



The Society of Thoracic Surgeons

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Dana Gelb Safran, ScD
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Health Care Payment Learning & Action Network
1550 Westbranch Drive
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Re: Accelerating and Aligning Population-Based Payment Models: Data Sharing Draft White Paper

Dear Ms. Safran,

On behalf of The Society of Thoracic Surgeons, I would like to thank you for the opportunity to comment on the HCP-LAN whitepaper, “Accelerating and Aligning Population-Based Payment Models: Data Sharing.” Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 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.

STS wholeheartedly supports the premise articulated in the whitepaper, that data sharing is essential to the development and implementation of population-based payment (PBP) and alternative payment models (APMs) in that:

- 1) It promotes the availability and use of real-time, comprehensive, patient-level data and other information to inform clinical care decision making, enable true integration of care, and improve care delivery and outcomes; and
- 2) It improves the functioning of the health care marketplace such that care is purchased on the basis of transparent and reliable assessments of cost and quality performance.

In fact, STS has been developing a physician-focused payment model proposal that blends the STS National Database with claims information from Medicare and other payers to create a new clinical/financial tool. This tool will enable tracking of both patient outcomes and costs, identifying high frequency and/or costly complications. This new linked database would be used to develop best practice protocols aimed at reducing health care costs by minimizing complications, improving quality, and cutting excess resource utilization.

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The STS National Database was established in 1989 as an initiative to improve quality and patient safety. The STS National Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. STS has also 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 procedure. The Adult Cardiac Database collects robust clinical information on 90-95 percent of the adult cardiac surgeries performed in the country, and the Congenital Heart Surgery Database captures 95 percent of the pediatric congenital heart surgery cases in the country. The percentage of US general thoracic cases captured is less certain, as some general thoracic procedures are being performed by non-Thoracic Surgery Board certified surgeons who might not participate in the STS Database.

The STS National Database core principles are collection of clinical data on every case, risk-adjustment based on national benchmarks and regular feedback of results to each program. These activities provide both the incentive and the information necessary to improve practice, which in turn benefits patients and the health care system. We believe that formal reports on these data should be distributed to participants at least two times per year, and participants should have the ability to constantly mine their own data for internal quality improvement.

A current functional example of an organization that has demonstrated the ability to develop a clinical and financial tool that tracks patient outcomes relative to costs is the Virginia Cardiac Surgery Quality Initiative (VCSQI). In 1994, this initiative created an innovative clinical/financial tool using the STS National Database and all-payor claims data derived from hospital UB04 forms. Utilizing this tool, VCSQI demonstrated success in reducing complications which both improved quality and decreased costs. Although the Virginia model has also had documented success in their ability to access cost data from hospitals, a direct and ongoing linkage to payor data would be preferred. Such a link would allow access to administrative data for longer periods following hospitalization with quantification of readmissions and other cost data (e.g. procedures, medicines) which can shed light on the efficacy of the initial cardiac surgical procedure performed. Adding unique device identifiers (UDIs) and mortality data from the Social Security Death Master File (SSDMF) to this claims information would also yield important information on long-term efficacy and durability of medical devices. Future iterations of this tool would ideally include clinical and demographic data from the period leading up to cardiac surgical intervention. Such data could be linked with the American College of Cardiology's National Cardiovascular Data Registry (NCDR®) and would further facilitate a longitudinal, population management payment model.

STS is working to develop a physician-focused payment model that fosters collaboration among a multi-disciplinary team of cardiothoracic care providers. We plan to use the STS National Database to combine clinical and cost data to develop evidence-based protocols with the goal of improving clinical performance in targeted aspects of care, such as atrial fibrillation prophylaxis, transfusion reduction, early extubation, perioperative glucose management, and postoperative wound management, among others. The draft STS APM proposal is specifically related to both cardiac (coronary artery bypass grafting (CABG) as well as heart valve repair/replacement procedures) and thoracic (treatments for lung cancer) disease processes. Previous data support

the premise that the use of evidence-based team care with feedback of results data can avoid unnecessary testing and inappropriate or futile therapy while improving clinical outcomes for this procedure¹². In addition, the identification and reduction of high cost postoperative complications can substantially improve quality and reduce spending.

The additive cost of complications in cardiac surgery is well described by the VCSQI and their impact on health care spending is substantial. For example, reductions in postoperative atrial fibrillation (afib) and transfusions through the implementation of statewide protocols have led to substantial savings of over \$70 Million dollars in the VCSQI program. Such a combined clinical/financial database tool has been an essential cornerstone of the Virginia project and has been critical to its success. Building on the success of the VCSQI, STS seeks to create a comprehensive database that blends clinical data derived from the STS National Database with claims data from CMS. This will be an unprecedented effort to define health care value and become an extraordinarily powerful tool.

The above describes our considerable experience with data acquisition and data sharing. Below we describe a number of initiatives STS has already undertaken to promote access to difference sources of data to inform these efforts.

Access to Claims Data

STS has long pursued direct and continuous access to Medicare claims data as well as similar opportunities for data sharing with private payers. Our ultimate goal is to capture claims data for the majority, if not all of the cases in the STS National Database. We welcome collaboration with all of the HCP-LAN committed partners to achieve this goal.

The *clinical* data from the STS National Database have been linked with *administrative* claims data from CMS for specific research projects through the Research Data Assistance Center or through our data warehouse at the Duke Clinical Research Institute (DCRI). The blending of these two databases allows for calculations and determinations that neither one alone can accomplish. The *clinical* data are granular, structured, standardized, and externally validated, thus allowing for precise reporting of episode based, short term mortality and morbidity results that are accurately risk-adjusted. The *administrative* data provide information on both short and long-term outcomes such as post-discharge survival rates, readmissions (and their causes), follow-up procedures (both diagnostic and therapeutic), medication use, and costs. The combination of these two types of data make available to the researcher both the risk/benefit results (short term risk adjusted outcomes, long term survival) as well as the cost/resources over time and thus make it possible to perform valid comparative effectiveness

¹ Alan M. Speir, MD, Vigneshwar Kasirajan, MD, Scott D. Barnett, PhD, and Edwin Fonner, Jr, DrPH, Additive Costs of Postoperative Complications for Isolated Coronary Artery Bypass Grafting Patients in Virginia, *Ann Thorac Surg* 2009;88:40–6

² Ruben L. Osnabrugge, MS, Alan M. Speir, MD, Stuart J. Head, PhD, Philip G. Jones, MS, Gorav Ailawadi, MD, Clifford E. Fonner, MA, Edwin Fonner, Jr, DrPH, A. Pieter Kappetein, MD, PhD, and Jeffrey B. Rich, MD, Prediction of Costs and Length of Stay in Coronary Artery Bypass Grafting, *Ann Thorac Surg* 2014;98:1286–93

An example of such a project is the American College of Cardiology Foundation-The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies (ASCERT™) Trial. This investigation was designed to compare catheter-based and surgery-based procedures for coronary artery disease. The clinical data came from existing databases from the ACC and STS combined with long-term patient outcomes data following revascularization were harvested from an administrative database - the Centers for Medicare and Medicaid Services' 100% denominator file data. ASCERT showed that in the first few months after the procedure, procedural mortality results favored PCI. However, long-term data demonstrated a clear overall survival advantage for CABG. The benefits of CABG progressively increased over time, demonstrating the long-term durability of the procedure. ASCERT is just one example of how patients and society might benefit from the research that could be conducted with continuous access to long term patient outcomes information.

In light of this demonstration documenting the intrinsic value of such data integration, we were then very disappointed with a proposed rule indicating CMS's decision *not* to adopt new policies or procedures to implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). Section 105(b) requires CMS to provide qualified clinical data registries (QCDRs, which are registries that are certified for quality reporting under the Medicare physician quality reporting system) with access to Medicare data. We had expected, as per Congressional instruction, that a new policy would be announced which would allow ongoing, real-time linking of such administrative data with clinical outcomes data enabling the performance of scientifically valid analyses to support quality improvement and patient safety. CMS originally decided not to issue a rulemaking on this section of the law based on its assertion that QCDRs can currently request Medicare claims data through the ResDAC data request process. This proposed rule failed to take into account the legal distinction between "research" and quality improvement" activities. CMS has appeared to address these concerns in a final rule, issued on July 1, 2016. However, it remains to be seen whether or not the revisions to the Qualified Entity program, as articulated in the final rule, are sufficient to address our concerns.

Access to Death Information – The Social Security Death Master File and the National Death Index

Because surgeons do not typically see patients outside of the 90 day surgical episode of care, the STS National Database cannot reliably provide long-term clinical data. To access that information, the STS National Database had in the past been able to access vital status data from the SSDMF. Those data allowed us to verify the life status of patients who otherwise would be lost to follow up after treatment. Utilizing clinical data, combined with claims information and the SSDMF, STS had been able to provide long-term information on patient treatment outcomes and estimate patient survival rates. STS members used this information to evaluate their respective outcomes against national standards or benchmarks. Outcomes data also help physicians, patients, and their families make informed treatment decisions.

In November 2011, General Counsel to the Social Security Administration (SSA) determined it was illegal for the SSA to "re-disclose" the death records that it receives from individual states.

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As a result, SSA eliminated access to the full SSDMF, sharing only those data that were not directly attributable to state reporting. Prior to that time, STS had been able to access all SSDMF files and pair them with data contained in the STS National Database. The reason for this change in policy was related to privacy concerns and instances of fraud being committed by others using Social Security data. However, the STS National Database upholds rigorous privacy protocols and is fully compliant with Health Insurance Portability and Accountability Act (HIPAA) requirements and Federal Common Rule protections for human subjects' research. STS, through its contract with the Duke Clinical Research Institute, maintains patient identifier information separately from the clinical and other demographic data. Externally derived data, like those from the SSDMF, were used to supplement the data in the individual record, but these clinical, patient-level data would never leave the database, except in de-identified form.

We acknowledge the impetus behind the decision to limit access to the SSDMF; ensuring the protection and appropriate use of personal information is responsible governmental policy. However, the incomplete data contained in the limited access SSDMF (i.e., no sharing of death reports from states) severely impairs our ability to advance quality and research initiatives that are designed to improve the delivery of, and access to, optimal care. Achieving certification under new Department of Commerce policies to access the limited SSDMF file would not help the STS regain access to the full, comprehensive dataset needed to catalogue outcomes, improve care, and potentially lower health care costs. Should access to the full SSDMF be reinstated, STS would be interested in applying for certification status which would provide us access to these files for our legitimate purposes while also demonstrating our commitment to privacy and security.

As a path forward with the SSDMF does not currently exist, we have also pursued alternate sources of death data. For example, the Centers for Disease Control and Prevention maintains the National Death Index (NDI). NDI data is not currently a viable option for clinical registries for several reasons. First, despite recent and continuing enhancements, the data in the NDI are not updated in a timely manner. Second, the pricing structure for access to NDI data is cost prohibitive. Lastly, NDI research use criteria exclude the quality improvement efforts currently conducted utilizing clinical registries. If these challenges were addressed, NDI data would actually be preferable to SSDMF data because they provide more specific information on cause of death and other information that could facilitate quality improvement as well as meaningful observational research. There are no other reasonable options for obtaining death information for research and quality improvement purposes.

Interestingly, the Secretary of Health and Human Services has the authority under 42 U.S.C. § 405(r)(9) to match Medicare claims data with death data contained in the full SSDMF data file (not just the public SSDMF available to entities that meet certification criteria). Therefore, we have petitioned CMS to match claims data with SSDMF files before sharing those data with use under (the correct interpretation of) section 105b of MACRA.

Access to Data from Electronic Health Records

The Society has supported The Improving Health Information Technology (HIT) Act (S. 2511). We believe that the definition of a clinician-led clinical data registry included in Section 6. “Leveraging Health Information Technology (HIT) to Improve Patient Care,” represents a great step forward for registries that contribute to the advancement of health care quality.

Further, the language in the bill preventing HIT vendors from activities that constitute “information blocking” will ensure that such registries have every opportunity to execute on their quality improvement missions. Additional data not necessarily captured by clinical registries (e.g., all laboratory data) could substantially enhance the utility of clinical registry data, particularly in the age of “big data” analyses, where pre-specified variable selection may fail to detect subtle but important patterns that could impact patient management and outcomes.

Notably, the proposed definition of a clinician-led clinical data registry also imposes certain controls on registry data to ensure validity and accuracy. Specifically, it requires a registry under this definition to meet standards for data quality including systematically collecting clinical health care data, using standardized data elements, and having procedures in place (e.g., regular data checks or audits) to verify the completeness and validity of those data. We believe that the data received from EHRs have historically been inaccurate. They are unaudited and less reliable than clinical registry data. We have urged CMS to concentrate on establishing reporting criteria for EHRs and to monitor the submission of accurate data through the use of testing tools.

Incorporating Unique Device Identifiers

STS has also been a vocal proponent of the capture of UDIs in EHRs and medical claims forms. Cardiothoracic surgeons have made the commitment to collecting these data in the STS National Database but we support all efforts to align data reporting. We believe that, with more information, we can more effectively fulfill our professional responsibility to improve our patients’ health. Capturing UDI in claims and EHRs will help us to achieve that goal by providing rapid and continuous access to key information related to the device, simplifying the integration of device use information into the registry, and providing more rapid identification of adverse events related to medical devices. It will also help to facilitate observational comparative effectiveness research. By collecting patient demographic information along with UDIs, we will be able to determine if certain patient characteristics could make a successful outcome more likely with a specific device. Further, if certain adverse outcomes appear to be associated with a particular medical device, a robust database populated with UDI information could conceivably answer critical questions such as:

- Is a specific device failing?
- Are patients from a specific facility experiencing different outcomes?
- Are there unexpected side-effects in one type of device but not another?

STS believes that this approach to medical research will foster innovation in targeted healthcare rather than stifle the development of new products.

Obstacles to Data Sharing

We appreciate that the whitepaper outlines the following obstacles to data sharing:

- Proprietary approaches to data that the free sharing of information;
- The establishment and dissemination of meaningful standards;
- The lack of funding to develop and maintain data-sharing initiatives;
- Legislative and policy barriers to the sharing of data;
- Privacy and security concerns among patients who are leery of who will access their data and for which purposes; and
- Technical and infrastructural gaps that limit the collection and transmission of rich clinical and patient-reported data in electronic health records (EHRs).

Many of these principles are exemplified in the descriptions of STS's own efforts on these issues described above, especially as related to our privacy and security policies. To the extent that our experiences can be used to address these concerns, STS would like to work with the HCP-LAN to overcome these obstacles.

One additional policy barrier is the confusion over the inappropriate application of the Common Rule, for human subjects research, to the collection of data in a clinical data registry. Clinical data registries collect identifiable patient information or protected health information (PHI) primarily for purposes of improving quality at participating sites for those procedures or diseases covered by the registry. In doing so, these registries typically will enter into HIPAA-compliant business associate agreements with their participating hospitals or medical practice groups. They also will obtain institutional review board (IRB) waivers from HIPAA authorization and Common Rule informed consent requirements, thereby allowing for the collection and use of PHI for research purposes. STS has previously received legal opinions that collection of data in clinical data registries for quality improvement does not constitute research, though many hospitals and other data sources will not submit data to a registry that engages in some research analysis without such IRB waivers. These positions are creating significant barriers to the development and optimal utilization of clinical data registries that have quality improvement as their primary purpose.

The whitepaper articulates the following recommendations for steps that stakeholders can take to advance data sharing:

- 1) Payers and providers should identify, in advance aligned approaches and policies for data sharing to support population based payment (PBP) models.

STS agrees with this recommendation but we would not confine this collaboration to efforts that specifically cite development of PBP. Data-sharing contributes to a body of medical knowledge that will advance health care quality and efficiency. Both quality and efficiency are the cornerstones of payment reform but they are also worthwhile goals in and of themselves.

- 2) In order for data to follow the patient, payers and providers should collaborate on approaches to patient identifiers that enable mapping across systems. This effort should be scalable.

Unique patient identifiers that allow linking of information across data sources are critical to make optimum use of these various sources. In this case, the whole (aggregate information about patients) is clearly greater than the sum of the individual parts (e.g., clinical registries, EHRs, claims data sources)

STS understands that ownership of data and information are important considerations. We believe that creation of an atmosphere of trust and collaboration will be critical among those who are sharing data and we look forward to engaging in collaborations with partners who demonstrate responsible use of data.

- 3) Payers, providers, purchasers, and patients should convene a multi-stakeholder group to recommend solutions that assure patients that their personal data are appropriately protected and used.

We agree with this proposal but note that patient outreach and education will be an ongoing process. A firm commitment to responsible use of data will be critical to maintaining societal trust that data will not be misused.

- 4) Requirements for data sharing should be made explicit in agreements between purchasers (of health plans) and payers that participate in PBP models.

We agree with this recommendation, in principle. We would note that it is the STS position that personal clinical information should never be shared with an employer or payer.

- 5) Payers should give patients and purchasers easy access to cost information, alongside quality indicators, on what it costs to see different providers for the same, common procedure.

STS has a demonstrated history of providing quality information to the public in a meaningful and useful format. Through collaborations with Consumer Reports and US News and World Reports, STS Public Reporting is at the cutting edge. Should cost information on individual providers become available, STS could consider making those data available. However, we would note that the cost of a particular service provided is rarely under the complete control of the surgeon providing care, other than limiting unnecessary testing, repeat procedures, and other complications. More importantly, we wish to emphasize that information on value, which requires both cost and quality information, will be important to present to patients and payors in a relevant and informative way.

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Public reporting is no longer an “emerging trend” but rather a routine expectation of patients, payers, legislators and health care policy makers. In addition to adopting a heart team approach to patient management when different treatment options are available, public reporting will be an essential tool in helping the accountable entity to manage appropriate referrals. STS leadership believes that the public has a right to see and understand the quality of surgical outcomes, and regards public reporting as an ethical responsibility of the specialty. STS volunteer leaders have worked diligently to develop a mechanism whereby Database participants can voluntarily report their STS composite star ratings.

STS has long recognized the importance of taking a leadership role in developing fair, accurate, and meaningful reporting structures. Evaluations of quality based solely on administrative or claims data are incomplete at best and potentially inaccurate and misleading in the worst case, of which there are numerous real-world examples. STS methodologies for performance measurement use high quality, audited data in conjunction with the most advanced risk models to calculate composite quality measures that provide a more comprehensive assessment of provider excellence. STS has taken the lead in public reporting by providing easy to understand, clinical data on heart surgery outcomes to the public, using many of the data presentation principles developed by Professor Judith Hibbard. The Society’s ongoing collaboration with Consumer Reports seeks to better inform and educate consumers about their options in cardiac care.

Since its inception in 2010, the STS adult cardiac surgery public reporting initiative continues to grow, both in the number of voluntarily enrolled participants and the composite measures offered. STS now publicly reports outcomes for isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR), and AVR+CABG surgeries. As of mid-2016, 50% of STS adult cardiac surgery participants and 60% of congenital participants voluntarily publicly report their outcomes data, as well as outcomes for congenital heart surgery procedures.

We also believe that just as providers share clinical data, commercial payers should also be transparent and provide their cost data beyond a total cost metric. In order for providers to understand and help reduce resource utilization and their associated costs, they will need to be empowered with detailed information on data surrounding cost of care for procedures as well as chronic conditions. These data must include not only single provider or institutional costs but payor costs across a region and nationally for the costs of care their beneficiaries are receiving. Only when providers understand and can compare their resource utilization and costs against their local, regional and national peers will they be able to redesign their care delivery systems to match these efficiencies. Expecting providers to merely respond to a total cost metric is unrealistic and will never lead to focused resource reduction. Additionally, providers need to understand the liabilities payors are imposing on their beneficiaries so that there is a clear understanding of the fiscal impacts their decision making has on patients. With this information providers will no longer have a pricing carrot dangling in front of them but a complete understanding of multi-stakeholder responsibility in order to advance healthcare system

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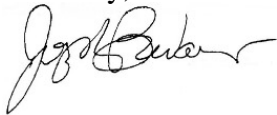
reform. Payers should not argue for provider transparency while being unwilling to share their cost infrastructure.

- 6) Payers, providers, and purchaser should actively participate in pilot programs to evaluate approaches to the sharing of data across multiple payers and providers.

We support this proposal.

Thank you for considering our comments. Should you have any questions, please contact STS Director of Government Relations Courtney Yohe at 202-787-1222 or cyohe@sts.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Bavaria", with a stylized flourish at the end.

Joseph E. Bavaria, MD
President