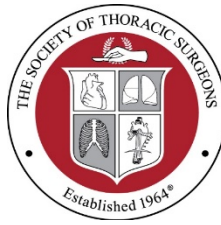


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May 29, 2018

*Sent Via Email*

Francis J. Crosson, MD  
Chairman  
Medicare Payment Advisory Commission  
425 I Street, N.W. Suite 701  
Washington, DC 20001

James E. Mathews, Ph.D.  
Executive Director  
Medicare Payment Advisory Commission  
425 I Street, N.W. Suite 701  
Washington, DC 20001

### **Re: Cost-Effectiveness in Health Care**

Dear Dr. Crosson and Dr. Mathews:

On behalf of The Society of Thoracic Surgeons (STS), I write to provide feedback on the Medicare Payment Advisory Commission's (MedPAC) efforts regarding low-value care and Cost-Effectiveness (CE) in Medicare. Founded in 1964, STS is an international not-for-profit organization representing more than 7,400 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

Many organizations have voiced concerns regarding MedPAC's renewed consideration of CE in Medicare policy. The fact that in 2014 Medicare was estimated to spend \$2.4 – \$6.5 billion on low-value care, defined as services with little or no clinical benefit, must be addressed.<sup>1</sup> However, a MedPAC presentation on CE using quality-adjusted-life-years (QALYs) by the Institute for Clinical and Economic Review (ICER) in September 2017, along with sessions on "Cost Effectiveness in Medicare" in March of 2018 and "Medicare Coverage Policy and Use of Low Value Care" in April, caused trepidation that MedPAC may try to remedy the issue by recommending the use of QALY's in Medicare payment and coverage decisions. As you know, QALY-based analyses can methodically overlook differences among patients with disabilities and complex conditions, thus hampering innovation, interfering with clinician-patient relationships, and harming patients. We were encouraged to hear Commissioner Pyenson's reminder that modern analyses can look at cost-effectiveness in much more sophisticated ways than QALYs, and Commissioner Gelb Safran's position that patient-reported outcomes (PROs) are a crucial consideration. As STS shares MedPAC's goal of reducing low-value care and costs, we would like to highlight another method of CE that utilizes advanced data analysis and does not rely on QALYs: combining Medicare claims data with the clinical quality data housed in registries.

The STS National Database, currently approved by the Centers for Medicare and Medicaid Services (CMS) as a Qualified Clinical Data Registry (QCDR), was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The fundamental principle underlying the STS National Database initiative has been that surgeon engagement in the process of collecting information on every case, combined with robust risk adjustment based on pooled national

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<sup>1</sup> Ariel Winter, Nancy Ray, and Carlos Zarabozo, "Medicare Coverage Policy and Use of Low-Value Care," April 2018

data, and feedback of that data provided to the individual practice and institution, will improve the practice of cardiothoracic surgery for the benefit of patients. Published studies indicate that quality of care has improved as a result of the STS National Database and that it has fostered cost savings by helping cardiothoracic surgeons find the most effective treatments.<sup>2</sup>

Clinical data from the STS National Database has been linked with administrative claims data from CMS on a number of occasions. These discrete instances have demonstrated important ways to assess the effectiveness of treatment options and offer novel avenues for future research. One example of this is the Virginia Cardiac Services Quality Initiative (VCSQI). In existence since 1993, the VCSQI currently has amassed a database by combining the STS National Cardiac Database for Virginia with the patient's UB-04 financial record for over 100,000 patients undergoing cardiac surgery. This database combines the patient's clinical outcome with their financial cost record for over 98% of all patients undergoing cardiac surgery in Virginia. Evidence-based protocols for treatment have saved approximately \$90 million dollars in reduction of post-operative mortality and morbidity. The innovative VCSQI project demonstrates our ability to fuse clinical outcome measures with cost projections derived from claims data.

Another example of the potential of this combination is the American College of Cardiology (ACC) Foundation / STS Collaboration on the Comparative Effectiveness of Revascularization Strategies (ASCERT) study. Funded by the National Heart Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH), the study was designed to examine the comparative long-term effectiveness of Coronary Artery Bypass Graft and percutaneous coronary intervention 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 used data from the STS Database and ACC registry, along with CMS Medicare Provider Analysis and Review (MEDPAR) data. Comparative analyses were performed using propensity score and inverse probability weighting approaches.<sup>3</sup> STS views the ASCERT study as a paradigm for a comparative effectiveness research enterprise based on linked clinical and administrative data. Clinically robust, generalizable data from thousands of patients, linked with longitudinal outcomes from claims data, could quickly and cost-effectively answer a broad range of questions regarding the value of care provided—without relying on QALYs.

While these applications are extremely promising, STS has not been able to implement the process on a wider scale due to a lack of access to comprehensive and continuous Medicare claims data. Congress directed CMS to provide QCDR's with Medicare claims data five years after explicitly prohibiting the use of QALY's as the basis for Medicare decision-making in 2010. Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required CMS to make Medicare claims data available

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<sup>2</sup>Alan M. Speir, et al, Regional Collaboration as a Model for Fostering Accountability and Transforming Health Care, *Seminars in Thoracic and Cardiovascular Surgery*. 2009, 21:12-19

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LaPar, MD, MS, Damien J., et al. "Postoperative atrial fibrillation significantly increases mortality, hospital readmission, and hospital costs." *The Annals of Thoracic Surgery*, 2014: 527-533. 7

<sup>3</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.

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>

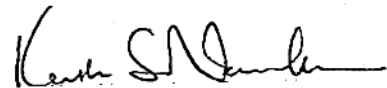
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to QCDRs for purposes of linking it with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement or patient safety, but this section of the statute has not been implemented correctly. QCDRs are still unable to adequately access Medicare claims data for quality improvement, research, and even alternative payment model design. At the same time, every new payment model released by CMS and the Center for Medicare and Medicaid Innovation includes a provision that every hospital or qualified participant be able to access their own claims data. CMS understands the value of claims data and is capable of providing it, yet it is failing to implement the statutory provision that speaks to that purpose.

Combining clinical data on quality with robust claims information is a key to value-based payment that we hope MedPAC will not overlook. STS joins the Partnership to Improve Patient Care and others in urging MedPAC to reject the use of QALY's in favor of more patient-centered, yet still data-driven, approaches to pursuing better value in the Medicare program. From precision medicine and the use of PROs, to the combination of Medicare claims with clinical outcomes data, we support aligning cost containment with the best outcomes for every individual. If you have any questions, please contact STS Director of Government Relations, Courtney Yohe at 202-787-1222 or [cyohe@sts.org](mailto:cyohe@sts.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Keith S. Naunheim". The signature is fluid and cursive, with a long horizontal stroke at the end.

Keith S. Naunheim, MD  
President