. Companies like JUUL have found themselves under federal scrutiny over reports that they marketed to children in health classes<sup>25</sup> and that they targeted youth on social media.<sup>26</sup> In the summer and fall of 2019, reports emerged of over 1000 people hospitalized across the U.S. with serious respiratory illnesses. Vaping was the common denominator among the patients.<sup>27</sup> Doctors from the Mayo Clinic compared the lung damage from vaping to that of an industrial chemical burn.<sup>28</sup> The CDC reported that about 70 percent of the patients were male, 80 percent under 35 years old and 16 percent younger than 18.<sup>29</sup> No single substance or brand has been shown to cause the illnesses. 77% of lung injury patients reported vaping tetrahydrocannabinol (THC), the main active ingredient of cannabis. 57% of patients reported vaping nicotine.<sup>30</sup> As of October 17, 2019, 33 vaping-related deaths had been reported in 24 states.<sup>31</sup>

### Secondhand Smoke

Secondhand smoke, a toxic mixture of more than 7,000 chemicals,<sup>32</sup> is smoke from the burning end of a tobacco product and the smoke breathed out by a smoker. Previous U.S. Surgeons General determined that there is no safe level of exposure to secondhand smoke, and people with heart and lung disease are at higher risk for health complications when exposed. Even brief exposure can trigger harmful changes in the cardiovascular system that increase the risk of heart attack or stroke. Secondhand smoke causes lung cancer, heart disease and stroke in non-smoking adults. Among babies and children, it causes sudden infant death syndrome, low birth weight, respiratory and ear infections, and more severe asthma attacks.

Secondhand smoke kills over 41,000 people in the U.S. each year, according to the Centers for Disease Control and Prevention (CDC). Worldwide, secondhand smoke kills more than 600,000 people each year.<sup>33</sup> Of those deaths, 47% occurred in women, 28% in children, and 26% in men.<sup>34</sup> In terms of years of life lost, children are by far the most affected. Preventing exposure to secondhand smoke is therefore a critical public health priority.

## Federal Law

In 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act (TCA) into law, giving the FDA authority to regulate the manufacturing, marketing, and sale of tobacco products for the first time. The FDA has subsequently taken a number of actions to protect people from the harms of tobacco by extending its regulatory authority to all tobacco products, including e-cigarettes, cigars, hookah, pipe tobacco, nicotine gels, and other products.<sup>35</sup>

## STS and Tobacco

The Society believes that cardiothoracic surgeons can encourage smoking cessation programs in their facilities and tobacco use prevention in their patients and communities. STS members are advised to speak with their patients about smoking cessation before any procedure. Quitting smoking before surgery reduces complications, and smoke-free hospital environments helps patients quit.<sup>36</sup> The Society provides several patient resources on the STS Patient Website, including a “Quit Smoking before Your Operation” guide and information on various quit lines that U.S. patients can call for assistance.

In addition to patient education, the Society advocates for smoking prevention and cessation and the regulation of tobacco products at the federal level. For a complete list of comments, visit [www.sts.org/advocacy/record](http://www.sts.org/advocacy/record).

In order to address the youth vaping epidemic, STS has endorsed bills that would raise the minimum legal sales age (MLSA) for all tobacco products from 18 to 21, and ban flavored e-cigarettes – including menthol – and online sales of tobacco products.

To address tobacco use at large and in specific populations, the Society has consistently supported increasing funding to OSH. STS has endorsed legislation that would reduce the nicotine level in cigarettes and e-cigarettes to non-addictive or minimally addictive levels, as well as a bill that would ban smoking on and in Veterans Health Administration (VHA) facilities and one that would encourage research into the discrepancy between rates of lung cancer in male and female non-smokers. Additionally, STS has endorsed various FDA actions, including: maintaining federal regulation of cigars; extending the marketing restrictions that FDA currently applies to cigarettes to all tobacco products, including e-cigarettes and cigars; prioritizing FDA enforcement of products that do not have a premarket application submitted by 2021; and approving authorized levels of user fees for all tobacco products for the FDA to oversee tobacco products. Finally, the Society endorsed creating new ICD-10 codes to capture patient use of e-cigarettes and other new tobacco products, such as the Altria iQOS, coming onto the market.

In January 2009, STS adopted a Declaration on Tobacco Control, which stated:

The consumption of tobacco products and exposure to tobacco smoke lead the world’s list of preventable causes of death, responsible for about 5 million deaths a year. It is estimated that this number will grow to 10 million by 2030. Smoking causes approximately 90% of lung cancer and contributes to 30% of all cancers. It is the major cause of chronic obstructive lung disease and one of the major risk factors for vascular disease, including ischemic heart disease. Programs to prevent initiation of smoking have an important long-term positive impact on tobacco-related illnesses, and individual efforts to stop smoking can mitigate many of the negative health effects of tobacco use within just a few years.

The Society believes that cardiothoracic surgeons are in a position to provide the impetus for smoking prevention programs and for tobacco use cessation in their patients and communities, both locally and globally. To achieve the shared goal of eliminating morbidity and mortality from smoking-related activities, The Society of Thoracic Surgeons supports the following efforts:

1. Ratification of the Framework Convention on Tobacco Control and implementation of its articles, as important steps toward addressing tobacco-related disease in the United States and worldwide;

2. Legislation and regulations that prohibit smoking in public places and places of work, as important tools to decrease exposure to tobacco smoke and encourage smoking cessation;
3. Education, as a valuable and essential weapon in the effort to eliminate tobacco-related death and disease, including early tobacco warning programs within the school systems, more graphic and visible warnings on tobacco packaging, and the prohibition in advertising or marketing of misleading terms such as “light” and “low tar;”
4. Elimination of incentives and subsidies that support the production of tobacco-related products; and
5. Referral of patients to smoking cessation programs by Society members, who also should avail themselves of such programs if necessary.

## STS Position on Tobacco Policy

STS is pursuing the following public policy options that may help address tobacco and nicotine use among adult and youth populations:

### Support funding for cessation & prevention programs

It is imperative for the government to fund cessation and smoking prevention programs. STS supports full funding for OSH, which conducts research on tobacco use, provides grants to support tobacco prevention and cessation programs, and runs an effective public education campaign called Tips from Former Smokers. From 2012–2018, the CDC estimates that more than 16.4 million people who smoke have attempted to quit and approximately one million have quit for good because of the Tips campaign.<sup>37</sup> Boosting OSH’s budget by \$100 million (from \$210 million) will allow it to address the epidemic of youth e-cigarette use while continuing to help people quit smoking cigarettes.

### Support legislative and regulatory efforts to address the youth e-cigarette epidemic

Interventions to reduce or eliminate tobacco use in young adults are critical, especially since studies have shown that young e-cigarette users are more likely than nonusers to start smoking combustible cigarettes. STS strongly supports raising the minimum legal sales age (MLSA) for tobacco from 18 to 21. STS also supports the reduction of the nicotine content of tobacco products to non-addictive levels and the elimination of all flavored tobacco products, including menthol. Studies have shown that over 70% of underage e-cigarette users point to flavors as a main reason they use the products.<sup>38</sup> The Trump Administration proposed a ban on all flavored e-cigarettes, including menthol and mint, in September 2019. The FDA may finalize a compliance policy to clear the market of unauthorized flavored e-cigarette products.

STS supports maintaining the FDA’s authority to regulate all tobacco products, including cigars, e-cigarettes, and heated tobacco products that are just entering the U.S. market.

### Support efforts to make all public spaces in the US smoke-free

States can enact and enforce smoke-free laws in workplaces and public places. Twenty-eight states and the District of Columbia have passed comprehensive smoke-free laws. In order to protect the health of all Americans, all 50 states must pass laws prohibiting smoking in all public places and workplaces, including all restaurants, bars and casinos.<sup>39</sup> Studies have shown that smoke-free laws help improve the health of workers and the general population, quickly reducing hospital admissions for heart attacks.<sup>40</sup> Currently, 22 states do not ban secondhand smoke in all public spaces and workplaces. This means many U.S. employees face secondhand smoke exposure in order to do their job, which is unacceptable.

Most hospitals in the U.S. are smoke-free. STS supports Congressional codification of the VHA’s decision to bring their facilities in line with the private sector by banning smoking on campuses, thus protecting the health of veterans. Veterans are 25% more likely to be diagnosed with lung cancer than civilians. Besides lung cancer, many veterans suffer from COPD, hypertension, and coronary artery disease, all of which are exacerbated by secondhand smoke.



In addition to laws that apply to cigarette smoke, STS also supports efforts to ban vaping in public places. In 2016, the U.S. Surgeon General concluded that e-cigarette aerosol is not benign and can contain harmful chemicals. Eleven states and the District of Columbia have added e-cigarettes to their smoke-free laws. Per the World Health Organization (WHO) Framework Convention on Tobacco Control,<sup>41</sup> STS strongly supports the adoption and implementation of effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and other public places.

#### Divestment from the Tobacco Industry

Due to the harm caused by tobacco, both in the U.S. and globally, The Society of Thoracic Surgeons endeavors to no longer hold stock in, or mutual funds that include, companies that produce cigarettes or other tobacco products. (Adopted by the STS Board of Directors on January 26, 2020)

#### STS Declaration on U.S. Tobacco Control

The consumption of tobacco products and exposure to tobacco smoke lead the world's list of preventable causes of death, responsible for about 7 million deaths a year. In the United States, cigarette smoking and exposure to tobacco smoke causes about 480,000 premature deaths each year. Of those premature deaths, about 36% are from cancer, 39% are from heart disease and stroke, and 24% are from lung disease.<sup>42</sup> Tobacco is the major cause of chronic obstructive lung disease and one of the major risk factors for vascular disease, including ischemic heart disease. Programs to prevent initiation of smoking have an important long-term positive impact on tobacco-related illnesses, and individual efforts to stop smoking can mitigate many of the negative health effects of tobacco use within just a few years. Smoking cessation during treatment for diseases such as COPD, CVD, and cancer improves patient outcomes.

The Society believes that cardiothoracic surgeons are in a position to help create smoking cessation programs in their facilities and encourage tobacco use cessation in their patients and communities, both locally and globally. To achieve the shared goal of eliminating morbidity and mortality from smoking-related activities, The Society of Thoracic Surgeons supports the following efforts:

1. Ratification of the World Health Organization [Framework Convention on Tobacco Control](https://www.who.int/fctc/text_download/en/) ([https://www.who.int/fctc/text\\_download/en/](https://www.who.int/fctc/text_download/en/)) and implementation of its articles, as important steps toward addressing tobacco-related disease in the United States and worldwide. The U.S. signed but did not ratify the Convention;
2. Legislation/regulation that prohibits smoking in public places and places of work, including e-cigarettes and other inhaled tobacco products;
3. Education, as a valuable and essential weapon in the effort to eliminate tobacco-related death and disease, including early tobacco warning programs within school systems, and more graphic and visible warnings on tobacco packaging;
4. Legislation that raises the minimum legal sale age (MLSA) for all tobacco products from 18 to 21;
5. Legislation/regulation that requires all tobacco product manufacturers to pay user fees to the FDA;
6. Legislation/regulation that bans all flavored tobacco products, including menthol;
7. Legislation/regulation eliminating tobacco product subsidies;
8. Legislation/regulation increasing taxation on all tobacco products;

9. Referral of patients to smoking cessation programs by Society members, who also should avail themselves of such programs if necessary; and
10. STS Divestment of assets in the tobacco industry.

*Adopted: January 26, 2020 (STS Board of Directors)*

<sup>1</sup> World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011. Geneva: World Health Organization, 2011

<sup>2</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014

<sup>3</sup> "Fast Facts," Smoking & Tobacco Use, Centers for Disease Control and Prevention, 2/6/2019, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm)

<sup>4</sup> Angelica LaVito, "CDC says smoking rates fall to record low in US," CNBC, 11/8/2018, <https://www.cnbc.com/2018/11/08/cdc-says-smoking-rates-fall-to-record-low-in-us.html>

<sup>5</sup> The Health Consequences of Smoking - 50 Years of Progress: A report of the Surgeon General.

<sup>6</sup> "Current Cigarette Smoking Among U.S. Adults Aged 18 Years and Older," Burden of Tobacco Use in the U.S., Tips from Former Smokers, Centers for Disease Control and Prevention, 2/25/2019, <https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html>

<sup>7</sup> "Fast Facts"

<sup>8</sup> "Cigarette Smoking and Tobacco Use Among People of Low Socioeconomic Status," Smoking & Tobacco Use, CDC, 3/7/2018, <https://www.cdc.gov/tobacco/disparities/low-ses/index.htm>

<sup>9</sup> "Office on Smoking and Health at a Glance," National Center for Chronic Disease Prevention and Health Promotion, CDC, 5/25/2019, <https://www.cdc.gov/chronicdisease/resources/publications/aag/tobacco-use.htm>

<sup>10</sup> "United States Securities and Exchange Commission Form 10-K for Altria Group, Inc." <http://services.corporate-ir.net/SEC/Enhanced/SecCapsule.aspx?c=80855&fid=14852383>

<sup>11</sup> "Big Surprise: Tobacco Company Prevention Campaigns Don't Work," Campaign for Tobacco-Free Kids, 3/9/2019, <https://www.tobaccofreekids.org/assets/factsheets/0302.pdf>

<sup>12</sup> Federal Trade Commission. Federal Trade Commission Smokeless Tobacco Report for 2017.pdf. Washington: Federal Trade Commission, 2019

<sup>13</sup> The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General

<sup>14</sup> "Office on Smoking and Health (OSH)," Smoking & Tobacco Use, CDC, 3/8/2019, <https://www.cdc.gov/tobacco/about/osh/index.htm>

<sup>15</sup> "Youth and Tobacco Use," Smoking & Tobacco Use, CDC, 11/8/2019, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/youth\\_data/tobacco\\_use/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm)

<sup>16</sup> "Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018," Morbidity and Mortality Weekly Report, CDC, 2/14/2019, [https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s\\_cid=osh-vs-mmwr-full-001](https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s_cid=osh-vs-mmwr-full-001)

<sup>17</sup> "Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults," Smoking & Tobacco Use, CDC, 3/11/2019, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html)

<sup>18</sup> "Juul e-cigarettes gain popularity among youth, but awareness of nicotine presence remains low," truth initiative, 4/18/2018, <https://truthinitiative.org/press/press-release/juul-e-cigarettes-gain-popularity-among-youth-awareness-nicotine-presence>

<sup>19</sup> "Surgeon General's Advisory on E-cigarette Use Among Youth," Smoking & Tobacco Use, CDC, 4/9/2019, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/surgeon-general-advisory/index.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html)

<sup>20</sup> <https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html>

<sup>21</sup> "The Health Consequences of Smoking – 50 Years of Progress," A REPORT OF THE SURGEON GENERAL, CH. 12 p. 659 (2014), <http://www.surgeon-general.gov/library/reports/50-years-of-progress/index.html>

<sup>22</sup> "Progress Erased: Youth Tobacco Use Increased During 2017–2018," CDC Newsroom, CDC, 2/11/2019, <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html>

<sup>23</sup> Calculated by the Campaign for Tobacco-Free Kids based on data in the National Survey on Drug Use and Health (2016), U.S. Dep't of Health and Human Services. Substance Abuse and Mental Health Services Administration. Ctr. for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health (2016); David Hammond, Smoking Behaviour Among Young Adults: Beyond Youth Prevention, 14 Tobacco Control 181 – 5 (2005); Paula M. Lantz, Smoking on the Rise Among Young Adults: Implications for Research and Policy, 12 TOBACCO CONTROL (Suppl I) i60 – i70 (2003).

<sup>24</sup> "E-cigarettes: Facts, stats and regulations," Fact Sheet, truth initiative, 11/11/2019, <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations>

<sup>25</sup> Sheila Kaplan, "Juul targeted schools and youth camps, House panel on vaping claims," The New York Times, 7/25/2019, <https://www.nytimes.com/2019/07/25/health/juul-teens-vaping.html>

<sup>26</sup> Kathleen Chaykowski, "The Disturbing Focus of Juul's Early Marketing Campaigns," Forbes, 11/16/2018, <https://www.forbes.com/sites/kathleenchaykowski/2018/11/16/the-disturbing-focus-of-juuls-early-marketing-campaigns/#65e02ccb14f9>

<sup>27</sup> Sheila Kaplan, "Vaping Sicknesses Rising," The New York Times, <https://www.nytimes.com/2019/08/21/health/vaping-marijuana-e-cigarettes.html>

<sup>28</sup> Denise Grady, "Lung Damage from Vaping Resembles Chemical Burns," The New York Times, 10/2/2019, <https://www.nytimes.com/2019/10/02/health/vaping-illnesses.html>

<sup>29</sup> Denise Grady, "Vaping Illness Top 1000," The New York Times, 10/3/2019, <https://www.nytimes.com/2019/10/03/health/vaping-illnesses-cdc.html>

<sup>30</sup> Jonathan Corum, "Vaping Illness Tracker," The New York Times, 11/20/2019, <https://www.nytimes.com/interactive/2019/health/vaping-illness-tracker.html>

<sup>31</sup> "Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping," Smoking & Tobacco Use, CDC, 11/19/2019, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)

<sup>32</sup> "U.S. State and Local Issues: Smoke-Free Laws," Campaign for Tobacco-Free Kids, 6/4/2019, <https://www.tobaccofreekids.org/what-we-do/us/smoke-free-laws>

<sup>33</sup> "Worldwide burden of disease from exposure to second-hand smoke," Quantifying Environmental Health Impacts, World Health Organization,

[https://www.who.int/quantifying\\_ehimpacts/publications/shsarticle2010/en/](https://www.who.int/quantifying_ehimpacts/publications/shsarticle2010/en/)

<sup>34</sup> Ibid

<sup>35</sup> "The Facts on the FDA's New Tobacco Rule," U.S. Food & Drug Administration, 6/16/2016, <https://www.fda.gov/consumers/consumer-updates/facts-fdas-new-tobacco-rule>

<sup>36</sup> "Quit Smoking Before Your Operation," Surgical Patient Education Program, STS.org, <https://www.sts.org/sites/default/files/quitsmoking.pdf>

<sup>37</sup> "The Burden of Tobacco Smoking," About the Campaign, Tips from Former Smokers, CDC, 2/6/2019,

[https://www.cdc.gov/tobacco/campaign/tips/about/index.html?s\\_cid=OSH\\_tips\\_D9393](https://www.cdc.gov/tobacco/campaign/tips/about/index.html?s_cid=OSH_tips_D9393)

<sup>38</sup> "Flavored Tobacco Products Attract Kids," Campaign for Tobacco-Free Kids, 11/7/2019, <https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>

<sup>39</sup> "Smokefree Air Laws," Tobacco, American Lung Association, 3/8/2019, <https://www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html>

<sup>40</sup> "Smokefree Policies Improve Health," Smoking & Tobacco Use, CDC, 1/17/2018,

[https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/secondhand\\_smoke/protection/improve\\_health/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/protection/improve_health/index.htm)


<sup>41</sup> "WHO Framework Convention on Tobacco Control," 2003, [https://www.who.int/fctc/text\\_download/en/](https://www.who.int/fctc/text_download/en/)

<sup>42</sup> "Harms of Cigarette Smoking and Health Benefits of Quitting, About Cancer, National Cancer Institute, 12/19/2017, <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cessation-fact-sheet>

## Appendix A: TAVR NCD Highlights

TAVR NCD Highlights		
TAVR is covered for the treatment of severe aortic stenosis when furnished according to an FDA-approved indication. The NCD also requires that two cardiac surgeons have independently examined the patient and the patient is under the care of a heart team: a cohesive, multidisciplinary team of medical professionals that includes a cardiothoracic surgeon and a cardiologist.		
<b>Requirements</b>	TAVR must be furnished in a hospital with the appropriate infrastructure	
<b>Institution</b>	Without TAVR Experience	With TAVR Experience
	<ul style="list-style-type: none"> <li>• ≥ 50 total AVR in the previous year prior to TAVR, including ≥ 10 high risk patients; and</li> <li>• ≥ 2 physicians with cardiac surgery privileges; and</li> <li>• ≥ 1,000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year</li> </ul>	<ul style="list-style-type: none"> <li>• ≥ 20 AVR/yr. or ≥ 40 AVR every 2 years; and</li> <li>• ≥ 2 physicians with cardiac surgery privileges; and</li> <li>• ≥ 1,000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year</li> </ul>
<b>Operator</b>	<b>Heart Team With TAVR Experience</b>	
	<p>The Heart Team must include a cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:</p> <ul style="list-style-type: none"> <li>• ≥ 20 TAVR procedures in the prior year; or</li> <li>• ≥ 40 procedures in the prior 2 years; and</li> </ul> <p>Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.</p>	
	<b>Cardiovascular Surgeon Without TAVR Experience</b>	
	<ul style="list-style-type: none"> <li>• ≥ 100 career AVR, including 10 high-risk patients; or</li> <li>• ≥ 25 AVR in one year; or</li> <li>• ≥ 50 AVR in 2 years; and which include at least 20 AVR in the last year prior to TAVR initiation</li> </ul>	
	<b>Interventional Cardiologist Without TAVR Experience</b>	
	<ul style="list-style-type: none"> <li>• Professional experience with 100 structural heart procedures lifetime; or</li> <li>• 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures</li> </ul>	
<b>Registry</b>	The heart team and hospital must participate in a prospective, national, audited registry that consecutively enrolls TAVR patients, accepts all manufactured devices, follows the patient for at least one year, and complies with relevant patient privacy protections.	

## Appendix B: Adult Cardiac Surgery Checklist


Before Induction – SIGN IN	Before Skin Incision – TIME OUT	Before Patient Leaves Room – SIGN OUT
<p><b>Patient has confirmed:</b></p> <p><input type="checkbox"/> Identity</p> <p><input type="checkbox"/> Site</p> <p><input type="checkbox"/> Procedure</p> <p><input type="checkbox"/> Consent</p> <p><input type="checkbox"/> Site marked/not applicable</p> <p><input type="checkbox"/> Anesthesia safety check completed</p> <p><input type="checkbox"/> Pulse oximeter on patient and functioning</p> <p><input type="checkbox"/> UNOS ID# (if applicable)</p> <p><b>Does patient have a known allergy?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Drugs</p> <p><input type="checkbox"/> Latex</p> <p><input type="checkbox"/> Other: _____</p> <p><b>Difficult airway or aspiration risk?</b></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available</p> <p><b>Risk of &gt;500 mL blood loss</b></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, and adequate intravenous access and fluids planned</p> <p><b>Blood bank notified and blood available?</b></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable</p> <p><b>Conversion equipment readily available?</b> (Robotic, minimally invasive cases)</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable</p> <p>SIGN (NURSING): _____</p> <p>SIGN (ANESTH): _____</p>	<p><input type="checkbox"/> Confirm all team members have introduced themselves by name and role.</p> <p>Surgeon, anesthesia professional, and nurse verbally confirm:</p> <p><input type="checkbox"/> Patient <input type="checkbox"/> Site/Side</p> <p><input type="checkbox"/> Procedure <input type="checkbox"/> Position</p> <p><input type="checkbox"/> Perfusion temp. <input type="checkbox"/> Blood born path.</p> <p><input type="checkbox"/> Prep protocol <input type="checkbox"/> Implants and equip.</p> <p><b>Anticipated Critical Events</b></p> <p><b>Surgeon reviews:</b></p> <p><input type="checkbox"/> Critical or unexpected steps, airway or ventilatory issues</p> <p><input type="checkbox"/> Operative duration, anticipated blood loss, fluid management</p> <p><b>Anesthesia team reviews:</b></p> <p><input type="checkbox"/> Any patient-specific concerns</p> <p><b>Nursing team reviews:</b></p> <p><input type="checkbox"/> If sterility (including indicator results) has been confirmed</p> <p><input type="checkbox"/> If there are any equipment issues or concerns</p> <p><b>Has antibiotic prophylaxis been given within the last 60 minutes?</b></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Not applicable</p> <p><b>DVT prophylaxis?</b></p> <p><input type="checkbox"/> Compression stockings</p> <p><input type="checkbox"/> Medication</p> <p><b>Is essential imaging displayed?</b></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Not applicable</p> <p>SIGN (SURG): _____</p>	<p><b>Nurse verbally confirms with the team:</b></p> <p><input type="checkbox"/> Name of the procedure</p> <p><input type="checkbox"/> That instrument, sponge, and needle counts are correct or not applicable</p> <p><input type="checkbox"/> Post pump antibiotic</p> <p><input type="checkbox"/> Medication/Drips</p> <p><b>Specimen labeling:</b></p> <p><input type="checkbox"/> Verify patient name</p> <p><input type="checkbox"/> Number of specimens</p> <p><input type="checkbox"/> Specimen location description</p> <p><b>Are there any equipment problems to be addressed?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes: _____</p> <p><b>Surgeon, anesthesia professional, and nurse:</b></p> <p><input type="checkbox"/> Review the key concerns for recovery and management of this patient</p> <p>SIGN (NURSING): _____</p> <p>SIGN (SURG): _____</p> <div style="text-align: center;">  </div>

## Appendix C: General Thoracic Surgery Checklist

Before Induction – SIGN IN	Before Skin Incision – TIME OUT	Before Patient Leaves Room – SIGN OUT
<p><b>Patient has confirmed:</b></p> <p><input type="checkbox"/> Identity</p> <p><input type="checkbox"/> Site</p> <p><input type="checkbox"/> Procedure</p> <p><input type="checkbox"/> Consent</p> <p><input type="checkbox"/> Site marked/not applicable</p> <p><input type="checkbox"/> H&amp;P current (&lt; 30 d)</p> <p><input type="checkbox"/> Anesthesia safety check completed</p> <p><input type="checkbox"/> Pulse oximeter on patient and functioning</p> <p><input type="checkbox"/> UNOS ID# (if applicable)</p> <p><b>Does patient have a known allergy?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Drugs</p> <p><input type="checkbox"/> Latex</p> <p><input type="checkbox"/> Other: _____</p> <p><b>Difficult airway or aspiration risk?</b></p> <p><input type="checkbox"/> No    <input type="checkbox"/> Yes, and equipment/assistance available</p> <p><b>Risk of &gt;500 mL blood loss</b></p> <p><input type="checkbox"/> No    <input type="checkbox"/> Yes, and adequate intravenous access and fluids planned</p> <p><b>Blood bank notified and blood available?</b></p> <p><input type="checkbox"/> No    <input type="checkbox"/> Yes    <input type="checkbox"/> Not applicable</p> <p><b>Conversion equipment readily available?</b> (Robotic, VATS cases)</p> <p><input type="checkbox"/> No    <input type="checkbox"/> Yes    <input type="checkbox"/> Not applicable</p> <p><b>SIGN (NURSING):</b> _____</p> <p><b>SIGN (ANESTH):</b> _____</p>	<p><input type="checkbox"/> Confirm all team members have introduced themselves by name and role</p> <p><b>Surgeon, anesthesia professional, and nurse verbally confirm:</b></p> <p><input type="checkbox"/> Patient</p> <p><input type="checkbox"/> Site</p> <p><input type="checkbox"/> Procedure</p> <p><b>Anticipated Critical Events</b></p> <p><b>Surgeon reviews:</b></p> <p><input type="checkbox"/> Critical or unexpected steps, airway or ventilatory issues</p> <p><input type="checkbox"/> Operative duration, prosthetics, anticipated blood loss, fluid management</p> <p><b>Anesthesia team reviews:</b></p> <p><input type="checkbox"/> Any patient-specific concerns</p> <p><b>Nursing team reviews:</b></p> <p><input type="checkbox"/> If sterility (including indicator results) has been confirmed</p> <p><input type="checkbox"/> If there are any equipment issues or concerns</p> <p><b>Has antibiotic prophylaxis been given within the last 60 minutes?</b></p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> Not applicable</p> <p><b>DVT prophylaxis?</b></p> <p><input type="checkbox"/> Compression stockings</p> <p><input type="checkbox"/> Medication</p> <p><b>Is essential imaging displayed?</b></p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> Not applicable</p> <p><b>SIGN (SURG):</b> _____</p>	<p><b>Nurse verbally confirms with the team:</b></p> <p><input type="checkbox"/> Name of the procedure</p> <p><input type="checkbox"/> That instrument, sponge, and needle counts are correct or not applicable</p> <p><b>Specimen labeling:</b></p> <p><input type="checkbox"/> Verify patient name</p> <p><input type="checkbox"/> Number of specimens</p> <p><input type="checkbox"/> Tissue type/nodal stations</p> <p><b>Are there any equipment problems to be addressed?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes: _____</p> <p><b>Surgeon, anesthesia professional, and nurse:</b></p> <p><input type="checkbox"/> Review the key concerns for recovery and management of this patient</p> <p><b>SIGN (NURSING):</b> _____</p> <p><b>SIGN (SURG):</b> _____</p> <div data-bbox="1373 1192 1520 1338" style="text-align: center;"> </div>



## Appendix D: Congenital Heart Surgery Checklist

Before Induction – SIGN IN	Before Skin Incision – TIME OUT	Before Patient Leaves Room – SIGN OUT
<p><b>Patient has confirmed:</b></p> <p><input type="checkbox"/> Identity</p> <p><input type="checkbox"/> Site</p> <p><input type="checkbox"/> Procedure</p> <p><input type="checkbox"/> Consent</p> <p><input type="checkbox"/> H&amp;P current (&lt; 30 d)</p> <p><input type="checkbox"/> Weight re-checked</p> <p><input type="checkbox"/> Anesthesia safety check completed (Machine and medication)</p> <p><input type="checkbox"/> Pulse oximeter on patient and functioning</p> <p><b>Does patient have a known allergy?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Drugs</p> <p><input type="checkbox"/> Latex</p> <p><input type="checkbox"/> Other: _____</p> <p><b>Difficult airway or aspiration risk?</b></p> <p><input type="checkbox"/> No   <input type="checkbox"/> Yes, and equipment/assistance available</p> <p><input type="checkbox"/> Intravenous access and fluids planned</p> <p><input type="checkbox"/> Warmer (blankets and fluids) in place</p> <p><b>Blood bank notified and blood available?</b></p> <p><input type="checkbox"/> No   <input type="checkbox"/> Yes   <input type="checkbox"/> Not applicable</p> <p><b>SIGN (NURSING):</b> _____</p> <p><b>SIGN (ANESTH):</b> _____</p>	<p><input type="checkbox"/> Confirm all team members have introduced themselves by name and role.</p> <p><b>Surgeon, anesthesia professional, perfusionist, and nurse verbally confirm:</b></p> <p><input type="checkbox"/> Patient</p> <p><input type="checkbox"/> Site</p> <p><input type="checkbox"/> Procedure</p> <p><input type="checkbox"/> Imaging available and reviewed</p> <p><input type="checkbox"/> Transesophageal ECHO (TEE) or Other ECHO</p> <p><input type="checkbox"/> Antifibrinolytics</p> <p><input type="checkbox"/> Antibiotics administered (within last 60 min)</p> <p><b>Perfusion team reviews:</b></p> <p><input type="checkbox"/> Cannulation sizes</p> <p><input type="checkbox"/> Cannulae sizes</p> <p><input type="checkbox"/> Bypass prime (blood vs. prime)</p> <p><input type="checkbox"/> Targeted core temp</p> <p><input type="checkbox"/> Use or non-use of DHCA, selective cerebral perfusion</p> <p><input type="checkbox"/> Ice on the head</p> <p><input type="checkbox"/> Other bypass considerations (AR, cardioplegia, collaterals, LV, shunts, venting, etc.)</p> <p><b>Anesthesia team reviews:</b></p> <p><input type="checkbox"/> Any patient-specific concerns</p> <p><b>Nursing team reviews:</b></p> <p><input type="checkbox"/> Confirmation of equipment sterility</p> <p><input type="checkbox"/> If there are any equipment/prostheses issues or concerns</p> <p><b>SIGN (SURG):</b> _____</p>	<p><b>Nurse verbally confirms with the team:</b></p> <p><input type="checkbox"/> Name of the procedure</p> <p><input type="checkbox"/> That instrument, sponge, and needle counts are correct or not applicable</p> <p><b>Specimen labeling:</b></p> <p><input type="checkbox"/> Verify patient name</p> <p><input type="checkbox"/> Number of specimens</p> <p><input type="checkbox"/> Sent for appropriate tests</p> <p><b>Are there any equipment problems to be addressed?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes: _____</p> <p><b>Surgeon, anesthesia professional, and nurse:</b></p> <p><input type="checkbox"/> Review the key concerns for post-op recovery and management of this patient</p> <p><input type="checkbox"/> Blood products used</p> <p><input type="checkbox"/> Blood products still available</p> <p><input type="checkbox"/> Breaks in technique</p> <p><b>SIGN (NURSING):</b> _____</p> <p><b>SIGN (SURG):</b> _____</p> <div style="text-align: center;">  </div>

## Appendix E: Metrics for Assessing the Performance of Medical Liability Reforms

Metrics for assessing the performance of medical liability reforms <sup>1</sup>	
Liability measures	
Claims frequency	The number of malpractice claims filed
Indemnity costs	Settlement and verdict amounts among paid claims
Overhead costs	Administrative expenses associate with pursuing and defending litigation and running liability-insurance companies
Malpractice insurance costs	The premiums paid by health care providers for malpractice insurance coverage
Care-related measures	
Defensive medicine	Ordering tests, referrals, and other services primarily, though not solely, to reduce liability risk; or avoidance of high-risk services or patients
Patient access / physician supply	The availability of physician services in a state / region
Quality of care	The quality of care that patients receive, as indicated by patient outcomes and other measures

<sup>1</sup> Kachalia, A., & Mello, M. M. (2011). New Directions in Medical Liability Reform. *New England Journal of Medicine*, 364(16), 1564-1572.