National Quality Forum

Measure Comment Report for SURGERY ENDORSEMENT MAINTENANCE 2010, PHASE II

Comments received as of 10/27/2011

ID#	Council/ Public	Commenter	Comment	Response	Topic
1247	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	The Society for Vascular Surgery (SVS), a professional medical society representing over 3500 vascular surgeons who are dedicated to the prevention and cure of vascular disease, respectfully offers the following comments on the National Quality Forum Surgical Consensus Standards Endorsement Maintenance 2010 Phase II Draft Report. Measures Recommended for Full Endorsement NQF Measure #1519 – Statin Therapy at Discharge after Lower Extremity Bypass •SVS supports NQF's recommendation for full endorsement of this measure. NQF Measure #1540 – Postoperative Stroke or death in Asymptomatic Patients undergoing Carotid Endarterectomy •SVS supports NQF's recommendation for full endorsement of this measure. NQF Measure #1543 – Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS) SVS supports NQF's recommendation for full endorsement of this measure. SVS appreciates the opportunity to submit these comments and looks forward to working with NQF regarding these recommendations. Please feel free to contact Lindsey Adams, Health Policy Manager, Society for Vascular Surgery at 202-787-1231 or ladams@vascularsociety.org, if we can provide further information.	Measure Developer Response: These comments were submitted by SVS. Steering Committee Response: No action required.	General

ID#	Council/ Public	Commenter	Comment	Response	Topic
1250	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	Measures Recommended for Harmonization NQF Measures #1523 and #1534 SVS expresses concern over NQF's recommendation for harmonization with competing measures for the following reasons: •SVS anticipates that these measures will be recommended for harmonization with the competing AAA measures proposed by AHRQ. SVS has repeatedly expressed concern regarding the measures proposed by AHRQ. Despite AHRQ's recent decision to separate their mortality measures into separate measures for elective and emergent, and open surgical and endovascular repair, concerns remain regarding the risk adjustment and statistical models associated with the AHRQ measures. ◦The AAA mortality risk adjustment model should be tested prospectively for accuracy. •SVS continues to have serious misgivings regarding the validity and accuracy of the risk adjustment model associated with the AHRQ measures as it remains currently written. Additionally, we are troubled by the process with which it was developed and we have voiced these concerns to AHRQ and previously to the National Quality Forum (NQF). •Thus, SVS strongly supports development of accurate outcomes measures for AAA using clinical evidence, but we believe that the AHRQ mortality measures are conceptually flawed and operationally defective.	These comments were submitted by SVS. AHRQ was given the opportunity to respond to these comments. Their response is included below. Measure Developer Response: The Steering Committee recommended AHRQ meet with SVS to harmonize or blend measures concerning AAA, and AHRQ remains open to the recommendation. To facilitate a productive dialogue, we encourage SVS make a specific recommendation for an enhanced risk adjustment model using either administrative or clinical data. In the meantime, at the request of the Steering Committee, the measure was revised to report separate mortality rates and volume by procedure type (open vs. endovascular) and condition (ruptured vs. un-ruptured). The model performs as well as other endorsed measures on standard metrics of calibration and discrimination, and has been publically available to the research community for evaluation for almost 10 years. AHRQ views the AHRQ QIs as a dynamic set of measures. In that regard, AHRQ has evolved the measures over time with input from NQF and a variety of organizations. Steering Committee Response: The committee is charged with responsibility to evaluate related measures in terms of harmonization. NQF has provided direction in Guidance for Measure Harmonization dated December 30, 2010. As part of that guidance, it notes that efforts to address harmonization are required for consideration for NQF endorsement and that measures should not be recommended for endorsement unless measures are harmonized or lack of harmonization has been justified. To that end, measure developers are asked to collaborate on harmonization and bring the results of that collaboration to NQF through the Steering Committee for endorsement consideration.	General

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1251	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	NQF Measures #1523 and #1534 •We are encouraged that NQF is considering modifications to AAA quality measures that would differentiate between emergent vs. elective AAAs and open vs. endovascular procedures and would include risk adjustment. We will continue to actively work with NQF in the development of these measures, which should more accurately reflect patients' outcomes. We will also continue to work with NQF regarding how best to publicly report these measures. SVS thanks NQF for noting our concerns. SVS appreciates the opportunity to submit these comments and looks forward to working with NQF regarding these recommendations. Please feel free to contact Lindsey Adams, Health Policy Manager, Society for Vascular Surgery at 202-787-1231 or ladams@vascularsociety.org, if we can provide further information.	These comments were submitted by SVS. Steering Committee Response. NQF looks forward to updated information regarding use of the measures in PQRS and a timeframe from SVS regarding publication of the data by CMS as well as the status of SVS request to participating providers and hospitals to publish the measures on the SVS public website.	General

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1196	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We do not support this measure being used on its own because it appears to be topped out (mean value > 95%), which diminishes its importance. Rather, it should be combined with measures #126 and 127 in a patient-centered (all-or-none) composite measure. The patient needs to have all 3.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: While the mean is relatively high, please note the distribution as it is important as well. If endorsement is removed, there might be a subsequent decline in compliance. We appreciate your suggestion regarding the all-or-none composite measure. However, please note that the denominator of #126 (i.e., all cardiac procedures) differs from the denominator of #117 & 127 (i.e., isolated CABG only). In addition, the latter two are included in the all-or-none medication domain of NQF #696 The STS CABG Composite Score, which was recently endorsed by NQF. Steering Committee Response: While the mean value is 95.1 percent, the distribution of values for the STS population drops sharply indicating there is opportunity for improvement with this measure as a stand alone. While the measure was not submitted for consideration as part of a composite, endorsement as a stand alone measure does not preclude its reporting with, or inclusion in a composite with, other measures.	0117: Beta blockade at discharge
1255	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support the harmonization of the CMS and Society of Thoracic Surgeons (STS) measure.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This harmonization did not take place. It is STS's understanding that CMS does not have a measure that is related or similar to #117. Steering Committee Response: See response at ID# 1196 above.	0117: Beta blockade at discharge

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1275	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	Highmark supports measure.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: No action required	0117: Beta blockade at discharge
1282	CON	Debra L. Ness, MS; National Partnership for Women & Families	On behalf of the National Partnership for Women & Families, I feel that this measure should not be used on it's own given that performance on it is over 95%. It would be more useful if combined with measures #126 and #127, into a patient-centered, all-or-none composite measure on the processes that a patient should receive when presenting with the condition represented by these measures.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1196 Steering Committee Response: See response at ID# 1196 above	0117: Beta blockade at discharge
1197	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We do not support this measure being used on its own because it appears to be topped out (mean value > 90%), which diminishes its importance. Rather, it should be combined with measures #117 and 127 in a patient-centered (all-or-none) composite measure. The patient needs to have all 3.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1196 Steering Committee Response: See response at ID# 1196 above	0126: Selection of prophylaxis for cardiac surgery patients
1256	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support this measure but recommend ongoing review and changes to measure specifications to ensure that the measure is consistent with changes to the evidence base.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment STS agrees. Steering Committee Response: No action required at this time.	0126: Selection of prophylaxis for cardiac surgery patients

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1276	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support this measure but recommend frequent assessment to assure compliance with current evidence based guidelines.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. STS agrees. Steering Committee Response: No action required at this time.	0126: Selection of prophylaxis for cardiac surgery patients
1284	CON	Debra L. Ness, MS; National Partnership for Women & Families	Please see my comment under #117.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1196. Steering Committee Response: See response at ID# 1196 above	0126: Selection of prophylaxis for cardiac surgery patients
1198	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We do not support this measure being used on its own. Rather, it should be combined with measures #126 and 127 in a patient-centered (all-or-none) composite measure. The patient needs to have all 3.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1196. Steering Committee Response: See response at ID# 1196 above	0127: Preoperative beta blockade
1258	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support the harmonization of the Society of Thoracic Surgeons (STS) and CMS measure.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: See response at ID# 1196 above	0127: Preoperative beta blockade

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1277	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support this measure harmonized with CMS and STS measures.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: See response at ID# 1196 above	0127: Preoperative beta blockade
1285	CON	Debra L. Ness, MS; National Partnership for Women & Families	Please see my comment under #117.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1196. Steering Committee Response: See response at ID# 1196 above	0127: Preoperative beta blockade
1199	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	This measure appears to be topped out at 95% and should be put in reserve.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: While the mean is relatively high, please note the distribution as it is important as well. Steering Committee Response: While the mean is just below 95 percent, variation exists with compliance rates as low as 78.9 percent indicating opportunity for improvement that resulted in recommendation for endorsement in active status.	0134: Use of IMA in CABG
1259	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	While we support this measure, we suggest that this measure be reevaluated for placement in reserve status in the near future as performance on this measure has potentially topped out.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see STS's response to comment #1199 Steering Committee Response: See response at ID# 1199 above.	0134: Use of IMA in CABG

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1278	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support this measure.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: No action required.	0134: Use of IMA in CABG
1286	CON	Debra L. Ness, MS; National Partnership for Women & Families	We believe this measure should be put into the "reserve" category, given that performance appears to be at 95%.	STS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: While the mean is relatively high, please note the distribution as it is important as well. Steering Committee Response: See response at ID# 1199 above.	0134: Use of IMA in CABG
1200	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this measure being applied at the ASC level.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. Steering Committee Response: No action required	0264: Prophylactic IV timing
1257	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support this measure but recommend ongoing review and changes to measure specifications to ensure that the measure is consistent with changes to the evidence base.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. We agree that routine reassessment of measures is important. The ASC Quality Collaboration reviews its measures on an annual or as needed basis to ensure they remain consistent with the evidence base. Modifications are made as needed. Steering Committee Response: No action required at this time.	0264: Prophylactic IV timing

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1279	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support this measure and request frequent assessment to assure adherence to current evidence based guidelines.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. We agree that routine reassessment of measures is important. The ASC Quality Collaboration reviews its measures on an annual or as needed basis to ensure they remain consistent with the evidence base. Modifications are made as needed. Steering Committee Response: No action required required at this time.	0264: Prophylactic IV timing
1201	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this outcome measure for ASCs. We question whether this measure will generate the most valuable information possible. For example, this measure only gives a uni-dimensional picture of hospitalizations around ambulatory care, but does not tell the why of such outcomes. To be meaningful, this measure needs further finessing.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. We agree that additional insight into the reasons for transfer/admission is desirable. The ASC Quality Collaboration hopes to have access to additional data collection resources in the future that would allow further refinement of the measure to include this valuable information. Response: Support for this measure within the Steering Committee was based on the intent to improve the ASC reporting rate of less than 50 percent of eligible ASCs. Additionally, the steward has provided information that it will select a vendor in third quarter 2011 and begin collecting subpopulation performance data for this measure within three months thereafter.	0265: Hospital transfer/ admission

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1238	HPL	Thomas James, III, MD; Humana, Inc.	We are pleased to be able to comment on this measure; and are supportive of it. We agree with Dr. Hopkins comments, recognizing that ambulatory surgical centers have had few measures until now. We would anticipate that on future reviews, these ASC measures will be more sophisticated to recognize subpopulations and risk factors for transfer.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. We agree that additional information on risk factors and possible population disparities is desirable. The ASC Quality Collaboration hopes to have access to additional data collection resources in the future that would allow further refinement of the measure to include this valuable information. Steering Committee Response: See response at ID#1201 above.	0265: Hospital transfer/ admission
1260	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	While we support this measure, as it expands the number of measures for Ambulatory Surgical Centers (ASC), we recommend including a specified timeframe for the measure such as number of patients admitted within in a certain period (e.g., 30-day) to strengthen the meaningfulness of this measure.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their input and would like to clarify that measure does include a specified timeframe, which is from the time of admission through the time of discharge from the ASC. There has been interest in expanding that timeframe to 24 to 72 hours after discharge, and we are currently in the process of developing and testing a measure that would evaluate this delayed outcome. ASCs are in contact with the patients they serve for a very limited time; detection of delayed outcomes in ambulatory patient populations presents challenges to accurate and complete data collection that must be addressed. Steering Committee Response: The developer has committed to develop a measure that would capture "Ambulatory surgery center (ASC) admissions experiencing a hospital admission in the 24 hour period following discharge from the ASC." Until such time as that measure is fully developed and tested, the Steering Committee supports continued endorsement of Measure 0265 to avoid diminished effort toward improved reporting.	0265: Hospital transfer/ admission

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1280	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support this measure but recommend incorporating a specific timeframe for hospital transfer/admissions such as within 30 days.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their input and would like to clarify that measure does include a specified timeframe, which is from the time of admission through the time of discharge from the ASC. There has been interest in expanding that timeframe to 24 to 72 hours after discharge, and we are currently in the process of developing and testing a measure that would evaluate this delayed outcome. ASCs are in contact with the patients they serve for a very limited time; detection of delayed outcomes in ambulatory patient populations presents challenges to accurate and complete data collection that must be addressed. Steering Committee Response: See response at ID# 1260 above.	0265: Hospital transfer/admission
1287	CON	Debra L. Ness, MS; National Partnership for Women & Families	While we support the endorsement of this measure, we would also like to note the importance of understanding why such transfers and hospitalizations from an ASC setting occurred. To be truly meaningful, consumers need to know the reasons -- positive or negative -- for the action that this measure is calculating. Thus, we hope to see further work done on this measures and others like it, to make the data reported more useful to consumers.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure. We agree that additional information on the reasons for transfer/admission is desirable. The ASC Quality Collaboration hopes to have access to additional data collection resources in the future that would allow further refinement of the measure to include this valuable information. Steering Committee Response: See response at ID# 1201 above.	0265: Hospital transfer/admission
1202	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We are supportive of the AHRQ PQI 2 measures because it's a good measure for delivery/payment programs that require management of general populations, such as ACOs.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: No action required.	0273: Perforated appendix

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1237	HPL	Thomas James, III, MD; Humana, Inc.	Humana is pleased to have the opportunity to comment. This measure raises several concerns for us. First, in most communities simple appendicitis is managed surgically as outpatient surgery.so those who present late with perforation will represent a greater percentage of the discharges in the well-managed health systems than in those where simple appendicitis admissions dilute the sample. As a result better performing centers may have a higher percentage of discharges with perforated appendicitis. This trend toward ambulatory appendectomy may not have been a significant factor when this measure was first developed. Secondly, the denominator is for a Metro area or county making this measure one not useful for an ACO or any other organization that does not manage a county	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: As noted later in Dr. James' comment, this AHRQ Quality Indicator (QI) has a geographical area (e.g. county, state) as the unit of analysis. So the measure is designed with the intent to measure ready access to care and the quality of care in an area such as a county. AHRQ refers to this type of measure as an "area-level" AHRQ QI. The measure was previously endorsed as an area level measure and AHRQ is seeking to maintenance endorsement at this level of analysis. Steering Committee Response: The measure provides information about access and quality within a geographic area, rather than at institution level. A significant performance gap exists representing an opportunity for improvement in patient care and cost avoidance.	0273: Perforated appendix
1261	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support but recommend **expanding the scope** of this measure to include the out-patient setting as patients frequently receive care in an inpatient setting because they have a perforated appendix.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This AHRQ Quality Indicator (QI) has a geographical area (e.g. county, state) as the unit of analysis. So the measure is designed with the intent to measure ready access to care and the quality of care in an area such as a county. AHRQ refers to this type of measure as an "area-level" AHRQ QI. The measure was previously endorsed as an area level measure and AHRQ is seeking to maintain endorsement at this level of analysis. Steering Committee Response: See response at ID# 1237 above.	0273: Perforated appendix

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1281	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We appreciate the opportunity to comment. As other commenters have recommended, **expanding this measure to the ambulatory setting** would be of benefit. Additionally, the measure denominator includes only cases of appendicitis and we **suggest adding perforated appendix to the denominator** to capture those patients that perforated in the outpatient setting and were subsequently admitted.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The denominator does include both perforated appendix codes from the numerator for such cases: 5400 Acute appendicitis with generalized peritonitis (which includes perforation) 5401 Acute appendicitis with peritoneal abscess Steering Committee Response: See response at ID# 1237 above.	0273: Perforated appendix
1203	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level, noting that STS measures are recommended for both facility and clinician levels, with which we agree	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: It could be applied at the physician level. Because this measure was specifically developed for use in facilities, the specifications require submission at the facility level. Steering Committee Response: The Committee is sensitive to a number of issues that should be considered as organizations determine at what level of analysis measures should be structured and reported. The Committee believes it appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues. Based on the developer response, the developer has been asked to provide information regarding what changes and testing are needed to include clinicians in the level of analysis and if none, to do so in future maintanence of the measure.	0284: Surgery on beta blocker during perioperative period

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1239	HPL	Thomas James, III, MD; Humana, Inc.	Unlike the STS measures where the data source is a standard registry, this measure lists "electronic administrative dat/claims, paper medical record/flow sheet" This opens the measure for inconsistencies in data capture unless there is a standardized data acquisition protocol and one that is not too resource intensive.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The charts are only identified through administrative data. Vendors or facilities use the claims submitted to determine which charts will be abstracted, according to ICD-9-CM and ICD-9-PCS codes. The information documented in the medical record drives the coding assigned, so there should not be inconsistencies between the identification of the record and the actual abstraction of the data. Steering Committee Response: Use of specified codes and detailed abstraction protocol provides standardized data acquisition.	0284: Surgery on beta blocker during perioperative period
1262	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support the harmonization of the CMS and Society of Thoracic Surgeons (STS) measure.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment Steering Committtee Response: In its consideration of harmonization, the Steering Committee determined that this measure's focus made it unique and removed it from further harmonization discussion.	0284: Surgery on beta blocker during perioperative period
1283	HPL	Deborah J. Donovan Mills, RHIA, CPHQ; Highmark, Inc.	We support harmonization of this measure with STS and CMS measurement.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. Steering Committee Response: See response at ID# 1262 above.	0284: Surgery on beta blocker during perioperative period

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1288	CON	Debra L. Ness, MS; National Partnership for Women & Families	We support this measure, and urge that it be specified to apply to the clinician level.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. It could be applied at the physician level. Because this measure was specifically developed for use in facilities, the specifications require submission at the facility level. Steering Committee Response: See response at 1203 above.	0284: Surgery on beta blocker during perioperative period
1204	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this as a good measure of intermediate outcome.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. Steering Committee Response: No action required.	0300: Cardiac patients with postop glucose
1232	HPR	Denise Graham; Association for Professionals in Infection Control and Epidemiology	The Association for Professionals in Infection Control and Epidemiology (APIC) continue to support this measure.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. Steering Committee Response: No action required.	0300: Cardiac patients with postop glucose

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1235	HPR	Joseph P. Drozda, Jr., MD; American College of Cardiology	The level of glucose control in acute care scenarios including the postoperative setting has recently been the subject of some controversy. This includes concerns over the adverse impact of hypoglycemia on patient outcomes. For that reason, ACC would not support glucose control as a performance measure at this time.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We will discuss including a glucose range (to avoid hypo- or hyper- glycemia) in the measure with the Technical Expert Panel that supports this measure. Steering Committee Response: The Steering Committee will review the response and the plan and discuss it with CMS to determine appropriate action when the revisions are submitted in the future.	0300: Cardiac patients with postop glucose
1240	HPL	Thomas James, III, MD; Humana, Inc.	While the STS Guidelines for Glucose Management During Adult Surgery (Ann Thoracic Surgery 2009; 87:663-9) demonstrate the value to the patient of avoiding hyperglycemia, Dr. Drozda makes an excellent point about the risks of hypoglycemia. We would prefer to have the measure developers include a glucose range in the measure to avoid hypo- or hyper-glycemia	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We appreciate the feedback and will take this suggestion to the Technical Expert Panel that supports this measure. Steering Committee Response: See response at ID#1235 above.	0300: Cardiac patients with postop glucose
1263	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support controlled postoperative blood glucose in the 18 to 24 hour timeframe after Anesthesia End Time for cardiac surgery patients. While hyperglycemic patients are included, the measure could be strengthened to include hypoglycemic patients by adding low to high end control range.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We will discuss including a glucose range (to avoid hypo- or hyper- glycemia) in the measure with the Technical Expert Panel that supports this measure. Steering Committee Response: See response at ID#1235 above.	0300: Cardiac patients with postop glucose

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1325	SPI	Steven Brotman; AdvaMed	AdvaMed supports the use of the 180 mg/dL blood glucose threshold. This is in line with published guidelines that have been developed based on evidence demonstrating clinical benefits for both diabetic and non-diabetic patients with glucose levels less than or equal to 180 mg/dL. In addition, AdvaMed applauds the proposal to eliminate the use of the POD 6AM timeframe. This is an arbitrary timeframe and does not account for the various times of the day that surgical procedures can end. However, there is concern with how the measure proposal considers hospital non-compliance. Currently, the proposed measure states that if more than a single glucose measurement value >180 mg/dL is collected between 18 and 24 hours after Anesthesia End Time, the hospital fails. AdvaMed believes that any measure should not discourage the use of protocols and/or new technologies that can provide more insight into the challenges of glycemic control in cardiac surgery patients. Specifically, future protocols and technologies that may be designed to identify glucose level trends by capturing multiple and even continuous measurements within a short period of time may be clinically helpful but may be avoided due to the perceived concern that more measurements have a greater likelihood of a reading above 180 mg/dL. **An alternative method to avoid this unintended consequence is to use the average glucose level if more than one glucose measurement is obtained during the 18-24 hour timeframe.**	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The proposed update to the performance measure does not require that all blood sugars between 18-24 hours after the end of cardiac surgery be below 180 mg/dL. If there is a reported blood sugar above 180 mg/dL, a hospital can still pass the measure by responding appropriately and documenting a subsequent blood sugar that is less than 180 mg/dL. That said, the Society of Thoracic Surgeons recommends that the blood sugar in cardiac surgery patients be maintained consistently below 180 mg/dL. In the absence of automated technology to continuously record the minute-by-minute blood sugar in most hospitals, it is not feasible from a data collection standpoint to require hospitals to either calculate the average blood glucose or to collect all blood sugar levels between 18-24 hours into a data collection tool. However the measure could be modified in the future to allow a hospital to record the average blood sugar between 18 and 24 hours IF they document that they are using an automated continuous glucose monitoring device. Steering Committee Response: The measure will be evaluated at future maintenance cycles in light of the evidence and technologies available at those reviews.	0300: Cardiac patients with postop glucose

ID#	Council/ Public	Commenter	Comment	Response	Topic
1205	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	Performance measurement data should be collected efficiently and measures should be used where they promise to continually improve health outcomes. We do not support this measure because, unlike most process of care measures, there is a simple one-time solution for achieving compliance: removal of razors from the operating room. Once that is done, compliance has been shown to be 100%. This measure should be retired rather than continuing to take up space in the ever-expanding measure universe.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS is retaining the measure but has decided to suspend data collection requirements to address comments and concerns about the retirement of accountability measures. Steering Committee Response: Evidence supports shaving in select circumstances. To balance the need to reduce the number of measures in active endorsement against having measures available for use if needed, the Steering Committee recommends the measure be endorsed and placed in reserve status.	0301: Patients with hair removal
1289	CON	Debra L. Ness, MS; National Partnership for Women & Families	We believe that this measure no longer meets the high bar set by NQF endorsement, reflected by the fact that CMS will no longer be collecting data on inappropriate hair removal in the Inpatient Quality Reporting program. There is a simple, one-time solution for achieving 100 % compliance on this measure, which is to remove razors from the operating room. We feel that retiring this measure would make room for higher-bar measures that are desperately needed.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS is retaining the measure but has decided to suspend data collection requirements to address comments and concerns about the retirement of accountability measures. Steering Committee Response: See response at ID# 1205 above.	0301: Patients with hair removal
1206	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this outcome measure. We also support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level, noting that STS measures are recommended for both facility and clinician levels, with which we agree.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: See response at ID#1290 below.	0339: RACHS-1 ped heart mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1241	HPL	Thomas James, III, MD; Humana, Inc.	Since this is a facility level measurement of volume and has no description of risk adjustment or diagnostic subpopulations we have difficulty is seeing how beneficial this measure is. For that reason we do not support it . There would be greater value if there were listings of the volumes of such cases as extra-cardiac diagnoses, intra-cardiac, and complex cases that the developer could define. We do appreciate AHRQ's willingness to pair this measure with mortality to become a paired measure.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The NQF endorsed measure #0339 is indeed a risk adjusted mortality measure. The RACHS-1 risk adjustment systems used in this measure was developed, and continues to be maintained, by Children's Hospital Boston. Steering Committee Response: The Steering Committee has determined that this risk-adjusted measure, which represents harmonization of 0339 and PCS-021-09, is a strong measure. Reported as a pair with Measure 0340, it provides important information about pediatric heart surgery. The committee encourages the developers to continue to refine the measure based on the evidence and testing and would welcome a future measure specified for application at the clinician level.	0339: RACHS-1 ped heart mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1290	CON	Debra L. Ness, MS; National Partnership for Women & Families	While we support this measure, we question why it is not specified for application at the clinician level.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The pediatric quality indicator (PDI) module was aimed at populating the measures set with metrics at either the hospital level or area level (e.g. county, state). At the present time is it unknown as to the performance of the measure at the clinician level. AHRQ has yet to have the opportunity to test the application of the measure at this level. Steering Committee Response. The Committee is sensitive to a number of issues that should be considered as organizations determine at what level of analysis measures should be structured and reported. The Committee believes it appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues.	0339: RACHS-1 ped heart mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1207	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this outcome measure. We also support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level, noting that STS measures are recommended for both facility and clinician levels, with which we agree.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: When expert clinical panels were assembled for the development of the Pediatric Quality Indicator module of measures, the evidence was reviewed in regard to the volume - outcomes relationship at the hospital level. AHRQ has yet to have the opportunity to review the volume - outcome relationship at the clinician level. Steering Committee Response: The Steering Committee has determined that the measure, when paired with 0339 provides important information about pediatric heart surgery. The Committee is sensitive to a number of issues that should be considered as organizations determine at what level of analysis measures should be structured and reported. The Committee believes it appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues. As appropriate, the committee would welcome a future measure specified for application at the clinician level.	0340: Ped heart volume
1236	HPR	Joseph P. Drozda, Jr., MD; American College of Cardiology	Whereas it is clear that a certain level of experience, prior and ongoing, is required for surgeons and surgical teams to acquire and maintain their skills, defining the precise level of such experience (as is done with performance measures) required at the individual program and surgeon level remains difficult. For this reason, we cannot support a volume metric as a stand-alone performance measure. Perhaps it can be used in a bundle of measures. The concern is that volume measures are too easy to obtain and too easy to use as surrogates for quality—particularly as sine qua non requirements. This can lead to the unintended consequences of reduced access to services and reduced competition.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: In the development of the measure and the recent updating of the litature review, there is a clear volume - outcome relationship at the hospital level. In the initial NQF endorsement of the measure as well as in the measure maintenance, AHRQ has indicated the pediatric heart surgery volume measure (#0340) is a measure to be paired with the pediatric heart surgery mortality measure (#0339). Steering Committee Response: The measure was initially endorsed to be reported as a pair with 0339. The recommendation is that it be continued to be reported as a pair. The developer commits to this.	0340: Ped heart volume

ID#	Council/ Public	Commenter	Comment	Response	Topic
1264	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	While historically surgery volume has served as a proxy measure for quality, the value of this measure is unclear given the current availability of more specific measures of quality such as complication rate, readmissions etc.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: In the development of the measure and the recent updating of the litature review, there is a clear volume - outcome relationship at the hospital level. In the initial NQF endorsement of the measure as well as in the measure maintenance, AHRQ has indicated the pediatric heart surgery volume measure (#0340) is a measure to be paired with the pediatric heart surgery mortality measure (#0339). Steering Committee Response: See response at ID# 1236 above.	0340: Ped heart volume
1291	CON	Debra L. Ness, MS; National Partnership for Women & Families	While we support this measure, we question why it is not specified for application at the clinician level.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: When expert clinical panels were assembled for the development of the Pediatric Quality Indicator module of measures, the evidence was reviewed in regard to the volume - outcomes relationship at the hospital level. AHRQ has yet to have the opportunity to review the volume - outcome relationship at the clinician level. Steering Committee Response: See response at ID# 1207.	0340: Ped heart volume
1208	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We question why this measure uses hierarchical risk modeling (HRM) when other mortality measures in the set were deemed appropriate with standard logistic regression? HRM is known to reduce sensitivity to detect outliers. Otherwise, this is a good outcome measure.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The measure can be calculated to produce a risk adjusted rate and a smoothed rate. HRM is used in the smoothed rate, but not the risk adjusted rate. The user has the option to use either rate. Steering Committee Response: The availability of optional methods for risk adjustment are deemed acceptable.	0351: Death among inpatients with treatable complications

ID#	Council/ Public	Commenter	Comment	Response	Topic
1292	CON	Debra L. Ness, MS; National Partnership for Women & Families	While we support this outcome measure, we do question why there is continued reliance on hierarchical risk modeling (HRM), when standard logistic regression modeling is considered appropriate for other mortality measures in this set? We have long advocated against HRM, due to its reduced ability to show adequate distribution among the results, and its tendency to reduce all results to the mean.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developr Response: The measure can be calculated to produce a risk adjusted rate and a smoothed rate. HRM is used in the smoothed rate, but not the risk adjusted rate. The user has the option to use either rate. Steering Committee Response: See response at ID# 1208 above.	0351: Death among inpatients with treatable complications
1209	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this outcome measure. We also support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the **clinician** level, noting that STS measures are recommended for both facility and clinician levels, with which we agree.	Children's Hospital of Philadelphia (CHOP) was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: FTR has always been a hospital measure. (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeding to avoid an FTR is complex, and needs a systems approach. Directing the blame at a specific physician would seem counterproductive; (3) other measures may better assess physician quality, but this is outside of the research I have conducted in developing the FTR metric. Steering Committee Response: Failure to rescue in the hospital setting involves many systems and professional disciplines making it infeasible to apply the measure at the clinician level.	0352: Failure to rescue in-hospital mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1243	HPL	Thomas James, III, MD; Humana, Inc.	We support this measure as one that we have found is one consumers and patients feel is important. We do feel that measuring at the facility level is appropriate because of the matrix management of complicated measures by multiple physicians, it may not be appropriate to attribute a case to one doctor. A facility level measure does encourage a systems approach to management. We would **prefer to see if there were a way to capture DNR orde**rs so that hospitals would not be penalized for patient preferences at end of life	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We agree that FTR should be reported at the hospital level, not the physician level. There are many factors that may aid in improving FTR that are not necessarily controlled by a single physician. As for DNR status, we published a paper in Medical Care in 2005 (Tabak YP, Johannes RS, Silber JH, Kurtz SG, Gibber EM: Should do-not resuscitate status be included as a mortality risk adjustor? The impact of DNR variations on performance reporting. Med Care 2005; 43:658-666. PMID: 15970780). In this paper we showed that variation in the way DNR is obtained will lead to bias in hospital rankings if included in risk adjustment. The problem is that as of 2005, and probably still true today, we do not uniformly collect and obtain DNR status, so it allows hospitals to potentially game the system (at worst) or introduces bias regarding DNR policy (at best). Our sense is that until there are uniform systems in place ACROSS hospitals to determine how and when DNR is used, we are best off not using it. For FTR, where a decision was already made to perform surgery, we make the assumption that with adequate adjustment pre-operatively, and with consistent coding of comorbidities and complications, the pre-operative DNR status will sort similarly across hospitals. Until we can institute uniform policies regarding DNR, we do not see a better solution. Steering Committee Response: The Steering Committee agrees that at present use of DNR status as an exclusion could result in hospital differences due to DNR process differences.	0352: Failure to rescue in-hospital mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1265	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We recommend this measure is most appropriate for measuring hospital performance. We also support harmonization of this measure with the similar pediatric AHRQ measure.	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: I am not sure there is a pediatric FTR measure. Sometimes the AHRQ measure has been applied to pediatrics, but this has not been very successful. Pediatric measures are different from adult measures, and I am not sure what harmonization would achieve, as each needs to be developed separately to be most appropriate. The present FTR measure is for adults. Steering Committee Response. A review of the AHRQ pediatric quality indicators does not reveal a pediatric failure to rescue measure. The AHRQ measure of death among patients with serious treatable complications does not apply to the pediatric population.	0352: Failure to rescue in-hospital mortality
1293	CON	Debra L. Ness, MS; National Partnership for Women & Families	Again, we support this measure but question why it can't be specified to the clinician level?	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: FTR has always been a hospital measure. (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeding to avoid an FTR is complex, and needs a systems approach. Directing the blame at a specific physician would seem counterproductive; (3) other measures may better assess physician quality, but this is outside of the research I have conducted in developing the FTR metric. Steering Committee Response: See response at ID# 1209.	0352: Failure to rescue in-hospital mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1210	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this outcome measure. We also support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level, noting that STS measures are recommended for both facility and clinician levels, with which we agree.	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: FTR has always been a hospital measure. (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeding to avoid an FTR is complex, and needs a systems approach. Directing the blame at a specific physician would seem counterproductive; (3) other measures may better assess physician quality, but this is outside of the research I have conducted in developing the FTR metric. Steering Committee Response: See response at ID# 1209.	0353: Failure to rescue 30-day mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1245	HPL	Thomas James, III, MD; Humana, Inc.	Our comments for NQF#0352 also apply to this measure, which further encompasses the concepts of post-discharge care coordination.	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We agree that FTR should be reported at the hospital level, not the physician level. There are many factors that may aid in improving FTR that are not necessarily controlled by a single physician. As for DNR status, we published a paper in Medical Care in 2005 (Tabak YP, Johannes RS, Silber JH, Kurtz SG, Gibber EM: Should do-not resuscitate status be included as a mortality risk adjustor? The impact of DNR variations on performance reporting. Med Care 2005; 43:658-666. PMID: 15970780). In this paper we showed that variation in the way DNR is obtained will lead to bias in hospital rankings if included in risk adjustment. The problem is that as of 2005, and probably still true today, we do not uniformly collect and obtain DNR status, so it allows hospitals to potentially game the system (at worst) or introduces bias regarding DNR policy (at best). Our sense is that until there are uniform systems in place ACROSS hospitals to determine how and when DNR is used, we are best off not using it. For FTR, where a decision was already made to perform surgery, we make the assumption that with adequate adjustment pre-operatively, and with consistent coding of comorbidities and complications, the pre-operative DNR status will sort similarly across hospitals. Until we can institute uniform policies regarding DNR, we do not see a better solution. Steering Committee Response: See response at ID#1243.	0353: Failure to rescue 30-day mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1294	CON	Debra L. Ness, MS; National Partnership for Women & Families	Again, we support this measure but question why it can't be specified to the clinician level?	CHOP was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: FTR has always been a hospital measure. (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeding to avoid an FTR is complex, and needs a systems approach. Directing the blame at a specific physician would seem counterproductive; (3) other measures may better assess physician quality, but this is outside of the research I have conducted in developing the FTR metric. Steering Committee Response: See response at ID# 1209 above.	0353: Failure to rescue 30-day mortality

ID#	Council/ Public	Commenter	Comment	Response	Topic
1211	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	Performance measurement data should be collected efficiently and measures should be used where they promise to continually improve health outcomes. We do not support this measure because, unlike most process measures of care, there is a simple solution for achieving compliance: removal of razors from the operating room. Once that is done, compliance is at 100%. Finally, although ASC admissions who perform their own hair removal take some of the control out of provider's hands, there should be a way to account for which of these self-performers are told of the benefit of non-razor hair removal. For that reason, we question the wholesale exclusion of ASC admissions who perform their own hair removal.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their input, but do not agree with the assertion that this process can be managed in the manner suggested. There are circumstances in which the use of razors is appropriate (e.g. for preoperative removal of scrotal hair), therefore providers must manage the use of razors according to best practices. The idea of measuring the number of self-performers informed of the benefits of non-razor hair removal is an interesting one, and we will take this into consideration as we consider future revisions to the measure. However, we do not agree that excluding patients who perform their own hair removal invalidates the measure; we believe it sharply focuses the measure on processes the provider is able to control during their care of the patient. Steering Committee Response: The Steering Committee's support for continuing this measure in active status was based on the intent to increase the number of ASCs that report the measure to both drive and assess accomplishment of the measure. Absent evidence to the contrary, razors continue to be an acceptable method for preoperative removal of scrotal hair and scalp hair in select circumstances. The exclusion of patients who shave themselves does not diminish capability of the measure to assess ASC performance. In a measure assessing the relationship of method of hair removal to post-operative infection, self-shaving would be an appropriate consideration. As specified, the measure aligns with the similar hospital measure - #0301.	0515: Ambulatory patients with hair removal

ID#	Council/ Public	Commenter	Comment	Response	Topic
1266	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support the expansion of this measure to ASCs and recommend harmonization with the measure#0301 including exclusions.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their support of this measure and their input. The measure has been harmonized with other related measures to the extent practical and feasible in light of 1) the differences in the inpatient and outpatient surgical settings, patient populations and procedures performed, and 2) the importance of streamlining data collection to ensure usability in the ASC setting. Steering Committee Response: The measure is aligned with #0301.	0515: Ambulatory patients with hair removal
1295	CON	Debra L. Ness, MS; National Partnership for Women & Families	Please see my comment on measure 0301, Surgery Patients with Appropriate Hair Removal. I echo that comment here, because it applies in the ASC setting as well.	ASC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank the commenter for their input, but do not agree that current performance levels in the inpatient setting can be assumed to exist in the outpatient setting. The level of adherence to this infection prevention practice in the outpatient setting is unknown, and the available ASC data is subject to sample bias. We believe data for this measure should be collected and reported until broader measurement and reporting results in a determination of ASC performance levels. Once the data is in hand, apprporiate steps can be taken as necessary. Hospital inpatient performance levels indicate what may be achieved through measurement and reporting; the measurement and reporting process should be allowed to unfold in the outpatient surgical setting as well. We also disagree with the assertion that this process can be managed in the manner suggested. There are circumstances in which the use of razors is appropriate (e.g. for preoperative removal of scrotal hair), therefore providers must manage the use of razors according to best practices. Steering Committee Response: See response at ID# 1211 above.	0515: Ambulatory patients with hair removal

ID#	Council/ Public	Commenter	Comment	Response	Topic
1212	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We do not support this measure being used on its own. Rather, it should be combined with measure #528 and the already-endorsed measure of cessation of prophylactic antibiotic administration in a patient-centered (all-or-none) composite measure. The patient needs to have all 3.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This measure is collected as part of a bundle of measures. A chart is selected according to procedure codes and is then abstracted for ALL SCIP measures. Steering Committee Response: The measure assesses an important care process. While the measure was not submitted for consideration as part of a composite, endorsement as a stand alone measure does not preclude its reporting with, or inclusion in a composite with, other measures.	0527: Prophylactic received within 1 hour
1233	HPR	Denise Graham; Association for Professionals in Infection Control and Epidemiology	The Association for Professionals in Infection Control and Epidemiology (APIC) continue its support of this measure.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. Steering Committee Response: No action required.	0527: Prophylactic received within 1 hour
1296	CON	Debra L. Ness, MS; National Partnership for Women & Families	We strongly suggest that this measure be combined with measure #528, and the already-endorsed measure "Cessation of Prophylactic Antibiotic Administration" to create a patient-centered composite measure on use of prophylactic antibiotics in surgical settings.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This measure is collected as part of a bundle of measures. A chart is selected according to procedure codes and is then abstracted for ALL SCIP measures. Steering Committee Response: See response at ID# 1212 above.	0527: Prophylactic received within 1 hour

ID#	Council/ Public	Commenter	Comment	Response	Topic
1214	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We do not support this measure being used on its own. Rather, it should be combined with measure #527 and the already-endorsed measure of cessation of prophylactic antibiotic administration in a patient-centered (all-or-none) composite measure. The patient needs to have all 3.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This measure is collected as part of a bundle of measures. A chart is selected according to procedure codes and is then abstracted for ALL SCIP measures. Steering Committee Response: See response at ID# 1212 above	0528: Prophylactic selection
1234	HPR	Denise Graham; Association for Professionals in Infection Control and Epidemiology	The Association for Professionals in Infection Control and Epidemiology (APIC) continue its support of this measure.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: CMS appreciates the comment. Steering Committee Response: No action required.	0528: Prophylactic selection
1267	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	The measure as currently specified seems too prescriptive and relies on a specific type of antibiotic used for compliance which can pose challenges if the guidelines change.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The measure specifications are based on several guidelines and therefore have a variety of recommendations, not a single class of antimicrobials. OFMQ note: This comment seems applicable to the PCPI measure that recommends a 2nd generation cephalosporin only. Steering Committee Response: The measure is supported by the evidence. The measure developer is responsible for ongoing monitoring of the evidence and providing updates as the evidence evolves.	0528: Prophylactic selection

ID#	Council/ Public	Commenter	Comment	Response	Topic
1297	CON	Debra L. Ness, MS; National Partnership for Women & Families	We strongly suggest that this measure be combined with measure #528, and the already-endorsed measure "Cessation of Prophylactic Antibiotic Administration" to create a patient-centered composite measure on use of prophylactic antibiotics in surgical settings.	CMS OK was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This measure is collected as part of a bundle of measures, but a composite measure of antibiotic administration (timing and selection) will be reviewed for consideration. CMS is willing to participate in harmonization efforts with other stakeholders. Steering Committee Response: See response at ID# 1212 above	0528: Prophylactic selection
1213	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	This is a prescription measure that does not generate the most valuable information possible. We encourage NQF to replace this measure with one that looks at health outcomes and whether treatment recommended at discharge is adhered to by patients. Also, the extent of linkage to outcomes is not clear.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreciates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response. The focus of the measure was determined to be important and is guideline based and performance rate is at 79 percent. NQF will continue to seek outcome measures that can supplement or supplant process measures.	1519: Statin therapy after LEB

ID#	Council/ Public	Commenter	Comment	Response	Topic
1242	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	SVS supports NQF's intent of providing superior vetting and endorsement of surgical quality measures. SVS continues to strive to be a leader in the area of surgical quality and therefore offers the following recommendations and comments for consideration at this time: Measures Recommended for Full Endorsement NQF Measure #1519 – Statin Therapy at Discharge after Lower Extremity Bypass •SVS supports NQF's recommendation for full endorsement of this measure.	These comments were submitted by SVS. Steering Committee Response: No action required.	1519: Statin therapy after LEB
1249	HPL	Thomas James, III, MD; Humana, Inc.	This is a process measure rather than an outcome measure, which would be preferable. However if there is a gap in care, then we would support this measure until an outcome measure could be developed.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreciates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: See response at ID#1213 above.	1519: Statin therapy after LEB

ID#	Council/ Public	Commenter	Comment	Response	Topic
1268	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support this measure for which clinical guidelines already exist. The burden to health plans could be reduced through the use of claims data for calculating the measure.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreciates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: Comment appreciated.	1519: Statin therapy after LEB
1298	CON	Debra L. Ness, MS; National Partnership for Women & Families	We do not support this measure, and feel that it would be much more meaningful to have a measure that looks at health outcomes for patients with LEB, and whether patients are adhering to the treatments recommended at discharge. As currently specified, this measure does not generate what we would consider meaningful information, and it is unclear how strongly this process is linked to outcomes.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: See response at ID# 1213 above.	1519: Statin therapy after LEB

ID#	Council/ Public	Commenter	Comment	Response	Topic
1215	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this as a good outcome measure. It would be more useful, however, if it were reported in categories reflecting the amount of improvement that the patient experiences.	AAO was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Academy appreciates your support of this important outcome measure. The scientific literature does not currently support categories that reflect the amount of improvement in visual function. Based on the literature, the Academy has proposed the following method to define improvement: Improvement in visual function is defined by the quantitative scale used in the VF-8R survey instrument pre and post surgery. The VF-8R uses a Rasch model based on Item Response Theory, which is based on item difficulty in relationship to an individual's ability and weighs the overall score accordingly, providing a gain in precision. The function scale is from 0-100, with 0 indicating the lack of ability to perform any of the daily activities and 100 indicating full capability of performing the daily activities included in the survey. Thus, any difference between the pre-operative and post-operative scores on the VF-8R would indicate an improvement in functional activities. The average difference found between preoperative and post-operative assessment on the VF-8R was 15.39 (Standard error = 2.66). In the literature, there have been two studies looking at the clinically important differences for the VF-14 index. One study found that the minimal clinically important difference was 15.57; another study found that the minimally clinically important difference was 5.5. Steering CommitteeResponse: With additional experience and evidence, categories reflecting amount of improvement may prove possible. The developer is encouraged to continue evolution of the measure as evidence emerges.	1536: Cataracts-Improv. in visual function

ID#	Council/ Public	Commenter	Comment	Response	Topic
1252	HPL	Thomas James, III, MD; Humana, Inc.	We support this measure, based upon work through the work of the Cataract Patient Reported Outcomes Team, AHRQ and the Academy This is the start of more Patient Reported Outcomes Measures, which may be difficult to obtain but get to the real determiner of the outcomes of care--the patient	AAO was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We agree. Thank you for your support. Steering Committee Response: No action required.	1536: Cataracts-Improv. in visual function
1269	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	In general, measures of patient functional status can serve as useful quality indicators. However, this measure poses certain challenges as there appear to be no guidelines defining meaningful levels of improvement in patient status. It would be important to establish a threshold of “improvement” to make this measure more objective.	AAO was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Academy agrees that measures of patient functional status are essential to assessing quality. Improvement in visual function is defined by the quantitative scale used in the VF-8R survey instrument pre and post surgery. The VF-8R uses a Rasch model based on Item Response Theory, which is based on item difficulty in relationship to an individual's ability and weighs the overall score accordingly, providing a gain in precision. The function scale is from 0-100, with 0 indicating the lack of ability to perform any of the daily activities and 100 indicating full capability of performing the daily activities included in the survey. Thus, any difference between the pre-operative and post-operative scores on the VF-8R would indicate an improvement in functional activities. The average difference found between preoperative and post-operative assessment on the VF-8R was 15.39 (Standard error = 2.66). In the literature, there have been two studies looking at the clinically important differences for the VF-14 index. One study found that the minimal clinically important difference was 15.57; another study found that the minimally clinically important difference was 5.5. Steering Committee Response: See response at ID# 1215 above.	1536: Cataracts-Improv. in visual function

ID#	Council/ Public	Commenter	Comment	Response	Topic
1216	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this as a good outcome measure.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: No action required.	1540: Postop stroke or death undergoing carotid endart.
1230	HPR	Christopher White, MD, FSCAI; The Society for Cardiovascular Angiography and Interventions	SCAI recommends endorsement of this measure. Our comments have been submitted to the National Quality Forum.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: No action required.	1540: Postop stroke or death undergoing carotid endart.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1244	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	SVS supports NQF's intent of providing superior vetting and endorsement of surgical quality measures. SVS continues to strive to be a leader in the area of surgical quality and therefore offers the following recommendations and comments for consideration at this time: Measures Recommended for Full Endorsement NQF Measure #1540 – Postoperative Stroke or death in Asymptomatic Patients undergoing Carotid Endarterectomy •SVS supports NQF's recommendation for full endorsement of this measure.	These comments were submitted by SVS. Steering Committee Response: No action required.	1540: Postop stroke or death undergoing carotid endart.
1270	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	The intent of this measure seems to be unclear. The measure would be more meaningful if either the current scope is broadened to include all adverse outcomes such as post-operative AMI and not just death, or if the measure scope is limited to only neurovascular complications.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: The Steering Committee opined that carotid endarterectomy may be over utilized in asymptomatic patients and that **the** measure would be useful in assessing that possibility. It suggests that, in future updates to the measure, SVS consider inclusion of additional adverse outcomes including myocardial infarction. SVS has noted that it will request that this and other of its measures be included in PQRS data which it expects CMS to publish in the near term.	1540: Postop stroke or death undergoing carotid endart.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1185	P	Jon George, MD; Deborah Heart and Lung Center	It is absolutely imperative that Carotid Surgery be held to the same standard as Carotid Artery Stenting with strict follow up of neurological outcomes post-procedure. This is analogous to performing a follow up test to confirm adequate completion of a procedure.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: Comment appreciated.	1543: Postop stroke or death undergoing CAS
1217	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support this as a good outcome measure.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: No action required.	1543: Postop stroke or death undergoing CAS

ID#	Council/ Public	Commenter	Comment	Response	Topic
1246	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	SVS supports NQF's intent of providing superior vetting and endorsement of surgical quality measures. SVS continues to strive to be a leader in the area of surgical quality and therefore offers the following recommendations and comments for consideration at this time: Measures Recommended for Full Endorsement NQF Measure #1543 – Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS) •SVS supports NQF's recommendation for full endorsement of this measure.	These comments were submitted by SVS. Steering Committee Response: No action required.	1543: Postop stroke or death undergoing CAS
1271	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	The intent of this measure seems to be unclear. The measure would be more meaningful if either the current scope is broadened to include all adverse outcomes such as post-operative AMI and not just death, or if the measure scope is limited to only neurovascular complications.	SVS was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Society for Vascular Surgery (SVS) appreciates all comments provided in response to SVS-owned measures. SVS feels our initial application covered all concerns raised during the public comment period, and believe these concerns were well addressed in the significance section of our applications. SVS appreicates the time and input of those who took time comment on the measures, and looks forward to working with NQF in the future to further improve our measures in anyway possible. Steering Committee Response: See response at ID# 1270	1543: Postop stroke or death undergoing CAS

ID#	Council/ Public	Commenter	Comment	Response	Topic
1189	P	William Martin, III, MD; American Association of Orthopaedic Surgeons	Risk Adjustment Vulnerable Populations: The AAOS believes more work needs to be done on risk adjustment in order to avoid the unintended consequence of denying care to the most vulnerable patients. The AAOS urges NQF to further develop a means for risk adjusting for the wide variation in patient characteristics. Socioeconomic Status: Specifically, the AAOS believes socioeconomic status (SES) should be included in the risk-adjustment models because low-SES patients are known to be at higher risk for post-operative complications and readmissions, and not including SES in the models could result in low-SES patients being denied much needed quality-enhancing treatments like THA and TKA. While the relationship between readmissions and quality of care is complex, income and socioeconomic status have been shown to play a role in risk of readmission for post-operative complications. SES is usually measured by level of education, income, occupation, or a composite of these dimensions. A patient's life circumstances are important factors in outcome determinations. Researchers involved in analyses of risk-adjusted outcomes and costs have suggested the need for a SES adjustment for patient populations, in addition to traditional risk-adjustment variables.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The goal of outcomes measurement is to identify variation in the quality of health care so that hospitals can implement measures to improve patient outcomes. Variation in quality associated with population characteristics, such as SES, may be indicative of disparities in the quality of the care provided to vulnerable populations, and risk adjusting for these factors would obscure these disparities. It is a national health priority to bring the outcomes for low SES patients to that of the level of all patients. If vulnerable populations, including low SES patients, are not receiving care that is of similar quality to that of the general population, we want to illuminate that difference. Furthermore, outcomes for low SES patients can be influenced by the health care system. Per the NQF's measure evaluation criteria, risk models should not "obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender." Steering Committee Response: The goal of both AAOS and CMS, with respect to the issue of low SES patients appears to be to ensure these patients have equal access to appropriate care. As noted by CMS, the ability to report disparities is important, including those related to vulnerable populations such as low SES. NQF looks forward to seeing this data reported within the next three years. As NQF continues to develop guidance related to the many aspects of measure development, it welcomes Member and public suggestions related to risk adjustment.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1218	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We question why this measure uses hierarchical risk modeling (HRM) when other mortality measures in the set were deemed appropriate with standard logistic regression? HRM is known to reduce sensitivity to detect outliers. Otherwise, it would be a good outcome measure.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We use HGLM because it accurately reflects the structure of the data being analyzed (patients nested within hospitals). Second, hierarchical models distinguish within-hospital variation and between-hospital variation to estimate the hospital's contribution to the risk of complications. This allows for an estimation of the hospital's influence on patient outcomes.More specificaly, HGLM allows for hospital contribution to patients' risk to vary across hospitals, which is something that logistic regression cannot address. Finally, within hierarchical models we can account for both differences in case mix and sample size to fairly profile hospital performance. If we did not use hierarchical modeling we could overestimate variation and potentially misclassify hospitals' performance. Accurately estimating variation is an important objective for models used in public reporting and potentially used in value-based purchasing programs. Steering Committee Response: See CMS rationale above. It is important that measures take into account patient risk factors while ensuring that variations in care are not obscured by risk adjustment. NQF will have a white paper on risk adjustment for CSAC review in Fall 2011.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1219	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The Centers for Medicare & Medicaid Services (CMS) contracted with YNHHSC/CORE to develop hospital-level measures. It is a CMS policy decision to develop/implement a measure at the clinician level. Steering Committee Response: The use of the measure requires facility level measurement which is appropriate. With respect to performance of providers at all levels, the Committee is sensitive to a number of issues that should be considered as organizations determine at what level of analysis measures should be structured and reported. The Committee believes it appropriate to consider reporting at the various levels mentioned where appropriate after consideration of the attendant issues. Application at the clinician level will be explored with CMS in the future.	1550: Hospital-level RSCR following THA and TKA
1253	HPL	Thomas James, III, MD; Humana, Inc.	We are supportive of this measure as one that meets a need for a high volume procedure with significant regional variation, and is a strong outcomes measures.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: No response warranted. Steering Committee Response: No action required.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1272	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support this measure and recommend that the measure be expanded to the commercial population for persons aged 18 to 64.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We are currently performing analyses to support this recommendation and plan to specify the measure in all-payer data and for persons aged 18 and older in 2012. These changes will then be submitted to the NQF. Steering Committee Response: No action required at present.	1550: Hospital-level RSCR following THA and TKA
1299	QMRI	John Shaw; Next Wave	Comment 1 1.) The overall structure and intent of the measure is appropriate. •The composite measure components are relatively frequent and at least partially actionable. •The variable time frames (7 days, 30 days, and 90 days) are appropriate for their respective components. •The rationales for each of the denominator exclusions are appropriate to exclude high risk patients. •The basic risk adjustment structure is reasonable, and incorporates demographic, THA/TKA procedure, and clinical risk factors likely to impact the frequency of the complication components. •This overall approach is in use in several NQF endorsed Medical measures (for AMI, Heart Failure, and Pneumonia). 2.) While we support this measure in concept, in practice we cannot support endorsement of this measure as currently specified for the reasons outlined below.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We thank Dr. Shaw for his thoughtful and detailed comments, which we respond to in the rows below. Steering Committee Response: See response at ID#s 1309 below.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1300	QMRI	John Shaw; Next Wave	Comment part 2 3.) This is the first application of this methodology approach to a Surgical event. It is previously used and endorsed for medical conditions. For surgery, the timing of the event relative to associated ICD-9-CM diagnoses is necessary for appropriate attribution. The current detailed Measure Specification for specific ICD9-CM code use is sufficiently incomplete such that it does not meet the intent of the measure, and is significantly biased and includes large numbers of complications occurring prior to the index admission surgical procedure to which the complications are attributed. 1.The lists of ICD-9-CM codes in the final Measure Denominator Specification used to exclude hip fracture cases, revisions, and partial hip replacements from the denominator are incomplete, leaving many patients at high risk for mortality, complications, and readmissions in the measure denominator. Since these patients are disproportionately treated in a small number of hospitals, this produces a systematic bias in the results. 2.The ICD-9-CM code logic in the Measure Numerator Specification does not distinguish diagnoses that are already present prior to admission for the index procedure (in either primary or secondary positions – risk factors) versus those occurring after the index admission and THA/TKA surgery (complications). See additional comments for continuation and further details.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Regarding inadequate denominator exclusions, we identified the denominator exclusions in consultation with an advisory group of orthopedic surgeons with experience in identifying relevant procedures in claims data. In addition, we conducted a medical record validation study of the complications measure to determine the overall agreement between patients identified as having a complication (or no complication) in the claims-based measure and those who had a complication (or no complication) also documented in the medical record. We also conducted a detailed review of all discrepancies to identify opportunities for measure improvement. We reviewed the medical records for 644 patients who underwent elective total hip arthroplasty or total knee arthroplasty in 2007-2008 at 8 hospitals. We found no examples of fractures that were inapproproiately captured as index admissions. As part of measure maintenance of the proposed measure, we will revisit the codes used to identify and exclude fractures from the measure cohort and wll make any necessary adjustments to the measure specifications. Regarding conditions present on admission that may be erroneously considered complications, based on findings from the validation study, we determined that numerous patients were admitted for the index arthroplasty due to a mechanical complication from a prior orthopedic procedure; the claims-based measure identified these complications as related to the index arthroplasty, even though the complication was present on admission. Based on these findings, we are now excluding from the measure cohort those patients with a mechanical complication coded in the principal discharge diagnosis field on the index admission. Furthermore, we are excluding these patients from the measure cohort because they may require more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications. Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1301	QMRI	John Shaw; Next Wave	Continuation - Part 3 3.) Incomplete and significantly biased 2. diagnoses prior to admission •Because of this, patients admitted specifically for revision of failed screws, plates, wires, implants, etc. from a previous partial hip replacement or previous hip fracture repair (frequently performed at a different hospital) are included in the numerator complications. •Since these patients were not excluded from the denominator and are disproportionately treated in a small number of hospitals, this produces an additional systematic bias in the results. 3. Since treatment of failed hip fracture or partial hip by use of a total hip replacement is very common, the magnitude of the bias is very large, and overwhelms many of the other measure components. 1.From analysis of several large datasets, we estimate that as specified, complications of prior orthopedic surgery accounts for over 1/3 of the "Mechanical Complication" component. See additional comments for continuation and more details	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see response to comment #1300. Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1302	QMRI	John Shaw; Next Wave	Part 4 3.) Bias is very large, 1. For Mechanical Complications (cont.) 1.Many joint prosthesis specific complications are also POA - e.g. 98% of ICD-9-CM code 99641 – Mechanical loosening of prosthetic joint are POA, and represent failed partial hip replacements used to treat a prior hip fracture – usually caused by wear debris from the implant over a long period of time. 2.This component has the greatest impact on the composite measure, with a frequency of occurrence more than three times the average of the other 8 measures in the composite. 3.As a result, the systematic bias error has a greater weight on the composite measure than the average of the other 8 measures.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please refer to our response to comment #1300. Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1303	QMRI	John Shaw; Next Wave	Part 5: Other components are similarly biased with pre-existing numerator complications - to a lesser degree individually, but with a combined significant impact on the composite measure. 1.For example, many orthopedic surgeons will not perform a THA/TKA on a patient with a history of an AMI, referring these higher risk patients to regional referral centers with protocols in place to safely treat them. 2.ICD-9-CM coding rules require that the referral center code the AMI as a secondary diagnosis, since it requires additional monitoring resources, but with a Present on Admission (POA) code to indicate that the AMI occurred prior to the index THA/TKA admission. The current Measure Specification would count this as a numerator complication (ANY diagnosis listed during the index admission in ANY position, regardless of whether it occurred prior to the admission and surgery). See further comments	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The measure specifications for AMI include only those ICD-9 codes that reflect an acute myocardial infarction occurring in the initial episode of care or during an episode of care, unspecified (ICD-9 codes 410.x1 and 410.x0, respectively). The measure specifications exclude 410.x2 codes, acute myocardial infarction, subsequent episode of care. Accordingly, the measure is designed to only capture those AMIs that occured during the index admission. To further examine this issue, we calculated the number of patients who had a complication of pneumonia, pulmonary embolism, sepsis or AMI, that was identified through a secondary diagnosis during the index admission and then looked back through the claims history for one year (both inpatient and outpatient diagnoses) to see if any of these matched the same diagnosis potentially occurring prior to the index admission. This approach will overestimate the number of complications that were present prior to surgery, because some patients will have had, for instance, both a prior pulmonary embolism and a pulmonary embolism as a complication of care during their admission for hip or knee replacement. We found that only 3% of all patients with any complication had both a complication (specifically pulmonary emobolism, sepsis, pneumonia or AMI) identified in a secondary diagnosis in the index admission and the same diagnosis found in claims in the prior year. Given that many of these occurred remote to the admission, many may be recurrent events as opposed to present on admission, and that they represent a small fraction of the complications found, it is unlikely such use of secondary diagnoses has a substantial impact on the measure. However, we also plan to explore the use of POA codes in the future. Lastly, during the validation study of over 600 patients, we did not identify any instance where the claims-based measure captured AMI, pneumonia, sepsis, or pulmonary embolism via a code in a secondary diagnosis field in the index admission and the complication was not also documented in the medical record. Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1304	QMRI	John Shaw; Next Wave	Part 6- 1.Hospital level impacts using the current Measure Specification of this systematic bias are perverse, with the hospitals in our sample admitting the greatest number of high risk patients with complications of prior orthopedic surgery receiving the worst complication scores, whereas, they actually have the best scores. %Num. POA vs. Mean Hospitals Rate per Specs Ratewo POA 2+ SD above mean 84.90% 1.70% 1-2 SD above mean 144.10% 1.90% Above mean 393% 2.00% Below mean 973.30% 2.90%	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see response to comment #1303. Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1305	QMRI	John Shaw; Next Wave	Part 7 - Risk Adjustment: Since the bias is both systematic and large, the existing risk adjustment structure is also likely biased, since it is disproportionately affected by the propensity to explain the likelihood for patients with failures of prior orthopedic surgery to seek treatment in regional referral centers that specialize in orthopedic revision surgery. Complications, particularly common orthopedic complications, occurring prior to the index admission and surgery should be added to the risk model, not left in the measure numerator. The current risk adjustment Measure Specification is also incomplete, making quantitative evaluation of the risk methodology impossible. Specification of ICD-9-CM codes included in each of the CC "condition categories" that comprise the majority of the risk adjustment (as well as those considered and not included in the model) do not appear available in the public domain. The CMS link provided in the draft specifications did not work, and follow-up attempts to obtain this information from CMS directly were similarly unsuccessful. We did note a significant quantitative risk on the other risk factors that were specified (Age, sex, THA vs. TKA procedure, and number of procedures performed). These should remain in the risk model.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Of the 290,329 patients in the initial measure cohort, 930 patients had a mechanical complication coded in the principal discharge diagnosis field on the index admission. After excluding these patients the measure cohort decreased by 930 patients to 289,399 patients (a less than 0.5% decrease). It is unlikely that such a small decrease in the cohort will affect the variables selected for risk adjustment in the model. The ICD-9-CM map to the condition categories can be found at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1182785083979 . Steering Committee Response: See response at ID# 1309 below	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1306	QMRI	John Shaw; Next Wave	Part 8 - Disparities: The current Measure Specification does not risk adjust or stratify for Socio-Economic-Status (SES). The details in the application for Disparities Data addressed a companion measure (1551 Readmissions after THA/TKA), not this complication measure. It used Medicaid eligibility as a proxy for SES. 1.We cannot comment on findings for this measure since they were not provided. 2.We remain concerned over this issue, since large historical disparities have been shown historically in at risk populations for THA/TKA. Medicaid eligibility is a crude measure, since it relies on individual State Medicaid coverage policies which vary significantly from state to state. 3.Other measures such as local population characteristics and minority serving “safety net” hospital status are currently being reviewed as alternatives to simply using Medicaid eligibility as an indicator. Overall refinements to NQF SES stratification policies are in process as a result of a number of other initiatives (Addressing Health Disparities, the Measures Application Partnership, etc.). The THA/TKA measures have demonstrated variability, and should be incorporated as examples into these broader initiatives.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see response to comment #1189. Steering Committee Response: See response at ID#1189	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1307	QMRI	John Shaw; Next Wave	Part 9 - Corrections: Our specification and systematic bias concerns can be easily addressed by the measure developer by updating the measure specification and re-running the risk model on a complete data set with all relevant factors and using appropriate ICD-9-CM codes. We hope that these refinements will be implemented prior to presenting these measures for a final vote: 1.Adding other appropriate diagnoses to the denominator exclusion list for high risk patients with hip fractures and/or revision procedures (list of candidate codes will be provided to NQF and the measure developer). 2.Exclude all numerator complication codes listed on the index admission in either the principle diagnosis position or a secondary position if it is indicated as Present On Admission (POA). 3.Note: Only exclude for the index admission – leave in the numerator for ALL readmissions during the 7, 30, or 90 day time periods, since these likely ARE complications of the index THA/TKA. 4.Rerun the risk adjustment analysis, including reevaluation of the CC condition categories that did not make it into the current biased specification. 5.Complications from prior orthopedic surgeries present on admission in the index stay and surgery should be considered as potential risk factors for future complications, consistent with the literature. Also, make the map of ICD-9-CM code to “CC condition category” (for all candidate measures) available for full transparency.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We have updated the measure specifications to reflect the exclusion of patients with a mechanical complication coded in the principal discharge diagnosis field on the index admission. Because these patients represented less than 0.5% of the measure cohort, we do not feel it is necessary to re-run the risk adjustment analysis at this time. Steering Committee Response: See response at ID# 1309 below.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1309	QMRI	John Shaw; Next Wave	Part 10 - Future Refinements: We have seen in our analysis (after making the recommended corrections to eliminate bias) that these same measures are also significant complications in the younger and non-Medicare population. While relative frequencies of the component measures and risk factor predictors differ, the corrected methodology can serve as a template for broader application to the growing number of patients receiving THA/TKA prior to age 65.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We are currently performing analyses to support this recommendation and plan to specify the measure in all-payer data and for persons aged 18 and older in 2012. These changes will then be submitted to the NQF. Steering Committee Response: The Steering Committee appreciates the comments and their handling by the developer. It believes that such careful consideration serves to strengthen the measure at present and going forward.	1550: Hospital-level RSCR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1190	P	William Martin, III, MD; American Association of Orthopaedic Surgeons	Risk Adjustment Vulnerable Populations: The AAOS believes more work needs to be done on risk adjustment in order to avoid the unintended consequence of denying care to the most vulnerable patients. The AAOS urges NQF to further develop a means for risk adjusting for the wide variation in patient characteristics. Socioeconomic Status: Specifically, the AAOS believes socioeconomic status (SES) should be included in the risk-adjustment models because low-SES patients are known to be at higher risk for post-operative complications and readmissions, and not including SES in the models could result in low-SES patients being denied much needed quality-enhancing treatments like THA and TKA. While the relationship between readmissions and quality of care is complex, income and socioeconomic status have been shown to play a role in risk of readmission for post-operative complications. SES is usually measured bylevel of education, income, occupation, or a composite ofthese dimensions. A patient's life circumstances are important factors in outcome determinations. Researchers involved in analyses of risk-adjusted outcomes and costs have suggested the need for a SES adjustment for patient populations, in addition to traditional risk-adjustment variables.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please refer to prior response #1189. Steering Committee Response: The goal of both AAOS and CMS, with respect to the issue of low SES patients appears to be to ensure these patients have equal access to appropriate care. As noted by CMS, the ability to report disparities is important, including those related to vulnerable populations such as low SES. NQF looks forward to seeing this data reported within the next three years. As NQF continues to develop guidance related to the many aspects of measure development, it welcomes Member and public suggestions related to risk adjustment.	1551: Hospital-level 30-day all-cause RSRR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1220	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We question why this measure uses hierarchical risk modeling (HRM) when other mortality measures in the set were deemed appropriate with standard logistic regression? HRM is known to reduce sensitivity to detect outliers. Otherwise, it would be a good outcome measure. We support measuring the performance of providers at all levels (e.g. individual physicians, physician groups, hospitals, ACOs, etc.). We question why this measure would not apply at the clinician level.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please see response to comment #1218. Steering Committee Response: See CMS rationale at ID#1218 above.	1551: Hospital-level 30-day all-cause RSRR following THA and TKA
1254	HPL	Thomas James, III, MD; Humana, Inc.	We are supportive of this measure as it stands but if the 30-day all cause readmission rate measure is endorsed, then this should become a specific submeasure. In such a case the methodologies should be harmonized.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: This measure is intended as a paired measure with the hospital risk-standardized complications measure to evalutate hospital performance after total hip and knee arthroplasty procedures. Steering Committee Response: NQF approach to harmonization should ensure that where appropriate measures are evaluated for similarity and potential for harmonization.	1551: Hospital-level 30-day all-cause RSRR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1273	HPL	Carmella Bocchino, MBA, RN; America's Health Insurance Plans	We support this measure and recommend that the measure be expanded to the commercial population for persons aged 18 to 64.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: We are currently performing analyses to support this recommendation and plan to specify the measure in all-payer data and for persons aged 18 and older in 2012. These changes will then be submitted to the NQF. Steering Committee Response: No action required at this time.	1551: Hospital-level 30-day all-cause RSRR following THA and TKA
1308	QMRI	John Shaw; Next Wave	Comments are similar to those provided under the THA/TKA Complication measure (see detailed comments under measure 1550): 1.We agree with the overall concept and approach. 2.We could not endorse as currently specified. 3.The denominator exclusions are similarly biased by not excluding all hip fractures, revisions, and patients with a partial hip replacement from the denominator. This will bias the measure against the smaller number of regional referral centers that admit these patients with a higher risk for readmission. 4.Better adjustments are necessary to address health disparities and SES. This measure (after correcting for bias in the current measure specification) should be an example for use in other NQF initiatives addressing disparities. 5.The specification for “CC condition categories” is incomplete, and does not provide a transparent description of the specific ICD-9-CM codes included in each CC. 6.The corrected measure can also inform application to other populations (e.g. <65). 7.Corrections could be easily implemented by the measure developer.	CMS YALE was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Please refer to comments above regarding denominator exclusions (comment # 1300), risk adjustment for SES (comment # 1189), ICD-9-CM to condition category map (comment # 1305), and application to other populations (comment # 1273). Steering Committee Response: Please see relevant responses at ID#s above.	1551: Hospital-level 30-day all-cause RSRR following THA and TKA

ID#	Council/ Public	Commenter	Comment	Response	Topic
1181	PUB/COM	Denise Love, MBA, RN; National Association of Health Data Organizations	The National Association of Health Data Organizations (NAHDO) represents states with statewide hospital data reporting programs. NAHDO requests reconsideration of measures not recommended for endorsement: . - Incidental Appendectomy in the Elderly (IQI 24) (NQF #364): States and policymakers are seeking to reduce unnecessary costs and reduce variation in overuse. Incidental appendectomies introduce risk of complication, add to costs. The uninsured/underinsured could end up paying more. This measure gets at one low hanging fruit of cost reduction. - Postoperative Wound Dehiscence (PDI 11) (pediatrics) (NQF #367) - Postoperative Wound Dehiscence (PSI 14) (adults) (NQF #368) These measures indicate non-optimal care, add to the cost of care, and negatively affect the patient. Patient factors may affect the occurrence of this event, good post-op care and coordinated follow-up care can make a difference. This measure can be used today in most states, fits the NQF care coordination domains (medical home, transitions/handoffs, communication). NQF should reconsider its two-state hierarchical modeling approach, as this tends to wash out provider variation, which limits information's utility to consumers and purchasers.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: In regard to the last sentence as it relates to AHRQ Quality Indicators that are risk adjusted: The measure can be calculated to produce a risk adjusted rate and a smoothed rate. Hierarchical modeling is used in the smoothed rate, but not the risk adjusted rate. The user has the option to use either rate. Steering Committee Response: The Steering Committee does not recommend endorsement for the reasons stated; 0364 - The surgery is rarely performed (2 percent) thus did not meet the criterion of importance based on value and relevance with respect to the impact and performance gap subcriteria. The cost of applying a measure that is relevant for such a small group of patients is potentially significant. 0367 and 0368 - The occurrence of wound dehiscence is concerning; however, the measures, as constructed, did not pass the criterion of importance and does not provide actionable data. This is based on the low rate of dehiscence that has remained stable over a period of time during which the measures have been in use; cited evidence that the underlying problem is infection; lack of a standard of care for prevention; and inability to reduce the rate due to lack of non-patient specific factors that can be influenced.	Measures Not Recommended: 0364-Incidental append. In elderly, 0367-Postop wound (PDI 11) and 0368-Postop wound (PSI 14)

ID#	Council/ Public	Commenter	Comment	Response	Topic
1183	PUR	Barbara Rudolph, PhD, MSSW; The Leapfrog Group	The Leapfrog Group strongly encourages the reconsideration of the following measures: Incidental Appendectomy in the Elderly (IQI 24) (NQF #364): There are few overuse/misuse measures available. Incidental appendectomies introduce risk of complication, and add to costs for patients and payers. Postoperative Wound Dehiscence (PDI 11) (pediatrics) (NQF #367) and Postoperative Wound Dehiscence (PSI 14) (adults) (NQF #368) indicate sub-optimal care for patients and add to cost of care. While some patients may be at higher risk, good post-op care can make a difference. These measures fit with the NQF care coordination domains.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: See response at ID# 1181 above. Note: These measures have been moved to the addendum that will follow this report to allow consideration of the developer's request for reconsideration.	Measures Not Recommended: 0364-Incidental append. In elderly, 0367-Postop wound (PDI 11) and 0368-Postop wound (PSI 14)

ID#	Council/ Public	Commenter	Comment	Response	Topic
1221	PUR	David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	The Surgical Steering Committee voted down three measures that we consider of importance: •0364: Incidental appendectomy in the elderly rate (IQI 24) •0367: Postoperative wound dehiscence rate (PDI 11) (pediatric population) •0368: Postoperative wound dehiscence rate (PSI 14) (adult population) We believe the rejection of these three measures is in error for the following reasons. Postoperative wound dehiscence (pediatric and adult populations): Evidence was provided to the Steering Committee showing that 30% of these are preventable. Furthermore, there are numerous other measures endorsed with similar or lower rates of preventability. We disagree with the committee's stance and see these measures as having the potential for a clear impact on the quality of care provided to patients. Incidental appendectomy in the elderly: The Steering Committee said it only happens 2% of the time and that there is questionable evidence of adverse affects; however, there are other endorsed measures that occur less than 2% of the time. Given that there is no evidence it does any good to remove the appendix while patients are already in surgery, we question why surgeons are doing the removals. There are precious few overuse measures endorsed and this one would be a good start in the right direction.	AHRQ was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: Thank you for your comment. Steering Committee Response: See response at ID# 1181 above.	Measures Not Recommended: 0364-Incidental append. In elderly, 0367-Postop wound (PDI 11) and 0368-Postop wound (PSI 14)

ID#	Council/ Public	Commenter	Comment	Response	Topic
1186	P	Cesar Jara, MD, FACC, FSCAI; Cape Canaveral Hospital	Carotid artery stenting (CAS) has shown consistently in recent trials adequate outcomes compared with surgery (CEA) in the right patient population, and with an experienced physician. In spite of these clinical data, CAS is limited in availability and reimbursement. One assumption is that outcomes with CEA are similar to the ones achieved in trials, and no further data is being collected post-surgery, as opposed to CAS. Supporting collecting data for both, will help to elucidate better the equivalence of both procedures, as well as provide to the patient a more accurate statement of risk vs benefits at a local level, and not general statistics.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that valid, standardized data on outcomes for carotid revascularization will be helpful in physician and patient decisionmaking regarding these procedures. Steering Committee Response: The Steering Committee determined that such a measure could encourage standardized neurologic assessment and strongly supports the concept underlying the measure. Its concerns are that a) there is little evidence that this process measure, as constructed, is strongly linked to improvement in outcome; b) data ascertainment may not be uniformly possible and c) baseline and post procedure testing given post-procedure assessment requirements may not be comparable. The committee encourages the developer to continue its effort to refine the measure for practical implementation, including submission for inclusion in PQRS, and bring the refined measure to NQF for endorsement. Note: This measure has been moved to the addendum that will follow this report to allow consideration of the developer's request for reconsideration.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1187	P	Timothy Murphy, MD; Society of Interventional Radiology	The Society of Interventional Radiology, a professional association representing 4,700+ physicians & allied professionals committed to improving public health through image-guided therapy, submits the following comments on the draft report Surgery Consensus Standards Endorsement Maintenance (SCSEM). As a partner society on the ACCF's National Cardiovascular Data Registry (NCDR) Care Registry®, we support ACCF's comments on the measure: "1531 Follow-up assessment of stroke or death after carotid revascularization." We also recommend that patients post carotid revascularization have post procedure outcomes measured with the NIHSS and mRS. Per the SCSEM's comments, NQF is unclear that measuring outcomes improves outcomes for carotid revascularization. This criticism is surprising. In order for outcomes to improve, they must be measured. Given the narrow benefit over harm of carotid revascularization, it is impossible to identify inadequately performing facilities and physicians unless outcomes are measured. The measured outcomes from carotid stenting are an essential part of the carotid stent accreditation program that SIR and other societies have created, and we anticipate that CMS may soon require measured outcomes meeting national benchmarks. For the benefit of patients we recommend SCSEM reconsider its decision and move this important measure forward for endorsement by NQF.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with these comments supporting the value of this measure for tracking of outcomes after carotid revascularization. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1191	HPL	Mark D. Grant, MD, MPH; BCBSA	When carotid endarterectomy or angioplasty and stenting are used to treat atherosclerotic stenosis, the balance of benefits and harms is determined largely by periprocedural stroke and death rates. The net health outcomes depend on the tradeoff of early (periprocedural or 30-day) stroke and death risk for a subsequent reduction in stroke incidence. The lack of accurate stroke and death rates following either procedure prevents facilities, providers, and patients from knowing whether net health outcomes are favorable. Only by having valid stroke and death data can the outcomes of care be evaluated, reported and improved. Furthermore, lacking those data the ability to identify safety signals is limited. A valid stroke ascertainment requires a certified examiner or neurologist. Furthermore, carotid angioplasty and stenting procedures may be followed by a certified exam, while endarterectomy may not. Consequently, comparing outcomes and quality of care for the two procedures is hampered. The CARE registry offers an important opportunity—to provide information that can potentially make certain carotid procedures are being performed safely and with likely benefit. Absent inclusion of a standard follow-up assessment that opportunity is limited.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCFF agrees that valid, standardized data on outcomes for carotid revascularization will be helpful in physician and patient decisionmaking regarding these procedures. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1231	HPR	Christopher White, MD, FSCAI; The Society for Cardiovascular Angiography and Interventions	We are writing to support the ACCF's comments regarding the measure: "Follow-up assessment of stroke or death after carotid revascularization." This measure was developed and tested through the NCDR Care Registry®. We recommend that patients post carotid revascularization have post procedure outcomes measured with the NIHSS and mRS. Per the SCSEM's comments, NQF is unclear that measuring outcomes improves outcomes for carotid revascularization. This criticism is surprising. In order for outcomes to improve, they must be measured. Given the narrow benefit over harm of carotid revascularization, it is impossible to identify inadequately performing facilities and physicians unless outcomes are measured. The measured outcomes from carotid stenting are an essential part of the carotid stent accreditation program that SCAI and other societies have created, and we anticipate that CMS may soon require measured outcomes meeting national benchmarks. We recommend that the SCSEM reconsider its decision and recommend this measure move forward for endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCFF agrees that additional data on outcomes for carotid revascularization will be helpful in physician and patient decisionmaking regarding these procedures. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1274	HPR	Sarah Tonn, MPH; American Academy of Neurology	The AAN supports measure #1531: Follow-up assessment of stroke or death after carotid revascularization. The AAN requests the NQF Review Steering Committee (SC) decision be reconsidered and that the #1531 measure be recommended for endorsement. The AAN believes that following carotid revascularization procedures, a 30 day assessment (+- 5 days) of the NIH stroke scale and modified Rankin Scale are desirable. The reasons for including this are as follows: 1. Clinical trials in the past have included a 30 day assessment of stroke status and functional status. The periprocedure period traditionally extends 30 days after the index carotid procedure. 2. In order to determine whether real world results are matching clinical trials, a 30 day assessment is important. If 30 day results are worse than the benchmark clinical trials, this becomes a patient safety issue. 3. Carotid revascularization procedures in some cases have a narrow risk/benefit ratio. Documentation of the patient's status at 30 days is an important element in assessing the local hospital's performance, as recommended in a previous statement from the AAN. The AAN supports Measure #1531 and we believe that the 30 day assessment is in the best interests of patients and the larger health care system. We ask that the SC reconsider their decision and recommend for endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that valid, standardized data on outcomes for carotid revascularization will be helpful in physician and patient decisionmaking regarding these procedures. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1310	P	Stan Thornton, MD, FACC, FSCAI	I am astounded at the decision not to endorse the reporting of outcomes following carotid revascularization. Not only is it a disservice to patients in their ability to choose a physician who provides the highest quality care, but allows operators who perform below the standard to continue to do so in relative obscurity. Please reconsider and support this measure.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with this comment in support of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.
1311	P	Jay K. Patel, MD, FACC, FSCAI, FACP; Hamilton Cardiology Associates	We have reviewed the draft report and respectfully request the project Steering Committee reconsider the decision regarding the NCDR measure: "Follow-up assessment of stroke or death after carotid revascularization" and recommend the measure for endorsement by NQF. We offer the following comments for your consideration. This measure has been developed and tested through the National Cardiovascular Data Registry's (NCDR) Care Registry®. NCDR was given an opportunity to respond to concerns raised by the Steering Committee (SC) members regarding the importance, feasibility, relationship to outcomes, and reliability testing data criteria for this measure. Given that the SCSEM SC discussion regarding the NCDR response during a review conference call indicated consensus that all of these concerns had been adequately addressed, and in light of the fact that the SCSEM SC members vote indicated that the aforementioned criteria was deemed met or almost met by a majority of members and the vote to not endorse this measure was by a very narrow margin, we would like to request that the SCSEM SC SC reconsider its decision and recommend this measure move forward for endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with these comments supporting the value of this measure for tracking of outcomes after carotid revascularization. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1312	P	Jay K. Patel, MD, FACC, FSCAI, FACP; Hamilton Cardiology Associates	Importance of this process measure: Data from the CARE Registry indicate that hospitals on average perform follow-up consistent with this measure 21% of the time, with 50% of hospitals performing it only 11% of the time. Given the risk and cost of this procedure, it is essential that patients be assessed after discharge to determine if the procedure prevented stroke and death, and to identify any complications. This measure encourages standardization of follow-up for this importance procedure to ensure that patients are evaluated using a standard neurologic evaluation by a certified examiner so that outcomes can be monitored reliably. Feasibility of collecting follow-up data, NIHSS certification: Many hospitals who participate in the CARE Registry (approximately 180 institutions) have been reliably and consistently submitting follow-up to the CARE Registry for several years and find the information provided to them from the registry for benchmarking to be valuable in quality improvement efforts. In addition to the modified Rankin score data, which is an option for data submission, SCSEM SC discussion focused on feasibility and potential burden of requiring individuals be certified on the National Institutes of Health Stroke Scale (NIHSS). The NIHSS stroke scale certification is available as on online learning module: http://www.nihstrokescale.org/. Certification can be obtained in under an hour by a variety of clinicians or therapists, and only needs to be renewed every other year. There is no cost for certification. Patient assessment using the NIHSS tool takes approximately 10 minutes. Timeframe of data collection and reliability data: In response to the SCSEM SC request to reconsider the follow-up data collection timeframe, NCDR modified the timeframe from 21-60 days to 14-60 days. In addition, we have provided additional reliability data to the SC to support expanding the measure timeframe	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that valid, standardized data on outcomes for carotid revascularization will be helpful in physician and patient decisionmaking regarding these procedures. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1313	P	Jay K. Patel, MD, FACC, FSCAI, FACP; Hamilton Cardiology Associates	Importance of measures for quality improvement and public reporting: NCDR intends to include this measure as part of the portfolio of measures to be implemented in the ACCF's voluntary public reporting program currently under development and targeted for launch in 2012. The additional NCDR registry measures intended for use in this public reporting effort are undergoing review by the NQF Cardiovascular Endorsement Maintenance (CEM) Project, and while it would have been our preference to have all the measures considered under the same project, we deferred to the recommendation of the NQF to separate this measure for review under the SCSEM project. As such, the relationship of this measure to the NCDR's overall public reporting effort may not have been apparent to the SCSEM SC as it is to the CEM SC. Relationship of process measure to outcomes measure: NCDR recognizes the emphasis and importance of outcomes measures in quality improvement efforts. In putting this particular process measure forward for endorsement; ACCF contemplated submitting an outcome measure focused on stroke as the end point. Ultimately, as this submission reflects, the College determined a process measure is more appropriate for endorsement at this time as it demonstrates enough variation in practice for improvement and that variation would raise reasonable questions regarding the quality of assessments upon which an outcome measure would be based.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure will fill an important gap in measurement for outcomes following carotid revascularization. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1314	P	Jay K. Patel, MD, FACC, FSCAI, FACP; Hamilton Cardiology Associates	Commitment to efforts that support improvement on the measure: While the NCDR is nationally recognized as a model of excellence for its systematic, standardized data collection and quality and outcomes reporting activities, SCAI and ACCF are just as committed to assisting physicians, clinical care teams, hospitals and practices in "moving the measure" to improve the quality of care provided to patients. Specific to this measure, details related to the two possible neurological assessments (NIHSS and the modified Rankin score) are disseminated to participating hospitals in a variety of ways. Definitions of the NIHSS, information concerning the need for the assessment to be performed by a healthcare professional other than the operator (i.e. independent assessment), and information indicating that NIHSS examiners may become certified through the American Stroke Association are included in the CARE Registry data dictionary that is publically available on the NCDR.com website. Additionally, the secure login portion of the website provides participating hospital staff with frequently asked questions (FAQ) addressing issue about the assessments. Each hospital is provided with a CARE Registry welcome kit upon enrolling in the registry, which includes information about the NIH Stroke Scale and Modified Rankin Scale. Finally, NCDR clinical quality consultants who respond to calls and e-mails from current or potential participating hospital staff are trained in how to answer questions about the NIHSS and Rankin scores, including stroke scale tool training and implementation as well as data capture for the CARE Registry.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is valuable for hospital internal quality improvement and is feasible and usable for hospitals to implement. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1315	P	Bryan W. Kluck, DO, FACC; Heart Care Group	I would like to have my voice join the many others responding on the topic of carotid revascularization outcomes. I strongly feel that it is in the interest of optimal patient care to measure all carotid procedure outcomes, and it is the responsibility of the performing physician and the hospital - both of whom collect fees - to make certain they assess the result of their procedure. This should apply evenly to CEA and CAS. The emphasis on choosing the strategy of revascularization may have unfortunately drifted away from the most important consideration, that of patient safety and well being. I think this measure is necessary to refocus the entire field on that goal.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this the measurement of outcomes following carotid revascularization is very important and that hospitals should be the accountable for collection of these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.
1316	P	Mike Schaeffer; Saint Joseph Medical Foundation	I would like to comment on the draft report of the National Quality Forum's Surgery Consensus Standards Endorsement Maintenance (SCSEM) project. As a member of the Society for Cardiovascular Angiography and Interventions (SCAI), I support your overall efforts to expand the NQF portfolio and to ensure that only the best measures become NQF-endorsed voluntary consensus standards. I respectfully request the project Steering Committee reconsider the decision regarding the NCDR measure: "Follow-up assessment of stroke or death after carotid revascularization (#1531)" and recommend the measure for endorsement by NQF.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with this comment in support of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.
1317	PRO	Tim Bevelacqua, MN, RN, CENP; Memorial Hermann Healthcare System	Please accept this communication as formal commentary and endorsement of the National Quality Forum (NQF) proposed national standard related to "Follow-up assessment of stroke or death after carotid revascularization (#1531). Endorsement of this standard is on behalf of patients who should expect outcomes of this procedure to be measured by both hospitals and physicians performing the procedures. Thank you for your attention to this important issue.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this the measurement of outcomes following carotid revascularization is very important and that hospitals should be the accountable for collection of these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1318	CON	Julia Hallisy, DDS; The Empowered Patient Coalition	I am writing on behalf of The Empowered Patient Coalition and as a voting member of NQF consumer council. We are supportive of the submitted process measure "Follow-up assessment of stroke or death after carotid revascularization" as an opportunity to monitor outcomes and collect follow-up data. We simply will never improve outcomes if we don't collect data and measure results. The NCDR Care Registry is a working example of data collection as a precursor to evidence-based medicine. Patients vigorously support data collection as a means to allow access to the information they need when making health care decisions. Without cutting-edge data, patients cannot make the best decisions for their individual situations and their physicians will make recommendations based on limited knowledge of the risks and outcomes. This is exactly what evidence-based medicine is seeking to change and improve. Progress is always challenging but taking that first step is a necessary part of the process. **The availability of the Care Registry, free courses for NIHSS stroke certification, an amended time frame for collection of follow-up data and the fact that a variety of clinicians can perform the brief patient assessment make this measure workable and practical.** We hope that the SCSEM will revisit its decision against this measure and decide to move forward for endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is very important and feasible and will lead to standardization in collection of outcomes necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1319	P	Ryan Saadi, MD, MPH; Cordis Corporation	Cordis Corporation appreciates the opportunity to comment on the draft report of the National Quality Forum's (NQF) Surgery Consensus Standards Endorsement Maintenance (SCSEM) project. Cordis Corporation (Cordis), a Johnson & Johnson Company, is a worldwide leader in the development and manufacturing of interventional vascular technologies. Cordis partners with physicians worldwide to treat millions of patients who suffer from vascular diseases. Cordis is an affiliate member of the NQF through the Johnson & Johnson membership maintained by Ortho-McNeill-Janssen Pharmaceutical, Inc. Cordis supports NQFs' efforts to identify and endorse measures that will result in quality improvements across all settings of care. We agree that only those measures providing a reasonable likelihood of enhancing patient care should become NQF endorsed voluntary consensus standards. We have reviewed the draft report pertaining to the Steering Committee's recommendation against endorsing measure #1531 and respectfully request that the Steering Committee reconsider their decision and recommend this measure move forward for endorsement. We offer the following comments to support our request for reconsideration.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with these comments in support of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1320	P	Ryan Saadi, MD, MPH; Cordis Corporation	The objective of the CARE registry is to improve outcomes of carotid revascularization patients. In their recent publication of the CARE protocol, White et al.,[i] noted that the findings of CARE will help to identify areas of excellence as well as opportunities for improvement. While the CARE registry provides an opportunity to report on early post-procedural stroke and death risk, currently fewer than 25% of hospitals are participating in this measure. National endorsement of this measure will increase the likelihood that these critical outcomes of stroke and death be monitored systematically which will allow for the development of an evidence base that would have important research and practical value. The availability of national data that is based on a valid and reliable standardized assessment of outcomes following carotid endarterectomy and stenting can address some limitations found in the published literature. It has been demonstrated that variation exists in the reported risk of stroke contingent upon the method and duration of assessment. Approved clinical studies currently being conducted for carotid stenting require the reporting of peri-operative outcomes assessment including completion of the National Institutes of Health (NIH) Stroke Scale by a certified examiner. Outcomes for patients currently undergoing carotid endarterectomy are not consistently reported upon in a similar manner. Such differences in methods of outcomes assessment and reporting requirements make it difficult to reliably compare real-world data for these two interventions. [i] White CJ et al. The Carotid Artery Revascularization and Endarterectomy (CARE) Registry: Objectives, Design and Implications. Catheterization and Cardiovascular Interventions 2008; 71: 721-725.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1321	P	Ryan Saadi, MD, MPH; Cordis Corporation	Clinical trials of carotid stenting and endarterectomy in higher surgical risk patients have incorporated neurological examinations, including assessment according to the NIH Stroke Scale, and have found higher risk of peri-procedural (i.e., 0 to 30 days) stroke, myocardial infarction or death compared to past publications.[ii] These findings may be partially due to increased sensitivity of detection of minor strokes. It would thus be important to validate findings of clinical trials in large populations of observed real-world practice using the proposed standardized assessment of stroke and death for both carotid stenting and endarterectomy patients. Finally, updating the carotid revascularization evidence base with standardized knowledge of stroke and death outcomes for different population types may help to better inform national decision-making. National guideline recommendations[iii] for patient selection of carotid endarterectomy versus stenting, as well as Medicare's coverage criteria, are both fundamentally dependent on knowledge of the true peri-procedural risk of stroke and death. Such knowledge may thus contribute to enhancing the appropriateness of procedure selection for various population types. Having the most current and best available data for carotid revascularization outcomes in the real-world is anticipated to lead to improved clinical practice in the long-term through the identification of areas requiring quality improvement efforts, as well as the facilitation of clinical decision-making at both the national and hospital level. [ii] Ouriel K et al. Preprocedural risk stratification: identifying an appropriate population for carotid stenting. J Vasc Surg 2001; 33: 728-32. [iii] Brott TG et al. Guidelines on the management of patients with extracranial carotid and vertebral artery disease; JACC 2011; 57(8): e16-94.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1322	SPI	Steven Brotman; AdvaMed	AdvaMed recommends reconsideration of the decision to not approve this measure and recommends the measure for endorsement by NQF. We offer the following comments for your consideration. This measure has developed and tested through the NCDR Care Registry®. The ACCF was given an opportunity to respond to concerns raised by the Steering Committee members regarding the importance, feasibility, relationship to outcomes, and reliability testing data criteria for this measure. The SCSEM Steering Committee has since indicated consensus that the ACCF adequately addressed all of those concerns. In light of the fact that the SCSEM Steering Committee members vote indicated that the aforementioned criteria was deemed met or almost met by a majority of members and the vote to not endorse this measure was by a very narrow margin, we would like to request that the SCSEM Steering Committee reconsider its decision and recommend this measure move forward for endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees with this comment in support of the strength of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.
1323	SPI	Steven Brotman; AdvaMed	AdvaMed recommends that NQF consider that data from the CARE Registry indicate that hospitals on average perform follow-up consistent with this measure 21% of the time, with 50% of hospitals performing it only 11% of the time. Given the risk and cost of carotid artery interventions, it is essential that patients be assessed after discharge to determine if the procedure prevented stroke and death, and to identify any complications. While data on the end point of death may be obtained through other options, such as matching patient data in the CARE Registry with the National Death Index or Social Security Master Death File, the only mechanism to determine the far more sensible end point of stroke is through direct patient follow-up. This measure encourages standardization of follow-up for this importance procedure to ensure that patients are evaluated using a standard neurologic evaluation by a certified examiner so that outcomes can be monitored reliably.	ACC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1324	SPI	Steven Brotman; AdvaMed	AdvaMed recognizes the concerns expressed by the Steering Committee about the feasibility of collecting follow-up data, however, many hospitals who participate in the CARE Registry (approximately 180 institutions) have been reliably and consistently submitting follow-up to the CARE Registry for several years and find the information provided to them from the registry for benchmarking to be valuable in quality improvement efforts. Additionally, concerns about the burden of requiring individuals to be certified on the National Institutes of Health Stroke Scale (NIHSS) before using the modified Rankin score data should be minimal as the NIHSS stroke scale certification is available as on online learning module: http://www.nihstrokescale.org/. Certification can be obtained in under an hour by a variety of clinicians or therapists, and only needs to be renewed every other year. There is no cost for certification. Patient assessment using the NIHSS tool takes approximately 10 minutes.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is feasible for hospitals to implement given the importance of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1326	SPI	Carol O'Brien, Esq; Abbott Laboratories	We have reviewed the SCSEM draft report and respectfully request the Steering Committee reconsider the decision regarding measure #1531: "Follow-up assessment of stroke or death after carotid revascularization." Abbott strongly recommends the measure for endorsement by NQF. Below, we review some of the concerns raised by the SCSEM Steering Committee and address them individually. • Proposed process measure is not strongly linked to patient outcomes: Abbott recognizes the importance of outcomes measures for quality improvement efforts. However, the proposed process measure is appropriate at this time. Furthermore, variation in this measure would raise reasonable questions regarding the quality of assessments upon which an eventual outcome measure would be based. The proposed measure demonstrates sufficient variation in practice to allow room for meaningful improvement as data from the National Cardiovascular Data Registry's CARE Registry ('CARE Registry' hereafter) indicate only a minority of hospitals perform follow-up consistent with this measure.	ACC was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1327	SPI	Carol O'Brien, Esq; Abbott Laboratories	• Data collection is not feasible or would represent a major drain on hospital resources: As the CARE Registry has demonstrated, hospitals can reliably and consistently collect and submit these data. Given the high likelihood of post-procedure follow-up visits, the assessment could be conducted as part of such visits. In addition, patient assessment using the National Institutes of Health Stroke Scale (NIHSS) tool only takes about 10 minutes. • Certification of hospital staff conducting NIHSS stroke assessments represents an undue burden for hospitals: Since hospitals are our major customers, Abbott Vascular is particularly sensitive to any additional burdens placed on them and their staff. However, certification is far from onus. The certification process is available on-line (at no cost) and certification can be obtained in less than an hour by a broad range of clinicians. Certifying staff need only renew annually. Given the risks and costs of revascularization procedures, Abbott believes it is essential for patients to be assessed after discharge, as proposed measure #1531 would support. This post-discharge assessment would systematically determine if the revascularization procedure prevented stroke and / or death through the follow-up period, as well as identify any procedure-related complications. The proposed measure encourages post-discharge follow-up to ensure that patients are evaluated using a standard neurologic evaluation by a certified examiner so that outcomes can be monitored consistently and reliably. Abbott appreciates your consideration of these comments.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is feasible for hospitals to implement given the importance of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

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1328	HPR	Paul McCormick, MD, MPH; American Association of Neurological Surgeons	As a partner society on the American College of Cardiology Foundation's (ACCF) National Cardiovascular Data Registry (NCDR) Care Registry®, we request that the project Steering Committee (SC) reconsider its decision to not recommend for endorsement the ACCF measure titled, "Follow-up assessment of stroke or death after carotid revascularization." This measure was developed and thoroughly tested through the NCDR CARE Registry®, and the vote to not endorse this measure was by a very narrow margin. The major concerns raised by the SCSEM SC and addressed by ACCF are summarized below: • Importance of this process measure: Data from the CARE Registry indicate that hospitals, on average, perform follow-up consistent with this measure 21% of the time, with 50% of hospitals performing it only 11% of the time. Given the risk and cost of this procedure, it is essential that patients be assessed after discharge to determine if the procedure prevented stroke and death, and to identify any complications. This measure also encourages standardization of follow-up for this important procedure to ensure that patients are evaluated using a standard neurologic evaluation by a certified examiner so that outcomes can be monitored reliably. The 30-day outcome data that would result from this measure is critical for internal, as well as external, validity and is usually obtained not only by hospitals, but by physician offices, as well.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

ID#	Council/ Public	Commenter	Comment	Response	Topic
1329	HPR	Paul McCormick, MD, MPH; American Association of Neurological Surgeons	• Feasibility of collecting follow-up data, NIHSS certification: Many hospitals who participate in the CARE Registry (approximately 180 institutions) have been reliably and consistently submitting follow-up data to the CARE Registry for several years and find the information provided to them from the registry for benchmarking to be valuable in quality improvement efforts. In addition to the modified Rankin score data, which is an option for data submission, SCSEM SC discussion focused on feasibility and potential burden of requiring individuals be certified on the National Institutes of Health Stroke Scale (NIHSS). The NIHSS stroke scale certification is available as on online learning module: http://www.nihstrokescale.org/. Certification can be obtained in under an hour by a variety of clinicians or therapists and only needs to be renewed every other year. There is no cost for certification. Patient assessment using the NIHSS tool takes approximately 10 minutes. The burden of collecting this data is quite minimal relative to the benefit of this measure. • Timeframe of data collection and reliability data: In response to the SCSEM SC request to reconsider the follow-up data collection timeframe, NCDR modified the timeframe from 21-60 days to 14-60 days. In addition, we have provided additional reliability data to the SC to support expanding the measure timeframe. Again, the AANS supports the ACCF measure, “Follow-Up Assessment of Stroke or Death after Carotid Revascularization.” We request that the SCSEM reconsider its decision and recommend this measure for NQF endorsement.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is feasible for hospitals to implement given the importance of this measure. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.

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1330	HPR	Steven Lichtman, EdD, FAACVPR; American Association of Cardiovascular and Pulmonary Rehabilitation	AACVPR would like to comment on and express our support of the ACCF's comments regarding the measure: "Follow-up assessment of stroke or death after carotid revascularization." This process measure would recommend using the NIH Stroke Scale 30 days after carotid revascularization. This would enable measurement and standardization of outcomes after this procedure. To ensure that processes improve and patients receive optimal care outcomes must be measured. Without measurement, improvement is at best unlikely and may not be achievable at all. Therefore, AACVPR recommends that the SCSEM reconsider its decision and recommend this measure move forward for endorsement. We thank you, in advance, for considering these comments.	The ACCF was given the opportunity to respond to this comment. Their response is included below. Measure Developer Response: The ACCF agrees that this measure is important to encourage standardization of collection of outcomes after carotid revascularization necessary to eventually measure and report on these outcomes. Steering Committee Response: See response at ID# 1186 above.	Measures Not Recommended: 1531-Follow-up assessment after carotid resvas.
1248	HPR	Richard Cambria, MD and Timothy Kresowik, MD; Society for Vascular Surgery	Measures not Recommended for Endorsement NQF Measure #1548 – Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR) SVS urges NQF to reconsider endorsement for measure #1548. SVS supports the efforts of this measure to establish imaging after EVAR as an important component of surgical quality measures. Measure #1548 was also chosen for inclusion in PQRS for 2012 pending final approval by CMS. SVS would ask NQF for full endorsement of this measure. SVS appreciates the opportunity to submit these comments and looks forward to working with NQF regarding these recommendations. Please feel free to contact Lindsey Adams, Health Policy Manager, Society for Vascular Surgery at 202-787-1231 or ladams@vascularsociety.org, if we can provide further information.	These comments were submitted by SVS. Steering Committee Response: The Steering Committee agreed that the measure focus is important but had significant concerns related to inability to discern reasons that follow up testing is not completed therefore it is not actionable as specified and, depending on how used/reported, could lead to unintended consequences. The committee encourages the developer to look to the potential of submitting a refined measure as part of PQRS to ease data capture.	Measures Not Recommended: 1548-Surveillance after EVAR