**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0507

**Measure Title**: Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/2/2021

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1) that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1) that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3) evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

## Outcome: Click here to name the health outcome

* + - Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

* Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome
* Process: The process of standardizing the method for stenosis calculation
  + Appropriate use measure:
* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Accurate assessment of the degree of carotid artery stenosis is essential to guiding proper treatment decisions for patients with carotid artery disease. Trials have demonstrated the ability of the degree of carotid artery stenosis to predict which patients will receive the greatest benefit from surgical intervention. To ensure accurate assessment of stenosis, it is important to use a standardized, validated approach. A more accurate quantification of stenoses will lead to more appropriate treatment, based on the percentage of stenoses.

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Carotid endarterectomy for symptomatic carotid stenosis (Review)  Orrapin S, Rekasem K  2017  Orrapin S, Rerkasem K. Carotid endarterectomy for symptomatic carotid stenosis. *Cochrane Database of Systematic Reviews* 2017, Issue 6. Art. No.: CD001081.  DOI: [10.1002/14651858.CD001081.pub3.](https://doi.org/10.1002%2F14651858.CD001081.pub3) |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the  conclusions from the SR. | With the exception of near-occlusions, the degree of stenosis above which surgery is beneficial was shown to be 50% (by the measurement used in the NASCET 1991 and VACSP 1991 trials: equivalent to about 65% stenosis by the method used in ECST 1998). Benefit in people with 50% to 69% stenosis became more modest with longer duration of follow-up. Lack of benefit for moderate stenosis in the original ECST 1998 report is not inconsistent with this but reflects the differences between the analyses in the measurement of stenosis and the definition of outcome events. The re-analysis of individual patient data has shown that the effects of surgery in ECST 1998 and NASCET 1991 in people with 50% to 69% stenosis were consistent.  The process of standardizing the method for stenosis calculation, as indicated in the measure language, will lead to improved health outcomes such as more accurate quantification of stenoses and more appropriate treatment, based on the percentage of stenoses. |
| Grade assigned to the **evidence** associated with the recommendation with the  definition of the grade | **Moderate** using GRADE scale.  Moderate: The authors believe that the true effect is   probably close to the estimated effect. |
| Provide all other grades and definitions  from the evidence grading system | **Very low:** The true effect is probably markedly different from the estimated effect  **Low:** The true effect might be markedly different from the estimated effect  **Moderate:** The authors believe that the true effect is probably close to the estimated effect  **High:** The authors have a lot of confidence that the true effect is similar to the estimated effect |
| Grade assigned to the **recommendation**  with definition of the grade | **Moderate** using GRADE scale.  **Moderate:** The authors believe that the true effect is  probably close to the estimated effect. |
| Provide all other grades and definitions  from the recommendation grading system | **Very low:** The true effect is probably markedly different from the estimated effect  **Low:** The true effect might be markedly different from the estimated effect  **Moderate:** The authors believe that the true effect is probably close to the estimated effect  **High:** The authors have a lot of confidence that the true effect is similar to the estimated effect |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | This review identified three randomized controlled trials (6343 participants randomized), which compared carotid surgery with no carotid surgery (i.e. best medical therapy plus surgery versus best medical therapy alone) in participants with carotid stenosis and recent transient ischemic attacks (TIA) or minor ischemic strokes in the territory of that artery. The trials were carried out in Europe, USA, and Canada and included some centers in Israel, South Africa, and Australia. The gender ratio of participants was 2.6:1 (72% men and 28% women); 90% of participants were younger than 75 years old.  Generally, the three included trials had adequate strategies to avoid bias in their study except VACSP 1991, which did not provide information on allocation concealment. Analysis of individual patient data has advantages over meta-analysis of overall trial results and was essential for the endarterectomy trials. Differences between the trials in the method of measurement of carotid stenosis and in the definition of outcome events made it impossible to combine tabular results satisfactorily. By re-analyzing the individual patient data and reassessing the carotid angiogram, the authors found that the results of ECST 1998 and NASCET 1991 were consistent, removing the uncertainty that was generated by the apparent disparities between the originally reported results of the trials. |
| Estimates of benefit and consistency  across studies | Endarterectomy was of some benefit for participants with 50% to 69% symptomatic stenosis (moderate-quality evidence), and highly beneficial for those with 70% to 99% stenosis without near-occlusion (moderate-quality evidence). The authors found no benefit in people with carotid near-occlusion (high-quality evidence).  The quality of the evidence for near occlusion and less than 30% of carotid stenosis is high. The quality of the evidence for 50% to 99% of carotid stenosis is moderate for any stroke or operative death as well as ipsilateral ischemic stroke and any operative stroke or death outcome.  Patients with stenoses will benefit from physicians using a standardized method for stenosis calculation. Accuracy is extremely important as the calculation will justify the intervention selected for the patient, as evidence-based guidelines base treatment recommendations on the patient´s percentage of stenosis. |
| What harms were identified? | It is possible that the intention-to-treat analysis may have underestimated the benefit of endarterectomy in the near occlusions because of the relatively high rate of endarterectomy during follow-up in the medical treatment group in NASCET 1991.  70% to 99% stenosis without near-occlusion was significant for each of the three main outcomes.  Some people may still wish to undergo surgery, particularly if they experience recurrent TIAs, but they should be informed that the benefit from endarterectomy in preventing a stroke is likely to be modest in the short-term and unknown in the long-term. |
| Identify any new studies conducted since  the SR. Do the new studies change the conclusions from the SR? | The authors updated this review in September 2020. The results are still the same -- carotid endarterectomy reduced the risk of recurrent stroke for people with significant stenosis. Endarterectomy might be of some benefit for participants with 50% to 69% symptomatic stenosis (moderate‐quality evidence) and highly beneficial for those with 70% to 99% stenosis (moderate‐quality evidence). |

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Systematic Review of Guidelines for the Management  of Asymptomatic and Symptomatic Carotid Stenosis  Anne L. Abbott, PhD, MBBS, FRACP; Kosmas I. Paraskevas, MD, PhD; Stavros K. Kakkos, MD, PhD; Jonathan Golledge, MB, BChir, BA, MA, MChir;  Hans-Henning Eckstein, MD, PhD; Larry J. Diaz-Sandoval, MD; Longxing Cao, MD, PhD; Qiang Fu, MD, PhD; Tissa Wijeratne, MD, FRACP; Thomas W. Leung, MD; Miguel Montero-Baker, MD; Byung-Chul Lee, MD, PhD; Sabine Pircher, BNutrDiet, MPH; Marije Bosch, PhD; Martine Dennekamp, PhD, MSc; Peter Ringleb, MD, PhD  August 31, 2015.  Abbott, A. L., Paraskevas, K. I., Kakkos, S. K., Golledge, J., Eckstein, H. H., Diaz-Sandoval, L. J., Cao, L., Fu, Q., Wijeratne, T., Leung, T. W., Montero-Baker, M., Lee, B. C., Pircher, S., Bosch, M., Dennekamp, M., & Ringleb, P. (2015). Systematic Review of Guidelines for the Management of Asymptomatic and Symptomatic Carotid Stenosis. Stroke, 46(11), 3288–3301. https://doi.org/10.1161/STROKEAHA.115.003390  <https://pubmed.ncbi.nlm.nih.gov/26451020/> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the  conclusions from the SR. | Moderate and severe (50%–99%) carotid artery stenosis is an important public health issue. This condition affects ≈10% of the general population by their 8th decade, and it causes ≈10% of all strokes. For many years, procedural management has been  commonly recommended for stroke prevention. However, important relatively recent discoveries should improve treatment decisions for patients with carotid stenosis. These include:   1. The 60% to 80% fall in stroke risk associated with asymptomatic carotid stenosis (ACS) with medical treatment alone (encouraging a healthy lifestyle and appropriate medication) since the start of the randomized trials of medical treatment alone versus additional carotid endarterectomy (CEA). This improved stroke prevention efficacy also has implications for better outcomes for patients with symptomatic carotid stenosis (SCS) given medical treatment, with or without additional CEA. 2. Stroke risk stratification studies of patients with ACS showing that transcranial embolus detection, degree of stenosis, plaque echolucency, and asymptomatic progression are not sufficiently powerful individually to identify asymptomatic patients likely to benefit from carotid procedures. Combinations of markers are most likely to provide clinically meaningful stroke risk stratification. 3. Falls in the risk of stroke or death associated with CEA for patients with ACS or SCS. 4. The significantly higher overall risk of stroke or death associated with carotid angioplasty/stenting (CAS) than with CEA. |
| Grade assigned to the **evidence** associated with the recommendation with the  definition of the grade | **Moderate** using GRADE scale.  Moderate: The authors believe that the true effect is   probably close to the estimated effect. |
| Provide all other grades and definitions  from the evidence grading system | **Very low:** The true effect is probably markedly different from the estimated effect  **Low:** The true effect might be markedly different from the estimated effect  **Moderate:** The authors believe that the true effect is probably close to the estimated effect  **High:** The authors have a lot of confidence that the true effect is similar to the estimated effect |
| Grade assigned to the **recommendation**  with definition of the grade | **Moderate** using GRADE scale.  **Moderate:** The authors believe that the true effect is  probably close to the estimated effect. |
| Provide all other grades and definitions  from the recommendation grading system | **Very low:** The true effect is probably markedly different from the estimated effect  **Low:** The true effect might be markedly different from the estimated effect  **Moderate:** The authors believe that the true effect is probably close to the estimated effect  **High:** The authors have a lot of confidence that the true effect is similar to the estimated effect |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Each guideline was checked for completeness in defining asymptomatic carotid stenosis (ACS) and symptomatic carotid stenosis (SCS) within the target populations for the degree of stenosis, method of quantifying stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET], European Carotid Surgery Trial [ECST], or other), and the timing and territory/laterality of any previous clinically defined strokes or transient ischemic attacks (TIA).  The authors included all guideline recommendations for routine practice use of CEA and CAS published from January 1, 2008, to January 28, 2015. To be considered a guideline, it had to include a recommendation covering carotid endarterectomy (CEA) and/or carotid artery angioplasty/stenting (CAS) and/or SCS, or both based on evidence.  The authors identified 34 guidelines meeting the inclusion criteria. These were sets of recommendations on CEA or CAS, or both for ACS or SCS, or both published between January 1, 2008, and January 28, 2015, in 41 separate documents from 23 different regions/countries (including 2 representing Europe and 5 the United States). They were written by 32 different groups in 6 languages (English, Chinese, Korean, Spanish, Dutch, and German). One group (American Heart Association/ American Stroke Association) published a guideline on carotid stenosis for men and women together and a separate one for women only; both were included in this study. |
| Estimates of benefit and consistency  across studies | Only 2 of 28 (7%) guidelines with procedural recommendations on ACS completely defined ACS according to degree of stenosis, method of determining degree of stenosis, and timing and territory of any previous stroke or TIA. Even then, in 1 case, the timing of any previous stroke or TIA (<6 months) was deduced from the definition of SCS. Three guidelines  contained no definition of ACS. Among the remaining  23 guidelines, degree of stenosis was always specified, and 1 distinct cutoff value was given (producing 2 stenosis ranges) for determining procedural use. 4 guidelines used different ranges of stenosis severity according to different recommended imaging techniques or procedures or the same treatment recommendations. In 2 guidelines, there were no recommendations for ACS of 50% to 60% or 69%, but there were recommendations for higher and lower degrees of ACS.  Where the method of measuring ACS was indicated, it was by the NASCET method in all cases.  Of 25 guidelines with CEA recommendations for patients with moderate or severe ACS (≈50%–99% by NASCET criteria), 24 (96%) endorsed CEA for average-CEA-risk patients by either recommending that it should be provided (7 guidelines) or that it may be provided (17 guidelines). In 6 guidelines, CEA endorsement for average-CEA-risk ACS was limited to patient subgroups: men with >80% stenosis, life expectancy >3 to 5 years, men <75 years, younger fitter women, high-medical-risk patients (not defined), high medical-risk because of progression of ACS, embolic signals on transcranial Doppler, history of contralateral TIAs, or silent ipsilateral cerebral infarction.  Most guidelines indicated that CEA or CAS were not recommended for mild ACS (<50%–70% by NASCET) or SCS (<50% by NASCET) by not including procedural recommendations or explicitly stating that these procedures should not be done or that medical treatment alone was indicated. |
| What harms were identified? | A potential harm could be that all the guidelines in this review with endorsements of CEA and CAS are based on trials of CEA versus medical treatment alone, with randomized patient data from 12 to 34 years ago. There was a lack of evidence on stroke risk stratification for ACS. |
| Identify any new studies conducted since  the SR. Do the new studies change the conclusions from the SR? | This is the most up-to-date review. |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

# 1a.4.2 What process was used to identify the evidence? 1a.4.3. Provide the citation(s) for the evidence.