



The Society of Thoracic Surgeons

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February 15, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Request for feedback on episode groups

Dear Mr. Slavitt:

On behalf of The Society of Thoracic Surgeons (STS), I write to provide feedback on episode groups created by CMS and specific criteria and patient characteristics CMS plans to use to create care episode and patient condition groups. We appreciate the opportunity to respond to CMS on this matter. However, we note that this task was very challenging. We look forward to continuing to work with CMS on the implementation of these episode groups so we might all avoid unintended consequences.

Founded in 1964, STS is an international not-for-profit organization representing more than 7,100 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.

As mentioned above, this request for feedback has produced some confusion and concern within the medical community. STS appreciates CMS soliciting input from medical stakeholders. However, we would propose that a more refined approach, with collaboration from multiple medical specialties and stakeholders would better serve the public and the medical professionals who provide care. Answers to questions posed in this request for feedback are most likely an inadequate basis for developing episode groups. Constructive responses to these questions require familiarity with specific clinical procedures, statistical risk modeling, and medical outcomes research.

If CMS intends the proposed “Episode Groupers” to be defined by combining procedure codes, diagnosis [ICD10] codes, and various medical outcomes to be formulated for use in apportioning reimbursement for an episode of medical care, then the agency will need the help of experienced investigators to produce credible models. The STS contends that relying solely on “claims data” as entered on the ANSI ASC X12 837P will not permit construction of

valid risk stratified outcome models for comparison of provider and facility performance. ICD-10 diagnosis codes may define a medical condition; however, measured clinical data are required to define the relative severity necessary for more accurate risk prediction. Accuracy of predictive models is most improved by using ICD-10 codes modified by condition dependent clinical data.

STS has pioneered the utilization of clinical data to develop models for operative risk assessment and patient outcomes measurement. The Society's procedure composite scoring continues to lead all of medicine in meaningful public reporting. The National Quality Forum (NQF) endorsed the CABG composite comparisons in January 2011 and the AVR and AVR + CABG composites in November 2014. We understand why CMS might seek to develop an 'Episode Grouper' to linking procedures, diagnoses, and outcomes to reimbursement. However, we also recognize the importance of creating such a program with appropriate and transparent scientific bases. Failure to utilize appropriate methodology will likely result in contentious opposition from multiple sources and delayed or failed implementation.

The STS has published experience in combining 'medical' outcome variables with 'financial' outcome variables into models that can be used to change behavior. The Society and other groups could offer several plausible data sharing strategies but if such strategies prove impractical, medical specialty groups must still have input into the development of CMS statistical models. Experience dictates that developers "keep it as simple as possible" in the initial phases until there is agreement among the medical specialty groups and CMS that the analytic methods are valid and transparent. The medical specialty societies have plenty of subject matter experts to help with the assessment.

Care episode and patient condition groups

- 1) *Within a specialty, a limited number of conditions and procedures account for the bulk of spending. Focusing on the top conditions and procedures for a specialty, what care episode groups and patient condition groups would you suggest?*

For episode grouping, it should be noted at the outset that there is a significant risk in defining a patient population by the procedure that they receive, as there may be multiple disease processes which lead to the same procedure. An example is mitral valve replacement, where the etiology can include ischemic mitral regurgitation, rheumatic mitral valve disease, mitral regurgitation due to endocarditis, myxomatous degeneration (Barlow's disease), congenital mitral valve anomalies, and connective tissue disorders. Each of these underlying disease processes confer different risks for survival, and there are multiple other risk factors including pre-operative hemodynamic condition, non-cardiac diagnoses (e.g. diabetes, systemic hypertension, pulmonary hypertension, neurologic defects), and other associated cardiac diagnoses (e.g. aortic valve disease, tricuspid valvular regurgitation, ventricular dysfunction, coronary artery disease) which can affect operative risk.

Additionally, data from the STS Adult Cardiac Database indicate that these (and potentially other) factors can affect length of stay and also demonstrate that, for the entire population of patients undergoing mitral valve replacement, there is not a normal distribution of lengths of

stay. Therefore, it seems that a single episode group for mitral valve replacement would be fraught with potential inaccuracies when applied to individual patients. Further, even a busy institution is likely to have insufficient annual volume of cases over which to spread the risk among multiple etiologies. Adverse selection effects, particularly for an institution which gains a reputation for care of higher risk patients or for patients with a given etiology for their mitral valve disease, may also come into play when patient volumes do not generate statistically significant analyses. Attempts at “risk-adjustment” would require extensive analyses for each individual combination of diagnoses and procedures in the episode group.

Similar difficulties would exist for a single episode group for coronary artery bypass, aortic valve replacement, and other “common” adult cardiac surgical procedures. It is noteworthy that the STS risk adjustment models are different for “common” cardiac operations, including isolated mitral valve replacement, isolated aortic valve replacement, coronary artery bypass, mitral valve replacement plus coronary artery bypass, aortic valve replacement with coronary artery bypass, etc. Although the STS Database has high quality information on the effect of many clinical and demographic variables on mortality and has allowed the derivation of mortality risk models for these individual procedures, there is no STS risk model for resource utilization. Use of administrative claims data to develop such risk models is of significant concern because of the discrepancies between diagnosis and procedure data in clinical registries vs. administrative claims datasets.¹ The underlying risk is that if a robust risk-adjustment mechanism for resource utilization is not available, patient selection could be significantly affected by risk aversion. Some of these problems could be mitigated by incorporation of resource utilization data from administrative claims datasets into clinical registries, but the personnel and clinical expertise and statistical resources required to carry out scientifically and statistically credible analyses that would be required represent a major expense. Similar comments are applicable for other major cardiothoracic surgery “episodes” such as lung or esophageal cancer resections, heart failure device implantation, arrhythmia surgery, thoracic aortic aneurysm surgery, etc.

With this in mind, we recommend that initial Cardiovascular Surgery “episode groups” should be limited to the following:

- Aortic Aneurysm Procedure
- Aortic Valve Surgery
- Mitral Valve Surgery
- Coronary Bypass Surgery

Each episode group should be derived from the principle diagnosis and the principle procedure CPT code. Initial episode groups should not contain “compound procedures” (e.g. Mitral valve disease + CABG). We also recommend that these procedures are stratified according to MS-DRGs with a complicating condition (CC) or major complicating condition (MCC) and those without either. Within

¹ Pasquali S, et al The Annals of Thoracic Surgery, Volume 99, Issue 3, March 2015, Pages 932-938
Pasquali SK, et al The Annals of Thoracic Surgery, Volume 98, Issue 5, November 2014, Pages 1660-1666
Pasquali SK, et al. The Annals of Thoracic Surgery, Volume 95, Issue 1, January 2013, Pages 197-203;
Shahian DM, et al Circulation., Volume 115 Issue 12, March 2007, Pages 1518-1527)

February 15, 2016
Acting Administrator Slavitt
4

a DRG resource utilization is directly related to the presence of CC and MCC and the use of such stratification therefore represents a significant first step towards risk adjustment for costs for these procedures.

Although we are not proposing analysis of compound procedures at this time we do feel that stratification based on significant conditions that are increasingly present pre-operatively and which significantly impact resource utilization should be considered. This would include, for example, CABG with cardiogenic shock, CABG with End-Stage Renal Disease (ESRD) and CABG with acute myocardial infarction (AMI). EGM currently produces episodes for cases by stratum and therefore this would not represent any system logic modifications. These can all be treated as concurrent open treatment episodes, a fundamental concept that applies in high frequency for cardiac surgical operations and a concept deserving in depth conversation between CMS and the STS. We urge CMS to implement these groups in a transparent manner that incorporates medical specialty societies.

Again, thank you for the opportunity to provide these comments. We look forward to working with CMS on these concepts as more information becomes available. If you have any additional questions, please contact Courtney Yohe, Director of STS Government Relations (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