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.

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 #: 1548 NQF Project: Surgery Endorsement Maintenance 2010

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR)

De.2 Brief description of measure: Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair who have at least one follow-up imaging study after 3 months and within 15 mos of EVAR placement that documents aneurysm sac diameter and endoleak status. This measure is proposed for individual providers.

1.1-2 Type of Measure: Process

De.3 If included in a composite or paired with another measure, please identify composite or paired measure N/A

De.4 National Priority Partners Priority Area: Population health, Safety

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.4 Measure Steward Agreement attached: Agreement With Measure Stewards_Agreement	A Y⊠ N□

Between_National Quality Forum (12-6-2010).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: Public reporting, Internal quality improvement Accountability, Payment incentive 	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 (if submission returned): 1) Is surveillance a suitable measure for public reporting? Is the time interval supported? 2) 1b.2: The item reports surveillance at 50% & 75% for two facilities; though is a measure of surveillance, would SC want information regarding follow up or outcome of the failure? 3) Is the information provided sufficient to test and replicate the measure in non-registry participating institutions? 4) Cost of participating in registry not provided. 5) 3a.3: notes that data collected since 2003 - Consider potential availability of information to allow interpretability by consumers as well as public reporting initiatives.	Met Y⊠ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s): Melinda Murphy	

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: Safety - prevention	
1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Patient/societal consequences of poor quality 1a.2	
1a.3 Summary of Evidence of High Impact: Despite the overall success rate of EVAR, there are multiple publications demonstrating the potential failure of endograft therapy. Wyss et al. just published a manuscript entitled "Rate and predictability of graft rupture after endovascular and open abdominal aortic aneurysm repair: data from the EVAR Trials4." The authors describe 27 ruptures that occurred in EVAR patients (in 848 treated) as compared to 0 ruptures in 594 patients treated with open surgery. Five ruptures occurred in the first 30 days after surgery. The risk of rupture increased in the setting of an identified problem (endoleak type 1, type 2 with sac expansion, type 3, migration or kinking). The authors concluded that few ruptures after EVAR seem to be spontaneous without complications identified during optimal surveillance.	1a C P M N

Brown and colleagues also published some concerning findings in regards to EVAR and initial anatomy5. Elective EVAR was performed in 756 patients. Over almost four years of follow-up, 179 serious graft complications occurred (rate 6.5 per 100 person years) and 114 reinterventions (rate 3.8 per 100 person years) were needed. The highest rate of complication was during the first 6 months. In addition, graft-related complication and reintervention rates were common after EVAR in patients with a large aneurysm. The data from these two publications stress the need for CT imaging within one year of EVAR.

Persistent type 2 endoleak treatment is controversial. But, persistent type 2 endoleak can lead to complications of EVAR therapy. Jones et al. identified 164 patients with a type 2 endoleak on the initial CT scan performed within 30 days of treatment6. The majority of these endoleaks resolved on follow-up imaging, but 33 persisted. Persistent type 2 endoleak was associated with an increased incidence of adverse outcomes, including aneurysm sac growth, the need for conversion to open repair, reintervention rate, and rupture in their paper. Therefore, these data suggest that patients with persistent type 2 endoleak (>6 months) should be considered for more frequent follow-up.

When can surveillance be minimized in the setting of possible EVAR failure? Houballah et al. described the rate of significant sac retraction after EVAR7. SSR was observed in 24.8% (92/371) of the patients after an average of 26 ± 21 months of FU. In this series, SSR was accurately predictive of a durable success after EVAR. It occurred mostly in patients with a favorable anatomy. But, the percentage of patients was low. This data also suggests that failure can occur in a large number of patients unless surveillance is performed. This surveillance must include assessmane of AAA sac diameter and determination of endoleak status by imaging (CT,MR or ultrasound).

Current Surveillance Paradigms

The goal of aneurysm repair, whether open or endovascular is to prevent rupture. With EVAR, there is an ongoing risk of endoleak and/or migration which can lead to re-pressurization of the residual aneurysm sac and renew the possibility of subsequent rupture. Therefore, post-EVAR surveillance is necessary for monitoring of these complications. Current recommendations for post-EVAR surveillance include contrasted CT scans and four view abdominal radiographs at 1, 6, and 12 months and then annually thereafter. These recommendations were derived from early clinical trials without substantial data. A recent trial looking at surveillance for a single device found that if at 30 days there was absence of endoleak, 92 % of those patients remained free of aneurysm related morbidity at 1 year and the 6 month surveillance studies did not correlate with any difference in 5 year freedom from aneurysm related morbidity. 8 As a result of their findings, the authors recommended continued aggressive surveillance for patients with endoleak present at 30 days but even in those without endoleak, a CT scan at one year was still recommended. In a separate study Go et al9 looked at the utility of the 6 month CT scan in those patients with a normal CT scan at 1 month. In the 130 people who underwent CT scan at 6 month only two were abnormal. However among those who did and did not undergo 6 month CT scan (n=332), 11 had abnormal CT scans at 1 year. Therefore they recommended a CT at 1 month and if normal, eliminating the 6 month CT, but continuing to obtain the 1 year CT. As stated previously, the goal of EVAR is to prevent aneurysm rupture. In a literature search study looking at rupture after EVAR, Schlosser et al10 identified 270 ruptures reported in the literature and found that the majority of them occurring within the first 3 years. As a result, they also concluded that surveillance should focus on the first few years post EVAR.

Although CTA is considered the "gold standard" for followup, patients with renal insufficiency cannot safely receive contrast for CTA, so endoleak status must be determined by duplex ultasound or dynamic MRA.

- **1a.4 Citations for Evidence of High Impact:** 1. Prinssen M, Verhoeven EL, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med. 2004 Oct 14;351(16):1607-18.
- 2. Greenhalgh RM, Brown LC, Kwong GP, et al. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet. 2004 Sep 4-10;364(9437):843-8.
- 3. Lederle FA, Freischlag JA, Kyriakides TC, et al. Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial. JAMA. 2009 Oct 14;302(14):1535-42.
- 4. Wyss TR, Brown LC, Powell JT, Greenhalgh RM. Rate and predictability of graft rupture after endovascular and open abdominal aortic aneurysm repair: data from the EVAR Trials. Ann Surg. 2010 Nov:252(5):805-12.
- 5. Brown LC, Greenhalgh RM, Powell JT, et al. Use of baseline factors to predict complications and reinterventions after endovascular repair of abdominal aortic aneurysm.

Br J Surg. 2010 Aug;97(8):1207-17.	
6. Jones JE, Atkins MD, Brewster DC, et al. Persistent type 2 endoleak after endovascular repair of abdominal aortic aneurysm is associated with adverse late outcomes. J Vasc Surg. 2007 Jul;46(1):1-8. Epub 2007 Jun 1.	
7. Houbballah R, Majewski M, Becquemin JP. Significant sac retraction after endovascular aneurysm repair is a robust indicator of durable treatment success. J Vasc Surg. 2010 Oct;52(4):878-83. Epub 2010 Jul 17.	
8. Sternbergh WC, Greenberg RK, Chuter AM, et al. Redefining Postoperative Surveillance after Endovascular Aneurysm Repair: Recommendations based on 5-year follow-up in the US Zenith Multicenter Trial. J Vasc Surg. 2008. 48:2, 278-285.	
9. Go MR, Barbato JE, Rhee RY et al. What is the Clinical Utility of a 6-month Computed Tomography in the Follow-up of Endovascular Aneurysm Repair Patients? J Vasc Surg. 47:6, 1181-1187.	
10. Schlosser FJV, Gusberg RJ, Dardik A, et al. Aneurysm Rupture after EVAR: Can the Ultimate Failure be Predicted? Eur J of Vasc Endo Surg. 37, 15-22.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: By ensuring follow-up within the first year after EVAR this measure will reduce the number of complications including rupture after EVAR placement and thus reduce morbidity and mortality after EVAR. The time window has been set at 15 months to allow for minor variation in when patients return for one year followup. The minimum time interval has been set as >3mo to insure that followup occurs beyond the typical 30-day followup point.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across	
providers: Non-published data for inappropriate endograft surveillance exists from two major medical centers. This data is in the process of being published in peer-reviewed journals. Both centers are high-volume, well-respected hospitals that care for many patients with abdominal aortic aneurysms. One center had a 50% rate of endograft surveillance and the other center had a compliance rate of 75%. This data demonstrate the need for more compliance with endograft surveillance.	
1b.3 Citations for data on performance gap: artiles are in press, have been peer reviewed by members of the SVS Measures Committee	
1b.4 Summary of Data on disparities by population group: None currently available. 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: None	M D
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): As explained above, surveillance is critical to determine need for reintervention, which is required in 15-20% of patients, to avoid subsequent AAA rupture and death. Incrasing sac size and endoleak are the best predictors of the need for reintervention. This measure is designed to report compliance with recommended surveillance studies after EVAR.	
1c.2-3. Type of Evidence: Cohort study, Evidence-based guideline, Expert opinion	1c
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): As described above, endoleak and sac dia increase are the best predictors of subsequent need for	P M N

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reintervention and late rupture.	
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): Guidelines of Society for Vascular Surgery	
1c.6 Method for rating evidence: Expert opinion.	
1c.7 Summary of Controversy/Contradictory Evidence: The only controversy about surveillance after EVAR is which type of imaging modality should be used at exactly which interval. We have eliminated this controversy by including any of the imaging modalities at a broad time frame of 3-15 months. There is no debate that some imaging is required in every case during this interval.	
1c.8 Citations for Evidence (<i>other than guidelines</i>): Wyss TR, Brown LC, Powell JT, Greenhalgh RM. Rate and predictability of graft rupture after endovascular and open abdominal aortic aneurysm repair: data from the EVAR Trials. Ann Surg. 2010 Nov;252(5):805-12.	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): Followup imaging surveillance is mandatory after EVAR (See citation below for pages)	
1c.10 Clinical Practice Guideline Citation: Clinical practice guidelines for endovascular abdominal aortic aneurysm repair: written by the Standards of Practice Committee for the Society of Interventional Radiology and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association.	
Walker TG, Kalva SP, Yeddula K, Wicky S, Kundu S, Drescher P, d'Othee BJ, Rose SC, Cardella JF; Society of Interventional Radiology Standards of Practice Committee; Interventional Radiological Society of Europe; Canadian Interventional Radiology Association.	
J Vasc Interv Radiol. 2010 Nov;21(11):1632-55 1c.11 National Guideline Clearinghouse or other URL: None	
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 <u>USPSTF system</u> , also describe rating and how it relates to USPSTF): NA	
1c.14 Rationale for using this guideline over others: There are no competing guidelines.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y_ N_
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (<u>evaluation criteria</u>)	Eval Rating
2a. MEASURE SPECIFICATIONS	

NQ	F #15
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 18 years or older undergoing EVAR who have at least one follow-up CTA, duplex, or MRA of the abdomen and pelvis after 3 months but within 15 months of placement, assessing for sac size and endoleak	-
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Lifetime for provider reporting	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):	
A registry that includes surgical details or CPT procedure codes is required to identify patients for numerator inclusion, and this registry must link the original operation with outpatient followup information. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) registries records such information. Patients undergoing EVAR, recorded in the registry (CPT codes 34800, 34802, 34803, 34804, 34805, 34825, 34826, 34900) who undergo CTA, MRA, or duplex imaging completed after 3 months but within 15 months of the original procedure with documentation of aneurysm sac size and presence or absence of endoleak as recorded in an appropriate registry during a subsequent physician office visit that is linked to the original procedure.	
2a.4 Denominator Statement (Brief, text description of the denominator - target population being	
measured): Patients 18 years or older undergoing EVAR for abdominal aortic aneurysms excluding patients who died prior to follow-up within 15 months postoperatively.	
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): Lifetime for provider reporting	
2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions): A registry that includes surgical details or CPT procedure codes is required to identify patients for denominator inclusion. This registry must also collect followup data based on an outpatient visit that links to the original EVAR procedure and documents aneurysm sac size and endoleak status based on an outpatient imaging study (CT, MR or ultrasound). The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) registries record this information. CPT codes that define the initial cohort of EVAR operations include: 34800, 34802, 34803, 34804, 34805, 34825, 34826, and 34900.	
2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): Death of patient as recorded in registry before followup imaging could be obtained during the first 15 months after EVAR. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of	

New England (VSGNE) registries record this information.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator,* including all codes, logic, and definitions):

Patients who died before imaging could be obtained within 15 months of original operation, as recorded in an appropriate registry that links outpatient followup information with the original EVAR procedure.

2a.11 Stratification Details/Variables (All information required to stratify the measure including th	e
stratification variables, all codes, logic, and definitions):	
NA ·	

?a.12-13 Risk Adjustment T	vpe: N	o risk ac	diustment necessary
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2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method): None needed for this process measure.	
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 = Higher score 2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps): Patients undergoing EVAR who have CTA, MRA, or duplex with AAA sac diameter and endoleak status recorded in registry after 3 months but within 15 months of EVAR / (All patients undergoing EVAR - EVAR patients who have died before imaging could be obtained within 15 months of EVAR)	
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): NA	
2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Registry data	
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.): Society for Vascular Surgery Vascular Quality Initiative Registry New Vascular Study Group of New England Registry	
2a.26-28 Data source/data collection instrument reference web page URL or attachment: Attachment Endo_AAA_Repair_v1.9-634367278132053234.xls	
2a.29-31 Data dictionary/code table web page URL or attachment: Attachment EVAR defs v.01.09-634367278260803234.doc	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested) Clinicians: Individual, Clinicians: Group, Can be measured at all levels	
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Ambulatory Care: Office	
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, a random sample of 20 patients with one year followup was selected and outpatient office records were reviewd.	
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.	2b C P M N
2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test	N

conducted): The key variables for this measure and testing results were:	
 Correct procedure (EVAR of abdominal aortic aneurysm) performed. Kappa =1.0 Imaging (MR, CT, or duplex) obtained with endoleak status and sac diameter recorded recorded. Kappa = 1.0. 	
3. Death within 15 months before imaging could be obtained. Kappa=1.0.	
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): The validity testing of imaging obtained between 3 and 15 months after EVAR used the the imaging report document as the gold standard. Correctness of operation type compared the operative report as the gold standard with the progress note in the medical record. We compared the rates with published literature.	
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):	
100% agreement was found between the imaging document and the outpt record and the registry data that documented endoleak status and aneurysm sac size. Aneurysm sac size measurements were accurate (56.5 mm imaging report, 56.6 mm registry (mean, no significant difference). 100% agreement was also found between the procedure type reported in the operative note and that recorded in the daily progress notes.	2c C□
We could not find recorded data in the literature regarding the rate of performance of imaging within 15 months of EVAR, but VSGNE data analysis shows that this is recorded for 85% of living patients after EVAR, which ideally should be 100%.	P M N
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s): Patients who died within 15 months before imaging cannot be included in the calculation since no imaging data are available.	
2d.2 Citations for Evidence: face validity	
2d.3 Data/sample (description of data/sample and size): In VSGNE there were 1,135 primary EVAR procedures performed from 2003-2009.	
2d.4 Analytic Method (type analysis & rationale): Calculation of measure rates	24
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): Of the 1135 EVAR patients, 87% had followup, but only 67% had followup between 3-15 months postop. Of patients who had followup, across 9 centers, the median rate of imaging for sac diameter and endoleak was 90%, with an interquartile range of 87% to 91%. Among 41 surgeons, the median rate of imaging for sac diameter and endoleak was 93%, with an interquartile range of 86% to 100%.	2d C P M N NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Not needed for this process measure.	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):	20
2e.3 Testing Results (risk model performance metrics):	2e C P M
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA _

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): see above 2,d,5	C P M N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): no other data sources available	24
2g.2 Analytic Method (type of analysis & rationale):	2g C□ P□ M□
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N NA
2h. Disparities in Care	26
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): NA	2h C□ P□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	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	N
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). <u>If not used for QI</u> , state the plans to achieve use for QI within 3 years):	3a C□
Vascular Study Group of New England www.vsgne.org Data have been successfully collected in this quality registry since 2003, and reports provided to	P ☐ M ☐

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, Ql project): Semi-annual meetings of providers in VSGNE	
3a.6 Results (qualitative and/or quantitative results and conclusions): Benchamrk reports of this process 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.	
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 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?	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: 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: 	3c C P M N
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i> ?	NA
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met?	3
Rationale:	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 C□
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	P M N

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
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 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. Although imaging may be done in other institutions, it is the responsibility of the treating surgeon to monitor EVAR patients long term because of the potential need for reintervention to prevent AAA rupture. Thus, this information (a report of the imaging study) needs to be available in the surgeons office. Thus, there is little chance for error in this measure.	4d C P M N
4e. Data Collection Strategy/Implementation	l
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: We have found followup data for patients in the VSGNE registry in >85% of patients undergoing EVAR, at a mean time interval of 12.8 months after surgery. We believe that this quality measure will further improve	
the rate of followup, which should be 100%.	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Hospitals participating in the SVS VQI or VSGNE registries have no additional costs to report this measure.	
4e.3 Evidence for costs:	4e C□ P□ M□
4e.4 Business case documentation:	Ν
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, <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-
(10) No. Start use) effect it integrate is untested and only engible for time inflicted endorsement.	limited
Steering Committee: Do you recommend for endorsement? Comments:	Y □ N □ A □
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner)	
OU.1 Measure Steward (intellectual Froperty 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 N/A

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.

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): 03/27/2011

Vascular Quality Initiative - Endo AAA Repair

Last Name	Fire	st Name		Middle Initial
Date of Birth		dical Record Number		Social Security Number
General Information		aloui record reamber		Coolai Coolai Yilainoo
Patient Data				
Zip/Postal Code			Gender	male; female
Ethnicicty	☐ Not Hispanic or Latino; ☐ Hispanic or Lat	tino	Race	☐ White; ☐ Black or African American; ☐ Asian;
Height	inches or cm			☐ More than 1 race; ☐ American Indian or Alaskan Native;
Weight	lbs or kg			☐ Native Hawaiian or other Pacific Islander; ☐ Unknown/other
Admission Data				
Visit code (not required)				
Admit Date			Discharge Date	
Surgeon			Surgery Date	
Discharge Status	☐ home; ☐ rehab unit; ☐ pursing hom	ne;	Does the patient have	□ no; □ yes
	dead; other hospital; skilled nur	rsing facility	Medicare Part B?	□ 10, □ yes
If dead, date of death				
Tranfered from?	no; hospital; rehab unit			
Demographics				
Smoking	never; prior (>1 yr); current (v	vithin yr)	Hypertension	□ no; □ yes (>=140/90 or history)
Diabetes	none; diet; oral medi; in	nsulin	Beta blockers	☐ no; ☐ op day only; ☐ pre-op 1-30 days; ☐ chronic >30 days; ☐ no-intolerant
CAD symptoms	none; hx MI but no sx; stable and	gina; unstable angina or MI < 6 mos	CABG/PTCA	☐ none; ☐ <5yr; ☐ >=5yrs ago
CHF	☐ none; ☐ asymp, hx CHF; ☐ mild; ☐	severe	COPD	☐ no; ☐ not treated; ☐ on meds; ☐ on home oxygen
Dialysis	no; functioning transplant; on dia	alvsis	Creatinine	mg/dl OR µmol/L
Stress Test	normal; (+) ischemia; (+) MI;		Pre-adm Living	home; nursing home
	_	_	•	
ASA Class	1 normal/healthy;		Pre-op Hemoglobin	g/dl OR g/L
	5 moribund, not expected to survive w/o op	at to me;		
Previous arterial	э польши, пос сересы не загите и/о ор			
Bypass	☐ no; ☐ yes		CEA	□ no; □ yes
Aneurysm Repair	☐ no; ☐ yes		PTA/Stent	no; yes
Major Amp	☐ no; ☐ yes			
Pre-Op Medications				
ASA	☐ no; ☐ yes; ☐ intolerant ☐		Plavix	☐ no; ☐ yes; ☐ intoleran(☐
Statin	no; yes; intolerant			
History				
Family History of AAA	no; yes		Prior Aortic Surgery	none; AAA; SAAA; bypass; other
Ejection Fraction	☐ <30%; ☐ 30-50%; ☐ >50%; ☐ n	not done; unknown	Maximum AP AAA Diam	mm
Iliac Aneurysm	no; unilateral; bilateral		Maximum Diameter	mm
Urgency	elective; symptomatic; ruptured	ı		
Fill out the fields below if Ur	 ' '			
Lowest pre-intubation BP	Systolic- mmHg		Mental Status	normal; disoriented; unconscious
Cardiac Arrest	no; yes		Time: Symptoms to Incision	<u></u>
Time: Admission to Incision	hours		Abdomen Explored	no; yes
Procedure				
Unfit for Open AAA Repair		Infit for gen. anesthesia no;	<u> </u>	Anesthesia local; regional; general
Graft Type	☐ AneurRx; ☐ Excluder; ☐ Talent; ☐ Zenith; ☐ Powerlink; ☐ Endiprant;		bi-iliac;	Total Procedure Time minutes
	☐ Aorfix; ☐ Unifit; ☐ Zenith └─w Profile;		uni-illac len; 🔲 aorto-aortic	
	Aptus; Cother:	oends on Graft Configuration:		Depends on Graft Configuration:
Graft Body Diameter		Right Limb Diameter mm		Left Limb Diameter mm
Hypogastric Intentionally		dynogastric I Inintentionally		Skin Pren
Covered	none; unilateral; bilateral	Covered none;	unilateral; bilater	al iodine; chlor+iodine;
Arterial Injury		f Arterial Injury: none; ntervention none;	stent/PTA; stent-gra	all 3
Endoleak at Completion	_ : :: ::	Conversion to Open no;	yes;	If yes, Reason (If yes, also complete an Open unable to deploy appropriately;
	□ branch(type II); □ mid graft(type III); □ indeterminate			AAA Form)
Indinated Contract	ml	Crystalloid	ml	
Iodinated Contrast	<u> </u>	· —	units (during the procedure)	
EBL Heart Bata	P	PRBC (in OR)	(==:::: g #10 p10000010)	
Heart Rate				
On Arrival in OR	bpm	lighest intra-op	bpm	

Vascular Quality Initiative - Endo AAA Repair

Procedure (continued)					
Concomitant Procedure					
Hypogastric Coil Pre-Op Femoral Endarterectomy Thromboembolectomy	□ no; □ unilateral; □ bilateral □ no; □ yes □ no; □ yes	Hypogastric Coil Intra-Op Fem-Fem Bypass Iliac Angioplasty	□ no; □ unilateral; □ bilateral □ no; □ yes □ no; □ yes	Unplanned Graft Extension Ilio-Femoral Bypass Iliac Stent Placement	□ no; □ yes□ no; □ yes□ no; □ yes
Renal PTA/Stent	no; yes	Other Arterial Reconstruction	☐ no; ☐ planned; ☐ arterial injury		
Post-Op Data					
Time to Extubation	in OR;	Vasopressors Req. Post-Op	no; yes	ICU Stay	days
Myocardial Infarction	no; troponin only; EKG or clinical	Dysrhythmia (new)	☐ no; ☐ yes	CHF	☐ no; ☐ yes
Respiratory	no; pneumonia; ventilator	Change of Renal Function	□ none; □ creat. increase > 0.5 mg/dl (44.2 μmol/L); □ temp. dialysis; □ permanent dialysis	Leg Ischemia/Emboli	no; yes, rx w/o surgery; amputation
Bowel Ischemia	□ no; □ treated conservatively; □ return to OR	Wound Complication	□ no; □ superficial separation/infection; □ return to OR	Transfusion # Units PRBC	# of units
Return to OR	□ n □ yes	If yes, Bleeding	☐ no; ☐ yes		
Stroke	none; minor; major				
Discharge Medications					
ASA	☐ no; ☐ yes; ☐ intolerant ☐	Statin	☐ no; ☐ yes; ☐ intolerant ☐		
Plavix	☐ no; ☐ yes; ☐ intolerant ☐	Beta Blocker	☐ no; ☐ yes; ☐ intolerant ☐		
Peri-Op Antibiotic Ordered					
Start <1hr Pre-op	no; yes; no, for medical reason	Stop <24hr Post-op	no; yes; no, for medical reason		
1st-2nd Gen Cephalosporin	no; yes; no, for medical reason				

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Vascular Quality Initiative - Endo AAA Repair 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 Visil 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;
Beta Blocker	☐ No; ☐ Yes; ☐ Intolerant	Statin	No; Yes; Intolerant		Intolerant
Endo AAA Repair					
Current Max AAA Diameter Number New Interventions Conversion to Open Repair	mm	Current Endoleak	No; Attachment site(type I); Indeterminate	Branch(type II);	graft(type III);
Performed for:	ino, inc.,	ii yes, Date			
Endoleak	□ No; □ Yes;	Sac Growth	□ No; □ Yes	Migration	No; Yes;
Infection	□ No; □ Yes;	Symptom Rupture	□ No; □ Yes		
Other Op Related to Endo	□ No; □ Yes;				

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ENDOVASCULAR AAA DEFINITIONS- v.01.09

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

Pre-op Data

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 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 discontinued prior to surgery it should be coded = 0.

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

Family history of AAA: First-degree relative (parents, sibling, aunt, uncle, child)

Prior Aortic Surgery: AAA = infrarenal aneurysm repair. SAAA = Suprarenal aneurysm repair. Bypass = A-1 or A-F for occlusive disease. Other = endarterectors only or other.

Ejection Fraction: Left ventricular ejection fraction (%), by Echo, nuclear scan, or cath estimate, within 6 months

Maximum AP AAA diameter: Largest AP diameter. If AP not specified, use largest diameter. If multiple imaging modalities, use most accurate in following hierarchy: CT>MRI>Echo>arteriogram.

Iliac aneurysm: Iliac diameter > 1.5 cm. Use maximum diameter of largest iliac artery, common or internal.

Procedure

Urgency: Symptomatic = surgery within 24 hours of pain and/or tenderness without rupture. Ruptured = CT or angio evidence of rupture.

Unfit for open AAA repair: Endovascular repair performed because patient was considered too high risk by surgeon for open repair, i.e., mandatory endovascular repair.

Unfit for general anesthesia: Local or regional anesthesia used because patient was considered too high risk by surgeon or anesthesiologist for general anesthesia, i.e., mandatory regional/local anesthesia.

Anesthesia: Local includes IV sedation. Regional = epidural or spinal

Graft Diameter: Body size = diameter of most proximal portion of graft. Limb size = diameter of distal most graft or extension.

Hypogastric covered: Intentionally = planned prior to procedure to treat distal aneurysm extent. Unintentionally = inadvertent extension of graft not necessary to treat distal aneurysm extent.

Endoleak: Attachment site [type I] = proximal or distal attachment site leak. Branch [type II] = retrograde filling of sac via lumbars, IMA, or accessory renals. Mid-graft [type III] = filling of sac via leak at component overlap sites or fabric tear.

Conversion to open: If yes, give reason. If yes, use Open AAA form also.

Total procedure time: From incision to closure.

Concomitant Procedure

Arterial Injury: Requiring intervention or resulting in occlusion. Use 5=multiple if > 1 site.

Ruptured AAA Repairs Only

Lowest pre-intubation BP: After arrival at hospital (lowest prior to intubation)

Mental status: Normal alert and oriented; Disoriented to person, place, or time.

Abdomen explored: To evacuate hematoma but not to repair rupture (use OPEN AAA Repair form for conversion to open repair.)

Post-op Data

Time to extubation: In OR; otherwise, beginning upon departure from OR

Vasopressors required post-op: Dopamine≥5mcg/kg/min, or neosynephrine, levophed, epinephrine, vasopressin, or other IV vasopressor during hospitalization. ICU stay: Any portion of 24 hours = 1 day.

Transfusion: Total of all PRBC transfusions pre-op, intra-op, and post-op during this hospitalization.

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.

Respiratory: Pneumonia = Lobar infiltrate on CXR and pure growth of recognized pathogen or 4+ growth of recognized pathogen in presence of mixed growth. Ventilator = required after initially extubated (if applicable).

Change renal function: New increase in creatinine of 0.5mg/dl. New dialysis includes peritoneal dialysis, hemodialysis, and hemo-filtration. (Applies to dialysis only if not required pre-op.)

Leg ischemia/emboli: Loss of previously palpable pulses, loss of previously present Doppler signals, decrease of >0.15 in ABI, or blue toe.

Bowel ischemia: Diagnosed by colonoscopic evidence of ischemia, bloody stools in a patient who dies prior to colonoscopy or laparotomy, or presumptive diagnosis with conservative treatment.

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.

1st-2nd 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.