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 <u>evaluation criteria</u> 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.

<u>Note</u>: 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 #: 1540 NQF Project: Surgery Endorsement Maintenance 2010

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy

De.2 Brief description of measure: 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.

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 Artery Stenting

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 measure submission 	A Y N

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A.4 Measure Steward Agreement attached: Agreement With Measure Stewards_Agreement Between_National Quality Forum (12-6-2010)-634273349246562246.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 <u>both</u> public reporting <u>and</u> 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.1Testing: 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 (<i>if submission returned</i>):	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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria</i> . (evaluation criteria) 1a. High Impact	<u>Eval</u> <u>Rating</u>
(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: Stroke or death following CEA has been the primary clinical endpoint for multiple randomized trials of CEA (Ref 1-3). Although this is sometimes reported after 30 days, most postoperative strokes or deaths occur in hospital following CEA for asymptomatic patients (Ref 1). This endpoint is easy to capture from claims data and registries. This outcome is particularly important for asymptomatic patients undergoing CEA, since this is a prophylactic operation being proposed to prevent future stroke. As such, 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% (Ref 4). This is based on Level 1 evidence from randomized trials which established the benefit of CEA in asymptomatic patients with at least 60% internal carotid artery (ICA) stenosis, but only if the surgical risk is appropriately low, since the subsequent stroke risk with medical management is not high (Ref 1-2). This contrasts with symptomatic patients with severe ICA stenosis where the stroke risk under medical therapy is high, and justifies CEA even when stroke risks are higher. 	1a C P M
Stroke is defined as an acute neurological deficit due to an occlusive or hemorrhagic brain lesion that	N

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 is 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 postoperative new neurologic deficit attributed to an occlusive or hemorrhagic brain lestion lasting more than 24 hours. From an operational standpoint, post-operative new stroke is defined by medical record coding, ICD-9-CM 997.02.	
While stroke or death following CEA 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. The rationale for this is as follows. Factors such as atrial fibrillation, congestive heart failure, contralateral carotid occlusion and diabetes have been shown to increase stroke risk following CEA, in addition to symptom status, and could be used to justify risk stratification (Ref 9). However, for asymptomatic patients, it is incumbent upon the surgeon to select only those patients of low perioperative risk to benefit from CEA. In fact, the recommendations of the AHA are that this surgery should not be done if risk is high (>3%), without risk adjustment in asymptomatic patients (Ref 4).	
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 after CEA reduced this outcome from 5.6% to 5.0% and in asymptomatic patients from 4.1% to 3.8% (Ref 5). The reporting time frame for hospitals should be on a yearly basis. The time frame for surgeons should be cumulative over their career.	
This is an important quality measure, since it is suspected that a number of surgeons and centers performing CEAs do not meet the high standards of the randomized trials which established the benefit of such treatment. It has been shown that mortality following CEA in Medicare patients was 1.4% in hospitals participating in randomized trials, 1.7% in high volume non-trial hospitals, 1.9% in average volume hospitals and fully 2.5% in low volume hospitals (Ref 5). Given that the stroke rate is generally 3 times the mortality rate, this means that some surgeons/centers are likely not achieving optimal results. A recent survey in Canada found that 45% of hospitals are not meeting published guidelines (Ref 7). Adoption of this outcome measure in the United States would likely disclose similar results and lead to quality improvement. The VSGNNE has shown that regional results are good for CEA outcomes, but significant variation does exist between surgeons and centers (Ref 8). This would be the first true outcome measure for vascular surgery, and it would apply to the most frequently performed vascular operation.	
 1a.4 Citations for Evidence of High Impact: 1. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Jama 1995;273(18):1421-8. 2. Halliday A, Mansfield A, Marro J, et al. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. Lancet 2004;363(9420):1491-502. 3. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 1991; 325: 	
 445-53. 4. 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. 5. Kresowik TF, Bratzler DW, Kresowik RA, et al. Multistate improvement in process and outcomes of carotid endarterectomy. J Vasc Surg 2004;39(2):372-80. 6. Wennberg DE, Lucas FL, Birkmeyer JD, Bredenberg CE, Fisher ES. Variation in carotid 	
 endarterectomy mortality in the Medicare population: trial hospitals, volume, and patient characteristics. Jama 1998;279(16):1278-81. Feasby TE, Kennedy J, Quan H, Girard L, Ghali WA. Real-world replication of randomized controlled 	

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 trial results for carotid endarterectomy. Archives of neurology 2007;64(10):1496-500. 8. Cronenwett JL, Likosky DS, Russell MT, Eldrup-Jorgensen J, Stanley AC, Nolan BW. A regional registry for quality assurance and improvement: The Vascular Study Group of Northern New England (VSGNNE). J Vasc Surg 2007. 9. Tu J, Wang H, Bowyer B, Green L, Fang J, Kucey D. Risk Factors for Death or Stroke After Carotid Endarterectomy: Observations From the Ontario Carotid Endarterectomy Registry. Stroke. 2003;34:2568-2575. 	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Numerous manuscripts have noted variation in the combined endpoint of stroke or death following carotid endarterectomy. In the Medicare population, the outcome has been shown to vary substantially as a function of hospital volume. This is an important consideration, since it is widely recognized that many surgeons and centers performing CEAs do not meet the high standards of the randomized trials which established the benefit of such treatment. It has been shown that mortality following CEA in Medicare patients was 1.4% in hospitals participating in randomized trials, 1.7% in high volume non-trial hospitals, 1.9% in average volume hospitals and fully 2.5% in low volume hospitals (Ref 6). Given that the stroke rate is generally 3 times the mortality rate, this suggests that some centers/surgeons are not achieving optimal results. A recent survey in Canada found that 45% of hospitals are not meeting published guidelines (Ref 7). Adoption of this outcome measure in the United States would likely disclose similar results and lead to quality improvement when this information was provided to surgeons and centers. This effect has been demonstrated in a midwest regional study by Kresowik et al where stroke and death rate after CEA improved after providing outcome data (Ref 5). The VSGNNE has shown that regional results are good for CEA outcomes, but significant variation does exist between surgeons and centers (Ref 8). Postoperative stroke or death is the accepted outcome paramenter for this surgery, and its measurement and reporting would demonstrate variation and opportunity for improvement	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across	
providers: It has been shown that mortality following CEA in Medicare patients was 1.4% in hospitals participating in randomized trials, 1.7% in high volume non-trial hospitals, 1.9% in average volume hospitals and fully 2.5% in low volume hospitals (Ref 6). Given that the stroke rate is generally 3 times the mortality rate, this means that many ill advised operations are likely being performed. A recent survey in Canada found that 45% of hospitals are not meeting published guidelines (Ref 7).	
For this measure propsal we reviewed 4,613 CEAs performed for asymptomatic patients in VSGNE between 2003 to 2010. Among 17 hosptials, the variation in postoperative stroke or death rate was as follows: The 25th quartile was 0%. The 75th quartile was 1.5%. The median was 0.6%. The range across centers was 0% to 6.4%. Similarly, among 89 individual surgeons the rates were as follows: The 25th quartile was 0%. The median was 0%. The range across surgeons was 0% to 25%. This demonstrates substantial variability and performance gap even though the regional average outcome was excellent.	
1b.3 Citations for data on performance gap: See list in 1a.4 above	
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 C P
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 C P M
1c.2-3. Type of Evidence: Cohort study, Expert opinion, Meta-analysis	N

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 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. **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, and has been used in multiple RCTs. 1c.6 Method for rating evidence: Expert opinion. 1c.7 Summary of Controversy/Contradictory Evidence: None **1c.8 Citations for Evidence (***other than guidelines***): 1. Endarterectomy for asymptomatic carotid artery** stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Jama 1995;273(18):1421-8. 2. Halliday A, Mansfield A, Marro J, et al. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. Lancet 2004;363(9420):1491-502. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of 3. carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 1991; 325: 445-53. 4. 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. 5. Kresowik TF, Bratzler DW, Kresowik RA, et al. Multistate improvement in process and outcomes of carotid endarterectomy. J Vasc Surg 2004:39(2):372-80. Wennberg DE, Lucas FL, Birkmeyer JD, Bredenberg CE, Fisher ES. Variation in carotid 6. endarterectomy mortality in the Medicare population: trial hospitals, volume, and patient characteristics. Jama 1998;279(16):1278-81. 7. Feasby TE, Kennedy J, Quan H, Girard L, Ghali WA. Real-world replication of randomized controlled trial results for carotid endarterectomy. Archives of neurology 2007;64(10):1496-500. Cronenwett JL, Likosky DS, Russell MT, Eldrup-Jorgensen J, Stanley AC, Nolan BW. A regional 8. registry for quality assurance and improvement: The Vascular Study Group of Northern New England (VSGNNE). J Vasc Surg 2007. 9. Tu J, Wang H, Bowyer B, Green L, Fang J, Kucey D. Risk Factors for Death or Stroke After Carotid Endarterectomy: Observations From the Ontario Carotid Endarterectomy Registry. Stroke. 2003;34:2568-2575. **1c.9** Quote the Specific guideline recommendation (including guideline number and/or page number): 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. 1c.10 Clinical Practice Guideline Citation: 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. 1c.11 National Guideline Clearinghouse or other URL: N/A **1c.12** Rating of strength of recommendation (also provide narrative description of the rating and by whom): Level 1 1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe

rating and how it relates to USPSTF): AHA 1c.14 Rationale for using this guideline over others: Universally accepted 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? 1 Rationale: YΓ N 2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about Eval the quality of care when implemented. (evaluation criteria) 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 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 **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 VOI) 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 CEA(CPT code 37215) who died or experienced postoperative inhospital stroke are included. **2a.4 Denominator Statement (Brief.** text description of the denominator - target population being measured): Asymptomatic patients (based on NASCET criteria) on the within one year of CEA 2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 years or older **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 2areporting every 12 months for hospital. Since surgeons have lower individual volume, we recommend specs annual reporting of the last 50 consecutive procedures, which may span more than one year, with C suppression if < 10 procedures (ie, reported as too low volume to report). Pĺ MI **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 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) 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): Patients with neurologic symptoms within one year of surgery

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 CEA

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***):** Asymptomatic patients undergoing CEA who experience inhospital stroke or death/all asymptomatic patients undergoing CEA

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): N/A

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_Endarterectomy_CB_v1.9.xlsx

2a.29-31 Data dictionary/code table web page URL or attachment: Attachment CEA 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)

	- #1540
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:	2b
 Correct procedure (carotid endarterectomy) performed. Kappa =1.0 Hospital mortality: Kappa = .91 (SE .01) Hospital stroke: Kappa = 1.0 Asymptometric 120 descent Para Para (SE .07) 	C P M
 4. Asymptomatic 120 days pre-Rx: Kappa = .90 (SE .07) 2c. Validity testing 	
2c.1 Data/sample (description of data/sample and size): see reliability testing	
2c.2 Analytic Method (type of validity & rationale, method for testing): Comparison of results with expected results from 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 with CEA in VSGNE of 68% corresponds to published	2c C□ P□
data on this cohort. The postop stroke or death rate of 1.5% also correponds to published results for asymptomatic patients.	M N 🗌
2d. Exclusions Justified	
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 862 asymptomatic patients undergoing elective CEA	
2d.4 Analytic Method (type analysis & rationale): measure calculation	2d C□
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): Death rate 0.7%, stroke rate 1.28% among 287 provider in 58 centers Interquartile range was 0.2-7.6% for the combined endpoint	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. CEA 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-CEA 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):	2e
2e.3 Testing Results (risk model performance metrics):	C P M N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	
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
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):	C P M N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): other sample not available	2g
2g.2 Analytic Method (type of analysis & rationale):	C P
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	
2h. Disparities in Care	2
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	2h C□ P□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: Disparities have not been reported.	
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	

NQF #1540

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. (<u>evaluation criteria</u>)	<u>Eval</u> 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). <u>If not publicly reported</u> , 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 (<i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u>, state the plans to achieve use for QI within 3 years): Vascular Study Group of New England www.vsgne.org Real time reports of outcome measures are provided to practitioners online. These are then used in regional quality improvement programs.</i>	
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
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.	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 <u>endorsed</u> or submitted measures:	
 3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? 	3b 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:	3c C□
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:	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, <i>Usability</i> , 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. (<u>evaluation criteria</u>)	<u>Eval</u> 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 C□ P□
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	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 C P M N
4c.2 If yes, provide justification.	
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 2003, 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.	4-
4e.3 Evidence for costs:	4e C P M
4e.4 Business case documentation:	N
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i> ?	4

	NQF #1540
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , 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	<u>I</u>
Co.1 Measure Steward (Intellectual Property Owner)	
Co.1 <u>Organization</u> Society for Vascular Surgery, 633 N. St. Clair, 22nd St., Chicago, Illinois, 60611	
Co.2 <u>Point of Contact</u> Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-	
Measure Developer If different from Measure Steward Co.3 <u>Organization</u> Society for Vascular Surgery, 633 N. St. Clair, 22nd St., 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 organization Describe the members' role in measure development.	ons.
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.9 When is the next scheduled review/update for this measure? Ad.10 Copyright statement/disclaimers:	

Carotid Endarterectomy			
Last Name	First Name	M	
Date of Birth	MRN	SSN	
General Information			
Zip Code		Gender 🗌 🦳 Male; 🗌 Female;	
Ethnicity	Not Hispanic or Latino; Hispanic or Latino;	Race White; Black or African American;	
Height	inches or cm	Asian; Asian; Asian or Other Pacific Islander	
Weight	lbs or kg	Asian; Asive Hawaiian or Other Pacific Islander	
Visit code (not required)			
Admit Date		Discharge Date	
Surgeon		Surgery Date	
Discharge Status	home rehab unit; nursing home;	Does the patient have Medicare no; yes;	
	dead; other hospital; skilled nursing facility;	Part B?	
*If dead, date of death			
Transferred from?	no; hospital; rehab uni		
Demographics			
Smoking	never; prior (>1 yr) current (within yr);	Hypertension no; yes (>= 140/90 or history);	
Diabetes	none; diet; oral mec insulin;	Beta blockers no; Pre-op 1-30 days; Chronic >30 days;	
CAD symptoms	none; hx MI but no s stable angina;	CABG/PTCA none; <a>cli>= 5yr; >= 5yrs ago;	
	unstable angina or MI <6 mos		
CHF	none; asymp, hx CH mild; severe;	COPD no; not treated; on meds; on home oxygen;	
Dialysis	no; functioning transplant; on dialysis	Creatinine mg/dl or µmol/L	
Stress Test	normal (+)ischemia (+)Mi (+)both; not done;	Pre-adm Living home; nursing hom	
ASA Class	1 normal/healthy 2 w/mild systemic dx	g/dl or g/L	
	3 w/severe systemic dx;	Pre-op Hemoglobin	
	4 w/severe systemic dx that is a constant threat to life;		
Previous arterial	5 moribund/not expected to survive w/o op.		
Bypass	no; yes;		
Aneurysm Repair	no; yes;	CEA no; ves;	
Major Amp	no; yes;	PTA/Stent ves;	
Pre-Op Medications		·····	
ASA	no; ves; intolerant;	Plavix no; yes; intolerant;	
Statin	no; yes; intolerant;		

History

Symptoms		_	
Ocular Ipsilat [asymptomatic; TIA; minor stroke <1 mo;	Ocular Contralat	asymptomatic; TIA; minor stroke <1 mo;
minor stroke >=1 mo;	major stroke <1 mo; major stroke >=1 mo;	minor stroke >=	=1 mo; major stroke <1 mo; major stroke >=1 mo;
Cortical Ipsilat	asymptomatic; TIA; minor stroke <1 mo;	Cortical Contralat	asymptomatic; TIA; minor stroke <1 mo;
minor stroke >=1 mo;	major stroke <1 mo; major stroke >=1 mo;	minor stroke >	=1 mo; major stroke <1 mo; major stroke >=1 mo;
Vertebrobasilar	asymptomatic; TIA; minor stroke <1 mo;	Non-specific	no; yes;
minor stroke >=1 mo;	major stroke <1 mo; major stroke >=1 mo;	Previous	no; ves;
Previous Ipsilat CEA	no; yes;	Contralateral CEA	
Previous Ipsilat on CT/MRI?	no; yes; not done;	Previous Radiation	no; yes;
Pre-op			
Duplex	no; yes;	MRA	no; yes;
СТА	no; yes;	Arteriogram	no; yes;
ICA Stenosis			
Ipsilateral		Contralateral	
	>80%; occluded;		>80%; occluded; unknown;
Procedure			
Urgency	elective; urgent; emergent;	Anesthesia	local; regional; general;
Side	right; left;	Туре	conventional; eversion;
Patch	none; vein; dacron; PTFE;	Shunt	no; yes (routine); yes (indication);
	bovine pericardium; dother;		
Skin Prep	chlorhexadine alcohol; iodine;	Drain	no; yes;
	chlor+iodine chlor+alcoho iodine+alcoho	;	
	all three		
Heparin	no; yes;	Protamine	no; yes;
Re-explore artery after closure	no; yes;	Dextran	no; yes;
Monitoring			
Awake	no; yes;	EEG	no; yes;
Stump Pressure	no; ves;	Other	no; ves;
Heart Rate			
On Arrival in OR	bpm	Highest intra-op	bpm
Completion			
Doppler	no; yes;	Duplex	no; yes;
Angiogram	no; yes;	Flowprobe	no; yes;
Concomitant Procedure			
CABG	no; yes;	Proximal	no; ves;
Other Arterial Op	no; yes;	Endovascular	

	· · · · · · · · · · · · · · · · · · ·				
Post-Op Information					
Cranial Nerve Injury					
VII	no; yes;	IX	no; yes;		
х	no; ves;	XII			
Other	no; ves;				
Ipsilat Neurological Event		Time of Onset	no; intra-op; 		
	Stroke, minor; Stroke, major;		>=6hrs post-op; unknown;		
Contralat Neurological		Time of Onset	no; intra-op; <pre><6hrs</pre> <6hrs post-op;		
Event	no; TIA;		interference in		
	Stroke, minor; Stroke, major;				
IV Med Required for:					
Hepertension	no; yes;	Hypotension	no; ves;		
Complications:					
Myocardial Infaction	no; troponin only; EKG or clinical;	Dysrhythmia (new)	no; yes;		
CHF	no; yes;	Wound Infection	no; yes;		
Reperfusion Symptoms	none seizure or hemorrhage;	Return to OR	no; yes;		
	If Return to OR is yes; enter an answer for				
Disc. d'a s		Bleeding and Neurol			
Bleeding	no; ye:	Neurologic Event	no; yes;		
Discharge Medications					
ASA	no; yes; intolerant;	Plavix	no; yes; intolerant;		
Other Antiplatelet	no; yes; intolerant;	Statin	no; yes; intolerant;		
Beta Blocker	no; yes; intolerant;				
Peri-Op Antibiotic Ordere	d?				
Start <1hr Pre-op	no; yes; no, for medical reasons;	Stop <24hr Post-	no; yes; no, for medical reasons;		
1st - 2nd Gen	no; yes; no, for medical reasons;	Ор			
Cephalosporin	-				
			٧		

Carotid Endarterectomy - Follow-up

Last Name:		First Name:		DOB:
Last Name.				
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; intolera	int; Coumadin	no; yes; intolerant;
Beta Blocker	no; yes; intolerant;	Statin no; yes; intolera	int;	
Carotid Endarterectomy				
Ipsilat Neurologic Event	no; TIA; Stroke, i	minor: Stroke, major;	Date of Event	
Contralat Neurologic Event	no; TIA; Stroke,	=	Date of Event	
Cranial Nerve Injury	none; resolved;	persistant;	Duplex CEA Site	
, , ,			•	>80% cccluded; not done; unknown;
CEA Site Re-operation	no; yes;		Date of Re-op	
CEA Site PTA	no; yes;		Date of PTA/Stent	v 1

CAROTID ENDARTERECTOMY DEFINITIONS - 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 \geq 140/90, either systolic or diastolic, at admission or within last 6 months, or clearly documented in medical record.

Beta-blockers: Peri-operative = started within one month before surgery or during surgery. Chronic = more than one month before surgery.

CAD Symptoms (Coronary artery disease): Stable angina = stable pattern or symptoms with or without anti-anginal 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. Medication includes 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.

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

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 discontinued 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.

CEA: Carotid endarterectomy

Previous radiation: Radiation therapy in a field including the affected carotid artery.

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. **Shunt:** If used, specify if routinely used (1), or if placed selectively in this patient for a specific indication (2). **Re-explore artery after closure:** for defect detected after closure during same operation.

Concomitant Procedure

Proximal endovascular: Angioplasty or stent of more proximal carotid, innominate artery.

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 $2=\leq 6$ hrs post-op if normal at completion of procedure, and then neurologic event developed.

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 cardioversion.

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

Return to OR for bleeding: Applies to carotid endarterectomy incision only. Use 666 if Return to OR = 0.

Return to OR for Neurologic Event: Use 666 if Return to OR = 0.

Peri-operative Antibiotics: Use 0=no if antibiotic was not ordered. To use 1=yes, antibiotic must be ordered to be given within 1 hour prior to skin incision and must be ordered to be discontinued within 24 hrs of end of time of operation. To use 2=no for medical reason, a medical reason must be documented in the chart that antibiotic not given. **Acceptable antibiotics include:** Ampicilin/sulbactam, Aztreonam,

Cefazolin, Cefmetazole, Cefotetan, Cefuroxime, Ciprofloxacin, Clindamycin, Ertapenem, Erythromycin base, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin, and Vancomycin.

 $1^{st}-2^{nd}$ Generation Cepahalosporin: (Cefazolin or Cefuroxime) Use response 1=yes, if ordered. If documented in medical record that not ordered for medical reason use 2. Otherwise use 0=no.