TO: Consensus Standards Approval Committee (CSAC)

FR: Christy Skipper, Project Manager, and Kathryn Streeter, Senior Project Manager

RE: Surgery 2015-2017

DA: December 6, 2016

CSAC ACTION REQUIRED: The CSAC will review recommendations from the Surgery project at its December 13, 2016 conference call.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

NQF Member voting on these recommended measures closed on December 5, 2016.

Accompanying this memo are the following documents:

1. **Surgery Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table**. Staff has identified themes within the comments received. This table lists 71 comments received and the NQF/Standing Committee responses.

BACKGROUND

The Surgery portfolio is one of NQF's largest measure portfolio with over 100 endorsed measures. This NQF project aimed to evaluate additional performance measures that will help guide cardiac, vascular, orthopedic, urologic, and gynecologic surgeries that include adult and pediatric population. The Surgery Standing Committee met for a 2-day in-person meeting to evaluate 24 measures: 10 new measures and 14 measures undergoing maintenance review against NQF's standard evaluation criteria. Fourteen measures were recommended for endorsement and, eight were not recommended, and consensus was not reached for two measures.

During the post-comment call, the Committee discussed and re-voted on the two measures where consensus was not reached; one was recommended for endorsement. The Committee also reviewed and accepted a request for reconsideration for one measure that was not recommended; the Committee re-voted and recommended this measure for endorsement.

DRAFT REPORT

The Surgery Draft Report presents the results of the evaluation of 24 measures considered under the Consensus Development Process. Sixteen measures are recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement and eight measures were not recommended. The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures considered	14	10	24
Withdrawn from consideration	7	--	7
Recommended	13	3	16
Not recommended	1	7	8
Reasons not Recommended	Importance- 1 Scientific Acceptability- 0 Overall- 0	Importance- 5 Scientific Acceptability- 2 Overall- 0	

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC is asked to consider approval of 16 candidate consensus measures.

Surgery Measures Recommended for Endorsement:

- 0117 Beta Blockade at Discharge
  Overall Suitability for Endorsement: Y-21; N-0
- 0127 Preoperative Beta Blockade
  Overall Suitability for Endorsement: Y-20; N-1
- 0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)
  Overall Suitability for Endorsement: Y-21; N-0
- 0351 Death Among Surgical Inpatients With Serious, Treatable Complications (PSI 4)
  Overall Suitability for Endorsement: Y-10; N-5
- 0697 Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure
  Overall Suitability for Endorsement: Y-20; N-0
- 0706 Risk Adjusted Colon Surgery Outcome Measure
  Overall Suitability for Endorsement: Y-20; N-0
- 1519 Statin Therapy at Discharge after Lower Extremity Bypass (LEB)
  Overall Suitability for Endorsement: Y-22; N-0
- 1523 Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive
  Overall Suitability for Endorsement: Y-18; N-5
- 1534 In-hospital mortality Following Elective EVAR of AAAs
  Overall Suitability for Endorsement: Y-20; N-2
- 1540 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy
  Overall Suitability for Endorsement: Y-19; N-4
- 1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)
  Overall Suitability for Endorsement: Y-13; N-2
- 1550 Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)
  Overall Suitability for Endorsement: Y-23; N-0
- 1551 Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)\

Overall Suitability for Endorsement: Y-21; N-1

- 3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery
  Overall Suitability for Endorsement: Y-18; N-1
- 3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score
  Overall Suitability for Endorsement: Y-19; N-0
- 3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score
  Overall Suitability for Endorsement: Y-18; N-0

Surgery Measures Not Recommended (See Appendix A for the Committee's votes and rationale)

- 0713 Ventriculoperitoneal (VP) Shunt Malfunction Rate in Children
- 2998 Infection Rate of Bicondylar Tibia Plateau Fractures
- 3024 Carotid Endarterectomy: Evaluation of Vital Status and NIH Stroke Scale at Follow Up
- 3016 PBM-01 Preoperative Anemia Screening
- 3017 PBM-02 Preoperative Hemoglobin Level
- 3019 PBM-03 Preoperative Blood Type Testing and Antibody Screening
- 3020 PBM-04 Initial Transfusion Threshold
- 3021 PBM-05 Blood Usage, Selected Elective Surgical Patients

COMMENTS AND THEIR DISPOSITION

NQF received 71 comments from six member organizations and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Surgery project page.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developers, who were invited to respond.

The Standing Committee reviewed all of the submitted comments (general and measure specific) and developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Theme 1 – Comments in support of Committee's recommendations

Most of the comments (68) were in support of the Committee's recommendations on all measures for which consensus was reached. Of these, 13 comments emphasized the importance of *#1534 In-hospital mortality following elective EVAR of AAAs*.

Committee Response: The Committee upheld their measure recommendations from the in-person meeting. On a review of comments submitted for measure #1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS) where consensus was not reached, the Committee re-voted on Evidence and Validity and recommended the measure for endorsement.

Theme 2 – Evaluation and discussion of the Sociodemographic Status trial period
Two comments expressed concern related to the "lack of rigor and robustness of the risk adjustment reviews" and suggested that other SDS factors must be considered "to understand the potential impact on a hospital's performance".

Committee Response: After a full discussion on SDS risk adjustment, the Committee accepted the developer's rationale not to include the SDS variables in the risk adjustment model. However, concerns were raised that the lack of effect might be lost in the variability of the overall low C statistic in the measure, and that the methodology used might not be capturing a community effect seen as a source of performance gaps in the relevant literature. The Committee recognizes that risk adjustment for SDS factors is a rapidly progressing area and that more work is needed to appreciate the effects of social risk, understand the most relevant patient and community level factors, collect data on these risk factors, and determine the best methods to incorporate these risk factors into performance measures. The Committee looks forward to continued deliberations on these issues and to reexamining these measures as better data emerge.

Reconsideration Request – #0351: Death Rate among Surgical Inpatients with Serious Treatable Complications (PSI 04)

During the comment period, the developer submitted a request for reconsideration on the grounds that the Committee did not appropriately review and evaluate the measure on the Validity criteria; the Committee's discussion included concerns about how the measures might be used rather than focusing solely on scientific acceptability of the measure; and a separate NQF committee reviewed a similar measure and reached a different conclusion than did the Surgery Standing Committee, e.g., inconsistent review of measures across NQF standing committees. The developer also submitted additional information on transfers, risk adjustment, and use of claims data to measure complications. The Committee accepted the developer's request and reviewed additional data submitted.

Committee Response: The Committee agreed that the additional data submitted on transfers were sufficient to address their concerns on Validity. The additional data showed that the inclusion or exclusion of transferred patients in the model would have little effect on the outcome. The Committee also acknowledged that the measure would risk adjust for transfers and whether the patient arrived at the hospital with a complication already present. Ultimately, the Committee recommended this measure for endorsement.

NQF MEMBER VOTING RESULTS
ALL of the recommended measures were approved with 100% approval or higher. Representatives of six member organizations voted; no votes were received from the Health Plan, Health Professional, Public/Community Health Agency, QMRI, and the Supplier/Industry Councils. Results for each measure are provided in Appendix B.

REMOVAL OF ENDORSEMENT

Seven measures previously endorsed by NQF were not re-submitted or were withdrawn from maintenance of endorsement:

Measure	Description	Reason for removal of endorsement
0218 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) Prophylaxis within 24 hours prior to Anesthesia Start Time to 24 hours after Anesthesia End Time.	Not re-submitted; Developer did not provide rationale
0284 Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period	Percentage of patients on beta blocker therapy prior to arrival who received a beta blocker during the perioperative period. To be in the denominator, the patient must be on a beta-blocker prior to arrival. The case is excluded if the patient is not on a beta-blocker prior to arrival.	Not re-submitted; Developer did not provide rationale
0300 Cardiac Surgery Patients With Controlled Postoperative Blood Glucose	Cardiac surgery patients with controlled postoperative blood glucose (less than or equal to 180 mg/dL) in the timeframe of 18 to 24 hours after Anesthesia End Time.	Not re-submitted; Developer did not provide rationale
0361 Esophageal Resection Volume (IQI 1)	Number of discharges with a procedure for esophageal resection	Not re-submitted; Developer reports resource constraints.
0534 Hospital specific risk-adjusted measure of mortality or one or more major complications within 30 days of a lower extremity bypass (LEB)	Hospital specific risk-adjusted measure of mortality or one or more of the following major complications (cardiac arrest, myocardial infarction, CVA/stroke, on ventilator >48 hours, acute renal failure (requiring dialysis), bleeding/transfusions, graft/prosthesis/flap failure, septic shock, sepsis, and organ space surgical site infection), within 30 days of a lower extremity bypass (LEB) in patients age 16 and older	Not re-submitted

Measure	Description	Reason for removal of endorsement
0714 Standardized mortality ratio for neonates undergoing non-cardiac surgery	This measure is a ratio of observed to expected rate of in-hospital mortality following non-cardiac surgery among infants <= 30 days of age, risk-adjusted.	Not re-submitted; Developer is revamping the measure to redefine the scope, incorporate ICD-10 codes, and complete additional testing.

Appendix A – Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
0713 Ventriculoperitoneal (VP) Shunt Malfunction Rate in Children	Evidence Y-11; N-9 Gap H-1; M-3; L-8; I-8	The Committee could not reach consensus that prompt treatment of shunt malfunctions would impact the shunt malfunction rates. They also were concerned that performance data were submitted from one institution although the measure had been endorsed since 2011. The Committee members also requested clarity on the definition of a shunt malfunction (e.g., device malfunction or clogging of the shunt). The Committee expressed concern that this measure had been endorsed since 2011 but the developers did not provide performance data from more than one institution and did not submit disparities data.
2998 Infection Rate of Bicondylar Tibia Plateau Fractures	Evidence Y-17; N-2 Gap H-10; M-7; L-0; I-1 Reliability H-1; M-18; L-1; I-0 Validity H-0; M-0; L-3; I-16	Committee members were in support of the measure concept but expressed concern that they could not sufficiently evaluate validity due to the lack of data available on bicondylar tibia plateau fractures.
3016 PBM-01 Preoperative Anemia Screening	Evidence H-0; M-3; L-10; I-8	Committee members agreed that anemia screening is important to perform in certain procedures and certain populations. However, there were concerns that the evidence presented was not sufficient to support the measure specifications. Committee members noted that there was not specific evidence to support the 14-45 day timeframe for preoperative anemia screening prior to surgery and also expressed concerns about potential unintended consequences of unnecessary preoperative testing.

Measure	Voting Results	Standing Committee Rationale
3017 PBM-02 Preoperative Hemoglobin Level	Evidence H-0; M-3; L-12; I-6	This measure is designed to identify patients who could have benefited from pre-surgical treatment to enhance iron stores and reverse anemia. The measure identifies the numbers of patients who are anemic (hemoglobin levels lower than 12 g/dL prior to elective surgery) of the elective surgical patients receiving a transfusion during or within 5 days after transfusion. The Committee agreed that unnecessary blood transfusions are undesirable and perioperative optimization of anemia is preferred, but the evidence is not clear on the hemoglobin threshold of 12 g/dl. Committee members also questioned the clinical significance of the ratio, particularly as the numerator is the number of patients and the denominator is the subset of patients who are transfused.
3019 PBM-03 Preoperative Blood Type Testing and Antibody Screening	Evidence H-0; M-5; L-10; I-6	Committee members noted that there is no graded evidence or systematic review to support this measure. American Association of Blood Bank (AABB) standards state that a blood sample shall be obtained from a patient with 3 days of a transfusion if the patient has been exposed to foreign red blood cell (RBC) antigens by means of transfusion or pregnancy within the prior 3 months. Otherwise, there is not a limit on the timing of the pre-surgical specimen. Committee members agreed that in order for safe and effective utilization of resources, the pre-transfusion testing should be completed prior to the beginning of surgery. However, the desired outcome is that the patients receive an appropriate unit of blood if transfusion is required.

Measure	Voting Results	Standing Committee Rationale
3020 PBM-04 Initial Transfusion Threshold	Evidence H-1; M-11; L-5; I-2 Gap H-2; M-13; L-0; I-5 eMeasure Trial Measure Specifications H-1; M-7; L-9; I-2 Feasibility H-3; M-6; L-6; I-2 Usability and Use H-0; M-5; L-6; I-6 Post Comment Call Vote: eMeasure Trial Measure Specifications: H-0; M-3; L-12; I-1	During the in-person meeting, the Committee could not reach consensus that the measure met the Trial eMeasure specifications, noting that there are other indications for a transfusion besides a hemoglobin measurement, such as hemorrhagic shock, bleeding, and current active bleeding, which are not reported as part of the measure. On the post comment call, the Committee continued to express concerns about how the evidence is aligned with the measure specifications. The Committee did not find the measure as specified to be a valid indicator of quality.
3021 PBM-05 Blood Usage, Selected Elective Surgical Patients	Evidence H-0; M-4; L-7; I-5	This measure is intended to assess the effectiveness of the preoperative anemia screening by identifying those patients who had the appropriate screening but still required a perioperative blood transfusion. A Committee member noted that once most patients are appropriately screened for anemia at a stage when results allow preoperative anemia management, then this measure would likely be of greater value. There was concern that, at this time, implementation of this measure is premature. Committee members were also concerned about the potential unintended consequence of hospitals deciding that they would have to do a type and screen or a type and cross match for a large proportion of patients unnecessarily.
3024 Carotid Endarterectomy: Evaluation of Vital Status and NIH Stroke Scale at Follow Up	Evidence H-0; M-0; L-12; I-8	The Committee agreed that the evidence presented by the developer is insufficient, noting that the first citation provided relates to an ungraded general guideline recommendation to monitor neurological outcomes and the second

Measure	Voting Results	Standing Committee Rationale
		relates to non-invasive imaging which is not a part of this measure. Committee members also suggested that the measure would be stronger if was using the NIH stroke scale to measure an actual outcome within 30 or 60 days post discharge as opposed to the process of administering the tool.

Appendix B – NQF Member Voting Results

NQF MEMBER VOTING RESULTS

The 16 recommended measures were approved with 100 % approval. Representatives of six member organizations voted; no votes were received from the Health Plan, Health Professional, Public/Community Health Agency, QMRI, and the Supplier/Industry Councils. Results for each measure are provided below.

NQF Member Council	Voting Organizations	Eligible to Vote	Rate
Consumer	1	40	3%
Health Plan	0	18	0%
Health Professional	0	105	0%
Provider Organizations	1	110	1%
Public/Community Health Agency	0	14	0%
Purchaser	4	22	18%
QMRI	0	78	0%
Supplier/Industry	0	36	0%
All Councils	6	423	3%

0117 Beta Blockade at Discharge

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

0127 Preoperative Beta Blockade

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

0351 Death among surgical inpatients with serious, treatable complications (PSI 4)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	

All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

Voting Comments

National Coalition for Cancer Survivorship: This is an important measure for patients and families, and we strongly support its continued endorsement.

0697 Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

0706 Risk Adjusted Colon Surgery Outcome Measure

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

1519 Statin Therapy at Discharge after Lower Extremity Bypass (LEB)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

1523 Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

1534 In-hospital mortality following elective EVAR of AAAs

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	

All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

1540 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	

Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

1551 Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)				100%	
Average council percentage approval				100%	

3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	0	0	0	0	
Health Professional	0	0	0	0	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	4	0	0	4	100%
QMRI	0	0	0	0	
Supplier/Industry	0	0	0	0	
All Councils	6	0	0	6	100%
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

Appendix C – Measure Evaluation Summary Tables

Measures Recommended for Endorsement

0117 Beta Blockade at Discharge

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who were discharged on beta blockers

Numerator Statement: Number of patients undergoing isolated CABG who were discharged on beta blockers

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if there was an in-hospital mortality or if discharge beta blocker was contraindicated.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-0; M-13; L-8; I-0;**

Rationale:

- This measure is based on Class 1C evidence that beta blockers should be prescribed to all CABG patients without contraindications upon discharge. Updated evidence was submitted for this measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- Performance on this measure was at nearly 98% across a four-year time period among gender, age, race, and insurance groups. The Committee acknowledged that performance at the 10th decile ranged from 73% in 2013-15 and 50% in 2014-15.
- Other Committee members voiced concern that the measure appears to be topped out and suggested data collection efforts and resources should be used in other areas.
- Another Committee member questioned considered the performance gap in terms of the debate on the use of beta blockers, noting that the measure could be passed if beta blockers are contraindicated. Specifically, the member asked whether documentation of contraindication needed to be supported by a reason. The developer confirmed that there needed to be documentation of a reason for not prescribing beta blockers.
- Committee members suggested that should the measure be endorsed in this project; the developer should bring the measure back indicating the number of patients represented in the gap.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Accepted Previous Evaluation** 2b. Validity: **Accepted Previous Evaluation**

Rationale:

- Measure score testing was completed on a sample of over 1,000 STS participants to indicate the measure is reliable. Sample size needed per participant to attain reliability of 0.50 and 0.70 was calculated; 95% of participants met the minimum required sample size for 0.50 reliability and 76% met required sample size

0117 Beta Blockade at Discharge

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who were discharged on beta blockers

Numerator Statement: Number of patients undergoing isolated CABG who were discharged on beta blockers

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if there was an in-hospital mortality or if discharge beta blocker was contraindicated.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

for 0.70 reliability.

- Data element and empirical validity testing of the measure score were used to support the validity of the measure. Data showed overall 96.17% agreement among 82 variables. Predictive validity was used to show stability of measure scores over time may indicate the measure capture an accurate indication of provider performance. Data showed that participants in low, middle, and high groupings for use of beta blocker at discharge in one-time period (10/2013—9/2014) had correspondingly low, middle, and high beta blocker at discharge in the following time period (10/2014-9/2015).
- A Committee member noted that this measure was a companion measure to #0127 Preoperative Beta Blockade and questioned the risk of prescribing a beta blockade at discharge if the patient did not receive it preoperatively. The developer clarified that there is a dose response to any medicine and noted that beta blockers are not typically prescribed at the maximum dosage upon discharge.
- Upon voting, the Committee agreed that this measure met reliability and validity criteria.

3. Feasibility: Accepted Previous Evaluation

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee believed that the percentage of adult cardiac surgery centers participating in the database (i.e., 95%) supported the feasibility of this measure and carried over the vote from #0134.

4. Usability and Use: Accepted Previous Evaluation

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently publically reported and widely used. Without additional discussion, the Committee carried over the vote from #0134.

5. Related and Competing Measures

- Measures 0117 and 0127 are STS measures of beta blocker use that are harmonized.

Standing Committee Recommendation for Endorsement: **Y-21; N-0**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

0117 Beta Blockade at Discharge

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who were discharged on beta blockers

Numerator Statement: Number of patients undergoing isolated CABG who were discharged on beta blockers

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if there was an in-hospital mortality or if discharge beta blocker was contraindicated.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0127 Preoperative Beta Blockade

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who received beta blockers within 24 hours preceding surgery.

Numerator Statement: Number of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if preoperative beta blocker was contraindicated or if the clinical status of the patient was emergent or emergent salvage prior to entering the operating room.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

0127 Preoperative Beta Blockade

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who received beta blockers within 24 hours preceding surgery.

Numerator Statement: Number of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if preoperative beta blocker was contraindicated or if the clinical status of the patient was emergent or emergent salvage prior to entering the operating room.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-3**; **M-17**; **L-1**; **I-0;**

Rationale:

- This maintenance measure is based on Class 1B evidence that beta blockers should be administered at least 24 hours prior to CABG for patients without contraindications to reduce incidence or clinical sequela of postoperative atrial fibrillation; and that preoperative use of beta blockers can reduce in-hospital mortality. Updated evidence was submitted for this measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- The Committee acknowledged that performance had improved to 93.5% from 84.8% during the 12-month period from October 2014 to September 2015.
- Other Committee members voiced that the measure appears to be topped out and suggested data collection efforts and resources should be used in other areas.
- Upon a vote, the Committee agreed the measure demonstrated a gap in performance.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-7**; **M-12**; **L-2**; **I-0;** 2b. Validity: **Accepted Previous Evaluation**

Rationale:

- Measure score testing was completed on a sample of over 1,000 STS participants to indicate the measure is reliable. Sample size needed per participant to attain reliability of 0.50 and 0.70 was calculated; 99% of participants met the minimum required sample size for 0.50 reliability and 97% met required sample size for 0.70 reliability.
- Data element and empirical validity testing of the measure score were used to support the validity of the measure. Data showed overall 96.17% agreement among 82 variables. Predictive validity was used to show stability of measure scores over time may indicate the measure captures an accurate indication of provider performance. Data showed that participants with high performance for use of perioperative beta blockers in one-time period (10/2013-9/2014), 77% were also high performers in the second time period (10/2014-9/2015). Twelve percent of mid-performing participants became high performers in the second time period, and low performers in the first time period were also likely to be low performers in the

0127 Preoperative Beta Blockade

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who received beta blockers within 24 hours preceding surgery.

Numerator Statement: Number of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if preoperative beta blocker was contraindicated or if the clinical status of the patient was emergent or emergent salvage prior to entering the operating room.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

second time period.

- A Committee member questioned the timeframe of when the patient is given the beta blocker. The member also asked about the likelihood that a patient would receive a beta blocker the morning of surgery or as a first dose and considered the effect on patient safety.
- The developer clarified that the numerator is patients who received a beta blocker within 24 hours of surgery, regardless of whether the patient is already on beta blockers prior to surgery. The developer acknowledged that the difference in benefits between a patient who is already on beta blockers versus a patient who receives their first dose on day of surgery is unclear.
- Upon a vote, the Committee agreed the measure met reliability and validity criteria.

3. Feasibility: H-12; M-8; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee acknowledged that the percentage of adult cardiac surgery centers participating in the database (i.e., 95%) supported the feasibility of this measure, but one member questioned how many participating institutions have a direct pass-through from the electronic record to the registry.
- The developer did not know how many institutions have a direct pass through but noted that it was probably a low number. The developer also stated that the importance of direct pass-through has not been overlooked and that they continue to work with electronic health record manufacturers.
- The Committee member then noted the cost-benefit of data collection.
- Upon a vote, the Committee agreed the measure met this criterion.

4. Usability and Use: Accepted Previous Evaluation

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Committee members discussed the cost of uploading to the registry and the true cost to a hospital for participating. The Committee acknowledged that an estimated 200-250 data fields have to be extracted per case to report the measure.
- Upon a vote, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

0127 Preoperative Beta Blockade

Submission | **Specifications**

Description: Percent of patients aged 18 years and older undergoing isolated CABG who received beta blockers within 24 hours preceding surgery.

Numerator Statement: Number of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if preoperative beta blocker was contraindicated or if the clinical status of the patient was emergent or emergent salvage prior to entering the operating room.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

- Measures 0117 and 0127 are STS measures of beta blocker use that are harmonized.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-1**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)

Submission | **Specifications**

Description: Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) who received an internal mammary artery (IMA) graft

Numerator Statement: Number of patients undergoing isolated coronary artery bypass graft (CABG) who received an internal mammary artery (IMA) graft

Denominator Statement: Patients undergoing isolated CABG

Exclusions: Cases are removed from the denominator if the patient had a previous CABG prior to the current admission or if IMA was not used and one of the following reasons was provided:

- Subclavian stenosis
- Previous cardiac or thoracic surgery
- Previous mediastinal radiation
- Emergent or salvage procedure
- No (bypassable) LAD disease

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 – 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation** 1b. Performance Gap: **H-2**; **M-11**; **L-8**; **I-0**

<u>Rationale</u>:

- The evidence for this maintenance measure is based on Class 1B recommendation that the left internal mammary artery should be used in coronary artery bypass graft. Updated evidence was submitted for this measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- Committee members pointed out that although performance was high on the measure, ranging from 93% to 100%, there was some variability indicating a performance gap.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-17**; **M-4**; **L-0**; **I-0** 2b. Validity: **H-18**; **M-3**; **L-0**; **I-0**

<u>Rationale</u>:

- Measure score testing was completed on a sample of over 1,000 STS participants to indicate the measure is reliable. Sample size needed per participant to attain reliability of 0.50 and 0.70 was calculated; 80% of participants met the minimum required sample size for 0.50 reliability and 41% met required sample size for 0.70 reliability.
- Data element and empirical validity testing of the measure score were used to support the validity of the measure. Data showed overall 96.17% agreement among 82 variables. Predictive validity was used to show stability of measure scores over time may indicate the measure captures an accurate indication of provider performance. Data showed that participants with high performance for use of IMA in one time period (10/2013-9/2014), 21.1% were also high performers in the second time period (10/2014-9/2015). 1.6% of mid performing participants became high performers in the second time period, and low performers in the first time period were also likely to be low performers in the second time period.
- The Committee noted the auditing standards of the database and the percentage of cardiac surgery centers participating in the database (i.e., 95%). On a vote, the Committee agreed that this measure met reliability and validity criteria.

3. Feasibility: H-14; M-6; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee believed that the measure was feasible since 95% of cardiac surgery centers participate in the database.

4. Usability and Use: H-14; M-6; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The measure is currently publically reported and widely used. Without additional discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- Several other STS measures (listed below) were listed as related to this measure, however, the

0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)

developer notes the measures are harmonized to the extent possible.

- 0114 Risk-Adjusted Postoperative Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117 Beta Blockade at Discharge, 0118 Anti-Lipid Treatment Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Preoperative Beta Blockade, 0129 Risk-Adjusted Postoperative Prolonged Intubation (Ventilation), 0130 Risk-Adjusted Deep Sternal Wound Infection, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident and 2514 Risk-Adjusted Coronary Artery Bypass Graft (CABG) Readmission Rate

Standing Committee Recommendation for Endorsement: **Y-21**; **N-0**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0351 Death Rate among Surgical Inpatients with Serious Treatable Complications (PSI 04)

Submission | **Specifications**

Description: In-hospital deaths per 1,000 surgical discharges, among patients ages 18 through 89 years or obstetric patients, with serious treatable complications (shock/cardiac arrest, sepsis, pneumonia, deep vein thrombosis/ pulmonary embolism or gastrointestinal hemorrhage/acute ulcer). Includes metrics for the number of discharges for each type of complication. Excludes cases transferred to an acute care facility. A risk-adjusted rate is available. The risk-adjusted rate of PSI 04 relies on stratum-specific risk models. The stratum-specific models are combined to calculate an overall risk-adjusted rate.

Numerator Statement: Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.

Denominator Statement: Surgical discharges, for patients ages 18 through 89 years or MDC 14 (pregnancy, childbirth, and puerperium), with all of the following:

- any-listed ICD-9-CM or ICD-10-PCS procedure codes for an operating room procedure; and
- the principal procedure occ

Exclusions: Exclude cases:

- transferred to an acute care facility (DISP = 2)
- with missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing), or principal diagnosis (DX1=missing)

Adjustment/Stratification: Statistical risk model

"The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, age (in 5-year age groups, except for the youngest age range), Modified Diagnosis Related Groups (ie. MS-DRGs without any distinction for “comorbidity and complications” (CC/MCC), Elixhauser Comorbidity Index (https://www.hcup-us.ahrq.gov/toolssoftware/comorbidity/comorbidity.jsp), Major Diagnosis Categories (MDC) based on the principal diagnosis, and transfer in from another acute care hospital. A parsimonious model was identified using a backward stepwise selection procedure with bootstrapping. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital). The risk-adjusted rate for the overall PSI 04 is calculated as the observed to expected ratio multiplied by the reference population rate, where the observed and expected values are summed across five strata (categories) of PSI 04 risk. This approach differs from other AHRQ Patient Safety Indicators without strata, in that each discharge-record’s expected value is computed using one of five distinct stratum-specific risk adjustment models that correspond to an assigned PSI 04 stratum. The five PSI 04 strata

0351 Death Rate among Surgical Inpatients with Serious Treatable Complications (PSI 04)

group records together based on secondary diagnoses that represent complications of care, and place the patient at risk of death (which is the numerator of PSI 04).

Additional information on methodology can be found in the Empirical Methods document on the AHRQ Quality Indicator website (www.qualityindicators.ahrq.gov). The Empirical Methods are also attached in the supplemental materials.

The specific covariates for this measure are provided for each Stratum as part of the Technical Specifications attached to section S.2b.

Source: http://www.qualityindicators.ahrq.gov/Modules/psi_resources.aspx"

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted previous evaluation**; 1b. Performance Gap: **H-6**; **M-16**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee noted that evidence presented with the recent submission is directionally the same as when last considered, at which time the measure passed on evidence, thus the Committee accepted the previous evaluation of evidence without vote.
- A member observed that the performance gap has improved by about 6% per year; however, significant gap remains in that there are some 43,000 deaths/year in 34 states as measured in all payer datasets. Further there are variations in the deaths by age, insurance status and other groupings. The Committee agreed that there is an actionable gap.
- The Committee noted that consideration should be given to including the pediatric population in this measure going forward.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1**; **M-15**; **L-5**; **I-2;** 2b. Validity: **H-0**; **M-9**; **L-10**; **I-4**

<u>Rationale</u>:

- In discussing inclusion of conditions that are present on admission (POA), AHRQ staff stated that analyses had shown that excluding patients with conditions POA did not improve validity of the measure but did reduce the number of cases that could be captured.
- The Committee discussed the specification that excludes patients from the denominator who are transferred to an acute care hospital in terms of potential for "gaming" the measure by transferring patients, particularly if patient condition worsens. The developer representative agreed there is a small window for gaming but stated there is not a way to assess the outcome of interest in such cases since hospitalizations cannot now be linked.
- The Committee raised several concerns about transfers, specifically:
    - In addressing the effect of cases where hospitals receive patients in transfer, with complications of interest who then die, the developer stated that these cases are not excluded from the measure because they contribute to detectable signal; rather they are handled with risk adjustment. They further noted that patients received in transfer have lower rates of death.
    - The Committee noted that it did not see specific testing data that the measure assesses what it is

supposed to be measuring. Members also noted that, based on the data provided the number of patients transferred out and excluded is not a high number (3% of 300,000).

- The Committee noted that transferring patients to higher levels of care is often the right thing to do but expressed concern that risk adjustment to handle patients transferred in cannot fully address the issue that the receiving hospital becomes responsible for events it cannot control. Further, the Committee stated that retaining these patients to improve signal is concerning and penalizes the receiving hospital.
- The Committee also questioned whether the transfer issues were addressed adequately to understand threats to validity and, separately, that the handling of transfers make it impossible to validate that appropriate effort was made to save the patient while in-hospital analysis over time could provide useful information.
- The Committee suggested that the developers provide sensitivity data around transfers out including facility variability analyzed in terms of such things as rural/urban, high technology/low technology, large/small as well as impact of transfers by looking at hospitals with and without that data. The developers stated they could provide this information.

- The Committee expressed concern that while claims data are a reliable way to identify a population of interest and will provide patient death, it has limitations in its ability to accurately capture complications.
- Members noted that studies comparing clinical to administrative data, false negative and high false positive rates have been found. Committee members acknowledged that coding variability among institutions can occur with clinical as well as administrative data and further noted that, particularly for multifactorial complications, significant discrepancies using administrative data have been found.
- In its discussion of SDS, the Committee agreed that there is no conceptual basis for inclusion of SDS factors in risk adjustment model.

3. Feasibility: H-6; M-10; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- On the post-comment call, the Committee agreed the measure was feasible, noting that the measure was straightforward and data sets are readily available.

4. Usability and Use: H-2; M-4; L-9; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- On the post-comment call, the Committee discussed that the measure was not specific enough to aid providers in performance improvement and may not be useful in comparing hospital quality. The developer stated the measure should be used to track rates over time and not tracked by individual cases.

Standing Committee Recommendation for Endorsement: **Y-10; N-5**

Rationale:

Since the measure failed on Validity during the in-person meeting, the Committee did not take a vote for overall suitability for endorsement. During the post-comment call, the Committee re-voted and passed the measure on Validity and voted on the remaining criteria. The Committee then voted on overall suitability for endorsement.

6. Public and Member Comment

- The developer submitted a request for reconsideration during the member and public commenting period:

We are writing to request that the National Quality Forum (NQF) Surgery Standing Committee reconsider the decision to remove endorsement of Death Rate Among Surgical Inpatients with Serious Treatable Complications (PSI 04), (NQF 0351). This long-standing Patient Safety Indicator (PSI) has been endorsed by NQF since 2008. Our

request for reconsideration is based on concern that NQF's standard review process was not applied properly during the in-person meeting on August 16, 2016, particularly with respect to the following:

1) Appropriate review and evaluation of the measure for Criteria 2. Scientific Acceptability Sub-criteria 2a. Validity
2) Discussion of the use case of the measure prior to full discussion of the scientific acceptability for the measure
3) Consistent evaluation of related (not competing) measures across NQF standing committees

First, according to the NQF's Guidance for Evaluating Validity and as noted by Dr. Karen Johnson during the review, measure developers need only submit validity testing with respect to computed performance measures scores, not data element validity. AHRQ submitted information about construct validity, which should have been the focus of the validity discussion, not the detailed discuss of claims data and data element validity.

Second, although AHRQ acknowledges the difficultly of conducting reviews that are use-agnostic, the reviewers brought up concerns about the use of the measure by CMS during scientific acceptability discussions. It is AHRQ's understanding the NQF seeks to endorse measures that are deemed scientifically rigorous and suitable for not just quality improvement but also general accountability purposes (not specific accountability purposes). The NQF review process is intended to be use-agnostic. Specific use cases of the measure, particularly the appropriate use of the measures in CMS programs, are to be discussed during NQF's Measure Application Project committee meetings.

Third, while acknowledged in the introduction of the measure, NQF's re-endorsement of a related measure by the Patient Safety Standing Committee was not emphasized during the review discussions. In particular, in the course of that re-endorsement discussion for NQF 0352 (Failure to Rescue In-Hospital Mortality, risk adjusted), which was developed and is stewarded by the Children's Hospital of Philadelphia, the Patient Safety Committee carefully evaluated the design of "failure to rescue" measures. This Committee discussed and accepted the developer's evidence-based arguments in favor of including patients who had reported complications present on admission in the measure denominator. When different NQF Standing Committees fail to evaluate similar measures, with similar design features, in a consistent manner, the consequences include confusion across the stakeholder community and mixed messages to measure developers, stewards, and users.

In addition, as noted in the NQF-Endorsed Measures for Surgical Procedures 2015-2017: Draft Report for Comment (September 22, 2016), reviewers wanted additional information about transfers, risk adjustment and use of claims data to measure complications.

AHRQ respectfully requests that NQF ask that the Committee exercise the option to re-vote on the validity of the measure during the post-comment call to preserve the integrity of the NQF process, and consider the additional information being submitted by AHRQ.

<u>NQF Post Comment Call</u>

- On the post draft report comment call, the Committee reviewed the reconsideration request and the additional testing data submitted by the developer. Ultimately, the Committee agreed to reconsider the measure for endorsement.
    - The Committee noted that the issue of transfers was addressed through the additional sensitivity analysis showing that including or excluding transfers would have little effect on the outcome. The developer confirmed that the measure would risk adjust for transfers and whether the patient arrived at the hospital with a complication already present.
    - The Committee also questioned the potential surveillance bias of including deep vein thrombosis (DVT) and pulmonary embolism (PE), since hospitals that detect more DVT or PE will have more cases in the denominator. The developer stated that studies have shown high performing hospitals with effective multi-disciplinary teams can intervene early on and prevent an adverse outcome.

0351 Death Rate among Surgical Inpatients with Serious Treatable Complications (PSI 04)

- In addressing the Committee's concern that some hospitals may game the measure by transferring patients out before they die, the developer acknowledged that the issue was inherent among smaller or rural hospitals that transfer patients to larger, teaching hospitals. The developer also stated events such as post-operative complications that are counted in the denominator for this measure, are also identified in the numerator in other patient safety measures. The developer also stated they have tried to create a severity flag with the administrative data to be able to detect the severity of the patient's condition when transferred to the receiving hospital.
- The Committee again raised that while administrative data is more useful to track individual hospitals, there are still concerns in terms of hospitals' ability to compare their performance to others, based on how well administrative data are collected. Ultimately, the Committee re-voted and passed the measure on the Validity criterion
- The Committee agreed the measure was feasible, and in discussion of usability, did not agree that the measure met this criterion, noting that the measure was not specific enough to aid providers in performance improvement and in recognizing patterns. Overall, the Committee recommended the measure for continued endorsement.

Vote Following Consideration of Public and Member Comments:
Validity: H-4; M-10; L-2; I-1

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0697 Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure

Submission | Specifications

Description: This is a hospital based, risk adjusted, case mix adjusted elderly surgery aggregate clinical outcomes measure of adults 65 years of age and older.

Numerator Statement: The outcome of interest is hospital-specific risk-adjusted mortality, a return to the operating room, or any of the following morbidities as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP): Cardiac Arrest requiring CPR, Myocardial Infarction, Sepsis, Septic Shock, Deep Incisional Surgical Site Infection (SSI), Organ/Space SSI, Wound Disruption, Unplanned Reintubation without prior ventilator dependence, Pneumonia without pre-operative pneumonia, progressive Renal Insufficiency or Acute Renal Failure without pre-operative renal failure or dialysis, or urinary tract infection (UTI) within 30 days of any ACS NSQIP listed (CPT) surgical procedure. The original endorsed measure included venous thromboembolism (VTE) as eligible morbidity events, including deep venous thrombosis requiring therapy and pulmonary embolism.

Denominator Statement: Patients undergoing any ACS NSQIP listed (CPT) surgical procedure who are 65 years of age or older. (See appendix of roughly 2900 ACS NSQIP eligible CPT codes)

Exclusions: Cases must first have ACS NSQIP eligible CPT codes on the submitted list of ~2900 codes. Major/multisystem trauma and transplant surgeries are excluded. Patients who are ASA 6 (brain-death organ donor) are not eligible surgical cases. Surgeries following within 30 d of an index procedure are an outcome (return to OR) and are not eligible to be new index cases. Thus, a patient known to have had a prior surgical operation within 30 days is excluded from having the subsequent surgery considered an index case.

Adjustment/Stratification: Statistical risk model."ACS NSQIP performs hospital-level profiling by reporting case-mix adjusted and risk-adjusted postoperative outcomes. The statistical modeling is performed in three steps,

which include case-mix adjustment, variable selection, then risk adjustment, all of which are carried out using the SAS software package (v 9.2).

In the first step, clinically similar procedures (defined by CPT codes) are categorized into established groups. Generalized linear mixed modeling (GLMM, also called hierarchical modeling in this measure) is used to calculate linear predictor values for each procedure group (SAS PROC GLIMMIX). These linear predictors (referred to as "CPT Risk") rank each procedure group on a continuous scale based on the log probability for outcome, and are risk adjusted for patient factors. The CPT Risk variable provides case-mix adjustment for the hospital profiling.

For variable selection of risk factors, step-wise logistic regression (SAS PROC LOGISTIC) is performed using NSQIP predictors. The NSQIP predictors demonstrating statistical significance ($P<0.05$) are selected for the preliminary predictor list. A subset of this list is chosen based on clinical relevance, statistical importance, and ease of data extraction to create a small, fixed or "parsimonious" predictor set. This composite mortality or any serious morbidity outcome measure was evaluated based on the following three predictors: ASA class, CPT risk and functional status.

In the final step, both case-mix adjustment and risk adjustment are performed for the hospital profiling using the CPT Risk and the parsimonious predictor set, respectively. A GLMM is created (SAS PROC GLIMMIX) which reflects the hierarchical nature of the data, with patients clustered within hospitals (random intercept, fixed slope model with logistic regression). The model incorporates the empirical Bayes method, which optimally combines information from the particular hospital with information from the sample of all hospitals to arrive at a best prediction about each hospital's performance. Sometimes called a reliability adjustment, but more properly described as smoothing or pooling, this adjustment tends to shrink predicted hospital performance towards the grand mean hospital value, with the effect of shrinkage greatest when the hospital sample size is small and when the hospital's estimate is extreme compared to other hospitals.

Hospital performance is reported as an odds ratio (the odds for the hospital versus the odds for the statistically constructed average hospital). Hospitals with odds ratios less than 1.0 demonstrate better than average performance; those with odds ratios greater than 1.0 demonstrate worse than average performance. Odds ratios are reported with 95% confidence intervals: the interval does not overlap 1.0, the hospital is designated as a statistically significant high or low outlier, depending on whether the interval is entirely above or below 1.0, respectively.

An outcome was defined as 30-day mortality or any serious morbidity including: cardiac arrest requiring CPR, myocardial infarction, sepsis, septic shock, organ space SSI, deep incisional SSI, wound disruption, unplanned reintubation without prior ventilator dependence, pneumonia without pre-operative pneumonia, progressive renal insufficiency or acute renal failure without pre-operative renal failure or dialysis, urinary tract infection, or return to the operating room, according to ACS NSQIP definitions.

Reliability is used to evaluate the hospital profiling; this metric describes how confidently the performance of one hospital can be distinguished from other hospitals. Reliability was assessed using a standard method (described in: Huffman, Cohen et al. 2015), which uses information provided by a random intercept, fixed slope, hierarchical model (implemented by SAS PROC GLIMMIX). Please see Measure Testing attachment.

Huffman, K.M., Cohen, M.E, Ko, C.Y., Hall, B.L. A comprehensive evaluation of statistical reliability in ACS NSQIP profiling models. Annals of Surgery, 2015, 261, 1108-1113"

Level of Analysis: Facility

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Management Data, Paper Medical Records, Electronic Clinical Data : Pharmacy, Electro

Measure Steward: American College of Surgeons

0697 Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evidence Evaluation**; 1b. Performance Gap: **H-9**; **M-11**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee noted that the new evidence since approval of the measure is a joint statement from the American College of Surgeons and American Geriatric Society about optimal perioperative case, adds to the evidence that there are processes that can be done to affect quality performance for this measure. Also, recent publications have demonstrated that venous thromboembolism (VTE) is subject to surveillance bias so it has been removed as an eligible morbidity event.
- With evidence that is directionally the same as prior evidence with exception of the VTE report; the prior evaluation of this criterion was accepted without further discussion.
- The Committee discussed evidence of gap in terms of observed to expected (O/E) occurrence ratios and outlier status. Of 460 hospitals that participate in ACS NSQIP, O/E ratios range between 0.59 and 1.69; 49 hospitals are low outliers; and 34 are high.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-10**; **M-9**; **L-0**; **I-0** 2b. Validity: **H-0**; **M-13**; **L-6**; **I-0**

<u>Rationale</u>:

- Questions that came to the Committee as preliminary comments focused on the age limitation of the measure (i.e., why the measure is not inclusive of individuals younger than 65) and the potential usefulness of analyzing the population of interest in more granular age ranges to assess potential differences, including cognitive differences. The developer responded that it is looking at patients who are > 80 and that there is good data showing that there is cognitive impact at age 60, so 65 has been deemed acceptable.
- A Committee member asked if the impact of removing pulmonary embolism (PE) from the measure as part of deep vein thrombosis (DVT) had been assessed given the seriousness of the outcome. The developer responded that PE is more rare than DVT and that the impact on its assessments was biased. A committee member noted that identification of sub-clinical PEs has resulted in an impact no different than that of DVT.
- The Committee accepted that data element reliability has been demonstrated. Reliability of ACS modeling programs has been tested and results published in peer-reviewed literature in 2015.
- The developer reported the sample size needed to reach a reliability threshold of 0.4 that it proposes is moderate reliability. Reaching that threshold requires a hospital sample size of 180 cases per year; the developer reported that 85% of participating hospitals meet that threshold.
- Committee discussion of validity reflected issues that are desirable in a geriatric surgery model. For example, while meaningful, post-operative delirium and falls outside of hospital are not captured. Functional status is included as are many other important elements.
- In response to question about validity of data collected in NSQIP versus the medical record, the developer representative reported that data element reliability is assessed through annual program audits for 5% to 10% (10,000 to 15,000 data fields) of participating programs with consistent inter-rater reliability of 97% to 98%. The developer was asked to include that information in future submissions.
- In response to a question about whether event outcomes are weighted based on frequency of occurrence, the developer reported that the outcomes are not weighted. It was suggested that some approach to patient-graded severity would be worth exploring.
- Death or any of the specified morbidities within 30 days, including those post-hospitalizations that are ascertained are included in the measure. Also, in the event of multiple specified morbidities, one case

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could count only as one event in the overall model.

- The reported C statistic is 0.75 to 0.77 (depending on whether VTE and SES/SDS are included) and the Committee agreed that data presented regarding inclusion or exclusion of SDS factors and VTE supports removal of VTE from the measure and not including SDS factors at this time.

3. Feasibility: H-4; M-15; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed that data from well-constructed registries is feasible and has the potential to provide more complete and accurate information than claims data.
- The developer reports the subscription fee for ACS NSQIP participation varies between $10,000 and $25,000 and employees needed vary from 0.25 to 1.0 full time equivalent. That cost covers 200 models across a number of surgical specialties. The developer estimates cost for this measure at less than 1% of the total cost to participate in the registry.
- The Committee noted that number of ACS NSQIP participating organizations and surgeons (approximately 800 and 30,000 respectively) demonstrates feasibility.

4. Usability and Use: H-12; M-9; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The developer reported that of 460 hospitals in the ACS NSQIP program, 131 publicly report on the measure and all, reportedly, make use of the information for internal quality improvement. In so doing, each participant can access all details of each of their individual cases contained within the database. Also, they can view grouped outcomes to better understand performance and improve quality.
- In response to a question about potential unintended consequences, the developer reported they review time decay function of different outcomes over time. As a result, a determination has been made that the 30-day cutoff is a balance of capturing enough signal to generate good quality improvement against burden of following patients for longer period in outlying settings. Also, JAMA published a study in 2016 (authored by one of the Standing Committee co-chairs) that reports there is no bias in using the 30-day cutoff.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-0**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0706 Risk Adjusted Colon Surgery Outcome Measure

Submission | **Specifications**

Description: This is a hospital based, risk adjusted, case mix adjusted morbidity and mortality aggregate outcome measure of adults 18+ years undergoing colon surgery.

Numerator Statement: The outcome of interest is 30-day, hospital-specific risk-adjusted (all cause) mortality, unplanned reoperation, or any of the following morbidities as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP): cardiac arrest requiring CPR, myocardial Infarction, sepsis, septic shock, deep incisional surgical site infection (SSI), organ space SSI, wound disruption, unplanned reintubation without prior ventilator dependence, pneumonia without pre-operative pneumonia, progressive renal insufficiency or acute renal failure without pre-operative renal failure or dialysis, or urinary tract infection (UTI). All outcomes are definitively resolved within 30 days of any ACS NSQIP listed (CPT) surgical procedure. All variables (fields) are explicitly defined in the tradition of the ACS NSQIP and definitions are also submitted in these materials. The original endorsed measure included venous thromboembolism (VTE) as eligible morbidity events, including deep venous thrombosis requiring therapy and pulmonary embolism.

The current set of mortality and major complications for this measure was chosen based on prior work revealing that these complications are related to other important criteria such as large contributions to excess length of stay, large complication burdens, or correlations with mortality. (Merkow et al. 2013) In addition, the desire to limit the outcomes to significant events (ie- some degree of severity according to certain criteria) is the reason that superficial wound infection is excluded from the measure. The current submission removes VTE from the measure as recent publications have demonstrated it is highly subject to surveillance bias. A recent study of 2,838 hospitals found that increased VTE prophylaxis adherence was associated with worse risk-adjusted VTE event rates. (Bilimoria 2013 JAMA) Paradoxically hospitals with higher quality, identified by number of accreditations and quality initiatives, had worse VTE rates. The explanation for this paradoxical relationship is suggested by the association of higher rates of VTE imaging studies among these hospitals with higher rates of VTE detection. (Bilimoria, Chung et al. 2013, Ju, Chung et al. 2014, Chung, Ju et al. 2015)

Bilimoria, K. Y., J. Chung, M. H. Ju, E. R. Haut, D. J. Bentrem, C. Y. Ko and D. W. Baker (2013). "Evaluation of surveillance bias and the validity of the venous thromboembolism quality measure." Jama 310(14): 1482-1489.

Chung, J. W., M. H. Ju, C. V. Kinnier, M. W. Sohn and K. Y. Bilimoria (2015). "Postoperative venous thromboembolism outcomes measure: analytic exploration of potential misclassification of hospital quality due to surveillance bias." Ann Surg 261(3): 443-444.

Ju, M. H., J. W. Chung, C. V. Kinnier, D. J. Bentrem, D. M. Mahvi, C. Y. Ko and K. Y. Bilimoria (2014). "Association between hospital imaging use and venous thromboembolism events rates based on clinical data." Ann Surg 260(3): 558-564; discussion 564-556.

Merkow RP, Hall BL, Cohen ME, et al. Validity and feasibility of the american college of surgeons colectomy composite outcome quality measure. Ann Surg. 2013;257(3):483-489.

Denominator Statement: Patients undergoing any ACS NSQIP listed (primary CPT) colon procedure. (44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, 44210)

Exclusions: As noted above, cases are collected so as to match ACS NSQIP inclusion and exclusion criteria, thereby permitting valid application of ACS NSQIP model-based risk adjustment. Therefore, trauma and transplant surgeries are excluded as are surgeries not on the ACS NSQIP CPT list as eligible for selection (see details in next item). Patients who are ASA 6 (brain-death organ donor) are not eligible surgical cases. Of note, the measure excludes patients identified as having had prior surgical procedures within 30 days of a potential index procedure, since this measure is based on 30 day outcomes. A patient who is identified as having had a prior surgical procedure within 30 days of the index case being considered is excluded from accrual. A patient who has a second surgical procedure performed within 30 days after an index procedure has the second procedure recorded as a "Return to the operating room within 30 days" (one of the outcomes defined), but the second procedure cannot be accrued into the program as a new index procedure.

0706 Risk Adjusted Colon Surgery Outcome Measure

Adjustment/Stratification: Statistical risk model.

"ACS NSQIP performs hospital-level profiling by reporting case-mix adjusted and risk-adjusted postoperative outcomes. The statistical modeling is performed in three steps, which include case-mix adjustment, variable selection, then risk adjustment, all of which are carried out using the SAS software package (v 9.2).

In the first step, clinically similar procedures (defined by CPT codes) are categorized into established groups. Generalized linear mixed modeling (GLMM, also called hierarchical modeling in this measure) is used to calculate linear predictor values for each procedure group (SAS PROC GLIMMIX). These linear predictors (referred to as "CPT Risk") rank each procedure group on a continuous scale based on the log probability for outcome, and are risk adjusted for patient factors. The CPT Risk variable provides case-mix adjustment for the hospital profiling.

For variable selection of risk factors, step-wise logistic regression (SAS PROC LOGISTIC) is performed using NSQIP predictors. The NSQIP predictors demonstrating statistical significance ($P<0.05$) are selected for the preliminary predictor list. A subset of this list is chosen based on clinical relevance, statistical importance, and ease of data extraction to create a small, fixed or "parsimonious" predictor set (described in: Merkow, Hall et al. 2013) This composite mortality or any serious morbidity outcome measure was evaluated based on the following six predictors: ASA class, CPT risk, functional status, operative indication, emergency case and wound class. Operative indication was categorized into eight separate groups based on ICD-9/ICD-10 codes: cancer, diverticular disease, enteritis/colitis, hemorrhage, volvulus, obstruction/perforation, vascular insufficiency and other.

In the final step, both case-mix adjustment and risk adjustment are performed for the hospital profiling using the CPT Risk and the parsimonious predictor set, respectively. A GLMM is created (SAS PROC GLIMMIX) which reflects the hierarchical nature of the data, with patients clustered within hospitals (random intercept, fixed slope model with logistic regression). The model incorporates the empirical Bayes method, which optimally combines information from the particular hospital with information from the sample of all hospitals to arrive at a best prediction about each hospital's performance. Sometimes called a reliability adjustment, but more properly described as smoothing or pooling, this adjustment tends to shrink predicted hospital performance towards the grand mean hospital value, with the effect of shrinkage greatest when the hospital sample size is small and when the hospital's estimate is extreme compared to other hospitals.

Hospital performance is reported as an odds ratio (the odds for the hospital versus the odds for the statistically constructed average hospital). Hospitals with odds ratios less than 1.0 demonstrate better than average performance; those with odds ratios greater than 1.0 demonstrate worse than average performance. Odds ratios are reported with 95% confidence intervals: if the interval does not overlap 1.0, the hospital is designated as a statistically significant high or low outlier, depending on whether the interval is entirely above or below 1.0, respectively.

An outcome was defined as 30-day mortality or any serious morbidity including: cardiac arrest requiring CPR, myocardial infarction, sepsis, septic shock, organ space SSI, deep incisional SSI, wound disruption, unplanned reintubation without prior ventilator dependence, pneumonia without pre-operative pneumonia, progressive renal insufficiency or acute renal failure without pre-operative renal failure or dialysis, urinary tract infection, or return to the operating room, according to ACS NSQIP definitions.

Reliability was assessed using a standard method (described in: Huffman, Cohen et al. 2015), which uses information provided by a random intercept, fixed slope, hierarchical model (implemented by SAS PROC GLIMMIX). Please see Measure Testing attachment.

Huffman, K.M., Cohen, M.E, Ko, C.Y., Hall, B.L. A comprehensive evaluation of statistical reliability in ACS NSQIP profiling models. Annals of Surgery, 2015, 261, 1108-1113

Merkow RP, Hall BL, Cohen ME, et al. Validity and feasibility of the american college of surgeons colectomy composite outcome quality measure. Ann Surg. 2013;257(3):483-489."

A detailed description of the parsimonious colon surgery outcome measure has been published recently (as described in: Merkow, Hall et al. 2013).

0706 Risk Adjusted Colon Surgery Outcome Measure

Merkow RP, Hall BL, Cohen ME, et al. Validity and feasibility of the american college of surgeons colectomy composite outcome quality measure. Ann Surg. 2013;257(3):483-489.

Level of Analysis: Facility, Population : National

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Management Data, Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: American College of Surgeons

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-17**; **M-1**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee noted that new evidence submitted addresses the rationale for excluding VTE from the measure as an eligible morbidity event. Based on the evidence available, the Committee accepted the prior evaluation of this criterion without further discussion.
- The developer reported that O/E ratios range in the last reporting period varied between 0.86 (better than expected outcomes) and 1.17 (worse than expected outcome) at the 10th and 90th percentiles respectively, noting that while improvement has occurred there remains significant variability. The developer noted that this represents a complication rate that varies from 5% to over 30%.
- The Committee concurred that the information provided represents a significant gap.
- Also, a Committee member noted that while appropriate for exclusion from this measure, the high morbidity of colon surgery in children, represents a gap and opportunity for measure development that is/can be addressed by the pediatric NSQIP.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-11**; **M-10**; **L-0**; **I-0** 2b. Validity: **H-0**; **M-18**; **L-2**; **I-0**

<u>Rationale</u>:

- The developer reported reliability testing that examined the measure with potential adjustments for inclusion or exclusion of both VTE and SDS factors.
- The Committee noted that reliability testing information reports that a minimum acceptable reliability of 0.4 is estimated to require a sample size of 99, which the developer considers an achievable target. Data provided by the developer indicates that 42.9% of all US hospitals and 68.7% of ACS NSQIP hospitals meet the 0.4 reliability requirement. Further, the developer noted that greater than 40% of US hospitals that meet the reliability requirement perform about 85% of all colectomies performed in the US.
- In response to Committee question, the developer stated that confidence intervals are reported with institutional O/E ratios.
- A Committee member noted that the risk model is proprietary and not available to review. In response, the developer representative noted that the risk elements in the model are provided and that, if the measure were implemented publicly, ACS would provide those specifications to the public.
- It was noted the Committee would like to see an improved standard of measurement with NSQIP in future in that, at present, there is no severity weighting of outcomes; e.g., urinary tract infection and death would result in the same score.
- A Committee member, while noting the clinical rationale for not including patients <18 years of age,

0706 Risk Adjusted Colon Surgery Outcome Measure

asked that ACS note the exclusion with a rationale.

- As noted during discussion of Measure #0697 in response to question about validity of data collected in NSQIP versus the medical record, the developer representative reported that data element reliability is assessed through annual program audits for 5% to 10% (10,000 to 15,000 data fields) of participating programs with consistent inter-rater reliability of 97% to 98%. The developer was asked to include that information in future submissions.
- The C statistic is reported as 0.72 under 4 conditions related to VTE and SES/SDS inclusion or exclusion. The data were accepted as support for removing VTE from the measure and not including SDS factors at this time.

3. Feasibility: H-7; M-13; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- As noted with Measure #0697, the Committee agreed that data from well-constructed registries is feasible and has the potential to provide more complete and accurate information than claims data.
- The Committee noted that number of ACS NSQIP participating organizations and surgeons (approximately 800 and 30,000 respectively) demonstrates feasibility. Subscription fees for ACS NSQIP participation and employee need was addressed in discussion of Measure #0697.

4. Usability and Use: H-10; M-10; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- As noted with Measure #0697, the developer reported that of 460 hospitals in the ACS NSQIP program, 131 publicly report on the measure and all, reportedly, make use of the information for internal quality improvement. In so doing, each participant can access all details of each of their individual cases contained within the database. Also, they can view grouped outcomes to better understand performance and improve quality.
- The Committee noted that both this measure and #0697 represent procedures that are done in critical access hospitals but would be difficult for them to do; however, the developer representative noted that there are critical access hospitals that do participate in the program at a cost reduction. It was also noted that in the future, implementation of the measure will not require NSQIP participation; rather those who desire to use it would be guided on acquisition of required fields.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-0**

6. Public and Member Comment

- One NQF member submitted a comment in support of the Committee's recommendation to recommend this measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1519 Statin Therapy at Discharge after Lower Extremity Bypass (LEB)

Submission | Specifications

Description: Percentage of patients aged 18 years and older undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge. This measure is proposed for both hospitals and individual providers.

Numerator Statement: Patients undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge.

Denominator Statement: All patients aged 18 years and older undergoing lower extremity bypass as defined above who are discharged alive, excluding those patients who are intolerant to statins.

Exclusions: Chart documentation that patient was not an eligible candidate for statin therapy due to known drug intolerance, or patient died before discharge.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: Society for Vascular Surgery

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation** 1b. Performance Gap: **H-16**; **M-5**; **L-0**; **I-0;**

Rationale:

- The evidence base for this measure states that prescription of statin therapy at discharge reduces mortality and morbidity for patients undergoing lower extremity bypass. No new evidence was submitted for this maintenance measure and the Committee accepted the previous evaluation on this criterion.
- Performance data submitted during the initial endorsement of this measure ranged from 69% to 84%.
- Upon a vote, the Committee agreed the measure met the opportunity for improvement criterion.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-18**; **L-4**; **I-0** 2b. Validity: **H-0**; **M-15**; **L-5**; **I-2**

Rationale:

- Data element testing was completed on 100 patients in five institutions and showed a kappa statistic of 0.80, meaning there was 80% agreement between the discharge summary and the discharge order as to whether statins were prescribed.
- The Committee questioned the data source and learned that the Vascular Study Group of New England (VSGNE) registry had evolved into the self-reported Vascular Quality Initiative (VQI) database. The developer clarified that VQI covers nearly 400 institutions in the US and nearly a third of vascular surgeons participate in the registry.
- The Committee acknowledged there is less than 2% missing data in the measure. Overall, the Committee agreed the measure met the scientific acceptability criterion.

3. Feasibility: H-2; M-19; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee acknowledged that this registry measure was feasible for those participating in the

1519 Statin Therapy at Discharge after Lower Extremity Bypass (LEB)

registry.

4. Usability and Use: H-7; M-15; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee acknowledged that the measure is reported through the Centers for Medicare & Medicaid Services, Physician Quality Reporting System (CMS PQRS) program.
- The Committee clarified that measure is reported through the registry and then to CMS.

5. Related and Competing Measures

- This measure is related to #0118 Anti-Lipid Treatment Discharge. During the previous evaluation of this measure, Committee stated that the measures were related in terms of therapy used but involved different procedures and patient populations. Measure #0439 Discharged on Statin Medications was also listed as a related measure, however, the measure has been moved to reserve status by the Neurology Standing Committee.

Standing Committee Recommendation for Endorsement: **Y-22**; **N-0**

6. Public and Member Comment

- NQF Members and members of the public submitted 12 comments all in support of the Committee's recommendation to recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1523 Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive

Submission | **Specifications**

Description: Percentage of asymptomatic patients undergoing open repair of abdominal aortic aneurysms (AAA)who are discharged alive. This measure is proposed for both hospitals and individual providers.

Numerator Statement: Patients discharged alive/home following open repair of asymptomatic AAAs in men with < 6 cm diameter and women with < 5.5 cm diameter AAAs.

Denominator Statement: All elective open repairs of asymptomatic AAAs in men with < 6 cm dia and women with < 5.5 cm dia AAAs

Exclusions: = 6 cm minor diameter - men

= 5.5 cm minor diameter - women

Symptomatic AAAs that required urgent/emergent (non-elective) repair

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: Society for Vascular Surgery

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

1523 Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation;** 1b. Performance Gap: **H-7**; **M-15**; **L-0**; **I-0;**

Rationale:

- The evidence base for this measure states that rupture risk is assessed by AAA diameter, with larger AAAs more prone to rupture. Based on a trial, the measure specified that low risk patients (<6cm diameter in men and <5.5cm in women) should be offered open AAA repair if the predicted operative mortality is low. Updated evidence was submitted for this maintenance measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- Performance data showed that the average mortality was low and varied by geographic area. The Committee also discussed that providing feedback on performance to low volume centers that may have increased mortality rates compared to higher volume centers, could reduce the gap in performance.
- Upon a vote, the Committee agreed the measure met the opportunity for improvement criterion.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-17**; **L-6**; **I-0** 2b. Validity: **H-0**; **M-14**; **L-7**; **I-2**

Rationale:

- Data element testing was used to support the reliability and validity of this measure. Data showed a kappa statistic of 1 for identification of the correct procedure performed, the diameter of the aneurysm, and elective repair. Hospital mortality showed a kappa statistic of .91.
- Members questioned whether the measure collected length of stay and why the measure is not reported within a longer time frame (e.g., 30 days). The developer noted that length of stay data and up to 9 months' post-operative data are collected in the registry. Committee members then suggested that even if the measure is extended to 30 day follow up that mortality could go un-reported if clients were discharged some place other than home.
- The Committee noted that validity testing was done at the facility level but questioned why testing was not performed at the clinician level.
- The Committee discussed exclusions, noting that long-term acute care facilities could be considered an exclusion since the measures put forth by this developer are always 30 days or in hospital mortality rates.
- The Committee also raised the point that the measure is focused on low volume centers but data were not presented to show that lower volume centers have higher mortality rates. The Committee also pointed out that excluding providers with fewer than 10 cases calls to question the validity of the measure and that just one adverse event in a low volume center would impact the performance rate. Also of note was that the Committee believed it would be difficult to meet the threshold of 10 cases in order to report this measure.
- The Committee also questioned why risk adjustment was not completed, noting that the data showed disparities among age groups, with worse outcomes for older patients. Committee members also noted that there could be a factor beyond patient selection that could impact outcomes since there was no evidence to suggest that high volume surgeons better select their patients. The developer stated that risk adjustment was not justified since small aneurysms have the same low risk of rupture, regardless of the patient's age.
- Other members did not express concern that the measure was not risk adjusted since the measure focuses on elective procedures.
- The Committee made several requests and suggestions to the developer including: additional validity testing at the clinician level if there is sufficient volume to do so; consider risk adjustment to reflect that even in small aneurysms the risk of death does increase with age; and to expand the measure to 30 days and to aneurysms of all sizes.

1523 Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive

- Upon vote, the Committee agreed that the measure met the Validity criterion.

3. Feasibility: H-10; M-12; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee acknowledged that the measure is currently measured and that the measure cannot be used in claims since claims data do not contain diameter size. There were no other comments regarding feasibility.

4. Usability and Use: H-5; M-15; L-3; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee acknowledged that the measure is reported every six months in a rolling 12-month period.
- The Committee discussed the unintended consequence of this measure since its use could supersede patient choice. For example, the measure focuses on asymptomatic patients; patients at moderate risk of rupture may want the procedure but could be denied at the surgeon's discretion.
- Other members discussed that surgeons should be making that decision for patients that have increased risk of rupture or mortality and discuss with the patient that the risk of mortality from the procedure on symptomatic patients is greater than the risk of living with the aneurysm.
- Upon a vote, a majority of the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to #0357 Abdominal Aortic Aneurysm Repair Volume (IQI 4) and #0359 Abdominal Aortic Aneurysm Repair Mortality Rate (IQI 11). During the post-comment call, the Committee recalled that this measure was initially endorsed with a recommendation to be harmonized with 0357 and 0359 and to also include claims data. The Committee noted that the 0357 and 0359 are different measures since they do not distinguish by diameter of the aneurysm. The Committee also discussed that the AHRQ measures allow reporting using administrative claims for facilities that are not members of the registry. Another member noted that the AHRQ measures are facility level only measures whereas this measure generates information at the clinician level.

Standing Committee Recommendation for Endorsement: **Y-18**; **N-5**

6. Public and Member Comment

- NQF Members and members of the public submitted 12 comments all in support of the Committee's recommendation to recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1534 In-hospital mortality following elective EVAR of AAAs

Submission | **Specifications**

Description: Percentage of patients undergoing elective endovascular repair of asymptomatic infrarenal abdominal aortic aneurysms (AAA) who die while in hospital. This measure is proposed for both hospitals and individual providers.

1534 In-hospital mortality following elective EVAR of AAAs

Numerator Statement: Mortality following elective endovascular infrarenal AAA repair of asymptomatic AAAs in men with < 6 cm dia and women with < 5.5 cm dia AAAs

Denominator Statement: All elective endovascular repairs of asymptomatic AAAs in men with < 6 cm dia and women with < 5.5 cm dia AAAs

Exclusions: = 6 cm diameter - men

= 5.5 cm diameter – women

Symptomatic AAAs that required urgent/emergent (non-elective) repair

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: Society for Vascular Surgery

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-8**; **M-13**; **L-0**; **I-0**

<u>Rationale</u>:

- The evidence base for this measure states that rupture risk is assessed by AAA diameter, with larger AAAs more prone to rupture. Based on a trial, the measure specified that low risk patients (<6cm diameter in men and <5.5cm in women) should be offered AAA repair if the predicted operative mortality is low. Updated evidence was submitted for this maintenance measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- The Committee acknowledged that the performance gap data were similar to measure #1523 in that mortality was low and varied by geographic area. The Committee noted that a difference between the two measures was that the denominator was larger in this measure than in #1523. Without further discussion, the Committee agreed that the measure met this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-18**; **L-4**; **I-0** 2b. Validity: **H-0**; **M-16**; **L-5**; **I-0**

<u>Rationale</u>:

- Data element testing was used to support the reliability and validity of this measure. Data showed a kappa statistic of 1 for identification of the correct procedure performed, diameter size, and elective repair. Kappa for hospital mortality was 0.91.
- The Committee noted that the validity concerns with this measure had been discussed during the evaluation of #1523.
- Overall, the Committee agreed the measure met this criterion.

3. Feasibility: H-8; M-11; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee noted that the developer reported less than one percent missing data and therefore agreed the measure met this criterion.

4. Usability and Use: H-8; M-11; L-2; I-0

1534 In-hospital mortality following elective EVAR of AAAs

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently reported in PQRS and the Committee questioned whether the developer planned to combine this measure with #1523. The developer stated that the measures are different and that they preferred to keep the measures separate. Without further discussion, the Committee agreed the measure met this criterion.

5. Related and Competing Measures

- This measure is related to #0357 Abdominal Aortic Aneurysm Repair Volume (IQI 4) and #0359 Abdominal Aortic Aneurysm Repair Mortality Rate (IQI 11). During the post-comment call, the Committee recalled that this measure was initially endorsed with a recommendation to be harmonized with 0357 and 0359 and to also include claims data. The Committee noted that the 0357 and 0359 are different measures since they do not distinguish by diameter of the aneurysm. The Committee also discussed that the AHRQ measures allow reporting using administrative claims for facilities that are not members of the registry. Another member noted that the AHRQ measures are facility level only measures whereas this measure generates information at the clinician level.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-2**

6. Public and Member Comment

- NQF Members and members of the public submitted 13 comments all in support of the Committee's recommendation to recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1540 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy

Submission | **Specifications**

Description: Percentage of patients age 18 or older without carotid territory neurologic or retinal symptoms within the one year immediately preceding carotid endarterectomy (CEA) who experience stroke or death following surgery while in the hospital. This measure is proposed for both hospitals and individual surgeons.

Numerator Statement: Patients age 18 or older without preoperative carotid territory neurologic or retinal symptoms within the one year immediately preceding CEA who experience stroke or death during their hospitalization following carotid endarterectomy

Denominator Statement: Asymptomatic patients (based on NASCET criteria) within one year of CEA

Exclusions: DENOMINATOR EXCLUSIONS:

Symptomatic carotid stenosis: Ipsilateral carotid territory TIA or stroke less than 120 days prior to procedure: 9006F OR Other carotid stenosis: Ipsilateral TIA or stroke 120 days or greater prior to procedure or any prior contralateral carotid territory or vertebrobasilar TIA or stroke: 9007F

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

1540 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy

Measure Steward: Society for Vascular Surgery

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-1**; **M-18**; **L-3**; **I-0**

<u>Rationale</u>:

- The evidence base for this measure states that carotid endarterectomy is beneficial in stroke prevention in patients who are not at high risk of death or stroke. Updated evidence was submitted for this maintenance measure to which the Committee agreed still supported at least one action to a health outcome. The Committee then accepted the previous evaluation on this criterion.
- A Committee member questioned whether the developer had data on disparities among gender and age group. Another member noted that providers do not have screening guidelines for asymptomatic carotid disease so providers may not know about groups of people that do or do not have the disease and were thus not treated. Other Committee members expressed that there were variations in healthcare utilization in general that are not explained by disparity but by hospital region.
- The Committee acknowledged that although the performance gap is low, that there is enough variation by facility and region.
- Upon a vote, the Committee agreed the measure met this criterion.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-19**; **L-3**; **I-0** 2b. Validity: **H-2**; **M-13**; **L-6**; **I-2**

<u>Rationale</u>:

- Data element testing was used to support the reliability and validity of this measure. Data showed a Kappa statistic of 1 for correct procedure performed and hospital stroke. Kappa was 0.91 for hospital mortality and 0.90 for asymptomatic 120 days before treatment.
- The Committee noted that this outcome measure is a construct of two different outcomes that are reasonable and of important for both the patient and the provider. The Committee also discussed that the Rankin score is recorded by the provider and the coder enters that data.
- As with other SVS measures discussed, the Committee again debated the merits of in hospital mortality versus an extended window of time (e.g., 30 days) to capture mortality. Some Committee members stated that in hospital mortality allows for greater specificity of the measure and lesser data collection burden. The Committee also stated that the same predictors are present regardless of where the death takes place. Other Committee members believed that eventually patients would want to see an extended window of time since the measure is reported at a low rate.
- The Committee requested that the developer update the measure specifications, indicating that to use the measure, a facility must be part of the registry.
- Upon a vote, a majority of the Committee believed this measure met this criterion.

3. Feasibility: H-6; M-15; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The developer reported less than 1% missing data for this measure. The Committee expressed no concerns regarding the feasibility of this measure.

4. Usability and Use: H-3; M-15; L-5; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c.

1540 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy

Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee acknowledged the unintended consequence of this measure since its use could supersede patient choice in that some patients (i.e., at moderate risk of rupture) may be denied surgery.
- The Committee questioned if the measure was publicly reported. The developer noted the measure is reported through PQRS and will be reported on Physician Compare.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-4**

6. Public and Member Comment

- NQF Members and members of the public submitted 10 comments all in support of the
- Committee's recommendation to recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)

Submission | Specifications

Description: Percentage of patients 18 years of age or older without carotid territory neurologic or retinal symptoms within 120 days immediately proceeding carotid angioplasty and stent (CAS) placement who experience stroke or death during their hospitalization for this procedure. This measure is proposed for both hospitals and individual interventionalists.

Numerator Statement: Patients over age 18 without preoperative carotid territory neurologic or retinal symptoms within one year of their procedure who experience stroke or death during their hospitalization following elective carotid artery angioplasty and stent placement.

Denominator Statement: Patients over age 18 without preoperative carotid territory neurologic or retinal symptoms within one year immediately preceding carotid artery stenting.

Exclusions: Per PQRS Specifications for 2016:

DENOMINATOR EXCLUSIONS:

Symptomatic carotid stenosis: Ipsilateral carotid territory TIA or stroke less than 120 days prior to procedure: 9006F OR Other carotid stenosis: Ipsilateral TIA or stroke 120 days or greater prior to procedure or any prior contralateral carotid territory or vertebrobasilar TIA or stroke: 9007F

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: Society for Vascular Surgery

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: Consensus not reached

(1a. Evidence, 1b. Performance Gap)

1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)

1a. Evidence: **Y-12; N-10**; 1b. Performance Gap: **H-7**; **M-12**; **L-3**; **I-0**

Rationale:

- The evidence base for this measure is carotid stenting can decrease the risk of and prevent stroke. The Committee expressed concern that there are no published guidelines for carotid stenting in asymptomatic patients, pointing out that three of the four medical societies do not recommend the procedure. The Committee also noted that new evidence presented by the developer suggests stenting has an increased risk of stroke and death, compared to surgery for asymptomatic carotid disease.
- The developer stated that the indication for carotid stenting can be different than in endarterectomy and acknowledged that stenting carries a higher perioperative risk of stroke or mortality. Developers also clarified to the Committee that experienced surgeons in high volume centers are able to perform the procedure with outcomes similar to endarterectomy.
- The Committee questioned, in light of the increased risk of stroke or death with stenting, how this information would be shared with the various specialists who may also be performing the procedure.
- Committee members also considered whether the measure should be an appropriateness measure, while others members questioned whether the procedure is appropriate underscoring the importance to measure its outcome.
- Upon a vote, the Committee could not reach consensus on the Evidence criterion.
- Following the vote, the Committee acknowledged the American Heart Association's recommendation for carotid revascularization and that a randomized trial was interpreted in two ways (i.e., one found that stenting and endarterectomy have equal outcomes and the other favored endarterectomy), but did not definitively denounce stenting. The Committee indicated they would like additional comment from medical societies and the public to help them reach consensus.
- In discussion of performance gap, the Committee noted low variability in performance among providers. Another member pointed out that data presented in the measure are within a 30-day time window and not at discharge, as the measure states. Without further discussion, the Committee agreed the measure met this criterion.

2. Scientific Acceptability of Measure Properties: Consensus not reached

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-14**; **L-8**; **I-0** 2b. Validity: **H-0**; **M-13**; **L-9**; **I-0**

Rationale:

- Data element testing was used to support the reliability and validity of this measure. Data showed a Kappa statistic of 1 for correct procedure performed and hospital stroke. Kappa was 0.91 for hospital mortality and 0.90 for asymptomatic 120 days before treatment.
- The Committee questioned how patients were excluded from the measure. The developer clarified patients could be excluded if they have stroke like symptoms within one year before the procedure and based on PQRS specifications that include two codes for whether symptoms occur within or beyond 120 days.
- As discussed in #1540, Committee members debated whether the measure should be risk adjusted even though the measure focuses on elective procedures.
- On a vote, the Committee agreed the measure met the reliability criterion but could not reach consensus on validity.

3. Feasibility: H-1; M-15; L-5; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed that the measure is feasible to collect in a registry but noted that the measure would not be easily transferrable to claims or eMeasure collection due to the specific definition of stroke

1543 Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)

diagnosis. Upon a vote, the Committee agreed the measure met this criterion.

4. Usability and Use: H-2; M-9; L-9; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Committee members agreed that it is appropriate to continue to look at the outcomes of carotid stenting for quality improvement purposes. Given the controversy over the procedure, the Committee did not recommend that the measure be used for public reporting or accountability.
- The Committee also debated whether they should endorse a measure that is not reimbursable by CMS unless the procedure is performed in a trial and the data are in a carotid specific stenting registry.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y – 13; N – 2**

Rationale

- Since the Committee did not reach consensus on the Evidence and Validity criteria during the in-person meeting, the Committee did not take a vote for overall suitability for endorsement. During the post-comment call, the Committee re-voted on and passed the measure on evidence and validity. The Committee then voted on overall suitability for endorsement.

6. Public and Member Comment

- NQF Members and members of the public submitted 14 comments, many of which stated that the measure should be recommended for endorsement.
- During the post- comment call, the Committee re-discussed whether the measure met the evidence and validity criteria.
- In their discussion on subcriterion Opportunity for improvement, the Committee agreed that although carotid artery stenting is a controversial procedure, this measure currently provides a method to measure outcomes of the procedure. The Committee acknowledged that the procedure is still undergoing study in the CREST-2 trial but did not believe that should prevent them from recommending the measure for endorsement.
- In the Committee's discussion on Validity, the developer noted they submitted additional data to address the concern of whether the registry captured patient data at nine months. The Committee again questioned whether the measure should be risk adjusted but ultimately agreed that it should not be risk adjusted due to the benign natural history of high-grade internal carotid stenosis. Overall, the Committee recommended this measure for continued endorsement.

Vote Following Consideration of Public and Member Comments:

Evidence: Y-12; N-3

Validity: H-0; M-13; L-3; I-0

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Submission | Specifications

Description: The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort). The target population is patients 18 and over. CMS annually reports the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and hospitalized in non-federal acute-care hospitals.

Numerator Statement: The outcome for this measure is any complication occurring during the index admission (not coded present on arrival) to 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes".

Denominator Statement: The target population for the publically reported measure includes admissions for Medicare FFS beneficiaries who are at least 65 years of age undergoing elective primary THA and/or TKA procedures. Additional details are provided in S.9 Denominator Detail

Exclusions: This measure excludes index admissions for patients:

1. Without at least 90 days post-discharge enrollment in FFS Medicare;

2. Who were discharged against medical advice (AMA); or,

3. Who had more than two THA/TKA procedure codes during the index hospitalization.

After applying these exclusion criteria, we randomly select one index admission for patients with multiple index admissions in a calendar year. We therefore exclude the other eligible index admissions in that year.

Adjustment/Stratification: Statistical risk model.

"Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure, as articulated in the American Heart Association (AHA) Scientific Statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes" (Krumholz et al., 2006).

The measure employs a hierarchical logistic regression model to create a hospital-level RSCR. In brief, the approach simultaneously models data at the patient and hospital levels to account for the variance in patient outcomes within and between hospitals (Normand & Shahian, 2007). At the patient level, the model adjusts the log-odds of complications occurring within 90 days of the index admission using age, sex, selected clinical covariates, and a hospital-specific intercept. At the hospital level, the approach models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of complication at the hospital, after accounting for patient risk. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

Candidate and Final Risk-adjustment Variables: Candidate variables were patient-level risk-adjustors that were expected to be predictive of complication, based on empirical analysis, prior literature, and clinical judgment, including age and indicators of comorbidity and disease severity. For each patient, covariates are obtained from claims records extending 12 months prior to and including the index admission. For the measure currently implemented by CMS, these risk adjusters are identified using both inpatient and outpatient Medicare FFS claims data. However, in the all-payer hospital discharge database measure, the risk-adjustment variables can be obtained only from inpatient claims in the prior 12 months and the index admission.

The model adjusts for case-mix differences based on the clinical status of patients at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes (Pope et al., 2000). A file that contains a list of the ICD-9-CM codes and their groupings into CCs is attached in data field S.2b (Data Dictionary or Code Table). In addition, only comorbidities that convey information about the patient at admission or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. Hence, we do not risk adjust for CCs that may represent adverse events of care when they are only recorded in the index admission.

The final set of risk-adjustment variables is:

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Demographics
Age-65 (years, continuous) for patients aged 65 or over cohorts; or Age (years, continuous) for patients aged 18 and over cohorts
Male (%)

THA/TKA Procedure
Index admissions with an elective THA procedure
Number of procedures (two vs. one)

Clinical Risk Factors
Other congenital deformity of hip (joint) (ICD-9 code 755.63)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)
Morbid obesity (ICD-9 code 278.01)
Metastatic cancer or acute leukemia (CC 7)
Cancer (CC 8-12)
Respiratory/heart/digestive/urinary/other neoplasms (CC 11-13)
Diabetes mellitus (DM) or DM complications (CC 15-20, 119, 120)
Protein-calorie malnutrition (CC 21)
Bone/joint/muscle infections/necrosis (CC 37)
Rheumatoid arthritis and inflammatory connective tissue disease (CC 38)
Osteoarthritis of hip or knee (CC 40)
Osteoporosis and other bone/cartilage disorders (CC 41)
Dementia or other specific brain disorders (CC 49-50)
Major psychiatric disorders (CC 54-56)
Hemiplegia, paraplegia, paralysis, function disability (CC 67-69, 100-102, 177-178)
Cardio-respiratory failure and shock (CC 79)
Coronary atherosclerosis or angina (CC 83-84)
Stroke (CC 95-96)
Vascular or circulatory disease (CC 104-106)
Chronic obstructive pulmonary disease (COPD) (CC 108)
Pneumonia (CC 111-113)
Pleural effusion/pneumothorax (CC 114)
Dialysis status (CC 130)
Renal failure (CC 131)
Decubitus ulcer or chronic skin ulcer (CC 148-149)
Trauma (CC 154-156, 158-161)
Vertebral fractures (CC 157)
Other injuries (CC 162)
Major complications of medical care and trauma (CC 164)

References:
Krumholz HM, Brindis RG, Brush JE, et al. 2006. 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

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation 113: 456-462.

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

Pope G,Ellis R,Ash A, et al. Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26."

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Other, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-8**; **M-15**; **L-0**; **I-0;**

<u>Rationale</u>:

- The Committee noted that there is no new evidence for this measure and accepted the prior evaluation of this criterion without further discussion.
- Performance data for analysis of over 3,000 hospitals over the period 2011 – 2014 shows, while there has been performance improvement, a risk standardized complication rate (RSCR) of 3.2 at the mean and a range of 1.4 to 6.9. The Committee agreed that for a procedure for which the goal should be 0%, this represents a continuing opportunity for improvement.
- A Committee member suggested that, in the future, the developer consider weighting of the complications.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3**; **M-19**; **L-1**; **I-0** 2b. Validity: **H-3**; **M-19**; **L-1**; **I-0**

<u>Rationale</u>:

- The developer reported that the data are patient-specific, capturing every event for a patient regardless of the institution at which it occurs.
- The Committee expressed concern about whether the intraclass correlation coefficient of 0.45 reported for reliability, while considered moderate agreement in comparing hospital performance values, demonstrated sufficient reliability in identifying performance differences such that it is useful to potential patients in making hospital selections.
- When questioned about specifying the measure only for patients over 65, the developer noted that it has been validated in all-payer data but has been specifically tested and used with Medicare beneficiaries. They further noted that those Medicare beneficiaries under 65 usually have additional confounding issues, such as diagnosed disabilities or dialysis.
- In responding to a Committee question, the developer noted that the technical advisory panel that reviewed the measure agreed that it measures what they believe it should measure.
- The Committee noted that the data source is administrative data and that the reported validity study was

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

done with 6 hospitals in which an initial 30% discrepancy was reduced to 10% with refinement of outcomes and complications. This was addressed in terms of adjustments made over time based on feedback from users as well as NQF committees and analyses of fracture identification.

- It was noted that the reported validity test result could be raised by 0.5 to the 7.0 level by adding specific orthopedic-specific risk factors to the risk adjustment.
- The developer reported that a number of additional factors were analyzed and that every variable examined, including dual eligible status, was statistically significant in the multivariable model but are attenuated by combining them in the clinical model noting that none changed the c-statistic from 0.65. It was also noted that while there are other meaningful risk variables such as patient reported outcomes, functional status, lower extremity disability or pain these are not adequately coded in claims data so cannot be included in the model used.
- Disparities have remained essentially unchanged at 2.2% since 2013.
- The Committee debated whether this measure should include SDS factors in the risk model.
    - A Committee member stated that the entire population cared for by a hospital influences the outcome but the data presented did not counter this argument. The Committee member noted that patients with AHRQ scores below 42.7 and dual eligible patients do not solely define a hospital's patient population.
    - The developer reported the three SDS factors (i.e., AA race, dual eligibility, and low AHRQ scores) were statistically significant in the model. Using decomposition analysis, developers reported increased complication rates were due to hospital factors and not due to patient factors. The developers stated that inclusion of these factors would hide a component of hospital quality.
    - The Committee then noted that hospitals providing high quality care in economically disadvantaged areas may not perform well on the measure because of the exclusion of SDS factors. The developer stated that hospitals that care for non-minority, non-vulnerable patients could also perform poorly on the measure.
    - Other Committee members noted that they would not recommend risk adjustment for SDS, since finding disparities among groups is something that should be reported and followed.
- The Committee stressed that scientific assessment of the measure should be kept separate from any consideration about payment. Members also noted that such a measure at the surgeon level would be useful.

3. Feasibility: H-19; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed that use of the measure over the past several years demonstrates its feasibility.

4. Usability and Use: H-9; M-13; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is publicly reported.
- No unintended consequences were brought forward though a Committee member noted that, as an elective procedure, there might be temptation to avoid care of patients with slightly higher or marginal risk of complication.
- A Committee member noted that joint replacements are increasingly being done in outpatient surgery settings that will not be captured by the measure.
- In response to a question about the data provided to hospitals, the developer reported that hospitals

receive detail that includes the complication that occurred.

5. Related and Competing Measures

- Related measures identified by the developer include 0534 Hospital specific risk-adjusted measure of mortality or one or more major complications within 30 days of a lower extremity bypass (LEB); 0564 Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures; 1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA); and 2052 Reduction of Complications through the use of Cystoscopy during Surgery for Stress Urinary Incontinence. The Committee noted that while the measures address complications they are otherwise unrelated and that all are separately needed.

Standing Committee Recommendation for Endorsement: **Y-23**; **N-0**

6. Public and Member Comment

Comments received:

- One comment was received expressing concern related to the "lack of rigor and robustness of the risk adjustment reviews" and suggested that other SDS factors must be considered "to understand the potential impact on a hospital's performance".

Developer response:

- "CMS and Yale/CORE share the FAH's concern for the scientific rigor and robustness of the risk adjustment analyses. A risk adjustment model that is scientifically sound hinges to a large part on the use of data sources that are scrutinized, vetted, and representative of the population of interest. The process of variable selection must be done thoughtfully, as the inclusion of highly-correlated variables in a model often yields spurious results. In the context of socioeconomic status (SES) and quality reporting, there are questions that every developer and user must ask: If changes in the models result in changes in the findings, are these changes methodological artifacts? Do they alter the big picture of the overall ranking of the hospitals? Are these changes clinically meaningful? In order to identify relevant SES variables that can be used in a national measure of hospital quality, we have identified all available data sources assessing SES as patient-level variables, or proxies for patient-level variables, and can be linked to Medicare Fee-for-Service claims for all, or nearly all, over 65 year-old Medicare patients. We also performed a thorough review of relevant literature to identify SES variables that had a conceptual relationship with the measures' outcomes. The only SES variables that met the criteria above and were supported by evidence linking the variable to measure outcomes including mortality, readmission and complications were:
    - Dual eligible status (meaning enrolled in both Medicare and Medicaid)
    - Agency for Healthcare Research and Quality (AHRQ)-validated SES Index score (composite of 7 different variables found in census data: percentage of people in the labor force who are unemployed, percentage of people living below poverty level, median household income, median value of owner-occupied dwellings, percentage of people ≥25 years of age with less than a 12th-grade education, percentage of people ≥25 years of age completing ≥4 years of college, and percentage of households that average ≥1 people per room)

  In selecting variables for analyses across all measures, our intent was to be responsive to the NQF guidelines for measure developers in the context of the SES Trial Period, and to identify variables that are feasible to test and use in the near term. We examined patient-level indicators of both SES and race or ethnicity that are reliably available for all Medicare beneficiaries. We aimed to select those variables that are most valid and available. The variables used are aligned with what the National Academy of Medicine committee identified as available for use in outcome measures."

NQF response:

- The SDS trial period is a temporary change to NQF's policy. During this 2-year trial period, NQF is gathering information about the feasibility, limitations and challenges of including SDS factors in the risk-adjustment approach. Consideration of sociodemographic factors in risk adjustment models is a critical

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

issue in measurement science. The Committee was charged with evaluating the submitted measure specifications and testing by the measure developer. Given the constraints on the currently available data elements, the Committee relied on the methods used by the developer to test the conceptual and empirical relationship between SDS factors and readmissions and complications.

The developer stated there was a conceptual relationship between the SDS variables. Specifically, the developer reported socially disadvantaged patients had a higher disease burden or receive worse or disparate care, and that there is a source unrelated to hospital quality of care which could hinder patient adherence to things like post-discharge instructions. Using decomposition analysis to measure effects at the patient level and at the hospital level, the hospital effect had greater impact than patient level factors. These results were in contrast to the clinical data elements, where the patient effect tended to dominate. Due to the dominant hospital effect, the developer reported that they risk adjust away a component of hospital quality when the variables are included in the model. The developer reported that the three SDS factors were statistically significant in the model and inclusion of the variables in the model did not change the c-statistic. Ultimately, the Committee agreed that they would not recommend risk adjustment for SDS since finding disparities among groups on these measures is something that should be reported and followed.

NQF has maintained a non-prescriptive approach to the selection and testing of variables in risk adjustment models. NQF has not required that certain SDS variables be tested and does not set requirements around the inclusion of any specific variables. Similarly, NQF does not set "cut-points" for the statistical testing of a risk adjustment model. The evaluation of the model is left to the Standing Committee reviewing the measure. This approach applies to both clinical and SDS variables.

Committee response:

- After a full discussion on SDS risk adjustment, the Committee accepted the developer's rationale not to include the SDS variables in the risk adjustment model. The Committee recognizes that risk adjustment for SDS factors is a rapidly progressing area and that more work is needed to appreciate the effects of social risk, understand the most relevant patient and community level factors, collect data on these risk factors, and determine the best methods to incorporate these risk factors into performance measures. The Committee looks forward to continued deliberations on these issues and to reexamining these measures as better data emerges.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Submission | Specifications

Description: The measure estimates a hospital-level risk-standardized readmission rate (RSRR) following elective primary THA and/or TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (readmission) is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission (the admission included in the measure cohort). A specified set of planned readmissions do not count in the readmission outcome. The target population is patients 18 and over. CMS annually reports the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and hospitalized in non-federal acute-care hospitals.

Numerator Statement: The outcome for this measure is 30-day readmission. We define readmission as an

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge of the index hospitalization. If a patient has more than one unplanned admissions (for any reason) within 30 days after discharge from the index admission, only one is counted as a readmission. The measure looks for a dichotomous yes or no outcome of whether each admitted patient has an unplanned readmission within 30 days. However, if the first readmission after discharge is considered planned, any subsequent unplanned readmission is not counted as an outcome for that index admission, because the unplanned readmission could be related to care provided during the intervening planned readmission rather than during the index admission.

Denominator Statement: The target population for the publicly reported measure includes admissions for Medicare FFS beneficiaries who are at least 65 years of age undergoing elective primary THA and/or TKA procedures. Additional details are provided in S.9 Denominator Details.

Exclusions: This measure excludes admissions for patients:

1) Without at least 30 days post-discharge enrollment in FFS Medicare;
2) Who were discharged against medical advice (AMA);
3) Admitted for the index procedure and subsequently transferred to another acute care facility;
4) Who had more than two THA/TKA procedure codes during the index hospitalization; or
5) Who had THA/TKA admissions within 30 days of a prior THA/TKA index admission.

Adjustment/Stratification: Statistical risk model.

"Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure, as articulated in the American Heart Association (AHA) Scientific Statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz et al., 2006).

The measure employs a hierarchical logistic regression model to create a hospital-level 30-day RSRR. In brief, the approach simultaneously models data at the patient and hospital levels to account for the variance in patient outcomes within and between hospitals (Normand & Shahian, 2007). At the patient level, the model adjusts the log-odds of readmission within 30 days of discharge for age and selected clinical covariates. At the hospital level, the approach models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission at the hospital, after accounting for patient risk. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

Candidate and Final Risk-adjustment Variables: Candidate variables were patient-level risk-adjustors that were expected to be predictive of readmission, based on empirical analysis, prior literature, and clinical judgment, including age and indicators of comorbidity and disease severity. For each patient, covariates are obtained from claims records extending 12 months prior to and including the index admission. For the measure currently implemented by CMS, these risk adjusters are identified using both inpatient and outpatient Medicare FFS claims data. However, in the all-payer hospital discharge database measure, the risk-adjustment variables can be obtained only from inpatient claims in the prior 12 months and the index admission.

The model adjusts for case-mix differences based on the clinical status of patients at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes (Pope et al., 2000). A file that contains a list of the ICD-9-CM codes and their groupings into CCs is attached in data field S.2b (Data Dictionary or Code Table). In addition, only comorbidities that convey information about the patient at admission or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. Hence, we do not risk adjust for CCs that may represent adverse events of care when they are only recorded in the index admission.

The final set of risk-adjustment variables is:

Demographics

Age-65 (years, continuous) for patients aged 65 or over cohorts; or Age (years, continuous) for patients aged 18 and over cohorts

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Male (%)

THA/TKA Procedure
Index admissions with an elective THA procedure
Number of procedures (two vs. one)

Clinical Risk Factors
Other congenital deformity of hip (joint) (ICD-9 code 755.63)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)
Morbid obesity (ICD-9 code 278.01)
History of infection (CC 1, 3-6)
Metastatic cancer or acute leukemia (CC 7)
Cancer (CC 8-12)
Diabetes mellitus (DM) or DM complications (CC 15-20, 119-120)
Protein-calorie malnutrition (CC 21)
Disorders of fluid/electrolyte/acid-base (CC 22-23)
Rheumatoid arthritis and inflammatory connective tissue disease (CC 38)
Severe hematological disorders (CC 44)
Dementia or other specified brain disorders (CC 49, 50)
Major psychiatric disorders (CC 54-56)
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)
Polyneuropathy (CC 71)
Congestive heart failure (CC 80)
Coronary atherosclerosis or angina (CC 83-84)
Hypertension (CC 89, 91)
Specified arrhythmias and other heart rhythm disorders (CC 92-93)
Stroke (CC 95-96)
Vascular or circulatory disease (CC 104-106)
Chronic obstructive pulmonary disease (COPD) (CC 108)
Pneumonia (CC 111-113)
Dialysis status (CC 130)
Renal failure (CC 131)
Decubitus ulcer or chronic skin ulcer (CC 148-149)
Cellulitis, local skin infection (CC 152)
Other injures (CC 162)
Major symptoms, abnormalities (CC 166)

References:

Krumholz HM, Brindis RG, Brush JE, et al. 2006. 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 113: 456-462.

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2):

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

206-226."

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Other

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Previous Evaluation**; 1b. Performance Gap: **H-8**; **M-13**; **L-0**; **I-0;**

<u>Rationale</u>:

- The Committee noted that there is no new evidence for this measure and accepted the prior evaluation of this criterion without further discussion.
- The Committee agreed the performance data from analysis of over 3,000 hospitals over the period 2011 – 2014 shows, while there has been some performance improvement, the overall risk standardized readmission rate (RSRR) for the period of 4.9 at the mean with a range of 5.3 in 2011-2012 to 4.4 in 2013-2014 represents a continued opportunity for improvement.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-5**; **M-17**; **L-0**; **I-0** 2b. Validity: **H-2**; **M-18**; **L-2**; **I-1**

<u>Rationale</u>:

- The Committee noted that the intraclass correlation coefficient of 0.49 reported for reliability is accepted as moderate agreement in comparing hospital performance values.
- In response to a question about effect of transfers out including those to rehab, the developer commented that transfers to rehab are not included and that the outcome of readmission is assigned to the hospital that discharges the patient.
- The developer also noted that information about the hospital to which a patient is readmitted, including outlying institutions, is provided to the hospital at which the surgery was performed so that hospital has the information about its complications.
- A Committee member noted that the technical advisory panel that reviewed the measure agreed that it has face validity.
- It was noted that reported validity test result can be accepted on the basis of the dichotomous endpoint. The developer then clarified that validity of the outcome assessments was performed through medical record review that has been vetted by admission and readmission committees that have investigated other readmission measures.
- The Committee also debated whether this measure should include SDS factors in the risk model. The discussion is detailed in measure 1550.

3. Feasibility: H-20; M-3; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed that broad use of the measure over several years has demonstrated its feasibility.

4. Usability and Use: H-13; M-9; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c.

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee noted that the measure is publicly reported through Hospital Compare and is used in the Readmission Reduction Program from CMS.
- No unintended consequences were brought forward though a Committee member noted that, as an elective procedure, there might be temptation to avoid care of patients with slightly higher or marginal risk of complication.

5. Related and Competing Measures

- Related measures include Measure 1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) that is related and harmonized and 0330 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following heart failure (HF) hospitalization; 0505 Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization; 0506 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following pneumonia hospitalization; 1789 Hospital-Wide All-Cause Unplanned Readmission Measure (HWR); and 1891 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization
- The Committee noted that while the last 5 measures address readmission they are otherwise unrelated and that all are separately needed.

Standing Committee Recommendation for Endorsement: **Y-21**; **N-1**

6. Public and Member Comment

Comments received:

- One comment was received expressing concern related to the "lack of rigor and robustness of the risk adjustment reviews" and suggested that other SDS factors must be considered "to understand the potential impact on a hospital's performance".

Developer response:

- "CMS and Yale/CORE share the FAH's concern for the scientific rigor and robustness of the risk adjustment analyses. A risk adjustment model that is scientifically sound hinges to a large part on the use of data sources that are scrutinized, vetted, and representative of the population of interest. The process of variable selection must be done thoughtfully, as the inclusion of highly-correlated variables in a model often yields spurious results. In the context of socioeconomic status (SES) and quality reporting, there are questions that every developer and user must ask: If changes in the models result in changes in the findings, are these changes methodological artifacts? Do they alter the big picture of the overall ranking of the hospitals? Are these changes clinically meaningful? In order to identify relevant SES variables that can be used in a national measure of hospital quality, we have identified all available data sources assessing SES as patient-level variables, or proxies for patient-level variables, and can be linked to Medicare Fee-for-Service claims for all, or nearly all, over 65 year-old Medicare patients. We also performed a thorough review of relevant literature to identify SES variables that had a conceptual relationship with the measures' outcomes. The only SES variables that met the criteria above and were supported by evidence linking the variable to measure outcomes including mortality, readmission and complications were:
    - Dual eligible status (meaning enrolled in both Medicare and Medicaid)
    - Agency for Healthcare Research and Quality (AHRQ)-validated SES Index score (composite of 7 different variables found in census data: percentage of people in the labor force who are unemployed, percentage of people living below poverty level, median household income, median value of owner-occupied dwellings, percentage of people ≥25 years of age with less than a 12th-grade education, percentage of people ≥25 years of age completing ≥4 years of college, and percentage of households that average ≥1 people per room)

  In selecting variables for analyses across all measures, our intent was to be responsive to the NQF

1551 Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

guidelines for measure developers in the context of the SES Trial Period, and to identify variables that are feasible to test and use in the near term. We examined patient-level indicators of both SES and race or ethnicity that are reliably available for all Medicare beneficiaries. We aimed to select those variables that are most valid and available. The variables used are aligned with what the National Academy of Medicine committee identified as available for use in outcome measures."

NQF response:

- The SDS trial period is a temporary change to NQF's policy. During this 2-year trial period, NQF is gathering information about the feasibility, limitations and challenges of including SDS factors in the risk-adjustment approach. Consideration of sociodemographic factors in risk adjustment models is a critical issue in measurement science. The Committee was charged with evaluating the submitted measure specifications and testing by the measure developer. Given the constraints on the current, available data elements, the Committee relied on the methods used by the developer to test the conceptual and empirical relationship between SDS factors and readmissions and complications.
  The developer stated there was a conceptual relationship between the SDS variables. Specifically, the developer reported socially disadvantaged patients had a higher disease burden or receive worse or disparate care, and that there is a source unrelated to hospital quality of care which could hinder patient adherence to things like post-discharge instructions. Using decomposition analysis to measure effects at the patient level and at the hospital level, the hospital effect had greater impact than patient level factors. These results were in contrast to the clinical data elements, where the patient effect tended to dominate. Due to the dominant hospital effect, the developer reported that they risk adjust away a component of hospital quality when the variables are included in the model. The developer reported that the three SDS factors were statistically significant in the model and inclusion of the variables in the model did not change the c-statistic. Ultimately, the Committee agreed that they would not recommend risk adjustment for SDS since finding disparities among groups on these measures is something that should be reported and followed.
  NQF has maintained a non-prescriptive approach to the selection and testing of variables in risk adjustment models. NQF has not required that certain SDS variables be tested and does not set requirements around the inclusion of any specific variables. Similarly, NQF does not set "cut-points" for the statistical testing of a risk adjustment model. The evaluation of the model is left to the Standing Committee reviewing the measure. This approach applies to both clinical and SDS variables.

Committee response:

- After a full discussion on SDS risk adjustment, the Committee accepted the developer's rationale not to include the SDS variables in the risk adjustment model. The Committee recognizes that risk adjustment for SDS factors is a rapidly progressing area and that more work is needed to appreciate the effects of social risk, understand the most relevant patient and community level factors, collect data on these risk factors, and determine the best methods to incorporate these risk factors into performance measures. The Committee looks forward to continued deliberations on these issues and to reexamining these measures as better data emerges.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

Submission | Specifications

Description: The STS Individual Surgeon Composite Measure for Adult Cardiac Surgery includes five major procedures (isolated CABG, isolated AVR, AVR+CABG, MVRR, MVRR+CABG) and comprises the following two

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

domains:

Domain 1 – Risk-Adjusted Operative Mortality

Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Risk-Adjusted Major Morbidity

Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation,
2. Deep sternal wound infection,
3. Permanent stroke,
4. Renal failure, and
5. Reoperations for bleeding, coronary graft occlusion, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons.

All measures are based on audited clinical data collected in the STS Adult Cardiac Surgery Database. Individual surgeons with at least 100 eligible cases during the 3-year measurement window will receive a score for each domain and an overall composite score. In addition to calculating composite score point estimates with credible intervals, surgeons will be assigned rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

Numerator Statement: Due to the complex methodology used to construct the composite measure, it is impractical to separately discuss the numerator and denominator. The following discussion describes in detail this multiprocedural, multidimensional composite measure.

The STS Individual Surgeon Composite Measure for Adult Cardiac Surgery includes five major procedures, i.e., isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR), AVR+CABG, isolated mitral valve repair or replacement (MVRR), and MVRR+CABG, and comprises the following two domains:

Domain 1 – Risk-Adjusted Operative Mortality

Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Risk-Adjusted Major Morbidity

Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation
2. Deep sternal wound infection
3. Permanent stroke
4. Renal failure and
5. Reoperations for bleeding, coronary graft occlusion, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons

Individual surgeons with at least 100 eligible cases during the 3-year measurement window will receive a score for each domain and an overall composite score. In addition to calculating composite score point estimates with credible intervals, surgeons will be assigned rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

Patient Population: The analysis population consists of patients aged 18 years or older who undergo isolated CABG, isolated AVR, AVR+CABG, isolated MVRR, and MVRR+CABG.

Time Window: 3 years

By including composite performance scores for a portfolio of five procedures that account for nearly 80% of a typical STS Adult Cardiac Surgery Database participant surgeon's clinical activity, this metric provides a more balanced and comprehensive perspective than focusing on just one procedure or one end point. Recognizing that

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

surgeons' practices vary, each surgeon's composite performance is implicitly "weighted" by the proportion of each type of procedure he or she performs. For instance, the results of surgeons who primarily perform mitral procedures are affected most by their mitral surgery results. This approach is especially relevant for surgeons with highly specialized practices who may do relatively few isolated CABG procedures and whose performance would thus be difficult to assess using a CABG measure only. Finally, performance on each of these procedures is estimated using risk models specific to those procedures, in most cases the exact or slightly modified versions of previously published models (references provided below).

Final Composite Score:

The overall composite score was calculated as a weighted sum of (1 minus risk-adjusted mortality rate) and (1 minus risk-adjusted major morbidity rate). Mortality and morbidity rates were weighted inversely by their respective standard deviations across surgeons. This procedure is equivalent to first rescaling mortality and morbidity rates by their respective standard deviations across surgeons and then assigning equal weighting to the rescaled mortality rate and rescaled morbidity rate. Standard deviations derived from the data were used to define the final composite measure as 0.81 x (1 minus risk-standardized mortality rate) + 0.19 x (1 minus risk-standardized complication rate).

Details regarding the current STS adult cardiac surgery risk models can be found in the following manuscripts:

- Shahian DM, O'Brien SM, Filardo G, Ferraris VA, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1--coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.
- O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2—isolated valve surgery. Ann Thorac Surg 2009;88(1 Suppl):S23–42.
- Shahian DM, O'Brien SM, Filardo G, Ferraris VA, 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 Jul;88(1 Suppl):S43-62.

Additional details regarding the Individual Surgeon Composite Measure for Adult Cardiac Surgery are provided in the attached manuscript:

Shahian DM, He X, Jacobs JP, Kurlansky PA, Badhwar V, Cleveland JC Jr, Fazzalari FL, Filardo G, Normand SL, Furnary AP, Magee MJ, Rankin JS, Welke KF, Han J, O'Brien SM. The Society of Thoracic Surgeons Composite Measure of Individual Surgeon Performance for Adult Cardiac Surgery: A Report of The Society of Thoracic Surgeons Quality Measurement Task Force. Ann Thorac Surg. 2015;100:1315-25.

Denominator Statement: See response in S.4. Numerator Statement

Patient Population: The analysis population consists of patients aged 18 years or older who undergo isolated CABG, isolated AVR, AVR+CABG, isolated MVRR, and MVRR+CABG.

Exclusions: Measure exclusions: Individual surgeons who do not meet the minimum case requirement (i.e., at least 100 eligible cases during the 3-year measurement window) will not receive a score for each domain and an overall composite score.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Composite

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 – 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-21; N-0**; 1b. Performance Gap: **H-12**; **M-8**; **L-0**; **I-0;** 1c. Composite – Quality Construct and Rationale: **H-17; M-3; L-0; I-0**

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

Rationale:

- The Committee noted that the measures upon which this composite is based are NQF endorsed; complication rates remain significant and evidence is provided that action can be taken to reduce or prevent complications and mortality is provided.
- Performance gap was discussed in terms of the variability represented by data that 9% of surgeons perform worse than expected and the 18% perform better.
- In terms of reporting at the surgeon level, the developer stated that, although cardiac surgery is a "team sport," surgeon-level reporting using data from claims is occurring and it was the aim of the developer to provide clinical data through use of the registry as a more accurate way of measurement.
- In support of a surgeon-specific measure, a committee member noted that patients select individual surgeons, rather than institutions or teams and performance among individuals does vary.
- In terms of quality construct, the Committee noted that at 80% of a surgeon's practice, the measure gives a comprehensive view of an individual surgeon's practice; and the weighting and approach to measure construction is clearly described and has been vetted by an expert panel.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability -precise specifications, testing; 2b. Validity - testing, threats to validity, 2d. Composite Construction)

2a. Reliability: **H-18**; **M-3**; **L-0**; **I-0** 2b. Validity: **H-11**; **M-10**; **L-0**; **I-0** 2d. Composite Construction: **H-15; M-6; L-0; I-0**

Rationale:

- The developer states that this measure encompasses about 80% of a cardiac surgeon's workload by encompassing 5 procedures in 2 domains with 3 years of data, thus, provides high reliability.
- The Committee noted that the measure is well and clearly specified; audited and tested with reliability with surgeons with 100 or more cases at 0.81.
- Validity was discussed in terms of differences in performance among providers, missing data (0.4%) and related analyses (0.99% with and without missing data) as well as level of testing. Preliminary assessment was that testing of stability over time was provided, demonstrating face validity. The Committee determined that additional testing data presented made it eligible for higher rating.
- In response to a Committee question about SDS, the developer stated that it believes that the relationship of morbidity and mortality to SDS factors is questionable and that much of the analytic work for the measure was done prior to NQF's position on SDS; thus the developer did not have data it could use in that regard. Also, the developer noted that granularity of the data it has for sociodemographic factors is likely inadequate to demonstrate a difference and that what would likely be required is not now available to them.
- A Committee member states that theoretically, risk adjustment for clinical factors should correct for differences.
- With respect to composite construction, information was presented that correlations between morbidity and mortality were appropriately considered, including how much each drove the overall score. Weighting, done empirically and validated by an expert panel, was deemed acceptable.

3. Feasibility: H-10; M-10; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Data for the measure is captured in a standardized way through the STS database of which most surgeons and programs in the US are members.
- The Committee discussed resources required to collect the needed data from STS participant records and, after receiving information about average cases per year per abstractor, noted it would like to see more detail in this regard going forward.

4. Usability and Use: H-9; M-11; L-1; I-0

3030 STS Individual Surgeon Composite Measure for Adult Cardiac Surgery

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is not yet in use. It will be put into use later in 2016 and first reported to individual surgeons to determine whether there are issues that were not considered by the developer. The developer anticipates that public reporting will be required, likely within a year.

5. Related and Competing Measures

- No competing measures noted. Related measures are harmonized.

Standing Committee Recommendation for Endorsement: **Y-18**; **N-1**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score

Submission | Specifications

Description: The STS Mitral Valve Repair/Replacement (MVRR) Composite Score measures surgical performance for isolated MVRR with or without concomitant tricuspid valve repair (TVr), surgical ablation for atrial fibrillation (AF), or repair of atrial septal defect (ASD). To assess overall quality, the STS MVRR Composite Score comprises two domains consisting of six measures:

Domain 1 – Absence of Operative Mortality

Proportion of patients (risk-adjusted) who do not experience operative mortality. Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Absence of Major Morbidity

Proportion of patients (risk-adjusted) who do not experience any major morbidity. Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation,
2. Deep sternal wound infection,
3. Permanent stroke,
4. Renal failure, and
5. Reoperations for bleeding, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons.

Outcome data are collected on all patients and from all participants. For optimal measure reliability, participants meeting a volume threshold of at least 36 cases over 3 years (i.e., approximately one mitral case per month) receive a score for each of the two domains, plus an overall composite score. The overall composite score is created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score

Numerator Statement: Due to the complex methodology used to construct the composite measure, it is impractical to separately discuss the numerator and denominator. The following discussion describes how each domain score is calculated and how these are combined into an overall composite score.

The STS Mitral Valve Repair/Replacement (MVRR) Composite Score comprises two domains consisting of six measures:

Domain 1 – Absence of Operative Mortality

Proportion of patients (risk-adjusted) who do not experience operative mortality. Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Absence of Major Morbidity

Proportion of patients (risk-adjusted) who do not experience any major morbidity. Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation
2. Deep sternal wound infection
3. Permanent stroke
4. Renal failure and
5. Reoperations for bleeding, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons.

Participants receive a score for each of the two domains, plus an overall composite score. The overall composite score was created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

Patient Population: The analysis population consists of patients aged 18 years or older who undergo isolated MVRR with or without concomitant tricuspid valve repair (TVr), surgical ablation for atrial fibrillation (AF), or repair of atrial septal defect (ASD).

Time Window: 3 years

Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 36 isolated MVRR procedures in the patient population.

Estimation of Composite Scores and Star Ratings: The statistical methodology used to estimate the STS

MVRR composite score and star rating for each participant site was similar to that used for the STS isolated CABG, isolated AVR, and AVR+CABG measures. As with previous composite scores, we first translated risk-standardized event rates into risk-standardized absence of event rates so that a higher score indicated better performance. We then rescaled the morbidity and mortality domains by dividing by their respective standard deviations and then added the two domains together.

Denominator Statement: See response in S.4. Numerator Statement for complete description of measure specifications.

Patient Population: The analysis population consists of patients aged 18 years or older who undergo isolated MVRR with or without concomitant tricuspid valve repair (TVr), surgical ablation for atrial fibrillation (AF), or repair of atrial septal defect (ASD).

Exclusions: Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 36 isolated MVRR procedures in the patient population.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Composite

3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 – 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. Composite – Quality Construct and Rationale)

1a. Evidence: **Y-18; N-0**; 1b. Performance Gap: **H-9**; **M-9**; **L-0**; **I-0;** 1c. Composite – Quality Construct and Rationale: **H-16; M-3; L-0; I-0**

<u>Rationale</u>:

- The developer reported that the procedures of interest are frequently performed and further noted that over 62,000 patients had procedures within the area of interest of this measure during a 3-year period ending in June 2014.
- The Committee acknowledged that evidence supports the measure.
- The Committee agreed that there is a gap to be addressed. It was reported in terms of a) expected performance (mortality = 3.2%; morbidity = 16.9%); b) lower than expected, which was double that of each expected performance rate; and c) higher than expected, which was about half of the expected performance rates.
- In terms of quality construct, the Committee agreed it was high quality noting that, while mortality with mitral valve surgery is low, the addition of morbidity in the composite provides a potentially more variable and actionable picture of the surgical experience.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity, 2d. Composite Construction)

2a. Reliability: **H-15; M-4; L-0; I-0** 2b. Validity: **H-11; M-8; L-0; I-0** 2d. Composite Construction: **H-14; M-4; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed that reliability was high at 0.58 with 3 years of data tested for participants that had the required 36 cases over the 3 years.
- The Committee agreed that analysis of relatively consistent performance over two 3-year time periods (2011 – 2014 and 2012 – 2015) for which there was a 2-year overlap satisfied its expectation regarding validity. While this was initially assessed as stability over time; i.e., face validity, the Committee determined that additional testing data presented made it eligible for a higher rating.
- The developer indicated that conceptually the relationship of SDS factors to morbidity and mortality is open to question and has not been used these measures.
- With respect to composite construction, the Committee affirmed that its assessment of the measure was consistent with that of #3030, i.e., correlations between morbidity and mortality were appropriately considered, including how much each drove the overall score. Weighting, done empirically and validated by an expert panel, was deemed acceptable.

3. Feasibility: H-12; M-5; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Feasibility was addressed in terms of its similarity across STS measures; i.e. data for the measures is captured in a standardized way through the STS database of which most surgeons and programs in the US are members.
- As previously noted in measure #3030, resources required to collect data should be reported in more detail going forward.

4. Usability and Use: H-11; M-8; L-0; I-0

3031 STS Mitral Valve Repair/Replacement (MVRR) Composite Score

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee accepted the plan for implementation of the measure in 2016 with subsequent public reporting as put forth in the submission.

5. Related and Competing Measures

- No competing measures noted. Related measures are harmonized.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-0**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score

Submission | **Specifications**

Description: The STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score measures surgical performance for MVRR + CABG with or without concomitant Atrial Septal Defect (ASD) and Patient Foramen Ovale (PFO) closures, tricuspid valve repair (TVr), or surgical ablation for atrial fibrillation (AF). To assess overall quality, the STS MVRR +CABG Composite Score comprises two domains consisting of six measures:

Domain 1 – Absence of Operative Mortality

Proportion of patients (risk-adjusted) who do not experience operative mortality. Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Absence of Major Morbidity

Proportion of patients (risk-adjusted) who do not experience any major morbidity. Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation,
2. Deep sternal wound infection,
3. Permanent stroke,
4. Renal failure, and
5. Reoperations for bleeding, coronary graft occlusion, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons.

Outcome data are collected on all patients and from all participants. For optimal measure reliability, participants meeting a volume threshold of at least 25 cases over 3 years receive a score for each of the two domains, plus an overall composite score. The overall composite score is created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

Numerator Statement: Due to the complex methodology used to construct the composite measure, it is impractical to separately discuss the numerator and denominator. The following discussion describes how each

3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score

domain score is calculated and how these are combined into an overall composite score.

The STS Mitral Valve Repair/Replacement (MVRR) Composite Score comprises two domains consisting of six measures:

Domain 1 – Absence of Operative Mortality

Proportion of patients (risk-adjusted) who do not experience operative mortality. Operative mortality is defined as death before hospital discharge or within 30 days of the operation.

Domain 2 – Absence of Major Morbidity

Proportion of patients (risk-adjusted) who do not experience any major morbidity. Major morbidity is defined as the occurrence of any one or more of the following major complications:

1. Prolonged ventilation,
2. Deep sternal wound infection,
3. Permanent stroke,
4. Renal failure, and
5. Reoperations for bleeding, coronary graft occlusion, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other non-cardiac reasons.

Participants receive a score for each of the two domains, plus an overall composite score. The overall composite score was created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by the following:

1 star – lower-than-expected performance

2 stars – as-expected performance

3 stars – higher-than-expected performance

Patient Population: The analysis population consists of patients aged 18 years or older who MVRR + CABG with or without concomitant Atrial Septal Defect (ASD) and Patient Foramen Ovale (PFO) closures, tricuspid valve repair (TVr), or surgical ablation for atrial fibrillation (AF).

Time Window: 3 years

Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 25 MVRR + CABG procedures in the patient population.

Estimation of Composite Scores and Star Ratings:

To be consistent with the conventions of previous composite measures, risk-adjusted event rates were first converted into risk-adjusted absence-of-event rates. To calculate the composite, participant-specific absence of mortality rates and absence of morbidity rates were weighted inversely by their respective standard deviations across participants. This procedure was equivalent to first rescaling the absence of mortality rates and absence of morbidity rates by their respective standard deviations across participants, and then assigning equal weighting to the rescaled rates. Finally, in order to draw statistical inferences about participant performance, a Bayesian credible interval surrounding each participant's composite score was calculated. Unlike frequentist confidence intervals, Bayesian credible intervals have an intuitively direct interpretation as an interval containing the true value of the composite score with a specified probability (e.g., 95%). To determine star ratings for each participant, the credible interval of its composite score was compared with the STS average. Participants whose intervals were entirely above the STS average were classified as 3-star (higher than expected performance), and participants whose intervals were entirely below the STS average were classified as1-star (lower than expected performance). Credible intervals based on different probability levels (90%, 95%, 98%) were explored, and the resulting percentages of 1, 2, and 3-star programs were calculated.

Denominator Statement: See response in S.4. Numerator Statement for complete description of measure specifications.

Patient Population: The analysis population consists of patients aged 18 years or older who MVRR + CABG with or without concomitant Atrial Septal Defect (ASD) and Patient Foramen Ovale (PFO) closures, tricuspid valve repair (TVr), or surgical ablation for atrial fibrillation (AF).

3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score

Exclusions: Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 25 MVRR + CABG procedures in the patient population.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Composite

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING 08/16 – 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. Composite – Quality Construct and Rationale)

1a. Evidence: **Y-18; N-0**; 1b. Performance Gap: **H-12; M-7; L-0; I-0** 1c. Composite – Quality Construct and Rationale: **H-14; M-5; L-0; I-0**

<u>Rationale</u>:

- The developer reported that the procedures of interest in this measure are common operative procedures and that over 26,000 cases had procedures within the area of interest of this measure during a 3-year period ending in June 2014.
- The Committee stated that the evidence presented supports the measure.
- The Committee agreed there is a gap to be addressed based on the developer report that STS participants who had "as-expected" performance had 6.5% mortality and 29.7% morbidity whereas for those performing lower than expected, the rates were near double the expected rates and for those performing higher than expected, the rates were 4.3% and 19.8%.
- In terms of quality construct, the Committee agreed it was of high quality noting that mortality for the procedures of interest is low, the addition of morbidity provides a more actionable picture of the surgical experience.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability-precise specifications, testing; 2b. Validity testing, threats to validity, 2d. Composite Construction)

2a. Reliability: **H-11; M-9; L-0; I-0** 2b. Validity: **H-12; M-8; L-0; I-0** 2d. Composite Construction: **H-14; M-4; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed that reliability, using 3 years of data tested for participants that had a required 25 eligible cases over the 3 years was acceptable at 0.50. The developer had reported that it could opt for a higher reliability; (e.g., 0.62) but that doing so would reduce the number of eligible programs from 341 to 143.
- The Committee agreed that analysis of relatively consistent performance over two 3-year time periods (2011-2014 and 2012 – 2015) for which there was a 2-year overlap satisfied its expectation regarding validity. While this was initially assessed as stability over time; i.e., face validity, the Committee determined that additional testing data presented made it eligible for higher rating.
- The developer indicated that conceptually the relationship of SDS factors to morbidity and mortality is open to question and has not been used these measures.
- With respect to composite construction, the Committee affirmed that its assessment of the measure was consistent with that of #3030 and #3031, i.e., correlations between morbidity and mortality were appropriately considered, including how much each drove the overall score. Weighting, done empirically and validated by an expert panel, was deemed acceptable.

3. Feasibility: H-12; M-5; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/

3032 STS Mitral Valve Repair/Replacement (MVRR) + Coronary Artery Bypass Graft (CABG) Composite Score

unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Feasibility was address in terms of its similarity across STS measures; i.e., data for the measures is captured in a standardized way through the STS database of which most surgeons and programs in the US are members.
- As previously noted, resources required to collect data should be reported in more detail going forward.

4. Usability and Use: H-12; M-7; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee accepted the plan for implementation of the measure in 2016 with subsequent public reporting as put forth in the submission.

5. Related and Competing Measures

- No competing measures noted. Related measures are harmonized.

Standing Committee Recommendation for Endorsement: **Y-18**; **N-0**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

Measures Not Recommended for Endorsement

0713 Ventriculoperitoneal (VP) shunt malfunction rate in children

Submission | Specifications

Description: This measure is a 30-day malfunction rate for hospitals that perform cerebrospinal ventriculoperitoneal shunt operations in children between the ages of 0 and 18 years.

Numerator Statement: The number of initial ventriculoperitoneal (VP) shunt placement procedures performed on children between the ages of 0 and 18 years of age that malfunction and result in shunt revision within 30 days of initial placement.

Denominator Statement: The total number of initial cerebrospinal VP shunt procedures performed on children between the ages of 0 and 18 years.

Exclusions: Patients with evidence of VP shunt placement or removal in the year prior to their index procedure are excluded.

Adjustment/Stratification: Statistical risk model

"We used logistic regression models to determine the risk adjustment variables. The predicted value for each case is computed using a logistic regression model with covariates for with age at insertion (0-30 d, 31-365 d, and 1 y), congenital anomalies, intraventricular hemorrhage, low birth weight, prematurity and spina bifida. The reference population used in the regression is the PHIS database from 2008-2010."

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data

0713 Ventriculoperitoneal (VP) shunt malfunction rate in children

Measure Steward: Boston Children's Hospital, Center for Patient Safety and Quality Research

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-11; N-9**; 1b. Performance Gap: **H-1**; **M-3**; **L-8**; **I-8**

Rationale:

- New evidence for this measure included a retrospective study to identify risk factors for shunt malfunction or failure. None of the risk factors that were examined in the study were statistically significant in determining shunt failure.
- The Committee questioned why the measure was specified for 30 days rather than a longer time frame since the study cited in the evidence showed an increased complication rate after 90 days.
- Committee members also requested clarity on the definition of a shunt malfunction (e.g., device malfunction or clogging of the shunt).
- The Committee could not reach consensus that prompt treatment of shunt malfunctions would impact the outcome.
- The Committee expressed concern that this measure had been endorsed since 2011 but the developers did not provide performance data from more than one institution and did not submit disparities data.
- The Committee did not agree the measure met the criterion for opportunity for improvement. Therefore this measure was not recommended for endorsement.
- Several suggestions for improvement were made to the developer including extending the measure specifications beyond 30 days; providing data from more than one institution; collect data on the shunt malfunction device and better define what counts as a malfunction; and finally, to look at other factors that impact the outcome such as shunt infections.

Standing Committee Recommendation for Endorsement: **No votes taken.**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2998 Infection rate of bicondylar tibia plateau fractures

Submission | Specifications

Description: Percent of patients aged 18 years and older undergoing ORIF of a bicondylar tibial plateau fracture who develop a postoperative deep incisional wound infection based on CDC guidelines for deep infection associated with implants

Numerator Statement: Number of patients aged 18 years and older undergoing ORIF of a bicondylar tibial plateau fracture who develop a postoperative deep incisional infection associated with an implant within 1 year of fracture fixation. We do not have adequate data to provide adequate risk stratification at this time.

Denominator Statement: All patients undergoing ORIF of a closed bicondylar tibial plateau fracture aged 18 years or older. Patients can be identified with either an ICD-10 code (S82.141, S82.142) or by CPT billing codes. (27536). Risk calculation can be added once adequate volume of patients are enrolled.

Exclusions: N/A

2998 Infection rate of bicondylar tibia plateau fractures

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Clinician : Group/Practice, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Other, Electronic Clinical Data : Registry

Measure Steward: Orthopedic Trauma Association

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-17; N-2**; 1b. Performance Gap: **H-10**; **M-7**; **L-0**; **I-1**

<u>Rationale</u>:

- The developer reported that the rationale for this measure is that bicondylar tibial plateau fractures are difficult to treat and often complicated by infection at high volume centers, with experienced surgeons. The lowest infection rate reported for these fractures treated with open reduction and internal fixation (ORIF) is 8%. These surgeries have some of the highest reported infection rates of any operation; and they increase cost of care. The Committee expressed that this is an important measure concept and agreed that the evidence was sufficient.
- The developer provided information that the infection rate for these fractures ranges from 20 – 30% and provided literature that reports a high rate of deep infection when treating bicondylar tibial plateau fractures. The Committee agreed that the information presented suggests there is a performance gap.

2. Scientific Acceptability of Measure Properties: <u>The measure does meet the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1**; **M-18**; **L-1**; **I-0** 2b. Validity: **H-0**; **M-0**; **L-3**; **I-16**

<u>Rationale</u>:

- To demonstrate reliability of the measure, the developer presented information from a secondary evaluation of bicondylar tibial plateau fractures from two large studies for which it had access to patient data. Of the 440 patients in these studies, 77 were selected for further review based on the fact that the patients (23.6% of one study and 14.2% of the second study) were diagnosed with infected bicondylar tibial plateau fracture. Through radiographs and CT scans, all 77 were confirmed to be bicondylar tibial plateau fractures. Through review of operative reports for irrigation and debridement and organism positive laboratory data, 76 of the 77 fractures were confirmed to be infected for an agreement rate of 99.42%. The remaining patient from this group had a debridement of a fluid collection with negative culture. Additionally, of those patients identified as having closed bicondylar tibia plateau fractures on x-ray with no evidence of deep infection, 95 were randomly selected and evaluated. All 95 patients were confirmed as having closed bicondylar tibial plateau fractures without infection based on lack of operative reports for irrigation and debridement and no laboratory data indicating presence of infection. Agreement was found in 171 of 172 cases reviewed or 99.42% of observations with a Kappa of 0.988. Sensitivity = 100%; Specificity = 99%; Positive Predictive Value = 98.7%. The Committee found the reliability testing results to be sufficient.
- The developer stated that patient factors, injury factors and socioeconomic status have not been consistently associated with differences in surgical site infection (SSI) in patients with this surgery. Characteristics of the 43 patients with deep wound infection from one institution were further analyzed and a conclusion reached that there was no reason to believe that the demographics would be different in other institutions.
- While the Committee acknowledged the clinical importance of this measure, members expressed concern that they could not sufficiently evaluate validity due to the lack of data available. They strongly

2998 Infection rate of bicondylar tibia plateau fractures

encouraged the developer to continue collecting data to determine the need for risk adjustment as members were in support of the measure concept.

Standing Committee Recommendation for Endorsement: **No votes taken.**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3016 PBM-01: Preoperative Anemia Screening

Submission | Specifications

Description: This measure assesses the proportion of selected elective surgical patients age 18 and over with documentation of pre-operative anemia screening in the window between 45 and 14 days before the surgery start date

Numerator Statement: Patients with preoperative anemia screening done in the window between 45 and 14 days prior to the surgery start date.

Denominator Statement: Patients age 18 and older with a length of stay less than or equal to 120 days who undergo selected elective surgical procedures

Exclusions: • Patients whose surgical procedure is performed to address a traumatic injury • * Patients with a solid organ transplant recorded <=48 hours prior to the encounter or during the encounter

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-3**; **L-10**; **I-8**; 1b. Performance Gap: **No votes taken**

Rationale:

- Committee members agreed that anemia screening is important to perform in certain procedures and certain populations. However, there were concerns that the evidence presented was not sufficient enough to support the specifications of this measure. Committee members noted that there was not specific evidence to support the 14-45 day prior to surgery timeframe for preoperative anemia screening and also expressed concerns about potential unintended consequences of unnecessary preoperative testing.

Standing Committee Recommendation for Endorsement: **No votes taken.**

6. Public and Member Comment

- One comment was submitted in support of the Committee's concern with the underlying evidence for this

3016 PBM-01: Preoperative Anemia Screening
measure. The comment supported the Committee's decision to not recommend the measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3017 PBM-02: Preoperative Hemoglobin Level
Submission | Specifications
Description: This measure is designed to allow transfusion/blood use review committees to identify patients undergoing elective surgery with suboptimal, uncorrected hemoglobin levels that may have led to perioperative transfusion. This measure assesses, via stratification, pre-operative hemoglobin levels of selected elective surgical patients age 18 and over who received a perioperative red blood cell transfusion. **Numerator Statement**: Patients whose hemoglobin level measured on the most recent pre-operative hemoglobin level was: 12.0 grams or above >=11.0 and <12.0 grams (mild anemia) >=8.0 and <11.0 grams (moderate anemia) Below 8.0 grams (severe anemia) **Denominator Statement**: Selected elective surgical patients age 18 and over, who received a transfusion of whole blood or packed cells in the time window from anytime during the surgical procedure to 5 days after the surgical procedure or to discharge, whichever is sooner. **Exclusions**: • Patients under age 18 • Patients whose surgical procedure is performed to address a traumatic injury • Patients who have a solid organ transplant • Patients who are pregnant during the hospitalization, including those who delivered and those who did not deliver during this hospitalization • Patients who undergo extra-corporeal membrane oxygenation procedures (ECMO) prior to the elective surgical procedure. • Patients with sickle cell disease or hereditary hemoglobinopathy **Adjustment/Stratification**: No risk adjustment or risk stratification **Level of Analysis:** Facility **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory **Measure Steward**: The Joint Commission
STANDING COMMITTEE MEETING 08/16 - 08/17/16 **1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-0**; **M-3**; **L-12**; **I-6**; 1b. Performance Gap: **No votes taken** <u>Rationale</u>: • This measure is designed to identify patients who could have benefited from pre-surgical treatment to

3017 PBM-02: Preoperative Hemoglobin Level

enhance iron stores and reverse anemia. Identified in the measure are the numbers of patients who are anemic (hemoglobin levels lower than 12 g/dL prior to elective surgery) of the elective surgical patients receiving a transfusion during or within 5 days after transfusion. The Committee agreed that unnecessary blood transfusions are undesirable and perioperative optimization of anemia is preferred, but the evidence is not clear on the hemoglobin threshold of 12 g/dl.

- Committee members also questioned understand the clinical significance of the ratio, particularly, as the numerator is the number of patients and the denominator is the subset of patients who are transfused. It was suggested to the developers that the denominator could be patients with selected surgical and the numerator could be those that received transfusion and to then stratify by pre-operative hemoglobin.

Standing Committee Recommendation for Endorsement: **No votes taken.**

Rationale

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6. Public and Member Comment

- One comment was submitted in support of the Committee's concern with the underlying evidence for this measure. The comment supported the Committee's decision to not recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3019 PBM-03: Preoperative Blood Type Testing and Antibody Screening

Submission | Specifications

Description: This measure assesses the proportion of selected elective surgical patients age 18 and over who had timely preoperative assessment of blood type and crossmatch or type and screening.

Numerator Statement: Patients who had a type and crossmatch or type and screen completed within 45 days prior to the surgery start date and time.

Denominator Statement: Selected elective surgical patients age 18 and over

Exclusions: • Patients under age 18

• Patients whose surgical procedure is performed to address a traumatic injury

• Patients who have a solid organ transplant

• Patients who refuse transfusion

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-5; L-10; I-6**; 1b. Performance Gap: **No votes taken**

3019 PBM-03: Preoperative Blood Type Testing and Antibody Screening

Rationale:

- Committee members noted that there is no graded evidence or systematic review to support this measure. AABB Standards state that a blood sample shall be obtained from a patient with 3 days of a transfusion if the patient has been exposed to foreign red blood cell (RBC) antigens by means of transfusion or pregnancy within the prior 3 months. Otherwise, there is not a limit on the timing of the pre-surgical specimen. Committee members agreed that in order for safe and effective utilization of resources, the pre-transfusion testing should be completed prior to the beginning of surgery. However, the desired outcome is that the patients receive an appropriate unit of blood if transfusion is required. It was suggested that the numerator could be changed to number of elective surgery patients receiving un-cross matched blood.

Standing Committee Recommendation for Endorsement: **No votes taken.**

6. Public and Member Comment

- One comment was submitted in support of the Committee's concern with the underlying evidence for this measure. The comment supported the Committee's decision to not recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3020 PBM-04: Initial Transfusion Threshold

Submission | **Specifications**

Description: This measure assesses the proportion of various pre-transfusion hemoglobin levels in patients age 18 and over receiving the first unit of a whole blood or packed cell transfusion. Over time, in a patient blood management program, there should be a higher proportion of patients receiving blood at the lower hemoglobin threshold and a lower proportion receiving blood at the higher hemoglobin thresholds. It also identifies patients who receive transfusions that should be reviewed by hospital transfusion/blood usage committees so that appropriate educational programs can be developed as part of a patient blood management program.

Numerator Statement: Patients whose hemoglobin level measured prior to the transfusion and closest to the transfusion was:

• less than 7.0 grams

• >=7.0 and <8.0 grams

• >=8.0 and <9.0 grams

• >=9.0 and <10.0 grams

• 10.0 grams or greater

Denominator Statement: Patients age 18 and over receiving the first unit of a whole blood or packed cell transfusion

Exclusions: • Patients who have a surgical procedure performed to address a traumatic injury

• Patients who have a solid organ transplant

• Patients undergoing extracorporeal membrane oxygenation (ECMO) treatment at the time of initial transfusion.

• Patients whose first unit of whole blood or packed red blood cells was given while an Emergency Department patient.

• Patients with sickle cell disease or hereditary hemoglobinopathy

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

3020 PBM-04: Initial Transfusion Threshold

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-1**; **M-11**; **L-5**; **I-2**; 1b. Performance Gap: **H-2**; **M-13**; **L-0**; **I-5; ;** Evidence Exception: **Y-X; N-X**

Rationale:

- The focus of this measure is to monitor the proportions of patients transfused at initial hemoglobin levels from <7 to >10 g/dL. The developer presented clinical guideline recommendations to support this measure from the following organizations: AABB, Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists and The Society of Critical Care Medicine. Most Committee members agreed that the evidence is sufficiently strong to introduce a program of monitoring with the intent of having more transfusions occur at the lower restrictive end of the spectrum than at the higher liberal end.
- Although there is no performance data on the measure as specified, the developer provided data on blood transfusion appropriateness and rate of hospitalization with blood transfusion that indicates opportunity for improvement.

2. Scientific Acceptability of Measure Properties: This e-measure is a candidate for eMeasure Approval for Trial Use; therefore, testing for the measure will be submitted at a later time**.** (2b1. Specifications consistent with evidence): **Consensus not reached**

eMeasure Trial Measure Specifications: H-1; **M-7**; **L-9**; **I-2**

Rationale:

- The Committee expressed several concerns over the specifications of this measure. Members noted that there are other indications for a transfusion besides a hemoglobin measurement, such as hemorrhagic shock, bleeding, and current active bleeding, which are not reported as part of the measure.
- A Committee member suggested expanding the numerator to include a category for patients whose hemoglobin levels were not measured prior to a transfusion. It was also suggested that that the measure be expanded to include pediatric patients, as patients under the age of 18 can benefit from hemoglobin optimization.
- A Committee member suggested that pregnant patients undergoing postpartum hemorrhage should be excluded from the measure.
- The Committee did not reach consensus on the Scientific Acceptability of Measure Properties: eMeasure Trial Measure Specifications criterion due to concerns about the specifications.

3. Feasibility: H-3; M-6; L-6; I-2

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The feasibility analysis submitted by the measure developer met the requirements to be considered for eMeasure Trial Approval.

4. Usability and Use: H-0; M-5; L-6; I-6

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

3020 PBM-04: Initial Transfusion Threshold

- The Committee agreed that the numbers in the various hemoglobin thresholds are not sufficient to determine if a transfusion could have been avoided, and need to be evaluated by a clinician in relationship to the clinical signs and symptoms.
- The measure will trigger review by hospital transfusion or blood usage committees. The developer noted plans for the measure to be made available within a year for hospitals to use in fulfilling the requirements for a blood management certification program.
- A Committee member noted the value of having an eMeasure for this concept to establish the infrastructure to be able to monitor and report internally.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Approval for Trial Use: **No votes taken.**

Rationale

6. Public and Member Comment

Comments received:

- One commenter was not in support of the measure being recommended for Approval for Trial Use.
- One comment was submitted by the developer stating concerns with the NQF processes for evaluating eMeasure submitted for Approval for Trial Use. The commenter stated that the Committee's perceived issues with validity, a component of Scientific Acceptability, should have been outside the scope of Approval for Trial Use review.

NQF response:

- The Approval for Trial Use program was designed by NQF to facilitate the development of innovative quality eMeasures that could fill existing gaps in clinical care. The NQF requirements for endorsement with respect to an eMeasure require testing in at least two separate electronic health record (EHR) systems. This is in addition to the measures being specified according to the Health Quality Measures Format (HQMF) and aligning with the Quality Data Model (QDM) as well as having value sets published within the Value Set Authority Center (VSAC). NQF recognizes that for some measures, these requirements, particularly in identifying two EHRs to test in, may be challenging. However, NQF does not want to impede the progress of needed measures and thus the Trial Use program allows for the measure to be implemented into the field in which data can be collected and evaluated. Once enough data have been gathered, the measure can then be properly assessed and submitted to a committee for endorsement consideration.

  However, a measure for Trial Use consideration is evaluated in the same way as a measure being considered for endorsement. The measure must be scientifically acceptable, and must have a strong evidence base for consideration. The only difference is in the testing itself, in that a measure for Trial Use consideration only has to submit BONNIE results to demonstrate that the measure logic works as intended and that the metric produced by the measure match its objective. A committee that is evaluating a Trial Use measure will still consider its scientific acceptability and importance to measure. If the measure passes those criteria, and the BONNIE testing indicates that the measure functions as it should, then it would be considered as part of the Trial Use program. However, if the committee does not feel that the measure demonstrates importance to measure and collect; and/or does not meet the scientific acceptability criteria, then it may be rejected, as any other measure would. A measure for Trial Use is evaluated in the same manner as a measure for endorsement, with the exception being on the testing of the measure and, if the committee accepts the measure, it is placed into the Trial Use program instead of being endorsed. A eMeausure for Trial Use consideration is not evaluated solely on the basis of its technical specifications.

Committee response:

- After review of the comments, the Committee continued to express concerns about how the evidence is aligned with the specifications of the measure. The Committee did not find the measure as specified to be

3020 PBM-04: Initial Transfusion Threshold

a valid indicator of quality. The Committee then re-voted, and the measure did not pass the eMeasure Trial Measure Specifications subcriterion.

- Because the measure did not pass the Validity subcriterion upon re-vote, the Committee did not pursue further discussion of the measure and did not recommend it for Approval for Trial Use status.

Vote Following Consideration of Public and Member Comments:
eMeasure Trial Measure Specifications: H-0; **M-**3; **L-12**; **I-1**

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3021 PBM-05: Blood Usage, Selected Elective Surgical Patients

Submission | Specifications

Description: This measure assesses the proportion of selected elective surgical patients age 18 and over who had a timely preoperative anemia screening and subsequent perioperative transfusion. Since preoperative anemia is a predictor of perioperative transfusion, this measure can identify records of patients needing further review for uncorrected preoperative anemia or other blood management measures, such as a restrictive transfusion strategy or cell salvage, that should have been taken to avoid transfusion.

Numerator Statement: Patients who had a non-autologous whole blood or non-autologous packed red blood cell transfusion administered in the time window from anytime during the surgical procedure to 5 days after the surgical procedure or to discharge, whichever is sooner.

Denominator Statement: Selected elective surgical patients age 18 and older who had a preoperative anemia screening in the time window between 45 and 14 days before surgery start date.

Exclusions: • Patients under age 18

- Patients whose surgical procedure is performed to address a traumatic injury
- Patients who have a solid organ transplant
- Patients with sickle cell disease or hereditary hemoglobinopathy
- Patients who refuse blood transfusion.
- Patients who receive an autologous blood transfusion

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-4**; **L-7**; **I-5**; 1b. Performance Gap: **No votes taken**

Rationale:

3021 PBM-05: Blood Usage, Selected Elective Surgical Patients

- This measure is intended to assess the effectiveness of the preoperative anemia screening by identifying those patients who had the appropriate screening but still required a perioperative blood transfusion. A Committee member noted that once most patients are appropriately screened for anemia at a stage when results allow preoperative anemia management, then this measure would likely be of greater value. There was concern that, at this time, implementation of this measure is premature. Committee members were also concerned about the potential unintended consequence of hospitals deciding that they would have to do a type and screen or a type and crossmatch for a large proportion of patients unnecessarily.

Standing Committee Recommendation for Endorsement: **No votes taken.**

6. Public and Member Comment

- One comment was submitted in support of the Committee's concern with the underlying evidence for this measure. The comment supported the Committee's decision to not recommend the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3024 Carotid Endarterectomy: Evaluation of Vital Status and NIH Stroke Scale at Follow Up

Submission | Specifications

Description: Proportion of patients with carotid endarterectomy procedures who had follow up performed for evaluation of vital status and neurological assessment with an NIH Stroke Scale (by an examiner who is certified by the American Stroke Association

Numerator Statement: Patient Status (alive or Deceased) at follow-up AND neurologic status with an assessment using the NIH Stroke Scale (by an examiner who is certified by the American Stroke Association)

Denominator Statement: CARE Registry patients that underwent carotid endarterectomy

Exclusions: Patients with a discharge status of deceased.

Patients with was an acute, evolving stroke and dissection during the episode of care.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING 08/16 - 08/17/16

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-0**; **L-12**; **I-8**; 1b. Performance Gap: **No votes taken**

Rationale:

- This is facility- and population-level measure calculates proportion of patients with carotid endarterectomy procedures who had follow up performed for evaluation of vital status and neurological assessment with an NIH Stroke Scale (by an examiner who is certified by the American Stroke Association). Committee members had concerns about the overall measure construct as it is currently

3024 Carotid Endarterectomy: Evaluation of Vital Status and NIH Stroke Scale at Follow Up
specified and tested. • The Committee agreed that the evidence presented by the developer is insufficient, noting that the first citation provided relates to an ungraded general guideline recommendation to monitor neurological outcomes and the second relates to non-invasive imaging which is not a part of this measure. Committee members also suggested that the measure would be stronger if was using the NIH stroke scale to measure an actual outcome within 30 or 60 days post discharge as opposed to the process of administering the tool.
Standing Committee Recommendation for Endorsement: **No votes taken**
6. Public and Member Comment • One comment submitted did not support the Committee's recommendation to not recommend the measure for endorsement, noting the importance of process measures in measure physician performance and advancing quality of care. • One other comment received after the commenting period closed, expressed support of the Committee's recommendation not to recommend the measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals