NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE SURGERY ENDORSEMENT MAINTENANCE 2010 STEERING COMMITTEE

June 21, 2011

Committee Members Present: Arden Morris, MD, MPH, FACS (co-chair), University of Michigan; David Torchiana, MD (co-chair), Massachusetts General Physicians Organization; Nasim Afsar-manesh, MD, UCLA Medical Center; Curtis Collins, PharmD, MS, BCPS AQ-ID, University of Michigan Health System; Richard Dutton, MD, MBA, Anesthesia Quality Institute; Paula Graling, DNP, RN, CNS, CNOR, INOVA Fairfax Hospital; Vivienne Halpern, MD, FACS, Carl T Hayden VA Medical Center; Ruth Kleinpell, PhD, RN, FAAN, Rush University Medical Center; Dennis Rivenburgh, MS, ATC, PA-C, St. Anthony's Primary Care; Terry Rogers, MD, The Foundation for Health Care Quality; Nicholas Sears, MD, MedAssets, Inc.; Connie Steed, MSN, RN, CIC, Greenville Hospital System; Carol Wilhoit, MD, MS, Blue Cross Blue Shield of Illinois; Christine Zambricki, CRNA, MS, FAAN, American Association of Nurse Anesthetists.

NQF Staff Present: Heidi Bossley, MSN, MBA, Vice President for Performance Measures; Sarah Fanta, Project Analyst; Alexis Forman, MPH, Senior Project Manager; Melinda Murphy, RN, MS, NE-BC, Senior Director; Jessica Weber, MPH, Project Analyst; Ashlie Wilbon, RN, MPH, Senior Project Manager.

Measure Developers Present: Lindsey Adams, Society for Vascular Surgeons; John Bott, Agency for Healthcare Research and Quality; Dale Bratzler, Oklahoma Foundation for Medical Quality; Jack Cronenwett, Dartmouth-Hitchcock Medical Center; Sheryl Davies, Stanford University; Susan Fitzgerald, American College of Cardiology; Jeffrey Geppert, Agency for Healthcare Research and Quality; Jane Han, The Society of Thoracic Surgeons; Jeffrey Jacobs, The Society of Thoracic Surgeons; Candace Jackson, Iowa Foundation for Medical Care; Wanda Johnson, Oklahoma Foundation for Medical Quality; Rebecca Kaprich, Iowa Foundation for Medical Care; Tim Kresowik, Society for Vascular Surgery; Kelsey Kurth, American Academy of Ophthalmology; Kevin Lobdell, Carolina Health Care System; Flora Lum, American Academy of Ophthalmology; Victoria Lynch, Oklahoma Foundation for Medical Quality; Kristyne McGuinn, American College of Cardiology; Joan Michaels, American College of Cardiology; Mark Morasch, Society for Vascular Surgeons; Patrick Romano, University of California-Davis; Kenneth Rosenfield, Massachusetts General Hospital; Elvira Ryan, The Joint Commission; Jeffrey Silber, Children's Hospital of Philadelphia; Lara Slattery, American College of Cardiology; Donna Slosburg, ASC Quality Collaboration; Susan White, ASC Quality Collaboration; Quindella Williams, American College of Cardiology; Kim Wood, Surgical Care Affiliates; Janet Wright, American College of Cardiology.

Others Present: Kay Jewell, Center for Consumer Healthcare

The audio recordings from the meeting can be found here.

MEETING PROCESS

Ms. Murphy welcomed the Steering Committee and reviewed the agenda. Ms. Forman conducted a roll call of the roster to identify participating Steering Committee members.

Dr. Morris (co-chair) welcomed the Steering Committee members and measure developers and thanked them for their continued work and participation. The purpose of this follow-up conference call was to address outstanding agenda items from the in-person meeting held on May 4-5, 2011, including:

- review the related and competing Pediatric & Congenital Cardiac Surgery volume measures and make a recommendation to the Consensus Standards Approval Committee (CSAC) regarding "best in class";
- revisit the evidence for the wound dehiscence measures;
- review measure developer responses to the Committee's suggested modifications for two Phase I measures and twenty-one Phase II measures in preparation for final recommendation; and
- review Phase II related and competing measures.

The measure developers and stewards were available on the call to respond to questions from the Committee as needed. The audio recordings from the conference call can be found on the project web page.

MEASURE EVALUATION SUMMARY

The Committee reviewed three Pediatric & Congenital Cardiac Surgery Volume measures and determined that:

- *0340: Pediatric heart surgery volume (PDI 7)* was complementary to *PCS-007-09: Surgical volume for pediatric and congenital heart surgery; and*
- *PCS-008-09: Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS mortality levels* and *PCS-007-09: Surgical volume for pediatric and congenital heart surgery* should be combined into a single measure

They requested that the surgical volume data derived from the Society for Thoracic Surgeons' (STS) *PCS-007-09* be incorporated into STS *PCS-008-09*, the stratified mortality levels measure since the information in PCS-007-09, with some additional information, is included in PCS-008-09. In that way, overall volume data not captured within the stratified levels would be available along with data related to the five levels. This would make the relationship clear and obviate the need for two measures. STS representatives agreed with the modification to PCS-008-09. STS also noted that its measures include congenital heart surgery not limited to pediatrics in addition to pediatric heart surgery. The Committee agreed that the reconfigured STS measure and the Measure 0340 will be complementary.

The Committee noted that measures with an administrative data source should generally be considered complementary to similar measures that use registry data since the data sources are

available to different audiences and serve different purposes. The co-chairs will provide a statement for Committee review and subsequent incorporation into the Phase II final report, to describe the Committee's position with respect to similar measures using different data sources.

The Committee recommendations about the pairing of the Pediatric & Congenital Cardiac Surgery mortality and volume measures are as follows:

- Combined mortality measures *0339: Pediatric heart surgery mortality (PDI 6) (risk adjusted)* and *PCS-021-09: Standardized mortality ratio for congenital heart surgery, risk adjustment for congenital heart surgery (RACHS-1) adjusted* should be paired with *0340: Pediatric Heart surgery volume* as appropriate in light of the changes that occur as a result of combining Measures 0339 and PCS-021-09; and
- The STS volume measure that combines *PCS-007-09: Surgical volume for pediatric and congenital heart surgery* and *PCS-008-09: Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS mortality levels* should be paired with *PCS-018-09: Pre-operative mortality stratified by the five STS-EACTS mortality levels.*

The Committee revisited their previous review of measures *0367: Post operative wound dehiscence (PDI 11) (risk adjusted)* and *0368: Post operative wound dehiscence (PSI 14) (risk adjusted)* as a result of receipt of additional information regarding evidence citations, but requested additional time to familiarize themselves with the evidence and literature presented in the measure.

Measures and Evaluations

The following summary displays follow-up items from 13 measures considered at the May 4-5 in-person meeting, including actions taken by the Steering Committee on conditional recommendations or preliminary review. (See the summaries of the February 28-March 1 meeting for the Phase I measures and the May 4-5 meeting for the original evaluation of the Phase II measures.)

Information related to the measures that were discussed on this call is highlighted.

LEGEND: Y= Yes; N = No; A = Abstain; C = Completely; P = Partially; M = Minimally; N = Not at all

Phase I

Cardiac: CABG

Cardiac: CABG and Prophylaxis

Phase II

Cardiac, Appendectomy and Pancreatic Resection

Cardiac and Vascular

Phase I

0134 Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG)

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: All 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 LAD disease

Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Clinicians: Individual, Group, Team; Facility/Agency; Population: National, regional/network, states, counties or cities
Type of Measure: Process
Data Source: Registry data-STS Adult Cardiac Surgery Database, Version 2.73
Measure Steward: Society of Thoracic Surgeons | 633 North Saint Clair Street, Suite 2320 | Chicago | Illinois | 60611

Steering Committee Recommendation for Endorsement: Pending harmonization of 0134 and 0516
Rationale: This measure is tied to improved outcomes due to high patency rates of the IMA. The current compliance is 95 percent; however variation among programs exists; i.e., compliance rates as low as 80 percent. Final recommendation will be included in the Phase II report.

If applicable, Conditions/Questions for Developer:
1. 1b.4 Summary of Data on Disparities by Population Group: Please provide data on disparities.
2. 2a.9 Denominator Exclusions: Please remove "the IMA is not a suitable conduit due to size or flow" from the exclusions.

Developer Response:
1. Data on disparities are provided in the form.
2. STS staff agreed to remove the exclusion related to IMA suitability during Steering Committee meeting. The form was modified to reflect this.

If applicable, Conditions/Questions for Developer:
1. Harmonization: As agreed, please harmonize measures 0134 and 0516 by combining into a single measure which can allow reporting at the provider or institution level.

Developer Response:

1. Measures have been harmonized according to the instructions above. As requested by NQF, any modifications made have been provided in the measure submission form for #0134. Please note: the only change is in section "2a.32. Level of Measurement/Analysis." The denominator and exclusion sections will remain as they originally were submitted for #0134, as these specifications reflect the most recent (i.e., 2010-2011) STS Adult Cardiac Surgery Database specification upgrade.

Steering Committee Follow-up:
The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-20; N-1
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The literature points to disparities amongst women, with IMA used less often in women. The developer did not provide information or data on disparities related to performance on the measure.

2. Scientific Acceptability of Measure Properties: C-14; P-7; M-0; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The exclusion 'IMA not suitable,' can lead to the issue of gaming. This causes apprehension as to who determines if the IMA is not suitable. Currently, there is no criteria that classifies the IMA as suitable. The Committee requested this exclusion be removed.

3. Usability: C-20; P-1; M-0; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The information obtained is meaningful and useful.

4. Feasibility: C-20; P-1; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The information can be derived from electronic sources.

0300 Cardiac surgery patients with controlled postoperative blood glucose

Description: Cardiac surgery patients with controlled postoperative blood glucose (less than or equal to 180mg/dL) in the timeframe of 18 to 24 hours after Anesthesia End Time
Numerator Statement: Cardiac surgery patients with controlled postoperative blood glucose (less than or equal to 180mg/dL) in the timeframe of 18 to 24 hours after Anesthesia End Time.
Denominator Statement: Cardiac surgery patients with no evidence of prior infection
Include patients with an ICD-9-CM Principle Procedure code or ICD-9-CM Other Procedure codes of selected surgeries
AND
an ICD-9-CM for ICD-9-CM codes Principle Procedure code or ICD-9-CM Other Procedure codes of selected surgeries
Exclusions: Excluded Populations
• Patients less than 18 years of age
• Patients who have a length of Stay greater than 120 days
• Patients who had a principal diagnosis suggestive of preoperative infectious diseases (as defined in Appendix A, Table 5.09 for ICD-9-CM codes)
• Burn and transplant patients (as defined in Appendix A, Tables 5.14 and 5.15 for ICD-9-CM codes)
• Patients enrolled in clinical trials
• Patients whose ICD-9-CM principal procedure occurred prior to the date of admission
• Patients with physician/advanced practice nurse/physician assistant (physician/APN/PA) documented infection prior to surgical procedure of interest
• Patients who discharged prior to 24 hours after Anesthesia End Time.
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/Agency; Population: national; Program: QIO; can be measured at all levels
Type of Measure: Process
Data Source: Electronic administrative data/claims; paper medical record/flow-sheet. Vendor tools or CART.
Vendor tools or CART (both electronic). CART is available for download free at
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Conditional on updated measure submission reflecting change in numerator to patients having cardiac surgery whose highest blood sugar between 18 and 24 hours after surgery is 180mg/dL or less and any other modifications necessitated by that change as well as response to additional question and condition. Final recommendation will be included in the Phase II report.

Rationale: Subsequent to developer changing the timeframe from 6 am due to variation in time of surgery, Committee indicated that a more comprehensive measure would involve monitoring a patient's blood glucose over the 18-24 hour period after surgery and allowing a 4-hour window to reduce high glucose levels to ≤ 180mg/dL.

If applicable, Conditions/Questions for Developer:

1. 2a.1 Numerator Statement: The timeframe should be within 24 hours after surgery instead of 6 am.
2. 2a.10 Denominator Exclusion Details: Provide a more detailed definition of perioperative death.

Developer Response:

1. This recommendation was presented to the SCIP Infection TEP on April 6, 2011. The panel accepted changing the measure numerator to patients having cardiac surgery whose highest blood sugar, between 18 and 24 hours after surgery is 180mg/dl or less.
2. Patients that expire during the perioperative period are excluded from this measure, as they should not be held accountable for glucose values on POD 1 or 2. The data element has this definition: The patient expired during the timeframe from surgical incision through discharge from the post anesthesia care/recovery area. Additional abstraction instructions include:
   For patients discharged from surgery and admitted to the PACU: The end of the perioperative period occurs when the patient is discharged from the PACU.
   For patients discharged from surgery and admitted to locations other than the PACU (e.g., ICU): The perioperative period would end a maximum of six hours after arrival to the recovery area.

If applicable, Conditions/Questions for Developer:

1. 2a.1 Numerator Statement: Suggested modification-If serum glucose is above 180 mg/dl, was it decreased within a specific amount of time.
2. 2b Reliability Testing and 2c Validity Testing: Advise what additional testing will need to be completed in light of the suggested modification.

Steering Committee Follow-up:

The Steering Committee agreed that the response from the developer regarding POD was adequate.

Developer Response:

1. The numerator statement remains: 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.*

- However, the data element "Glucose" will still instruct the hospital to look at the recorded blood sugars between 18-24 hours after Anesthesia End Time and has been modified as follows:
  1. If all blood sugars are </= 180 mg/dL in this time frame, the case would pass the measure;
  2. If any blood sugar was > 180 mg/dL during this timeframe, the hospital would look to see if there was a subsequent blood sugar drawn in this time frame. If all subsequent blood sugars were </= 180 mg/dL, the case will pass the measure. If subsequent blood sugars were > 180 mg/dL, the case will fail.
  3. A single elevated blood sugar **without** any follow-up actions or levels drawn would cause the case to fail.
  4. If no blood sugars were recorded between 18-24 hours, the hospital would be instructed to look at the 12-18 hour time frame and use the same instructions.

2. These measure specifications changes have been thoroughly reviewed by the SCIP TEP. They have already provided valuable input and will continue to review the revised specifications after implementation. The specifications are also reviewed by the SCIP subject matter experts at the Joint Commission and at IFMC, the Hospital Inpatient Quality Reporting Program Support Contractor for CMS. This is standard procedure for all measure specification revision for the performance measures. The measure specifications will also be vetted via the Learning Laboratory. With the lengthy timelines for implementation of modifications to existing specifications and the short timeframe for preparing the changes, a joint venture called the Learning Laboratory has been developed and implemented for aligned measures. Both CMS and the Joint Commission are involved in this process and it has been used successfully in the recent past. A small group of relevant organizations (facilities and/or vendors) review and provide input on proposed measure modifications yielding a better product at relatively minimal costs, since participation is voluntary.

Steering Committee Follow-up:

The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-16; N-5

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The goal of the measure, to improve patient's blood sugar, is important. Performance at the aggregate is 93.4 percent; disparity information requested to understand if there are subpopulation disparities.

2. Scientific Acceptability of Measure Properties: C-2; P-12; M-7; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: There is a need for more flexibility in the timeframe to allow comparability since variation in patient times of departure from the operating room. Both the committee and developer have heard anecdotal reports that clinical staff is leaving patients on insulin drips

to meet the criteria of the measure. Assuming this to be accurate, the timeframe change will address such an unintended consequence of the measure.

3. Usability: C-5; P-6; M-10; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The Committee was unsure if this measure would provide additive value if the timeframe remains at 6 am.

4. Feasibility: C-5; P-9; M-7; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The measure cannot be easily implemented using the current timeframe.

Phase II

0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period

Description: Percentage of patients on beta blocker therapy prior to admission 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, as described below in 2a4.
Numerator Statement: Surgery patients on beta blocker therapy prior to admission who receive a beta blocker during the perioperative period
Denominator Statement:
All surgery patients on beta blocker therapy prior to arrival
NOTE: 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.
Data Element Data Collection Question: Is there documentation that the patient was on a daily beta-blocker therapy prior to arrival? Yes/No
Notes for Abstraction:
• If there is documentation that the beta-blocker was taken daily at "home" or is a "current" medication, select "Yes".
• If a beta-blocker is listed as a home medication without designation of how often or when it is taken, select "Yes".
• If there is documentation that the beta-blocker is a home/current medication and additional documentation indicates the beta-blocker was not taken daily, e.g., the medication reconciliation form lists a beta-blocker as a home/current medication, but documentation in the nurses notes state "patient denies taking beta-blocker every day", select "No".
• If there is documentation that the beta-blocker is on a schedule other than daily, select "No".
• If there is documentation that the beta-blocker was given on a "prn" basis for cardiac or non-cardiac reasons, select "No".
Exclusions:
• Patients less than 18 years of age
• Patients who have a Length of Stay greater than 120 days
• Patients enrolled in clinical trials
• Patients whose ICD-9-CM principal procedure occurred prior to the date of admission
• Patients who expired during the perioperative period
• Pregnant patients taking a beta-blocker prior to arrival
• Patients with a documented Reason for Not Administering Beta-Blocker-Perioperative
• Patients with Ventricular Assist Devices or Heart Transplantation
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/ Agency, Population : National, Program : QIO
Type of Measure: Process
Data Source: Electronic administrative data/ claims, Paper medical record/ flow-sheet
Vendor tools (electronic) or CART. CART is available for download free at
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Blvd, Mail Stop S3-02-01 | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Conditional; Criteria for Endorsement met: Y- 19; N -2; A-0
Rationale: The measure is meaningful for public reporting and quality improvement.

If applicable, Conditions/Questions for Developer:
1. 2a.4 Denominator Statement: Include definition of 'prior to arrival' and clarify the expected beta blocker dosing during the perioperative period (e.g., beyond homeopathic dose) – should be done to a specific parameter; i.e., hear rate or blood pressure.
2. 2a.9 Denominator Exclusions: Exclusion for laparoscopy verbally reported as removed effective January 1, 2012. Please

confirm.

3. 2a.9 Denominator Exclusions: Consider exclusions for patients on beta blockers for non-cardiac reasons.

Developer Response:

1. To be in the measure denominator, the patient must be on a beta-blocker prior to arrival. The data collection question and relevant notes for abstraction for the data element Beta-Blocker Current Medication are listed below. The case is excluded if the answer to this data element is "no." We do NOT use specific parameters for dosing because this measure was designed to ensure that patients on beta-blocker therapy at home have continued therapy. It is not evaluating whether the dose is therapeutic. There is simply no way to define a "homeopathic dose" for the purposes of data collection.
   Suggested Data Collection Question: Is there documentation that the patient was on a daily beta-blocker therapy prior to arrival? Yes/No
   Notes for Abstraction:
   • If there is documentation that the beta-blocker was taken daily at "home" or is a "current" medication, select "Yes".
   • If a beta-blocker is listed as a home medication without designation of how often or when it is taken, select "Yes".
   • If there is documentation that the beta-blocker is a home/current medication and additional documentation indicates the beta-blocker was not taken daily, e.g., the medication reconciliation form lists a beta-blocker as a home/current medication, but documentation in the nurses notes state "patient denies taking beta-blocker every day", select "No".
   • If there is documentation that the beta-blocker is on a schedule other than daily, select "No".
   • If there is documentation that the beta-blocker was given on a "prn" basis for cardiac or non-cardiac reasons, select "No".
2. The data element Laparoscope has been removed from all SCIP measures for January 1, 2012 discharges. Major surgeries performed laparoscopically may be included if their ICD-9 Principal Procedure Code is included in the denominator (Table 5.10).
   Those exclusions are accounted for in the Notes for Abstraction for the data element Beta-Blocker Current Medication. See above. The abstractor is instructed to answer "no" to this data element which excludes them from the measure.

Steering Committee Follow-up:

1. 2a.4 Denominator Statement: Further define "prior to arrival" to specify "all surgery patients on daily beta blocker therapy prior to arrival".

1. Importance to Measure and Report: Y-21; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Performance is above 90 percent; however, concern about discontinuation of beta blockers in the post-op period remains a concern that has the potential to affect large numbers. It was noted that beta blockers had to be titrated to a certain heart rate for them to provide a beneficial result to the patient.

2. Scientific Acceptability of Measure Properties: C-10; P-10; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The evidence, construction and testing of the measure meets requirements. The Committee questioned the period of time that was considered as part of the perioperative period and why laparoscopic procedures were included in the exclusions and set conditions related to these concerns.

3. Usability: C-12; P-9; M-0; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The measure is meaningful for public reporting and quality improvement.

4. Feasibility: C-12; P-9; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The required data is readily available; the Committee questioned whether the measure would continue to rely on paper records. It is not included in the list for electronic health records (EHR) at present; however, the developer was encouraged to consider capturing titration to heart rate when it does move to EHR. They were also encouraged to better convey the bradycardia exclusion.

0365 Pancreatic resection mortality rate (IQI 9) (risk adjusted)

Description: Percentage of discharges with procedure code of pancreatic resection with an in-hospital death.
Numerator Statement: Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.
Denominator Statement: Discharges, age 18 years and older, with ICD-9-CM pancreatic resection code procedure and a diagnosis code of pancreatic cancer in any field.
Exclusions: Exclude cases:
• missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year

(YEAR=missing) or principal diagnosis (DX1 =missing)
• transferring to another short-term hospital (DISP=2)
• MDC 14 (pregnancy, childbirth, and puerperium)
ICD-9-CM codes:
577.0
Acute pancreatitis
577.1
Chronic pancreatitis
Adjustment/Stratification: Risk adjustment method widely or commercially available The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, age in years (in 5-year age groups), All Patient Refined-Diagnosis Related Group (APR-DRG) and APR-DRG risk-of-mortality subclass. The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2007 (updated annually), a database consisting of 43 states and approximately 30 million adult discharges. 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, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate/User has the optin to stratify by gender, age (5-year age groups), race / ethnicity, primary payer, and custom stratifiers.
Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: The Steering Committee will vote on this measure after receiving feedback from the developer on the denominator details and exclusions.
Rationale: The measure was considered important and was based on strong evidence.

If applicable, Conditions/Questions for Developer:
Overarching comment: Please provide feasibility of reporting mortality stratified by institutional volume (e.g., high, medium, low volume with parameters for each) rather than having rate and mortality separated.

1. De.2 Ensure measure description accurately captures measure focus.
2. 2a.8 Denominator Details: Do not limit to pancreatic resection for cancer - could stratify by malignant and benign. Also, consider providing volume as well as rate.
3. 2a.9 Denominator Exclusions: Please remove 'transferring to another short-term hospital (DISP=2)' from the exclusions.
4. 2a.9 Denominator Exclusions: Add exclusion for pancreatitis.

Measures 0365 and 0366 should be fully harmonized in order to properly report as a pair. This will involve including all pancreatic disease in both the numerator and denominator of both measures. They can then be stratified by malignant and benign disease.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization.
Developer Response:
1. AHRQ agrees to revise the measure description to more accurately capture the measure focus
2. AHRQ agrees to harmonize the mortality and volume indicator denominators to include benign disease in the mortality measure. Note that the mortality and volume indicator (0366) are designated as paired measures
3. This request is problematic for a few reasons. First, the outcome of interest (in-hospital mortality) is not observed for these cases. Second, it is possible that a single case may be counted twice (once for the transferring hospital, once for the receiving hospital). Third, removing this exclusion would require using data that linked patients across hospitalizations (in order to avoid the issues #1 and #2), which is not readily available for individual hospitals across institutions. Therefore, we respectively defer a definitive response to this request pending the routine availability of linked hospitalization data, or at a minimum additional analysis using such data of the potential impact of removing the exclusion.
4. AHRQ agrees to add an exclusion for pancreatitis

Steering Committee Follow-up:
The Steering Committee expressed their concern about transferred patients being excluded from the measure. AHRQ responded that the number is less that 1 percent and the majority is transfer of convenience for the patient. The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report:
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The evidence supports the measure's focus on pancreatic resections for cancer and while it is a low-volume procedure,

mortality rates are high and merit tracking.

2. Scientific Acceptability of Measure Properties:
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The measure was considered scientifically acceptable. The Committee debated the importance of separate measures focusing on a pancreatic resection for cancer and a pancreatic resection for benign disease and determined that both could be captured in a single measure that is stratified to report each.

3. Usability:
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: This measure is in use in multiple states and healthcare systems and is reported on HCUPnet as well as used in the MONAHRQ system that is provided for public reporting and quality improvement.

4. Feasibility:
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: This measure was considered feasible; data is obtained from electronic claims and chart abstraction.

0366 Pancreatic resection volume (IQI 2)

Description: Number of discharges with procedure for pancreatic resection.
Numerator Statement: Discharges, age 18 years and older, with ICD-9-CM codes for pancreatic resection procedure.
Denominator Statement: Not applicable
Exclusions: Not applicable
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/ Agency
Type of Measure: Structure/management
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: The Steering Committee will vote on this measure after receiving feedback from the developer on the denominator details and exclusions.
Rationale: The measure was considered important and cited strong evidence.

If applicable, Conditions/Questions for Developer:

1. De.2 Ensure measure description accurately captures measure focus.
2. 2a.3 Numerator Details: Partial resections and partial operations should be included in 0366,
3. 2a.8 Denominator Details: Do not limit to pancreatic resection for cancer.
4. 2a.9 Denominator Exclusions: Please remove 'transferring to another short-term hospital (DISP=2)' from the exclusions.
5. 2a.9 Denominator Exclusions: Add exclusion for pancreatitis.
6. 2b.3 and 2.c.3 Testing Results: Text speaks to esophageal resection. Please provide correct information and advise if there are other such errors within the submission that have required correction.

Measures 0365 and 0366 should be fully harmonized in order to properly report as a pair. This will involve including all pancreatic disease in both the numerator and denominator of both measures. They can then be stratified by malignant and benign disease.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization.
Developer Response:

1. AHRQ agrees to revise the measure description to more accurately capture the measure focus
2. AHRQ agrees to include partial resections and partial operations
3. The volume measure contains no such exclusion. However, in general AHRQ agrees to harmonize the mortality and volume indicator denominators to include benign disease in the mortality measure. Note that the mortality (0365) and volume indicator are designated as paired measures.
4. The volume measure contains no such exclusion; however, see note above regarding harmonization
5. The volume measure contains no such exclusion; however, see note above regarding harmonization
6. Such erroneous references shall be corrected

Steering Committee Follow-up:
The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report:

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The evidence supports the measure's focus on pancreatic resections for cancer and while it is a low-volume procedure, the impact in terms of mortality is important to track and report.

2. Scientific Acceptability of Measure Properties:
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The measure was considered scientifically acceptable. The Committee debated the importance of separate measures focusing on a pancreatic resection for cancer and a pancreatic resection for benign disease and determined that both could be captured in a single measure to be stratified to report each.

3. Usability:
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: This measure is in use in multiple states and healthcare systems and is reported on HCUPnet as well as used in the MONAHRQ system that is provided for public reporting and quality improvement.

4. Feasibility:
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: This measure was considered feasible; data is obtained from electronic claims and chart abstraction.

0265 Hospital transfer/admission

Description: Rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC
Numerator Statement: Ambulatory surgical center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.
Denominator Statement: All ASC admissions
Exclusions: None
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Paper medical record/ flow-sheet
Measure Steward: ASC Quality Collaboration | 5686 Escondida Blvd S | St. Petersburg | Florida | 33715

Steering Committee Recommendation for Endorsement: Conditional Criteria for Endorsement met: Y-13; N-7; A-0
Rationale: This measure focus is important and will encourage reporting and provide the ability to analyze transfer rates among ASCs.

If applicable, Conditions/Questions for Developer:

1. 1b.2 Summary of Measure Results Demonstrating Performance Gap: Rates and percentages presented in the measure are confusing. Please review and revise as appropriate
2. 1b.3 Data/Sample: There is a discrepancy between the data that was collected and publicly reported. In the usability section, it states that 1,185 ASCs submitted data for 2nd quarter 2010 on this particular measure; however, in section 1b.3, it states that only 526 ASCs submitted data on this measure. Please reconcile.
3. 2a.2 Numerator Time Window: Revise numerator statement from "…discharge from the ASC" to a more appropriate interval this will also reduce potential perverse incentives. Time window should be at least 24 hours, which would also reduce potential for the unintended incentive to discharge home when admission needed.
4. 2f.2. Methods to Identify Statistically Significant and Practical or Meaningful Differences in Performance: The statistical analysis does not specify a method; validity is questioned. Please reevaluate and in doing so, be specific about what is known about what transfer rates should be expected to be.
5. 2h. Disparities in Care: Please submit any subpopulation performance data that is available for the measures. The committee understands that ASCs do not have a quality reporting system requirement; however, assessment of subpopulation data is important and should be collected and reported for this and other measures.

Developer Response:

1. Although data for 1,185 ASCs are included in the ASC QC database for this measure, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The rates for this measure are based on the 526 individually-reporting ambulatory surgery centers throughout the US for services provided during April to June 2010. The rate for unscheduled transfer or admission to a hospital ranged from a minimum of 0.0% to a maximum of 2.3%. The mean rate was 0.1% (SD: 0.2%), while the median rate was 0.1%. The maximum transfer rate of 2.3% and a third quartile value of 0.2% demonstrate that there is an opportunity for improvement in this measure.

2. Although data for 1,185 ASCs are included in the ASC QC database for this measure, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The 526 individually-reporting ambulatory surgery centers represent a convenience sample of the ASC population were used to assess the opportunity for improvement for this measure. The centers were located throughout the US. Services from the second calendar quarter of 2010 were included in this portion of the study.
3. Based on our experience to date, we have no reason to believe that patients requiring admission or transfer to the hospital are being discharged home in order to improve the ASC's performance on this measure. The malpractice risk from substandard care carries much graver consequences than any potential outcome from slightly higher rates of transfer/admission related to this measure. After discussion with NQF staff and if the Committee wishes to see a measure of the hospital admission rate for a more extended timeframe, we will create a separate measure using a sampling protocol. We propose to develop this measure using the following draft numerator and denominator statements, which may be modified during the development phase:
   Numerator statement: Ambulatory surgery center (ASC) admissions experiencing a hospital admission in the 24 hour period following discharge from the ASC.
   Denominator statement: All selected ASC patients (sampling protocol to be developed and tested)
4. An individual ASC's transfer rate may be compared to the standard rate from the ASC Quality website (http://www.ascquality.org/qualityreport.cfm#Transfer). A statistically significant difference in performance may be detected by using a standard test of proportions as outlined in most standard statistical texts. Since each transfer may represent increased risk exposure for the patient, a rate higher than the standard of 1 per 1000 is also of practical significance. The null hypothesis for this test is that the sample proportion from the ASC is not different from the industry standard taken from the ASC Quality website. The alternative is that there is a statistically significant difference. We recommend that this test be performed in its two-sided form so that the ASC may determine if they are either statistically higher or lower than the standard. The recommended p-value for this test is the 0.05 level, but ASCs may have justification for different value. Using this statistical method for detecting significant variances from the industry standard will allow users to determine if differences may be due to sampling error or may indicate a true difference in performance.
5. The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by third quarter of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three months thereafter.
6. **ADDITIONAL INFORMATION and Response from Measure Developer:**
   We have also revised 2f1 for this measure #0265 Hospital Transfer to provide additional clarity:
   2f.1. Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)
   Although data for 1,185 ASCs are included in the ASC QC database, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The rates for this measure were collected for the 526 individually-reporting ambulatory surgery centers throughout the US for services provided during April to June 2010.

Steering Committee Follow-up:
The Steering Committee agreed with and encourages the developer's plan to create a measure to be submitted to NQF in the future focused on hospital admission rates with an extended timeframe. They expressed reservations that the current measure may have the unintended consequence of patients who are sent home rather than admitted when admission appeared a likely outcome. The Committee was also concerned about the burden of data collection, but agreed that the measure was important and, through reporting across ASCs and to the public, should further encourage reporting by ASCs. They agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-15; N-5
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The Committee deems the focus of the measure important but has concerns about a) the potential for the unintended consequence of discharging a patient to home when potential need for admission is relatively high which argues for modification of the measure to include a time window for admission and b) the low admission rate reflected in the data provided does not demonstrate a meaningful performance gap. Modification of the measure with a broader time window could resolve the concerns.

2. Scientific Acceptability of Measure Properties: C-2; P-10; M-6; N-2
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The measure does not provide concise parameters for measurement benchmarking, since it does not establish an appropriate target rate of transfer. Developer has been asked to address this.

3. Usability: C-6; P-9; M-3; N-2
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The statistical analysis did not seem valid, since the outliers would vary by ambulatory surgical center. This measure may not be ready for public reporting since it does not have a specific target transfer rate. Developer has been asked to address this.

4. Feasibility: C-13; P-7; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: Data is derived from the patient medical record. The measure could have the unintended consequence of promoting a discharge to home rather than a transfer, since an admission would be viewed as "failing to meet the measure".

1519 Statin therapy at discharge after lower extremity bypass (LEB)

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 necessary/No stratification is required for this measure.
Level of Analysis: Can be measured at all levels, Clinicians : Group, Clinicians : Individual, Facility/ Agency
Type of Measure: Process
Data Source: Registry data
Measure Steward: Society for Vascular Surgery | 633 N. Saint Clair St., 22nd Floor | Chicago | Illinois | 60611

Steering Committee Recommendation for Endorsement: Conditional Criteria for Endorsement met: Y-19; N-0 ; A-1
Rationale: The focus of the measure is important and while the evidence cited speaks to statin use for LDL control, use of statins without reference to LDL is the current trend and, per the developer, it is expected that it will be supported in future guidelines.

If applicable, Conditions/Questions for Developer:
1. 2a.2 Numerator Time Window: Timeframe lacks precision. Please address.
2. 2a.7 Denominator Time Window: Timeframe lacks precision. Please address.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization
Developer Response: We have modified the form time window for all SVS measures as follows:
Since hospitals have sufficient annual volume to generate accurate reporting levels, these are proposed for reporting every 12 months for hospital. Since surgeons have lower individual volume, we recommend annual reporting of the last 50 consecutive procedures, which may span more than one year, with suppression if < 10 procedures (i.e., reported as too low volume to report).
Steering Committee Follow-up:
The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-19; N-1 ; A-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The measure is based on a guideline that focuses on statin use for LDL control while the measure focuses on statin use regardless of the LDL control; however the current trend in practice to use of statin without reference to LDL. Performance rates have improved from 41 percent to 79 percent, still short of the 90 percent goal.

2. Scientific Acceptability of Measure Properties: C-8; P-11; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The numerator and denominator timeframes lack precision.

3. Usability: C-14; P-5; M-1; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing

measures)
Rationale: The measure, which relies on registry data, was considered usable.

4. Feasibility: C-13; P-7; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The feasibility of implementation was questioned since the data comes from a registry. For registry participants the measure is quite feasible; a non-registry participant would have to collect manually or develop an electronic system.

0357 Abdominal aortic aneurysm (AAA) repair volume (IQI 4)

Description: Count of discharges with a procedure code of provider-level AAA repair.
Numerator Statement: Discharges, age 18 years and older, with an abdominal aortic aneurysm repair procedure and a primary or secondary diagnosis of AAA.
Denominator Statement: This volume measure does not have a denominator.
Exclusions: Numerator exclusions
• MDC 14 (pregnancy, childbirth, and puerperium)
Adjustment/Stratification: No risk adjustment necessary/ Stratified by endovascular and open repairs (additional methodological development will be required to ensure the measures have adequate reliability).
Level of Analysis: Facility/ Agency
Type of Measure: Structure/management
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: Conditional No
Rationale: The Committee had extensive discussion about the volume and related mortality measures before asking for additional information. Did not pass the threshold criterion of Importance to Measure and Report thus was not assessed against the remaining criteria.

If applicable, Conditions/Questions for Developer:
Overarching Comment: The Steering Committee vote regarding the NQF evaluation criterion of "Importance" was split with 10 voting yes and 11 voting no and a number of members noted the measure should only be reported with the related mortality measure. The developer will want to review the measure in its entirety in this light and provide whatever additional information/specification including value as a paired measure with mortality that it believes appropriate. Should specifications change, it is important to provide information regarding testing with the changes.

1. 2a. 11 Stratification Details/Variables: Measure should stratify the measure by endovascular and open repairs.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization. As discussed, the developer should meet with SVS to harmonize or blend measures concerning AAA

Developer Response:

1. AHRQ agrees to stratify the measure by endovascular and open repairs, but notes that additional methodological development will be required to ensure the measures have adequate reliability.
2. AHRQ noted at the meeting that the volume and mortality measures are to be reported as paired measures though some users may not have the information to report both.

Steering Committee Follow-up:
The Steering Committee was concerned about volume being reported as a singular measure.

1. The Steering Committee requested information regarding needed methodological changes for the measure based on the endovascular and open repair stratification and will further consider the measure with that information. AHRQ will also further clarify the risk adjustment model.

1. Importance to Measure and Report: Y-10; N-11 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)*
Rationale: The measure would provide key information to the public about AAA mortality, but does not provide separate information on EVARs and open repairs. The vote is reflective of the debate related to the value and implications of separately reporting open and endovascular repairs. AHRQ representatives indicated that the stratification is a component of the current software; however the Committee would like to see this specifically reflected in the specifications of the measure. AHRQ representatives indicated that a separate risk adjustment model could be developed for open and endovascular procedures with both ruptured and unruptured aneurysms. The majority of AAA repairs are done endovascularly and open repairs have become more complicated.

2. Scientific Acceptability of Measure Properties:
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f.

Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale:

3. Usability:
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale:

4. Feasibility:
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale:

0359 Abdominal aortic artery (AAA) repair mortality rate (IQI 11) (risk adjusted)

Description: Percent of discharges with procedure code of AAA repair with an in-hospital death.
Numerator Statement: Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.
Denominator Statement: Discharges, age 18 years and older, with ICD-9-CM AAA repair code procedure and a diagnosis of AAA in any field.
Exclusions: Exclude cases:
• missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1 =missing)
• transferring to another short-term hospital (DISP=2)
• MDC 14 (pregnancy, childbirth, and puerperium)
Adjustment/Stratification: Risk adjustment method widely or commercially available The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, age in years (in 5-year age groups), All Patient Refined-Diagnosis Related Group (APR-DRG) and APR-DRG risk-of-mortality subclass. The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2007 (updated annually), a database consisting of 43 states and approximately 30 million adult discharges. 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, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.Risk adjustment factors: sex
age 18-24; age 25-29; age 30-34; age 35-39; age 40-44; age 45-49; age 50-54; age 55-59; age 60-64; age 65-69; age 70-74; age 75-79; age 80-84; age 85+
each age category*female
ADRG 1731 (other vascular procedures-minor)
ADRG 1732 (other vascular procedures-moderate)
ADRG 1733 (other vascular procedures-major)
ADRG 1734 (other vascular procedures-extreme)
ADRG 1691 (major thoracic and abdominal vascular procedures-minor)
ADRG 1692 (major thoracic and abdominal vascular procedures-moderate)
ADRG 1693 (major thoracic and abdominal vascular procedures-major)
ADRG 1694 (major thoracic and abdominal vascular procedures-extreme
ADRG 9999 (other)/Gender, age (5-year age groups), race / ethnicity, primary payer, custom
Stratify the measure by endovascular and open repairs and stratify by ruptured vs. un-ruptured aneurysm; however, additional methodological development will be required to ensure the measures have adequate reliability; b) the risk stratification model is specified below; c) the model has been validated on the State Inpatient Databases (SID), which consists of hospital discharge data from 40 states (constituting about 90% of hospital discharges in the U.S) for the years 2001-2008
Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: The Steering Committee engaged in extensive discussion of the volume and mortality measures, as noted in review of 0357 above, and will vote on this measure after receiving feedback from the developer on separating or stratifying the measure into open and EVAR mortality rates since the procedures and complications vary significantly.
Rationale:

If applicable, Conditions/Questions for Developer:
1. 2a.11 Stratification Details/Variables: a) Stratify the measure by endovascular and open repairs as well as emergency vs

elective repair; b) specify the risk stratification model used; 3) identify settings where the model has been validated in addition to the training data set in which it was developed or provide other supporting data as to its validity.

2. 2b.3 Testing Results: Please provide information about signal to noise ratio.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization. As discussed, the developer should meet with SVS to harmonize or blend measures concerning AAA

Developer Response:

1. a) As noted above, AHRQ agrees to stratify the measure by endovascular and open repairs; in addition, AHRQ agrees to stratify by ruptured vs. un-ruptured aneurysm (which is what we assume you mean by emergency vs. elective repair); but AHRQ again notes that additional methodological development will be required to ensure the measures have adequate reliability; b) the risk stratification model is specified below; c) the model has been validated on the State Inpatient Databases (SID), which consists of hospital discharge data from 40 states (constituting about 90% of hospital discharges in the U.S) for the years 2001-2008
2. The signal to noise ratio is the ratio of the between hospital variance (signal) to the within hospital variance (noise). The formula is signal / (signal + noise). The ratio itself is only a diagnostic for the degree of variance in the risk-adjusted rate systematically associated with the provider. Therefore, what matters is the magnitude of the variance in the "smoothed" rate (that is, the variance in the risk-adjusted rate after the application of the univariate shrinkage estimator based on the signal ratio). What the data demonstrate is systematic variation in the provider level rate of 2.6 to 7.6 per 100 from the 5th to 95th percentile after a signal ratio of 0.307 is applied as the shrinkage estimator (that is, after accounting for variation due to random factors).

Table 3. Risk Adjustment Coefficients for IQI #11— AAA Repair Mortality

Parameter	Label	DF	Estimate	Standard Error	Wald Chi-Square	Pr > Chi-Square
Intercept		1	-6.6044	0.1713	1486.04	0.0000
Sex	Female	1	0.4539	0.0747	36.95	0.0000
Age	65 to 74	1	0.4879	0.1072	20.72	0.0000
Age	75 to 79	1	0.8737	0.1201	52.97	0.0000
Age	80 to 84	1	1.1092	0.1200	85.50	0.0000
Age	85+	1	1.4440	0.1359	112.97	0.0000
APR-DRG	'1691' to '1692'	1	1.6789	0.1623	107.05	0.0000
APR-DRG	'1693' to '1694'	1	3.9127	0.1523	659.72	0.0000
APR-DRG	'1733' to '1734'	1	3.1568	0.1676	354.55	0.0000
MDC	5	1	2.6400	0.1483	316.85	0.0000
MDC	Other	1	2.9536	0.2252	172.05	0.0000
RUPTURED		1	2.0565	0.0808	647.42	0.0000

c-statistic 0.937

Note: The APR-DRG consists of the DRG and the risk-of-mortality subclass (minor (1), moderate (2), major (3) and extreme (4)).

Steering Committee Follow-up:

1. The Steering Committee requested information regarding needed methodological changes for the measure based on the endovascular and open repair stratification and will further review the measure with that information. AHRQ will also further clarify the risk adjustment model.

1. Importance to Measure and Report: Y-10; N-11; A-1

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The measure would provide key information to the public about AAA volume, but does not provide separate information on EVARs and open repairs. The majority of AAA repairs are done endovascularly and open repairs have become more complicated.

2. Scientific Acceptability of Measure Properties:

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale:

3. Usability:

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing

measures)
Rationale:

4. Feasibility:
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale:

1523 In-hospital mortality following elective open repair of small AAAs

Description: Percentage of aymptomatic patients undergoing open repair of small abdominal aortic aneurysms (AAA)who die while in hospital. This measure is proposed for both hospitals and individual providers.
Numerator Statement: Mortality following elective open repair of asymptomatic AAAs in men with < 6 cm dia and women with < 5.5 cm dia 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 necessary/No stratification is required for this measure.
Level of Analysis: Can be measured at all levels, Clinicians : Group, Clinicians : Individual, Facility/ Agency
Type of Measure: Outcome
Data Source: Registry data
Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 24th floor | Chicago | Illinois | 60611

Steering Committee Recommendation for Endorsement: Conditional Y-9; N-11; A-1
Rationale: The evidence supports the measure's focus on small AAAs repairs and it provides important outcome data; however the Committee had a number of questions for which it requested developer response before further consideration of the measure.

If applicable, Conditions/Questions for Developer:
Overall comment: Based on the narrow margin of the Steering Committee vote related to having met criteria for endorsement the measure will be reconsidered with the response to the questions and conditions below.

1. De2. Brief Description and 2a.1 Numerator Statement: Suggested addition of 30-day mortality with in-hospital mortality. Also, please clarify whether aneurysm size can be collected using administrative (i.e., is widely available outside the Northern New England registry), or available clinical data and the added burden of such collection.
2. 2a. Measure Specifications: Provide a timeframe for availability of newly created CPT2 codes to make this a universally applicable measure.
3. 2a.3 Numerator Details: Reword the numerator details here and throughout where registry is specified to be clear that a specific registry (i.e., SVS, VSGNE) is not required to collect the data.
4. 2b Reliability Testing and 2c Validity Testing: Advise what testing will be needed and completed for the suggested modification to 30 day mortality?
5. 2d. Exclusions: Provide reconcile sample size and data for what is being measured. Also reconcile aneurysm size in the population of interest and the sizes specified throughout.
6. 2h. Disparities in Care: Provide information about disparities or plans to be able to provide data.
7. 3a.2 Use in a Public Reporting Initiative: Please provide plans for public reporting (within 3 years).

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization
Developer Response:

1. We suggest in-hospital instead of 30-day mortality for several reasons. We have previously studied mortality within the first year after open AAA repair. In-hospital mortality was 2.1% and 30-day mortality was 2.3% in VSGNE, since almost every patient who died within 30 days was never discharged. [Predicting 1-year mortality after elective abdominal aortic aneurysm repair. Beck et al, J Vasc Surg. 2009.49:838-44]. Further, in-hospital mortality is more easily obtained and audited, and is immediately available at the time of discharge. Finally, there is lower cost for obtaining in-hospital results, since subsequent patient contact after discharge is not necessary. We believe that these advantages make in-hospital mortality a more appropriate measure and have not changed this portion of the application. AAA size is readily available in the medical record, and is tracked not only in VSGNE, but the SVS VQI registry, which now comprises more than 80 centers in 30 states across the U. S., and is expected to comprise all states by 2012. The SVS VQI is the de facto national registry for vascular surgery. While AAA size cannot currently be collected using administrative data, we expect that the great majority of vascular surgeons in the U.S. will be participating in SVS VQI by 2012.
2. It is our plan to request CPT2 codes to allow coding of AAA diameter by claims data. These codes will be reviewed by the

CPT Performance Measures Advisory Group's next meeting, which is scheduled for July 18-19, 2011. The CPT Editorial Panel will then have to approve the codes before they can appear in any CPT publication. The Editorial Panel will meet October 13-15, 2011.

3. Numerator and denominator have been edited to clearly state than ANY registry tracking the appropriate variables can be used for reporting all of the current measures being proposed by SVS.
4. As stated above, we have already compared in-hospital and 30-day mortality in 748 patients undergoing open elective AAA repair in VSGNE and found no advantage to using 30-day mortality, which is more difficult and more expensive to collect.
5. This section has been expanded. Data are provided for large and small AAAs, showing difference in operative mortality, emphasizing the reason for including only SMALL dia AAAs in this measure. Patients with larger diameter AAAs cannot be included without complex risk adjusting that is not available. However, data indicate that MANY small AAAs are being electively repaired, and it is in this population that a quality measure is needed. Most patients with much larger AAAs always warrant treatment, since the AAA rupture risk is so high if not treated.
6. Disparities have not been reported. As additional data are acquired from the SVS registry across a much larger and varied population, future disparities may be discovered.
7. SVS intends to request that all of these measures be included in PQRS, and expects CMS to begin publishing PQRS data in the near future. Independent of this, SVS plans to request permission from participating providers and hospitals to publish these measures on the SVS public website.

Steering Committee Follow-up:
The Steering Committee expressed concern about the documentation and tracking of aneurysm size outside of the SVS registry though it was believed that this could be captured based on chart notes.

1. Importance to Measure and Report: Y-18; N-3; A-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The measure provides important outcome data. More AAA repairs are being conducted; although, they may not be medically necessary. However, the data provided in the measure included both small and large aneurysms, despite the stated measure's focus on only small AAAs. High mortality levels may encourage a process review.

2. Scientific Acceptability of Measure Properties: C-2; P-16; M-2; A-1
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The Committee described the importance of extending the measure to 30-day mortality to identify adverse outcomes. The Committee stated the numerator time window, while verbally explained satisfactorily, could be confusing to users. Testing was questioned; while the measure focused on small aneurysms, testing was conducted on large aneurysms.

3. Usability: C-4; P-11; M-4; A-2
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The data used for the measure is drawn from registry data that includes both claims and chart abstracted data thus is usable for registry participants although for non-registry participants, the data would prove challenging to collect.

4. Feasibility: C-4; P-10; M-3; A-4
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The registry group from which data for this measure is drawn is about 10 hospitals thus information about feasibility is limited both in terms of the number of facilities in which tested and testing with only registry data. At present there is no mechanism for identifying small aneurysms with administrative data. The developer is working to develop CPT II codes that would allow aneurysm size to be captured and reported with administrative data. This would require new/additional specifications for the measure. It was noted that the measure could be revised and limited to mortality unrelated to aneurysm size that could be collected using administrative data; this would require further modification of the measure.

1534 In-hospital mortality following elective EVAR of small AAAs

Description: Percentage of patients undergoing elective endovascular repair of small asymptomatic abdominal aortic aneurysms (AAA) who die while in hospital. This measure is proposed for both hospitals and individual providers.
Numerator Statement: Mortality following elective endovascular 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:
A registry that includes hospitalization details, AAA diameter and discharge status is required to identify patients for denominator

inclusion. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) registries records such information. Patients who underwent endovascular AAA repair are included if their aneurysm was asymptomatic and small (< 6cm dia in men, <5.5 cm dia in women, judged by preoperative imaging).
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Can be measured at all levels, Clinicians : Group, Clinicians : Individual, Facility/ Agency
Type of Measure: Outcome
Data Source: Registry data
Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 22nd Floor | Chicago | Illinois, 60611

Steering Committee Recommendation for Endorsement: Conditional Y-9; N-12; A-0
Rationale: The evidence supports the measure's focus on small AAAs repairs and it provides important outcome data; however, the Committee has a number of questions for which it requested developer response before further consideration of the measure.

If applicable, Conditions/Questions for Developer:
Based on the narrow margin of the Steering Committee vote related to having met criteria for endorsement, the committee will reconsider the measure with the response to the questions and conditions below.

1. De2. Brief Description and 2a.1 Numerator Statement: Suggested modification- addition of 30-day mortality with in-hospital mortality. Also, please clarify whether aneurysm size can be collected using administrative (i.e., is widely available outside the Northern New England registry), or available clinical data and the added burden of such collection.
2. 2a Measure Specifications: Scope of the measure as specified will have limited impact. Please reevaluate.
3. 2b Reliability Testing and 2c Validity Testing: Identify the testing that will need to be completed for the suggested modifications?
4. 2d. Exclusions: Provide reconcile sample size and data for what is being measured. Also reconcile aneurysm size in the population of interest and the sizes specified throughout.
5. 2h. Disparities in Care: Providing information about disparities or plans to be able to provide same.
6. 3a.2 Use in a public reporting initiative: Please provide plans for public reporting (within 3 years).

Developer Response:

1. We suggest in-hospital instead of 30-day mortality for several reasons. We have previously studied mortality within the first year after elective endovascular AAA repair. In-hospital mortality was 0.48% and 30-day mortality was 0.50% in VSGNE, since almost every patient who died within 30 days was never discharged. [Predicting 1-year mortality after elective abdominal aortic aneurysm repair. Beck et al, J Vasc Surg. 2009.49:838-44]. Further, in-hospital mortality is more easily obtained and audited, and is immediately available at the time of discharge. Finally, there is lower cost for obtaining in-hospital results, since subsequent patient contact after discharge is not necessary. We believe that these advantages make in-hospital mortality a more appropriate measure and have not changed this portion of the application. AAA size is readily available in the medical record, and is tracked not only in VSGNE, but the SVS VQI registry, which now comprises more than 80 centers in 30 states across the U. S., and is expected to comprise all states by 2012. The SVS VQI is the de facto national registry for vascular surgery. While AAA size cannot currently be collected using administrative data, we expect that the great majority of vascular surgeons in the U.S. will be participating in SVS VQI by 2012.
2. We are not certain as to the exact specification within 2a to which this comment is applied. However, we disagree that this measure will have limited impact. Most AAAs are small when detected, and there is a general suspicion that too many small AAAs are being repaired unnecessarily, with a resulting unnecessary operative mortality. This measure will focus attention on the elective mortality rate of endovascular AAA repair in these patients. Although the median mortality rate is low in VSGNE, there is significant variation among hospitals, and large clinical trials have documented this mortality to be 2-3%, even for small AAAs. If 10,000 patients per year in the US undergo unnecessary endovascular repair of such small AAAs, a 3% mortality results in 300 avoidable deaths. This is an important quality measure, and needs to be established in parallel with our open AAA repair measure, so that surgeons performing AAA repair can/must report their outcomes independent of which technique they use. We have not changed the measure form, because it was not clear where to insert this information.
3. As stated above, we have already compared in-hospital and 30-day mortality in 639 patients undergoing elective endovascular AAA repair in VSGNE and found no advantage to using 30-day mortality, which is more difficult and more expensive to collect.
4. This section has been expanded. Data are provided for large and small AAAs, showing difference in operative mortality, emphasizing the reason for including only SMALL dia AAAs in this measure. Patients with larger diameter AAAs cannot be included without complex risk adjusting that is not available. However, data indicate that MANY small AAAs are being electively repaired, and it is in this population that a quality measure is needed. Most patients with much larger AAAs always warrant treatment, since the AAA rupture risk is so high if not treated.
5. Disparities have not been reported. As additional data are acquired from the SVS registry across a much larger and varied population, future disparities may be discovered.
6. SVS intends to request that all of these measures be included in PQRS, and expects CMS to begin publishing PQRS data in the near future. Independent of this, SVS plans to request permission from participating providers and hospitals to publish

these measures on the SVS public website.

Steering Committee Follow-up:

The Steering Committee expressed concern about the documentation and tracking of aneurysm size outside of the SVS registry.

1. Importance to Measure and Report: Y-21; N-0 ; A-0

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The measure provides important outcome data. More AAA repairs are being conducted; although, they may not be medically necessary. However, the data provided in the measure included both small and large aneurysms, despite the measure's focus on only small AAAs. High mortality levels may encourage a process review.

2. Scientific Acceptability of Measure Properties: C-5; P-13; M-3; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: The Committee discussed the importance of extending the measure to 30-day mortality to identify adverse outcomes. The Committee stated that the time window may be confusing.

3. Usability: C-3; P-15; M-2; N-1

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: In the future the measure could be adjusted to be applicable for other procedures.

4. Feasibility: C-5; P-10; M-5; N-1

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale: The measure did not provide wide spread testing data and may not be feasible without the registry. The developer is attempting to create CPT II codes to facilitate use beyond the registry in the future.

1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy

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 sympotoms 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) on the within one year of CEA

Exclusions: A registry that includes hospitalization details and symptom status within 120 days is required to identify patients for denominator inclusion. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) registries records such information. Patients who were asymptomatic within one year of the CAS (CPT code 37215) are included.

Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.

Level of Analysis: Facility/ Agency; Can be measured at all levels; Clinicians: Individual; Clinicians: Group

Type of Measure: Outcome

Data Source: Registry data

Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 22nd St. | Chicago | Illinois, 60611

Steering Committee Recommendation for Endorsement: Conditional Y-13; N-8; A-0

Rationale: The measure will help determine the incidence of adverse outcome in the asymptomatic patient undergoing what is essentially a prophylactic procedure.

If applicable, Conditions/Questions for Developer:

1. 2a Measure Specifications: Provide information about type and accuracy of codes from registry data? Provide the codes. Diagnostic codes must be used and will need to ensure testing with these codes is complete.
2. 2h. Disparities in Care: Provide information about disparities or plans to be able to provide data.
3. 3a.2 Use in a Public Reporting Initiative: Please provide plans for public reporting (within 3 years).

Developer Response:

1. As indicated in the list of previously provided registry variables that was attached to the last submission, post-operative stroke (major or minor) and death are recorded in the SVS registry. These are not derived from ICD-9 codes, but rather are directly obtained by review of the medical record, usually during the time of admission by clinical personnel. Definitions for these variables were also reported. We are not certain which "codes" are being referred to, since this is a registry measure defined by clinical definitions within the registry, or any other available registry that records postoperative stroke (major or minor) and death in asymptomatic patients undergoing carotid endarterectomy.
2. Disparities have not been reported. As additional data are acquired from the SVS registry across a much larger and varied

population, future disparities may be discovered.

3. SVS intends to request that all of these measures be included in PQRS, and expects CMS to begin publishing PQRS data in the near future. Independent of this, SVS plans to request permission from participating providers and hospitals to publish these measures on the SVS public website.

Steering Committee Follow-up:
The Steering Committee discussed the importance of the measure. Carotid endarterectomy may be over utilized in asymptomatic patients. The Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-20; N-1
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The Committee considered the asymptomatic patient undergoing carotid endarterectomy important to measure.

2. Scientific Acceptability of Measure Properties: C-6; P-14; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The Committee noted the need to define and specify methods to document (e.g., ICD-9 coding, potential development and use of CPT-II codes) asymptomatic and then to standardize the definition. There was concern about whether the measure is, in fact, measuring what is intended. This relates to adequacy of testing.

3. Usability: C-5; P-14; M-1; N-1
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The Committee was unclear about the details of the measure steward's plan for publicly reporting the measure.

4. Feasibility: C-4; P-13; M-3; N-1
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: Concerns relate to capture of 'asymptomatic'. The Committee was interested in the potential of future CPT-II codes in this regard.

1543 Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS)

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 sympotoms 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: A registry that includes hospitalization details and symptom status within one year is required to identify patients for numerator inclusion. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) registries records such information. Patients who were asymptomatic within one year of the CAS (CPT code 37215) are included.
Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Registry data
Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 22nd floor | Chicago | Illinois, 60611

Steering Committee Recommendation for Endorsement: Recommended Y-15; N-6; A-0
Rationale: The measure will help determine the incidence of adverse outcome in the asymptomatic patient undergoing what is essentially a prophylactic procedure.

If applicable, Conditions/Questions for Developer:
The Committee suggested that measures related to carotid artery stenting be developed in conjunction with other specialties that perform the procedures; i.e., radiologists and cardiologists.
Developer Response:

1. The measure proposed for carotid artery stenting is identical to the measure proposed for carotid endarterectomy, two competing procedures used to treat the same disease. By limiting the measure to asymptomatic patients, we are eliminating the need for risk adjustment, since this is embodied in the decision to perform these prophylactic procedures to prevent future stroke, i.e., the operative risk of stroke and death must be certain to be low in order to justify these procedures. Stroke and

death is the combined endpoint used in all randomized trials of these procedures, and we believe it is critically important that surgeons who perform carotid endarterectomy and stenting should report their outcomes for BOTH of these procedures. Since this is such a clean outcome measure, without need for risk adjustment, we do not believe that its approval should be withheld because it has not yet been proposed by other specialties. In fact, SVS VQI has surgeons and radiologists who participate and support an outcome measure for both carotid endarterectomy and stenting. We respectfully ask the committee to approve both of these important measures in parallel. The form has been updated to reflect relevant comments provided for other SVS measures. **Steering Committee Follow-up:** The Steering Committee agreed that the response from the developer was adequate and suggested that SVS work to develop measures with other specialties in the future.
1. Importance to Measure and Report: Y-21; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* **Rationale:** The Committee considered the asymptomatic patient undergoing carotid artery stenting important to measure.
2. Scientific Acceptability of Measure Properties: C-6; P-14; M-1; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* **Rationale:** The Committee noted the need to define and specify methods to document (e.g., ICD-9 coding, potential development and use of CPT-II codes) asymptomatic and then to standardize the definition.
3. Usability: C-6; P-13; M-1; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* **Rationale:** The Committee was unclear about the public reporting plan.
4. Feasibility: C-6; P-11; M-3; N-1 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* **Rationale:** Concerns relate to capture of 'asymptomatic'. The Committee was interested in the potential of future CPT-II codes in this regard.

NEXT STEPS

Project staff will create a survey to determine the Committee's availability to review the remainder of the measure developer's responses to suggested modifications, any additional requested modifications and review Phase II related and competing measures. Following the completion of the Phase II measures' review, the Committee will then vote on final recommendations for endorsement via Survey Monkey. The Committee is scheduled to meet via conference call on July 25, 2011 to discuss the submitted comments from the Phase I draft report.