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Cristie Upshaw Travis, Chair
Lee Fleisher, MD, Vice Chair
Consensus Standards Approval Committee
National Quality Forum
1030 15th Street NW
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RE: Response to Appeals Letters regarding 0119 Risk-Adjusted Operative Mortality for CABG

Dear Ms. Upshaw Travis and Dr. Fleisher:

We are writing in response to letters requesting reconsideration of the 30-day (NQF 2558, CMS) and operative (NQF 0119, STS) CABG mortality measures recently endorsed by NQF. The similarity in these measures, which in many instances are nearly identical, allows us to address them as a group. These are the facts from our perspective:

1. Neither STS nor CMS suggest that CABG mortality should be the sole metric to assess quality in cardiothoracic surgery. To the contrary, STS has strategically and persistently worked to evolve cardiac surgery quality measurement beyond its historical focus on one procedure, CABG, and one outcome, risk-adjusted mortality¹⁻⁷. Our composite measures include not only mortality but also risk-adjusted occurrence of ANY of five major complications (stroke, renal failure, sternal infection, prolonged ventilation, reoperation for bleeding). These are the major morbidities most commonly responsible for the lengthy and difficult postoperative courses described in the letters to NQF. Furthermore, we have also moved beyond a focus solely on CABG and now have similar composite measures for aortic valve replacement (AVR), AVR + CABG, mitral repair/replacement, and mitral repair/replacement + CABG. Thus, we have purposely evolved our quality measurement enterprise to be much more expansive, both in terms of the adverse outcomes measured and the procedures covered.

To further expand our quality measurement portfolio, we have also developed a 30-day readmission measure for CABG (NQF 2514)⁸, recommended by the CSAC for endorsement, which will further enhance our ability to identify non-fatal but serious postoperative complications, as these are the most common causes for readmission.

STS has also nearly completed a study of failure to rescue as another potential component of our quality metrics portfolio and we expect to submit this for NQF endorsement next year. We are

also exploring the addition of patient satisfaction (e.g., HCAHPS) data to our measures portfolio, and we have applied for several grants to study patient-reported outcomes using the PROMIS instrument.

2. Notwithstanding our determined evolution towards more expansive and patient-centered outcomes, we cannot ignore the most important and longstanding metric in all complex operations—patient survival. As long as there is still substantial variability among providers in this archetypal outcomes measure, this must continue to be part of our measurement armamentarium. Patients are interested in the many other outcomes mentioned in the various letters you have received, but none of these outcomes can be evaluated unless the patient survives.

There are three currently used time frames for measuring CABG mortality: in-hospital, 30-day, and STS operative mortality. In-hospital mortality is the least desirable. It is a non-standardized ascertainment period that results in bias against hospitals that do not have nearby extended care facilities to which they can discharge patients early in their postoperative courses. Thus, their results will appear worse than those of other institutions that do have the ability to transfer patients to post-acute care facilities; the subsequent deaths of such patients may not be captured by in-hospital mortality metrics.

Thirty-day mortality (e.g., NQF 2558) is superior to in-hospital mortality as a quality metric, as it uses a standardized time frame for endpoint ascertainment^{9,10}. This is preferred by statisticians and is used in virtually all government accountability programs. It also mitigates the bias resulting from differential access to post-acute care facilities. However, as noted by the letter authors, it can have unintended negative consequences. Some providers may use supportive care measures in very ill patients until the 30-day threshold is reached, and only then discuss withdrawal of care. Despite anecdotes describing such occurrences, there are no hard data on their prevalence. Local hospital ethics committees are best positioned to identify and mitigate such questionable practices.

Although STS still has 30-day mortality measures, in virtually all of our current performance composites we preferentially use operative mortality instead of in-hospital or 30-day mortality^{11,12}. Operative mortality is defined in all components of the STS National Database as (1) all deaths, regardless of cause, occurring during the hospitalization in which the operation was performed, even if after 30 days (including patients transferred to other acute care facilities); and (2) all deaths, regardless of cause, occurring after discharge from the hospital, but before the end of the 30th postoperative day. It is this metric that is used in NQF 0119. This measure combines the other two metrics (in-hospital mortality and 30-day mortality), and, therefore, includes all in-hospital deaths regardless of timing, and all 30-day deaths regardless of venue. We believe this is the most comprehensive mortality measure, and it specifically addresses the objections raised in the recent letters to NQF. There is no incentive to discharge patients prematurely, as their out-of-hospital deaths will still be recorded out to 30 days (by which time most early outpatient deaths will have occurred). There is also no incentive to keep the patient alive using extraordinary

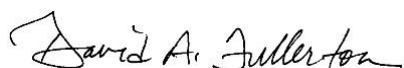
means until day 30, then to remove life-sustaining support. Because the patient is still hospitalized, their death is recorded, regardless of how long postoperatively it has occurred.

3. STS also has been actively developing strategies to longitudinally measure late mortality (after the time interval measured with operative mortality), using linkages of the STS National Database to both Medicare Data and data from national registries of death¹³⁻¹⁷.

In summary, STS supports the sentiments expressed in the recent letters to NQF which suggest that mortality is not the only metric we should use in cardiothoracic surgery. We have proven our commitment to this by relentlessly expanding our measure portfolio with numerous multidimensional composites, readmission measures, and in the near future, failure to rescue, patient satisfaction, patient-reported outcomes, and possibly long-term survival. However, we cannot ignore the continued importance of survival as an extremely important metric for complex surgery, as long as it occurs with measureable frequency and variability. Among the available risk-adjusted mortality metrics, we believe operative mortality (as used in NQF 0119) is the most comprehensive, and that 30-day mortality (NQF 2558) should also be retained as it provides a standardized time frame for ascertainment and is used in almost all governmental and commercial accountability programs.

We appreciate the opportunity to respond to the appeals letters. Thank you for your thoughtful consideration.

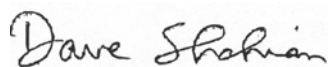
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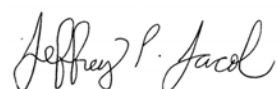
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Reference List

- (1) Shahian DM, Edwards FH, Ferraris VA, Haan CK, Rich JB, Normand SL et al. Quality measurement in adult cardiac surgery: part 1--Conceptual framework and measure selection. *Ann Thorac Surg* 2007; 83(4 Suppl):S3-12.
- (2) O'Brien SM, Shahian DM, DeLong ER, Normand SL, Edwards FH, Ferraris VA et al. Quality measurement in adult cardiac surgery: part 2--Statistical considerations in composite measure scoring and provider rating. *Ann Thorac Surg* 2007; 83(4 Suppl):S13-S26.
- (3) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1--coronary artery bypass grafting surgery. *Ann Thorac Surg* 2009; 88(1 Suppl):S2-22.
- (4) O'Brien SM, Shahian DM, Filardo G, Ferraris VA, Haan CK, Rich JB et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. *Ann Thorac Surg* 2009; 88(1 Suppl):S23-S42.
- (5) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 3--valve plus coronary artery bypass grafting surgery. *Ann Thorac Surg* 2009; 88(1 Suppl):S43-S62.
- (6) Shahian DM, He X, Jacobs JP, Rankin JS, Welke KF, Filardo G et al. The Society of Thoracic Surgeons Isolated Aortic Valve Replacement (AVR) Composite Score: A Report of the STS Quality Measurement Task Force. *Ann Thorac Surg* 2012; 94(6):2166-2171.
- (7) Shahian DM, He X, Jacobs JP, Rankin JS, Welke KF, Edwards FH et al. The STS AVR + CABG Composite Score: A Report of the STS Quality Measurement Task Force. *Ann Thorac Surg* 2014; 97(5):1604-1609.
- (8) Shahian DM, He X, O'Brien SM, Grover FL, Jacobs JP, Edwards FH et al. Development of a clinical registry-based 30-day readmission measure for coronary artery bypass grafting surgery. *Circulation* 2014; 130(5):399-409.
- (9) Krumholz HM, Brindis RG, Brush JE, Cohen DJ, Epstein AJ, Furie K et al. Standards for statistical models used for public reporting of health outcomes: an American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation* 2006; 113(3):456-462.
- (10) Krumholz HM, Lin Z, Normand SL. Measuring hospital clinical outcomes. *BMJ* 2013; 346:f620.
- (11) Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG et al. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. *Ann Thorac Surg* 2006; 81(5):1937-41.

- (12) Overman D, Jacobs JP, Prager RL, Wright CD, Clarke DR, Pasquali S et al. Report from The Society of Thoracic Surgeons National Database Work Force: Clarifying the Definition of Operative Mortality. *World J Pediatr Congenit Heart Surg* 2013; 4(1):10-12.
- (13) Jacobs JP, Edwards FH, Shahian DM, Haan CK, Puskas JD, Morales DLS et al. Successful Linking of The Society of Thoracic Surgeons Adult Cardiac Surgery Database to Centers for Medicare and Medicaid Services Medicare Data. *Ann Thorac Surg* 2010; 90:1150-1157.
- (14) Jacobs JP, Edwards FH, Shahian DM, Prager RL, Wright CD, Puskas JD et al. Successful Linking of the Society of Thoracic Surgeons Database to Social Security Data to Examine Survival after Cardiac Operations. *Ann Thorac Surg* 2011; 92(1):32-9.
- (15) Jacobs JP, O'Brien SM, Shahian DM, Edwards FH, Badhwar V, Dokholyan RS et al. Successful linking of the Society of Thoracic Surgeons Database to Social Security data to examine the accuracy of Society of Thoracic Surgeons mortality data. *J Thorac Cardiovasc Surg* 2013;145(4):976-83.
- (16) Weintraub WS, Grau-Sepulveda MV, Weiss JM, et al. Comparative effectiveness of revascularization strategies. *N Engl J Med* 2012; 366:2316–8.
- (17) Shahian DM, O'Brien SM, Sheng S, et al. Predictors of Long-Term Survival Following Coronary Artery Bypass Grafting Surgery: Results from The Society of Thoracic Surgeons Adult Cardiac Surgery Database (The ASCERT Study). *Circulation* 2012; 125(12):1491-500.