NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1543 **NQF Project:** Surgery Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS)
De.2 **Brief description of measure:** 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.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** Submitted SVS measure: Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy
De.4 **National Priority Partners Priority Area:** Population health, Safety, Overuse De.5 **IOM Quality Domain**: Effectiveness, Efficiency, Safety De.6 **Consumer Care Need:** Staying healthy

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of	A Y☐ N☐

measure submission A.4 **Measure Steward Agreement attached:** Agreement With Measure Stewards_Agreement Between_National Quality Forum (12-6-2010)-634274164751404870.pdf	
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Payment Program	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Percutaneous carotid intervention is a rapidly emerging field. Published trial results have established carotid stenting (CAS) in high risk surgical patients to be an effective alternative to carotid endarterectomy (CEA). It is well established that CEA benefits patients with asymptomatic >60% stenosis only if performed with a high degree of technical proficiency on appropriately selected patients. The same is proposed to hold true for CAS. This is particularly important when considering an asymptomatic population where the relative risk reduction with intervention is narrow when compared to medical management. Numerous publications have noted variation in the combined endpoint of stroke and death following carotid angioplasty and stent placement with embolic protection (5). Adoption of this outcome measure in the United States would likely disclose disperate results between hospitals and between providers, and lead to quality improvement when this information was provided to individual providers and participating centers. The SVS Vascular Registry has shown that outcome results are good for CAS, but variations exist between interventionalists and centers (8). Postoperative stroke or death is the accepted outcome parameter for this procedure, and its measurement and reporting would demonstrate	**1a** C☐ P☐ M☐ N☐

variation and opportunity for improvemement. CAS is an elective procedure in nearly all cases. Patients can be referred or transferred to a center with the personnel and experience to perform this procedure with a high level of competence and any procedure that has "stroke" as a potential risk should be performed only by individuals with appropriate training and experience. (1)

1a.4 Citations for Evidence of High Impact: 1.) Carotid Artery Angioplasty and Stent Placement: Quality Improvement Guidelines to Ensure Stroke Risk Reduction, J Vasc Interv Radiol 2003;14;S317-9. 2.) Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis, JAMA 1995;273:1421-8. 3.) Management of Atherosclerotic Carotid Artery Disease: Clinical Practice Guidelines of the Society for Vascular Surgery, J Vasc Surg 2008;48:480-6. 4.) Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting-Multispecialty Consensus Recommendations, J Vasc Surg 2005;41:160-8. 5.) Percutaneous Transluminal Angioplasty and Stenting for Carotid Artery Stenosis, Cochrane Database Syst Rev 2007;(4):CD000515. 6.) Endarterectomy vs Stenting for Carotid Artery Stenosis: A Systematic Review and Meta-analysis, J Vasc Surg 2008;48:487-93. 7.) Carotid Stenting and Angioplasty, Circulation 1998;97:121-3. 8. Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: Results from the SVS Vascular Registry, J Vasc Surg 2008.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Better patient selection to avoid treating high risk patients who will likely experience stroke or death after CAS for asymptomatic patients which eliminates any benefit of the procedure.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Stroke or death following CAS has been the primary clinical endpoint for a number of clinical CAS trials. Stroke or death within 30 days following intervention is captured in the SVS Registry. This endpoint is easy to capture from claims data and registries. This outcome is particularly important for asymptomatic patients undergoing CAS, since this is a prophylactic procedure being proposed to prevent future stroke. Guidelines from the American Heart Association recommend CEA for such patients only if the risk of surgical death or stroke combined is less than 3%. While there is no similar level published as a guideline, the same clinical threshold of 3% can be used for asymptomatic patients undergoing CAS. Cochrane Database analysis of stroke or death within 30 days of CAS for asymptomatic carotid stenosis showed no difference between CEA and CAS in all patients as well for a subset of patients deemed "not suitable for surgery" (CEA). Similarly, two large industry-sponsored carotid stent trials, CAPTURE-2 and EXACT, both demonstrated outcomes for CAS in asymptomatic patients that were "comparable to those established by the AHA for patients treated with CEA".

Stroke is defined as an acute neurological deficit due to an occlusive or hemorrhagic brain lesion that persists more than 24 hours. It can be substantiated by a new stroke seen on brain imaging, but this is not a requirement, i.e., clinical symptoms alone are sufficient. Both minor and major strokes will be counted, as long as the symptoms persist more than 24 hours. Stroke in either carotid distribution, or vertebrobasilar stroke is included, i.e., any postprocedural new neurologic deficit attributed to an occlusive or hemorrhagic brain lestion lasting more than 24 hours.

While stroke or death following CAS is an appropriate quality measure for either symptomatic or asymptomatic patients, we believe that the former group would require risk adjustment to allow fair comparisons, while we do not believe this is necessary for asymptomatic patients. For asymptomatic patients, it is incumbent upon the interventionalist to select only those patients of low periprocedural risk to benefit from CAS.

We propose that the denominator for this measure should be patients who have never been symptomatic in either the cerebral hemisphere ipsilateral to the carotid lesion, the contralateral hemisphere or the vertebrobasilar circulation(dizziness or lightheadedness alone are not considered symptoms). This group has the lowest risk of stroke with carotid intervention and also the lowest risk of stroke with medical therapy alone.

Adopting this outcome measure would likely have immediate impact on improving quality. Regional data have shown that feedback of the key outcome of stroke and death, in addition to some process measures

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after carotid endarterectomy reduced this outcome from 5.6% to 5.0% and in asymptomatic patients from 4.1% to 3.8%. The same is likely to hold true for CAS. Reporting time frame for hospitals should be on a yearly basis. The time frame for interventionalists should be cumulative over their career.

1b.3 Citations for data on performance gap:
To date, there is no strong evidence that CAS for asymptomatic carotid stenosis provides a significant benefit to patients over best medical therapy. Nevertheless, CAS is being performed for the treatment of asymptomatic stenosis in multiple centers in the US. The results of controlled randomized trials are pending and should soon provide the Level 1 evidence required.

Although CAS is not approved for reimbursement by CMS for asymptomatic patients, this procedure is performed for asymptomatic patients in 65% of patients in VSGNE undergoing CAS. We suspect overuse in many of these patients.

1b.4 Summary of Data on disparities by population group:
Such data will become available if this measure is adopted for reporting and used by more centers with more varied population demographics than found in the New England region.

1b.5 Citations for data on Disparities:
not available

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** discussed above

1c.2-3. Type of Evidence: Cohort study, Expert opinion, Meta-analysis

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The combined endpoint of stroke/death is the accepted primary endpoint for both CAS and carotid endarterectomy. Variation in outcome has been established in randomized trials,cohort studies and meta analyses. This outcome measure has face validity among all providers of this service. Studies cited above have shown substantial variation in outcomes by provider when CEA is performed in asymptomatic patients. While such data does not yet exist for CAS, similar findings are expected due to the same patient population being treated.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Stroke/death after CAS is the reporting standard recommended by the Society for Vascular Surgery.

1c.6 Method for rating evidence: Expert opinion.

1c.7 Summary of Controversy/Contradictory Evidence: The endpoint of stroke, death or myocardial infarction is a frequent endpoint in CAS studies. However, this is seldom used in CEA studies, and recent studies have shown that the impact of MI is much less than the impact of stroke after CAS. Thus, we favor stroke/death as the primary endpoint for this measure.

1c.8 Citations for Evidence (*other than guidelines***):** 1.) Carotid Artery Angioplasty and Stent Placement: Quality Improvement Guidelines to Ensure Stroke Risk Reduction, J Vasc Interv Radiol 2003;14;S317-9. 2.) Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis, JAMA 1995;273:1421-8. 3.) Management of Atherosclerotic Carotid Artery Disease: Clinical Practice Guidelines of the Society for Vascular Surgery, J Vasc Surg 2008;48:480-6. 4.) Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting-Multispecialty Consensus Recommendations, J Vasc Surg 2005;41:160-8. 5.) Percutaneous Transluminal Angioplasty and Stenting for Carotid Artery Stenosis, Cochrane Database Syst Rev 2007;(4):CD000515. 6.) Endarterectomy vs Stenting for Carotid Artery Stenosis: A Systematic Review and Meta-analysis, J Vasc Surg 2008;48:487-93. 7.) Carotid Stenting and Angioplasty, Circulation 1998;97:121-3. 8. Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: Results from the SVS Vascular Registry, J Vasc Surg 2008.

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1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*): Presently there is no published guideline that places a threshold for acceptable stroke and death rates following CAS for the treatment of asymptomatic carotid stenosis. There is, however, an acceptable and published threshold of 3% for patients treated with the established surgical alternative, CEA. The AHA has determined that CEA in particular should only be performed for asymptomatic carotid stenosis if the risk of the procedure was les than 3% stroke and/or death (2). It has been suggested that this is fairly generalizable to any form of intervention (1) **1c.10 Clinical Practice Guideline Citation:** Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: Results from the SVS Vascular Registry, J Vasc Surg 2008. **1c.11 National Guideline Clearinghouse or other URL:** NA **1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom*):** NA **1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)*:** NA **1c.14 Rationale for using this guideline over others:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met? **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome*): 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 **2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator*):** 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 (ie, reported as too low volume to report). **2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions*):** ANY registry that includes hospitalization details and symptom status within 120 days 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) are examples of registries that record such information,	**2a-specs** **C☐** **P☐** **M☐** **N☐**

but the measure is not limited to these registries. Patients who were asymptomatic within one year of the CAS (CPT code 37215) who died or had a stroke recorded in the registry during that admission.

2a.4 **Denominator Statement (***Brief, text description of the denominator - target population being measured***):**
Patients over age 18 without preoperative carotid territory neurologic or retinal symptoms within one year immediately preceding carotid artery stenting

2a.5 **Target population gender:** Female, Male
2a.6 **Target population age range:** Over 18

2a.7 **Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):**
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 (ie, reported as too low volume to report).

2a.8 **Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
ANY 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) are examples of registries that record such information, but the measure is not limited to these registries. Patients who were asymptomatic within one year of the CAS (CPT code 37215) are included.

2a.9 **Denominator Exclusions (***Brief text description of exclusions from the target population***):** Exclude patients with neurologic symptoms within one year of procedure

2a.10 **Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Patients with NASCET criteria neurologic symptoms (transient ischemic attack, amaurosis, or stroke) within the one year immediately proceeding CAS

2a.11 **Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
Not required

2a.12-13 **Risk Adjustment Type:** No risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
See "Scientific Acceptablility" section for rationale

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** Rate/proportion
2a.20 **Interpretation of Score:** Better quality = Lower score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
Number of asymptomatic patients undergoing CAS who have in hospital stroke or death / Number of asymptomatic patients undergoing CAS

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)*:
Standard statistical comparison of rates to provide confidence levels to discriminate meaningful differences from the mean.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Electronic Clinical Data : Registry

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
«data_source_instrument»

2a.26-28 Data source/data collection instrument reference web page URL or attachment: Attachment Carotid_Artery_Stent_CB_v_1.9.xlsx

2a.29-31 Data dictionary/code table web page URL or attachment: Attachment CAS defs v.01.09.doc

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Clinician : Group/Practice, Clinician : Individual, Facility

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital/Acute Care Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)***:** A random sample of 100 patient records representing 5 procedures relevant to the measure from 5 different hospitals based on data collected during the past 2 years. In addition, in-hospital mortality was examined by claims based analysis of 7,205 patients discharged and recorded in the VSGNE registry between 2003 to 2007.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)***:**
A nurse abstractor completed a form based on medical record review for the variables relevant to this measure. The results of this chart review were then compared with the original registry data. The Kappa statistic was used to judge reliability of the data. For mortality validation, claims data from each of 12 hospitals were matched to patient identified data within the VSGNE registry to compare discharge status (alive vs. dead). Any discrepencies were then further evaluated based on a medical record audit.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**
The key variables for this measure and testing results were:

1. Correct procedure (carotid artery stenting) performed. Kappa =1.0
2. Hospital mortality: Kappa = .91 (SE .01)
3. Hospital stroke: Kappa = 1.0
4. Asymptomatic 120 days pre-Rx: Kappa = .90 (SE .07)

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2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)***:** see reliability

2c.2 Analytic Method *(type of validity & rationale, method for testing)***:**
Multiple sources from the medical record were used as the gold standard, and rates compared with literature.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)***:**
The percentage of asymptomatic patients being treated in VSGNE of 60% corresponds to published data on this cohort. The postop stroke or death rate of 2.2% also correponds to published results for asymptomatic patients.

2c C☐ P☐ M☐ N☐

2d. Exclusions Justified — **2d**

2d.1 Summary of Evidence supporting exclusion(s):
Symptomatic patients are excluded because they would require complex risk adjustment that is not available. In such patients, treatment is more often indicated despite risk of treatment. However, for asymptomatic patients, complication rate must be low, less than 3% to justify intervention.

2d.2 Citations for Evidence:
Biller J, Feinberg WM, Castaldo JE, et al. Guidelines for carotid endarterectomy: a statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association. Stroke; a journal of cerebral circulation 1998;29(2):554-62.

2d.3 Data/sample *(description of data/sample and size)*: SVS Vascular Registry 805 asymptomatic patients undergoing elective CEA

2d.4 Analytic Method *(type analysis & rationale)*:
measure calculation

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
Death rate 2.0%, stroke rate 2.11% among 287 provider in 58 centers
Interquartile range was 0.3-8.6% for the combined endpoint

C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: See "Scientific Acceptablility" section for rationale. Risk adjustment is implicit within this quality measure as judged by the sponsor, the Society for Vascular Surgery, for the following reason. CAS in an asymptomatic patients is a prophylactic procedure designed to prevent future stroke. The decision to perform such a procedure requires the interventionist to calculate the patient´s risk-benefit ratio, in order to avoid post-CAS stroke or death that eliminate the benefit of the procedure. Risk adjustment based on patient factors should not be applied, since high risk patients should not undergo this prophylactic procedure, and using risk adjustment would reward interventionists who selected high risk patients for treatment.

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 Testing Results *(risk model performance metrics)*:
N/A

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

2e
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2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: see section 1.b.3 and above 2,d,5

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Standard statistial analysis to determine 95% confidence interval for hospitals and providers to determine practical difference from mean

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:

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2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: no other data sources available

2g.2 Analytic Method *(type of analysis & rationale)*:

2g
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2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	NA☐
2h. Disparities in Care 2h.1 **If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: N/A 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** No disparities have been reported.	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met? **Rationale:**	***2*** C☐ P☐ M☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** In use 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** *(If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years)*: Data from SVS VQI and VSGNE are reported to each hospital and provider in a format that can be transmitted to an appropriate public reporting mechanism. 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** Vascular Study Group of New England www.vsgne.org Data have been successfully collected in this quality registry since 2003, and reports provided to participating physicians and hospitals about their rates of outcomes. These results are used by the regional quality group to provide benchmark reporting, and to stimulate regional quality improvement projects. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)*: VSGNE samples previously described 3a.5 **Methods** *(e.g., focus group, survey, QI project)*: Semi-annual meetings of providers in VSGNE 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*: Benchamrk reports of this outcome measure have been provided to VSGNE member physician and hospitals since 2003, and discussed at semi-annual meetings. There have been no questions about interpretability.	**3a** C☐ P☐ M☐ N☐
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization	**3b**

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?**	C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** N/A **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** N/A	**3c** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** Data definitions regarding asymptomatic status based on NASCET criteria have eliminated confusion about symtoms. Death is an accurate endpoint. Stroke has been accurately collected as judged by chart audits and comparison to claims data that has been done within VSGNE.	**4d** C☐ P☐ M☐ N☐

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:
In the VSGNE experience which has been tracking stroke or death as a major endpoint since 2005, we have not experienced any difficulty with obtaining data related to this endpoint. Our percent missing for this variable has been less than 1%.

4e.2 Costs to implement the measure (*costs of data collection, fees associated with proprietary measures*)**:**
In the context of the VSGNE and SVS VQI registries, there is no additional cost as all of these data are already collected.

4e.3 Evidence for costs:

4e.4 Business case documentation: N/A

4e
C☐
P☐
M☐
N☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility?*

4

Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met?
Rationale:

4
C☐
P☐
M☐
N☐

RECOMMENDATION

(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**

Time-limited ☐

Steering Committee: Do you recommend for endorsement?
Comments:

Y☐
N☐
A☐

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
Society for Vascular Surgery, 633 N. St. Clair, 22nd floor, Chicago, Illinois, 60611

Co.2 Point of Contact
Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-

Measure Developer If different from Measure Steward
Co.3 Organization
Society for Vascular Surgery, 633 N. St. Clair, 22nd floor, Chicago, Illinois, 60611

Co.4 Point of Contact
Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-

Co.5 Submitter If different from Measure Steward POC
Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-, Society for Vascular Surgery

Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. N/A
Ad.2 If adapted, provide name of original measure: **Ad.3-5 If adapted, provide original specifications URL or attachment**
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** 2010 **Ad.7 Month and Year of most recent revision:** 12, 2010 **Ad.8 What is your frequency for review/update of this measure?** **Ad.9 When is the next scheduled review/update for this measure?**
Ad.10 Copyright statement/disclaimers:
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 06/13/2011

Carotid Artery Stent

Last Name | First Name | MI

Date of Birth | MR# | SSN

General Information

Zip Code

Ethnicity ☐ Not Hispanic or Lati ☐ Hispanic or Latino;

Height ☐ inches or cm

Weight ☐ lbs or kg

Visit code (not required)

Admit Date

Surgeon

Discharge Status ☐ home; ☐ rehab unit; ☐ nursing home; ☐ dead; ☐ other hospital; ☐ skilled nursing facility;

*If dead, date of death

Transferred from? ☐ no; ☐ hospital; ☐ rehab unit;

Gender ☐ male; ☐ female;

Race ☐ American Indian or Alaskan Nati ☐ Asian; ☐ Black or African A ☐ Native Hawaiian or other Pacific Is ☐ White; ☐ more than 1 race; ☐ Unknown/other;

Discharge Date

Surgery Date

Does the patient have Medicare Part B? ☐ no ☐ yes;

Medicare Health Insurance Claim Number

Demographics

Smoking ☐ never; ☐ prior (>1 yr); ☐ current (within yr);

Diabetes ☐ none; ☐ diet; ☐ oral meds; ☐ insulin;

CAD symptoms ☐ none; ☐ Hx MI but no sx; ☐ stable angina; ☐ unstable angina or MI < 6 mos;

CHF ☐ none; ☐ asymp, hx CHF; ☐ mild; ☐ severe;

Dialysis ☐ no; ☐ functioning transplant; ☐ on dialysis;

Stress Test ☐ normal ☐ (+) ischemia; ☐ (+) MI ☐ (+)both; ☐ not done;

ASA Class ☐ 1 normal/healthy; ☐ 2 w/mild systemic dx; ☐ 3 w/severe s ☐ 4 w/severe systemic dx that is a constant threat to life; ☐ 5 moribund, not expected to survive w/o op;

Hypertension ☐ no ☐ yes (>=140/90 or history);

Beta blockers ☐ no ☐ pre-op 1-30 days; ☐ chronic >30 days; ☐ no-intolerant ☐ op day only;

CABG/PTCA ☐ non ☐ <5yr; ☐ >=5yrs ago;

COPD ☐ no ☐ not treated; ☐ on meds; ☐ on home oxygen;

Creatinine ☐ mg/dl or µmol/L

Pre-adm Living ☐ home ☐ nursing home;

Pre-op Hemoglobin ☐ g/dl or g/L

Previous arterial

Bypass ☐ no; ☐ yes;

Aneur Repair ☐ no; ☐ yes;

Major Amp ☐ no; ☐ yes;

CEA ☐ no; ☐ yes;

PTA/Stent ☐ no; ☐ yes;

Pre-Op Medications

ASA ☐ no; ☐ yes; ☐ intolerant;

Statin ☐ no; ☐ yes; ☐ intolerant;

Plavix ☐ no; ☐ yes; ☐ intolerant;

History

Symptoms

Ocular Ipsilat ☐ asymptomatic; ☐ TIA; ☐ Minor stroke < 1 mo; ☐ Minor stroke >= 1 mo; ☐ Major stroke < 1 mo; ☐ Major stroke >= 1 mo;

Cortical Ipsilat ☐ asymptomatic; ☐ TIA; ☐ Minor stroke < 1 mo; ☐ Minor stroke >= 1 mo; ☐ Major stroke < 1 mo; ☐ Major stroke >= 1 mo;

Vertebrobasilar ☐ asymptomatic; ☐ TIA; ☐ Minor stroke < 1 mo; ☐ Minor stroke >= 1 mo; ☐ Major stroke < 1 mo; ☐ Major stroke >= 1 mo;

Ocular Contralat ☐ asymptomatic; ☐ TIA; ☐ Minor stroke < 1 mo; ☐ Minor stroke >= 1 mo; ☐ Major stroke < 1 mo; ☐ Major stroke >= 1 mo;

Cortical Contralat ☐ asymptomatic; ☐ TIA; ☐ Minor stroke < 1 mo; ☐ Minor stroke >= 1 mo; ☐ Major stroke < 1 mo; ☐ Major stroke >= 1 mo;

Non-specific ☐ no; ☐ yes;

Previous Ipsilat CEA ☐ no; ☐ yes;

Previous Ipsilat Carotid Stent ☐ no; ☐ yes;

Medical High Risk ☐ no; ☐ yes;

***NOTE:** If Ocular Ipsilat, Ocular Contralat, Cortical Ipsilat, and/or Cortical Contralat equals minor or major stroke, please complete Rankin Score.

Previous Contralat CEA ☐ no; ☐ yes;

Ipsilat Stroke on CT/MRI ☐ no; ☐ yes ☐ not done;

Anatomic High Risk ☐ no; ☐ yes;

Pre-op

Refused for Surgery ☐ no; ☐ yes;

Duplex ☐ no; ☐ yes;

CTA ☐ no; ☐ yes;

MRA ☐ no; ☐ yes;

Arteriogram ☐ no; ☐ yes;

*Rankin Score

☐ no symptoms; ☐ no significant disability (able to carry out all usual activities despite symptoms); ☐ slight disability (able to look after own affairs without assistances, but unable to carry out all); ☐ moderate disability (requires some help, but able to walk unassisted); ☐ moderately severe disability (unable to attend to own bodiy needs without assistance, and unable to walk unassisted); ☐ severe disability (requires constant nursing care and attention, bedridden, incontinent);

ICA Stenosis

Ipsilateral ☐ <50%; ☐ >50%; ☐ >60%; ☐ >70%; ☐ >80%; ☐ occlude

Contralateral ☐ <50%; ☐ >50%; ☐ >60%; ☐ >70%; ☐ >80%; ☐ occluded; ☐ unknown;

Procedure

Urgency ☐ elective; ☐ urgent; ☐ emergent;

Side ☐ right; ☐ left;

Stenosis by Angiography [ ] %

Upper Extent of Lesion (Location) ☐ C1; ☐ C2; ☐ C3; ☐ C4; ☐ C5; ☐ C6;

Pre-dilate Before Protection Device ☐ no; ☐ yes;

Site ☐ IR; ☐ cardiac cath; ☐ OR, fixed; ☐ OR, mobile;

Lesion Type ☐ atherosclerosi ☐ re-stenosis; ☐ dissection; ☐ other;

Second Stenosis ☐ no; ☐ yes;

Approach ☐ femoral; ☐ trans-femoral ☐ brachial;

Technical Failure ☐ no; ☐ yes;

Anesthesia ☐ local; ☐ general;

Second Stenosis Severity [ ] %

Lesion Length [ ] mm

Prophylactic Anti-bradyarrhythmic ☐ no; ☐ yes;

If Technical Failure equals yes, skip to Heparin; if Technical Failure equals no, answer all questions below.

Protection Device ☐ none; ☐ Angioguard; ☐ Accunet; ☐ Filterwire; ☐ Percusurg ☐ Retrograde flow; ☐ Neuroshield; ☐ other; ☐ Emboshield; ☐ Spider;

Pre-dilate Before Stent ☐ no; ☐ yes;

Stent Type ☐ Wall; ☐ Precise; ☐ Acculink ☐ Xact; ☐ Nextstent; ☐ Vivexx; ☐ other;

Stent Diameter [ ] mm smallest diameter used; 999 if Nexstent is used

Tapered ☐ no; ☐ yes;

Stent Length [ ] mm

Number of Stents [ ] # of stents used

Post Dilate ☐ no; ☐ yes;

Balloon Diameter [ ] mm

Proximal CCA Stent ☐ no; ☐ yes;

Heparin ☐ no; ☐ yes;

Protamine ☐ no; ☐ yes;

Contrast Volume [ ] ml

Bradyarrhythmia Requiring Tx ☐ no; ☐ yes;

Protection Device Failure ☐ no; ☐ yes;

Neurologic Change ☐ no; ☐ yes;

Neuro Change Type ☐ decreased LOC; ☐ seizure; ☐ TIA; ☐ Stroke; ☐ Other;

Heart Rate

On Arrival in OR [ ] bpm

Highest intra-op [ ] bpm

Post-Op Data

Ipsilat Neurologic Event ☐ no; ☐ TIA; ☐ stroke, minor; ☐ stroke, major;

Time of Onset ☐ no; ☐ intra-op; ☐ < 6hrs post-op; ☐ >= 6hrs post-op; ☐ unknown;

Contralat Neurologic Event ☐ no; ☐ TIA; ☐ stroke, minor; ☐ stroke, major;

Time of Onset ☐ no; ☐ intra-op; ☐ < 6hrs post-op; ☐ >= 6hrs post-op; ☐ unknown;

2b3a Inhibitor Post-Op ☐ no; ☐ yes;

Reperfusion Symptoms ☐ none; ☐ seizure or hemmorage;

Myocardial Infarction ☐ no; ☐ troponin only; ☐ EKG or clinical;

CHF ☐ no; ☐ yes;

Dysrhythmia (new) ☐ no; ☐ yes;

Access Site CX ☐ no; ☐ minimal hematoma / PA; ☐ hematoma / PA required transfusion; ☐ required operation; ☐ arterial occlusion;

IV Med Required for:

Hypertension ☐ no; ☐ yes;

Hypotension ☐ no; ☐ yes;

Discharge Medications

ASA ☐ no; ☐ yes; ☐ intolerant;

Plavix ☐ no; ☐ yes; ☐ intolerant;

Statin ☐ no; ☐ yes; ☐ intolerant;

Beta Blocker ☐ no; ☐ yes; ☐ intolerant;

Other Antiplatelet ☐ no; ☐ yes; ☐ intolerant;

Carotid Artery Stent - Follow-up

Last Name:		First Name:		DOB:	
MRN:		SSN:		Zip/Postal Code:	
Visit Code:		Surgeon:		Surgery Date:	
				Side:	

General Information

Date of Contact

Contact By ☐ Office Visit; ☐ Phone; ☐ Refused follow-up visit; ☐ Lost to follow-up;

Current Smoking ☐ No; ☐ Yes (within last 6 months);

Current Living Status ☐ Home; ☐ Nursing Home; ☐ Dead;

Date of Death

Cause ☐ Operation Related; ☐ Non-Related ☐ Unsure;

Current Medications

ASA ☐ No; ☐ Yes; ☐ Intolerant;

Plavix ☐ No; ☐ Yes; ☐ Intolerant;

Coumadin ☐ No; ☐ Yes; ☐ Intolerant;

Beta Blocker ☐ No; ☐ Yes; ☐ Intolerant;

Statin ☐ No; ☐ Yes; ☐ Intolerant;

Carotid Artery Stent

Ipsilat Neurologic Event ☐ No; ☐ TIA ☐ Stroke, minor; ☐ Stroke, major;

Date of Event

Contralat Neurologic Event ☐ No; ☐ TIA ☐ Stroke, minor; ☐ Stroke, major;

Date of Event

Duplex CAS Site ☐ <50%; ☐ >50%; ☐ >60%; ☐ >70%; ☐ >80% ☐ occluded; ☐ not done; ☐ unknown;

CAS Site RE-Intervention ☐ No; ☐ Yes;

Date of PTA/Stent

CAS Site Endarterectomy ☐ No; ☐ Yes;

Date of Procedure

v 1.9

CAROTID ARTERY STENT DEFINITIONS (Include only carotid bifurcation or internal carotid artery stents) v.01.09

If more than one response applies, select the most severe (highest number) response for each data field.

Pre-op

Smoking: Prior = quit ≥ 1 year ago. Current = still smoking within last 12 months. Include cigarettes, pipe, or cigar.

HTN (Hypertension): Defined as ≥ 140/90, either systolic or diastolic, at admission or within last 6 months, or clearly documented in medical record.

Beta-blockers: Peri-operative = started w/in one month before surgery or during surgery. Chronic = >than one month before surgery.

Symptoms (Coronary artery disease**):** Stable angina = stable pattern or symptoms with or without antianginal medication. Unstable angina = new onset, increasing frequency, lasting > 20 min and/or rest angina.

CABG/PTCA: Coronary artery bypass, angioplasty, or stent.

CHF (Congestive Heart Failure): Documented CHF: Mild = SOB on exertion; Severe = SOB at rest, pulmonary edema, or pitting ankle edema. (Use 2 = mild if severity not documented.)

COPD: Not treated = COPD documented in record but not treated with medication. Meds include theophylline, aminophylline, inhalers or steroids

Dialysis: Transplant = patient has functioning kidney transplant; Dialysis = currently on hemo- or peritoneal dialysis.

Creatinine: Last available measurement taken before procedure. If multiple measurements, use highest within 30 days of surgery.

Stress Test: Includes stress EKG, stress echo, nuclear stress scans, within 2 years of surgery.

Pre-admin living: Use last living status before any current, acute hospitalization or rehab unit.

Previous Arterial:

Bypass - Any non-cardiac arterial bypass for occlusive disease

CEA - Carotid endarterectomy

Aneurysm Repair – Any known true arterial aneurysm repair (excluding cerebral or pseudo-aneurysm)

PTA/Stent – Of any non-cardiac artery

Major Amputation – Any amputation above the foot or hand

Pre-Op Medications: Taken within 36 hours of surgery. Statins include any HMG-CoA reductase inhibitor, such as Lipitor, Mevacor, Pravachol, Zocor, Lescol, etc. If Plavix is disontinued prior to surgery it should be coded = 0.

Pre-op Hemoglobin: Most recent pre-op hemoglobin within past 30 days.

Symptoms: Ocular: unilateral visual loss or major blurring, etc. Cortical: unilateral motor and/or memory loss, or dysphagia/aphasia, etc. Vertebrobasiliar: bilateral motor, sensory, or visual loss, diplopia, ataxaia, etc. Major cortical or vertebrobasilar stroke = disability causing non-independent living status. Minor stroke is non-disabling. Major ocular stroke = blindness, otherwise minor. Stroke<1 month means stroke within previous month before surgery, etc. TIA=transient ischemic attack completely resolved within 24 hours.

Non-specific: Not clearly a carotid or vertebrobasilar TIA, e.g., light-headedness, dizziness

Ipsilat stroke on CT/MRI: Carotid territory only.

Medical high risk: At least one factor required: > 80 years old, severe O2 dependent pulmonary disease, CHF w/in one month, or abnormal stress test.

Anatomic high risk: Previous endarterectomy, previous neck surgery or radiation, tracheal or pharyngeal stoma, lesion above C3, contralat laryngeal nerve palsy, or contralateral carotid occlusion.

Refused for surgery: Surgeon has evaluated patient and refuses to operate due to excessive risk.

ICA stenosis: Use most severe category by modality thought to be most accurate if multiple modalities used.

Procedure

Urgency: Urgent = surgery within 24 hrs of admit or patient can't be discharged; emergent = surgery within 6 hrs of admission.

Lesion length: Length of stenosis intended to be covered with stent.

Prophylactic Anti-bradyarrhythmic: Atropine or Glycopyrolate given prior to angioplasty

Pre-dilate before protection device: Angioplasty required in order to cross lesion with a protection device.

Proximal CCA stent: Stent placement in the origin of the CCA.

Bradyarrhythmia requiring tx: Any dose given post post-dilation.

Technical failure: Can't complete procedure – CAS procedure defined as starting with attempting to place long sheath into CCA.

Protection device failure: Can't cross lesion, filter clogged, difficulty removing filter, ICA spasm requiring treatment, neurological change during procedure.

Post-op

Cranial nerve injury: Any occurrence, transient or persisting: VII-facial droop or more severe; IX-swallowing difficulty unless other diagnosis confirmed; X- hoarseness unless laryngoscopy normal; XII-any tongue deviation or dis-coordination

Ipsilat/Contralat neurologic event: Cerebral or ocular. TIA = cortical or ocular symptoms <24hrs duration. Major cortical or vertebrobasilar stroke = disability causing non-independent living status. Otherwise, minor. Major ocular stroke = blindness, otherwise minor. Minor stroke is non-disabling.

Time of Onset Ipsila/Contralat: Time when first noticed, but if noted on awakening from anesthesia code as 1=intra-op. Use 2=≤6 hrs post-op if normal at completion of procedure, and then neurologic event developed.

2b3a Inhibitor: Integrilin, Aggrastat.

Reperfusion Symptoms: Seizures associated with headache, or hemorrhage on CT/MRI.

IV meds required: Indicates continuous infusion or more than one dose required more than one hour after surgery.

Myocardial Infarction: Troponin: by local standards for MI. EKG: new Q waves, new ST and T wave changes. Clinical: documentation of MI by clinical criteria or ECHO or other imaging modality.

Dysrhythmia: New rhythm disturbance requiring treatment with medications or cardio-version.

CHF: Pulmonary edema with requirement for monitoring or treatment in ICU.

Access site cx: Complications at puncture site. PA=pseudo-aneurysm.