NATIONAL QUALITY FORUM

TO: Consensus Standards Approval Committee (CSAC)

FR: Heidi Bossley and Alexis Forman

RE: Result of Voting for *National Voluntary Consensus Standards: Surgery Endorsement Maintenance 2010, Phase II: A Consensus Report*

DA: December 8, 2011

The CSAC will review the recommendations from the project, *National Voluntary Consensus Standards: Surgery Endorsement Maintenance 2010, Phase II* on the December 12 call. This memo includes the list of recommended measures, summary information about the project, and the Member voting results. The individual measure evaluation summary tables from the draft report are in the Appendix. The complete voting draft report and detailed measure information are available on the project webpage.

CSAC ACTION REQUIRED

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of 24 candidate consensus standards. Of those recommended, 18 are National Quality Forum (NQF)-endorsed® measures that have been updated as part of the maintenance process (one of which was recommended for placement in "reserve status") and 6 are newly submitted measures that are recommended for initial endorsement.

Cardiac-CABG

- 0134 Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG) (STS)

Cardiac-CABG and Prophylaxis

- 0300 Cardiac surgery patients with controlled postoperative blood glucose (CMS)

Cardiac, Appendectomy and Pancreatic Resection

- 0127 Preoperative beta blockade (STS)
- 0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period (CMS)
- 0117 Beta blockade at discharge (STS)
- 0273 Perforated appendix admission rate (PQI 2) (AHRQ)
- 0265 Hospital transfer/admission (ASC Quality Collaboration)
- 1519 Statin therapy at discharge after lower extremity bypass (LEB) (SVS)

Cardiac and Vascular

- 1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy (SVS)
- 1543 Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS) (SVS)

General, Ophthalmology, Orthopedics and Pediatrics

- 0339 RACHS-1 pediatric heart surgery mortality (AHRQ)
- 0340 Pediatric heart surgery volume (PDI 7) (AHRQ)
- 0352 Failure to rescue in-hospital mortality (risk adjusted) (CHOP)
- 0353 Failure to rescue 30-day mortality (risk adjusted) (CHOP)
- 0351 Death among surgical inpatients with serious, treatable complications (PSI 4) (AHRQ)
- 0515 Ambulatory surgery patients with appropriate method of hair removal (ASC Quality Collaboration)
- 0301 Surgery patients with appropriate hair removal **(reserve status)** (CMS)
- 1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) (CMS)
- 1551 Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) (CMS)
- 1536 Cataracts: Improvement in patient's visual function within 90 days following cataract surgery (AAO and Hoskins Center for Quality Eye Care)

General, Prophylaxis and Wound Dehiscence

- 0528 Prophylactic antibiotic selection for surgical patients (CMS)
- 0126 Selection of antibiotic prophylaxis for cardiac surgery patients (STS)
- 0264 Prophylactic intravenous (IV) antibiotic timing (ASC Quality Collaboration)
- 0527 Prophylactic antibiotic received within 1 hour prior to surgical incision (CMS)

PROCESS

This project followed the National Quality Forum's (NQF's) version 1.8 of the CDP with the exception of the newly implemented 15-day voting period. All CDP steps were adhered to, and no concerns regarding the process were received.

Total Number of Measures Reviewed in Phase II	**40**
• Number of Measures not Recommended	2
• Number of Measures Withdrawn	1
• Number of Measures Pending Final Recommendation (decision will be reflected in an addendum report to Phase II)	13
o Number of Pending Measures due to a Request for Reconsideration	4

Measure Evaluation

The measures were evaluated against the 2009 version of the measure evaluation criteria (prior to implementing the task force recommendations). The Steering Committee encountered several overarching issues during its discussions and evaluations of the measures. These issues were factored into the Committee's ratings and recommendations for multiple measures and are explained below.

Clarity of Measure Specifications
Committee members requested clarification of a number of measure specifications related to incompleteness of specifications, inconsistencies in language, and construction of algorithms. The Committee considered the documents and appendices that were provided as attachments to the measure submissions to be useful in evaluating the measures; however, it urged measure developers to include all pertinent information within the submission forms to ensure accurate understanding of the measures for potential users and to provide clarity to the public.

Current Evidence and Relationship to Outcomes
The Committee expressed its preference for measures that provide clear and direct evidence of the measure's proximity to an improved outcome and in some cases asked measure developers to consider development of such measures as replacements for existing measures. Ensuring that the evidence provided to support the measure is current was highlighted, particularly for measures undergoing maintenance.

Disparities
The Committee noted that a number of measure submissions provided negligible information on disparities. In response, the Committee requested measure developers to submit additional information or, in the absence of disparities information, a plan to collect data in a way that permits disparities analyses in the future.

Impact on Quality
The Committee suggested measure developers provide detail on how their NQF-endorsed measure(s) have impacted quality since initial endorsement. The Committee considered such information as vital to the process of deciding whether a measure should retain endorsement.

Measures Recommended for Endorsement and Placement in Reserve Status
The Committee reviewed the NQF criteria for endorsed measures that continue to meet endorsement criteria during maintenance review but are deemed not to meet the criterion of "importance" due to having such a high rate of performance with little to no variation as outlined in subcriterion 1b. Discussed tentatively as an inactive status, such measures will be considered placed in "Reserve Status" signifying that they remained endorsed and in reserve until such time that they should be put back in use. There was concern that not continuing endorsement of a maintenance measure with a small performance gap could lead to reduced attention and decreased compliance with the measure. NQF will monitor the implications of the new status. The Committee noted that several maintenance measures could be considered for this status.

Participation in Registries
A number of measures that are advanced for continued endorsement rely on registry data, although they do not require participation in the identified registry. In its continued discussion of registries, the Committee took the position that endorsing a measure that requires use of registry data should be carefully considered because by default it requires participation in the registry. The data for a number of measures are not routinely collected outside the registry, which adds to the burden of collection for organizations. The use of such measures makes it essential that the specifications are fully detailed in a transparent fashion and that required data elements are standardized.

Public Reporting
The NQF endorsement criteria specify that measures submitted for endorsement must be intended for use for quality improvement and public reporting (accountability). The Committee noted that measure submission forms require and are expected to include public reporting plans. To that end, additional information was requested from developers that did not provide them. Additionally, the Committee asked developers to explain how measure information was conveyed to the public, in order to assess how a measure may be perceived.

Related and Competing Measures
A subset of the candidate consensus standards was related or competing with other candidate or current NQF-endorsed measures. The Steering Committee first evaluated each candidate standard on its own merits and then compared the measures that met NQF evaluation criteria with the related or competing measures using NQF's harmonization and competing measures guidance. Measures that were identified to be related were evaluated to determine if harmonization was needed. Requests for harmonization were sent to the developers. Measures 0127, 0134 and 0339 were harmonized as requested by the Committee. An additional 5 measures were not harmonized in part due to the number of developers involved and due to the need for additional discussions by the developers to address harmonization. The Committee determined that they would continue to recommend the measures with the expectation that harmonization would be accomplished at the next maintenance review in 2013.

Unintended Consequences
Committee members noted measures that could produce unintended consequences on patient care. They indicated that, where relevant, the care provided in healthcare institutions should be linked with patient outcome after discharge.

COMMENTS ON THE DRAFT REPORT AND THEIR DISPOSITION

The comment period for the draft report, *National Voluntary Consensus Standards: Surgery Endorsement Maintenance 2010, Phase II: A Consensus Report*, concluded on October 26, 2011. NQF received 135 comments from 29 individuals and organizations. A table of detailed comments submitted during the review period, with responses and actions taken by the Steering Committee and measure developers, is posted on the NQF project page under the Public and Member-Phase I comment section. A summary of comments and responses for each measure are also provided in the evaluation summary tables in the Appendix.

Comments about specific measure specifications were forwarded to the developers, who were invited to respond.

At its review of all comments, the Steering Committee had the benefit of developer responses. Committee members focused their discussion on recurring concerns and specific measures and topic areas that were most controversial or that questioned positions they had taken. Ultimately, the Committee made no changes to its measure recommendations.

Comments on Measures Recommended for Endorsement

Level of Assessment
A number of comments advocated the application of area or facility level measures be applied at other levels, most particularly the clinician level (*0273: Perforated appendix admission rate; 0284: Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period; 0339: RACHS-1 pediatric heart surgery mortality; 0340: Pediatric heart surgery volume; 0352: Failure to rescue in-hospital mortality (risk-adjusted); 0353: Failure to rescue 30 day mortality; 1550: Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)*).

The Committee revisited the expressed concerns as it had with similar concerns during Phase I; however, the Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed.

Topped Out Measures
A number of commenters indicated one or more measures were topped out and offered recommendations for handling those measures (*0117: Beta blockade at discharge; 0134: Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG); 0301: Surgery patients with appropriate hair removal; 0515: Ambulatory surgery patients with method of hair removal*).

With respect to 0117, commenters suggested that it be used as a composite with 0126 and 0127. The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed.

With respect to 0134, it was suggested the measure retain endorsement and be placed in reserve status.
The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed.

With respect to 0301 and 0515, suggestions were made to remove razors to ensure compliance and render these measures unnecessary. The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed.

Measures for Ambulatory Surgery Centers
Many comments were received in support of endorsing measures for use in ASCs. A number included recommendations that the measures be subjected to ongoing review and changes made to specifications as needed to ensure the measures remain current with the evidence base and, where appropriate, that they recognize subpopulations and risk factors and refine time frames for measurement.

The Steering Committee supports the recommendations and noted that as part of their commitment to maintain measures, developers are expected to engage in ongoing refinement of the measures based on the evidence and identification and reporting of disparities such as differences in performance among subpopulations. However, the Committee concluded that no

additional information was provided to revise evaluation of the measures and recommendations were not changed.

Hip and knee arthoplasty
During the comment period a number of comments specific to two measures *(1550: Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) and 1551: Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)).* In response to comments, the specifications were revised.

The Steering Committee has reviewed the revised specifications and determined that the measures with revised specifications can be advanced for voting without a further period of review or testing.

Comments on Measures Not Recommended for Endorsement

Encouragement to recommend measures 0364, 0367, 0368, 1531 and 1548
Comments were received about five of the measures that were not recommended for endorsement (*0364: Incidental appendectomy in the elderly; 0367 and 368: Post-operative wound dehiscence, pediatric and adult; 1531; Follow up assessment of stroke or death after carotid revascularization; 1548: Surveillance after endovascular abdominal aortic aneurysm repair*).

0364: Incidental appendectomy in the elderly. Commenters noted that this measure points to misuse and contributes to cost of care.
0367 and 368: Post-operative wound dehiscence, pediatric and adult. Commenters noted that these measures indicate less than optimal care, have negative patient impact and increase costs of care.

The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed. Measures 0364, 0367 and 0368 did not pass the NQF threshold criterion of importance. Of note, 0367 and 0368 were revisited by Steering Committee, with the evidence initially presented, to address developer concern regarding interpretation of the data.

1531: Follow up assessment of stroke or death after carotid revascularization; 1548: Surveillance after endovascular abdominal aortic aneurysm repair.

The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed. The decisions about the measures do not minimize the importance of assessment and surveillance. The Steering Committee strongly supports the concept underlying the measures and encourages the developers to continue effort to refine the measures and bring them to NQF for endorsement.

Four of the measures for which endorsement is not recommended (0364, 0367, 0368, and 1531) will not advance to vote in this phase. They have been moved to the addendum that will follow this report to allow time for consideration of developer requests for reconsideration.

NQF MEMBER VOTING

Effective July 1, 2011, the voting cycle changed from 30 days to **15 days** for NQF members to submit their votes. The 15-day voting period for the Surgery Endorsement Maintenance 2010, Phase I project concluded on December 5, 2011. Representatives of twenty-one member organizations voted; no votes were received from the Public/Community Health Agency.

All measures were approved with total approval ranging from 71% to 100%. Within the Councils, the lowest approval percentage was for measure 0301 Surgery patients with appropriate hair removal (recommended for placement in reserve status).

Three organizations submitted 19 voting comments. Below are the comments:

- Humana, Inc. submitted comments on seventeen specific measures:
    - Measure 0134 Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG) (STS)
    - "This measure appears to be one with a low gap, so may be considered for reserve status soon."

      While the mean is just below 95 percent, variation exists with complicate rates as low as 78.9 percent indicating opportunity for improvement that resulted in the Committee's recommendation for endorsement in active status instead of reserve status.

    - Measure 0300 Cardiac surgery patients with controlled postoperative blood glucose (CMS)
        - "We believe that this measure is good but should be strengthened by (a.) measurements to assure that there is no hypoglycemia; and (b.) expansion of the hours of measurement in the post-operative period."

          This comment was received during the Public and Member Comment period. The measure developer indicated that they would take the suggestion to their Technical Expert Panel. When revisions are made in the future, the Committee will review and discuss the revised measure with the measure developer.

    - Measure 117 Beta blockade at discharge (STS)
    - Measure 0127 Preoperative beta blockade (STS)
    - Measure 0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period (CMS)
        - "Good measure, but should be harmonized and made into a composite measure with #117, 127 and 284."

This comment was received during the Public and Member Comment period. The measure developer indicated that measures 0117 and 0127 were included in the all-or-none composite, The STS CABG Composite score (measure 0696) which was recently endorsed by NQF. In the Committee's consideration of harmonization, it determined that measure 0284's focus was unique to the other measures and decided to remove it from further harmonization discussion.

- Measure 273 Perforated appendix admission rate (PQI 2) (AHRQ)
  - "This measure is reflective only in part by the hospital team's management of the patient with abdominal pain. The low risk patients may be counted as 23 hour observation by some hospitals and inpatients by others. The results are also modified by the individual who presents late with a ruptured appendix."

- Measure 0265 Hospital transfer/admission (ASC Quality Collaboration)
  - "We support these measures from the ASCs and expect them to become stronger over time."

- Measure 1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy (SVS)
- Measure 1543 Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS) (SVS)
  - "The timing of the period of being asymptomatic for measure 1540 and 1543 should be the same. However, I believe the measure should be enlarged to encompass all patients having the procedure so as not to bias the sample with healthier individuals who would have better outcomes. This also helps in revealing who are appropriate surgical candidates."

    A similar comment regarding broadening the current scope was submitted during the Public and Member Comment period. The Committee suggested that in future updates to the measures, the developer consider inclusion of additional adverse outcomes.

- Measure 0340 Pediatric heart surgery volume (PDI 7) (AHRQ)
  - "Volume that is not differentiated among types of surgical procedures or risk of patients may not provide an accurate representation of the facility. The skill and effort in repair of a VSD is not the same as required to repair a tetrology of fallot."

    A similar comment regarding broadening the current scope was submitted during the Public and Member Comment period. The developer stated that in the recent updating of the literature review, there was a clear volume-outcome relationship at the hospital level. The Committee did have concerns regarding the reporting of pediatric heart surgery volume as a

stand-alone; however, this measure was initially endorsed to be reported as a pair with measure 0339. The Committee's recommendation is that it continue to be reported as a pair.

- Measure 515 Ambulatory surgery patients with appropriate method of hair removal (ASC Quality Collaboration)
- Measure 0301 Surgery patients with appropriate hair removal (CMS)
    - "Measure #515 and 0301 should be harmonized into a single measure as the physiology does not change between ASC and in-patient hospital setting."

      This comment was received during the Public and Member Comment period. The developer indicated that the measure has been harmonized and aligned with measure 0301.

- Measure 1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthoplasty (THA) and total knee arthroplasty (TKA) (CMS)
- Measure 1551 Hospital-level 30 day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthoplasty (THA) and total knee arthroplasty (TKA) (CMS)
    - "Agree with this measure and hope that it can be expanded to include those 18 to 64 as well as those 65 years and older."

      This comment was received during the Public and Member Comment period. The developer has indicated that they are currently performing analyses to support this suggestion and plan to specify the measure in all-payer data and for persons aged 18 and older in 2012. The revised changes will then be submitted to NQF.

- Measure 1536 Cataracts: Improvement in patient's visual function within 90 days following cataract surgery (AAO/Hoskins Center for Quality Eye Care)
    - "On the surface this appears to be intuitive; but it can also be used to judge those ophthalmologists who may have inappropriately selected individuals whose improvement may be minimal."

      The developer stated that providers are not responsible for collecting the data from patients and following up on their response.

- Measure 0264 Prophylactic intravenous (IV) antibiotic timing (ASC Quality Collaboration)
- Measure 0527 Prophylactic antibiotic received within 1 hour prior to surgical incision (CMS)
    - This is a good measure but measure #264 and 527 should be harmonized to become a single measure as place of service is irrelevant to this measure.

The Committee did not view these two measures as being related; thus, harmonization was not discussed. Possible harmonization between the two measures can be discussed in the future.

- Next Wave submitted one comment indicating their disapproval of endorsement on the following measure:

    - Measure 1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthoplasty (THA) and total knee arthroplasty (TKA) (CMS)
        - "I wanted to vote approval for this measure, but could not as currently specified, particularly since it is on the CMS list for near-term use for reporting and payment released last week. It still contains complications present on index admission in the numerator of the measure even after the recent modification. This will distort hospital comparisons and perversely reward hospitals that do not admit patients with existing complications. I would vote approval if ALL POA complication diagnoses in any position (in index admission only) were removed from the numerator."

          The developer stated that 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 occurred during the index admission. During the validation study of over 600 patients, the developer 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. The developer plans to explore the use of POA codes in the future.

- The Surgical Quality Alliance submitted one comment (and attached memo) indicating their disapproval of endorsement for reserve status for the following measure:

    - Measure 0301 Surgery patients with appropriate hair removal
        - "I want to let you know that at the last minute, American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS), requested the support of Surgical Quality Alliance (SQA) member organizations to oppose measure "NQF 301: Surgery Patients with Appropriate Hair Removal." Neurosurgery, with the support of the SQA, has tried for many years now to persuade the NQF, CMS, and others to discontinue the use of this measure due to a lack of evidence for its use across surgical specialties. Therefore, we opposed the hair removal measure, but voted in favor of all other measures in the draft report. In

case you are unfamiliar with the SQA, or need a refresher, the SQA was created by ACS and is a collaborative effort of over 20 surgical and anesthesia specialty societies united to define the principles of surgical patient quality measures, share methodologies to assist in the development of meaningful tools for quality improvement, and provide a forum for shared and coordinated efforts among the specialties to monitor and respond to federal and private sector initiatives. Attached for your reference is an SQA letter to CMS requesting the suspension of the SCIP hair removal letter."

The Committee was concerned about discontinuing regularly reporting of this measure due to the potential performance drop (e.g., return of the use of razors in the operating room for economic reasons).

Voting Results

Voting results for the 24 candidate consensus standards are provided below. (Links are provided to the full measure summary evaluation tables.)

Measure 0134: Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	1	0	3	67%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**15**	**2**	**4**	**21**	**88%**
Percentage of councils approving (>50%)					83%
Average council percentage approval					86%

*equation: Yes/ (Total-Abstain)

Measure 0300: Cardiac surgery patients with controlled postoperative blood glucose

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	1	1	6	80%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	2	0	0	2	100%
All Councils	**18**	**1**	**2**	**21**	**95%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					97%

*equation: Yes/ (Total-Abstain)

Measure 0127: Preoperative beta blockade

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**15**	**3**	**3**	**21**	**83%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					83%

*equation: Yes/ (Total-Abstain)

Measure 0284: Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	1	0	3	67%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**15**	**1**	**5**	**21**	**94%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					94%

*equation: Yes/ (Total-Abstain)

Measure 0117: Beta blockade at discharge

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**15**	**3**	**3**	**21**	**83%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					83%

*equation: Yes/ (Total-Abstain)

Measure 0273: Perforated appendix admission rate (PQI 2)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	2	1	0	3	67%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**15**	**1**	**5**	**21**	**94%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					94%

*equation: Yes/ (Total-Abstain)

Measure 0265: Hospital transfer/admission

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**17**	**0**	**4**	**21**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total-Abstain)

Measure 1519: Statin therapy at discharge after lower extremity bypass (LEB)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**15**	**3**	**3**	**21**	**83%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					83%

*equation: Yes/ (Total-Abstain)

Measure 1540: Postoperative stroke or death in asymptomatic patients undergoing carotid endarectomy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	1	1	2	0%
All Councils	**17**	**1**	**3**	**21**	**94%**
Percentage of councils approving (>50%)					86%
Average council percentage approval					86%

*equation: Yes/ (Total-Abstain)

Measure 1543: Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	1	1	2	0%
All Councils	**17**	**1**	**3**	**21**	**94%**
Percentage of councils approving (>50%)					86%
Average council percentage approval					86%

*equation: Yes/ (Total-Abstain)

Measure 0339: RSCHS-1 pediatric heart surgery mortality

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**17**	**0**	**4**	**21**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total-Abstain)

Measure 0340: Pediatric heart surgery volume (PDI 7)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	2	1	0	3	67%
Health Professional	4	1	1	6	80%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**15**	**2**	**4**	**21**	**88%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					91%

*equation: Yes/ (Total-Abstain)

Measure 0352: Failure to rescue in-hospital mortality (risk adjusted)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	1	1	6	80%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	0	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**18**	**1**	**2**	**21**	**95%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					97%

*equation: Yes/ (Total-Abstain)

Measure 0353: Failure to rescue 30-day mortality (risk adjusted)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	1	1	6	80%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	0	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**18**	**1**	**2**	**21**	**95%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					97%

*equation: Yes/ (Total-Abstain)

Measure 0351: Death among surgical inpatients with serious, treatable complications (PSI 4)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	0	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**18**	**0**	**3**	**21**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total-Abstain)

Measure 0515: Ambulatory surgery patients with appropriate method of hair removal

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**13**	**3**	**5**	**21**	**81%**
Percentage of councils approving (>50%)					67%
Average council percentage approval					81%

*equation: Yes/ (Total-Abstain)

Measure 1550: Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	1	0	2	50%
Supplier/Industry	1	1	0	2	50%
All Councils	**17**	**2**	**2**	**21**	**89%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					86%

*equation: Yes/ (Total-Abstain)

Measure 1551: Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	0	2	100%
Supplier/Industry	1	1	0	2	50%
All Councils	**18**	**1**	**2**	**21**	**95%**
Percentage of councils approving (>50%)					86%
Average council percentage approval					93%

*equation: Yes/ (Total-Abstain)

Measure 1536: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	3	0	0	3	100%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**17**	**0**	**4**	**21**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total-Abstain)

Measure 0528: Prophylactic antibiotic selection for surgical patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	4	0	2	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**13**	**3**	**5**	**21**	**81%**
Percentage of councils approving (>50%)					67%
Average council percentage approval					81%

*equation: Yes/ (Total-Abstain)

Measure 0126: Selection of antibiotic prophylaxis for cardiac surgery patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**15**	**3**	**3**	**21**	**83%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					83%

*equation: Yes/ (Total-Abstain)

Measure 0264: Prophylactic intravenous (IV) antibiotic timing

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	1	0	3	67%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**16**	**1**	**4**	**21**	**94%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total-Abstain)

Measure 0527: Prophylactic antibiotic received within 1 hour prior to surgical incision

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	5	0	1	6	100%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**15**	**3**	**3**	**21**	**83%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					83%

*equation: Yes/ (Total-Abstain)

Measure 0301: Surgery patients with appropriate hair removal

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	2	0	3	33%
Health Plan	3	0	0	3	100%
Health Professional	3	2	1	6	60%
Provider Organizations	3	0	0	3	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	2	2	
All Councils	**12**	**5**	**4**	**21**	**71%**
Percentage of councils approving (>50%)					67%
Average council percentage approval					74%

*equation: Yes/ (Total-Abstain)

Appendix

Evaluation Summary—Candidate Consensus Standards Recommended for Endorsement

0134 Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG)
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) who received an internal mammary artery (IMA) graft. Numerator Statement: Number of patients undergoing isolated coronary artery bypass graft (CABG) who received an internal mammary artery (IMA) graft. Denominator Statement: All patients undergoing isolated CABG. Exclusions: Cases are removed from the denominator if the patient had a previous CABG prior to the current admission or if IMA was not used and one of the following reasons was provided: - Subclavian stenosis - Previous cardiac or thoracic surgery - Previous mediastinal radiation - Emergent or salvage procedure - No LAD disease Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Clinicians: Group, Clinician: Individual, Clinician: Team, Facility/Agency, Population: National, regional/network, states, counties or cities Type of Measure: Process Data Source: Registry data-STS Adult Cardiac Surgery Database, Version 2.73 Measure Steward: Society of Thoracic Surgeons | 633 North Saint Clair Street, Suite 2320 | Chicago | Illinois | 60611
Steering Committee Recommendation for Endorsement: Y-20; N-0; A-2 Rationale: This measure is tied to improved outcomes due to high patency rates of the IMA. The current compliance mean is 95 percent; however variation among programs exists; i.e., compliance rates as low as 80 percent.
If applicable, Conditions/Questions for Developer: 1. 1b.4 Summary of Data on Disparities by Population Group: Please provide data on disparities. 2. 2a.9 Denominator Exclusions: Please remove "the IMA is not a suitable conduit due to size or flow" from the exclusions. Developer Response: 1. Data on disparities are provided in the form. 2. STS staff agreed to remove the exclusion related to IMA suitability during the Steering Committee meeting. The form was modified to reflect this. Steering Committee Follow-up: The Steering Committee agreed that the response from the developer was adequate. Additional Conditions/Questions for Developer: Harmonization: As agreed, 0134 and 0516 should be harmonized by combining into a single measure, which can allow reporting at the provider or institution level.
1. Importance to Measure and Report: Y-20; N-1 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The literature points to disparities amongst women, with IMA used less often in women. The developer did not provide information or data on disparities related to performance on the measure.
2. Scientific Acceptability of Measure Properties: C-14; P-7; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The exclusion 'IMA not suitable,' can lead to the issue of gaming. This causes apprehension as to who determines if the IMA is not suitable, since currently, there are no criteria that classifies the IMA as suitable. The Committee requested that this exclusion be removed.
3. Usability: C-20; P-1; M-0; N-0 (3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures) Rationale: The information obtained is meaningful and useful.

0134 Use of internal mammary artery (IMA) in coronary artery bypass graft (CABG)
4. Feasibility: C-20; P-1; M-0; N-0 (4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented) Rationale: The information can be derived from electronic sources.
Public and Member Comments It was suggested the measure retain endorsement and be placed in reserve status. The Committee concluded that no additional information was provided to revise evaluation of the measures and recommendations were not changed.
Voting: Total Approval: 88% Comments received: "This measure appears to be one with a low gap, so may be considered for reserve status soon." CSAC Approval: Board Endorsement:

0300 Cardiac surgery patients with controlled postoperative blood glucose
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Cardiac surgery patients with controlled blood glucose (≤180 mg/dl) in the timeframe of 18 to 24 hours after Anesthesia End Time. Numerator Statement: Cardiac surgery patients with controlled postoperative blood glucose (≤180 mg/dl) in the timeframe of 18 to 24 hours after Anesthesia End Time. Denominator Statement: Cardiac surgery patients with no evidence of prior infection. Include patients with an ICD-9-CM Principle Procedure code or ICD-9-CM Other Procedure codes of selected surgeries AND an ICD-9-CM for ICD-9-CM codes Principle Procedure code or ICD-9-CM Other Procedure codes of selected surgeries. Exclusions: Excluded Populations: • Patients less than 18 years of age • Patients who have a length of Stay greater than 120 days • Patients who had a principal diagnosis suggestive of preoperative infectious diseases (as defined in Appendix A, Table 5.09 for ICD-9-CM codes) • Burn and transplant patients (as defined in Appendix A, Tables 5.14 and 5.15 for ICD-9-CM codes) • Patients enrolled in clinical trials • Patients whose ICD-9-CM principal procedure occurred prior to the date of admission • Patients with physician/advanced practice nurse/physician assistant (physician/APN/PA) documented infection prior to surgical procedure of interest • Patients who discharged prior to 24 hours after Anesthesia End Time. Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility; Population: National, Population: Regional Type of Measure: Process Data Source: Electronic administrative data/claims; paper medical record/flow-sheet. Vendor tools or CART. CART is available for download free at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093 Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-20; N-0; A-2 Rationale: Subsequent to developer changing the timeframe from 6 am due to variation in time of surgery, Committee indicated that a more comprehensive measure would involve monitoring a patient's blood glucose over the 18-24 hour period after surgery and allowing a 4 hour window to reduce high glucose levels to ≤ 180mg/dl. This suggestion led to the developers revising the measure to include the timeframe of 18 to 24 hours.

0300 Cardiac surgery patients with controlled postoperative blood glucose

If applicable, Conditions/Questions for Developer:

1. 2a.1 Numerator Statement: The timeframe should be within 24 hours after surgery instead of 6 am.
2. 2a.10 Denominator Exclusion Details: Provide a more detailed definition of perioperative death.

Developer Response:

1. This recommendation was presented to the SCIP Infection TEP on April 6, 2011. The panel accepted changing the measure numerator to patients having cardiac surgery whose highest blood sugar, between 18 and 24 hours after surgery is 180mg/dl or less.
2. Patients that expire during the perioperative period are excluded from this measure, as they should not be held accountable for glucose values on POD 1 or 2. The data element has this definition: The patient expired during the timeframe from surgical incision through discharge from the post anesthesia care/recovery area. Additional abstraction instructions include:
   For patients discharged from surgery and admitted to the PACU: The end of the perioperative period occurs when the patient is discharged from the PACU.
   For patients discharged from surgery and admitted to locations other than the PACU (e.g., ICU): The perioperative period would end a maximum of six hours after arrival to the recovery area.

If applicable, Conditions/Questions for Developer:

1. 2a.1 Numerator Statement: Suggested modification-If serum glucose is above 180 mg/dl, was it decreased within a specific amount of time.
2. 2b Reliability Testing and 2c Validity Testing: Advise what additional testing will need to be completed in light of the suggested modification.

Steering Committee Follow-up:

The Steering Committee agreed that the response from the developer regarding POD was adequate.

1. Importance to Measure and Report: Y-16; N-5

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The goal of the measure, to improve patient's blood sugar, is important. Performance at the aggregate is 93.4 percent; disparity information to understand if there are subpopulations disparities was requested and obtained.

2. Scientific Acceptability of Measure Properties: C-2; P-12; M-7; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: There is a need for more flexibility in the timeframe to allow comparability since variation in patient times of departure from the operating room. Both the committee and developer have heard anecdotal reports that clinical staffs are leaving patients on insulin drips to meet the criteria of the measure. Assuming this to be accurate, the timeframe change will address such an unintended consequence of the measure.

3. Usability: C-5; P-6; M-10; N-0

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: The Committee was unsure if this measure would provide additive value if the timeframe remained at 6 am.

4. Feasibility: C-5; P-9; M-7; N-0

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale: The measure cannot be easily implemented using the current timeframe. The timeframe has been changed.

Public and Member Comments

- Do not support glucose control as a performance measure at this time;
- Prefer glucose range be included in the measure to avoid hypo-or hyper-glycemia; and
- Concerned with how measure considers hospital non-compliance

The measure developer indicated that they will discuss including a glucose range (to avoid hypo- or hyper- glycemia) in the measure with their Technical Expert Panel. The Committee will review the response from CMS' Technical Expert Panel and discuss it with CMS to determine a future appropriate action.

The developer indicated that the measure does not require that all blood sugars between 18-24 hours after the end of cardiac surgery be below 180 mg/dL.

Voting: Total Approval: 95%

Comments received: "We believe that this measure is good but should be strengthened by (a.) measurements to assure that there is no hypoglycemia; and (b.) expansion of the hours of measurement in the post-operative period."

0300 Cardiac surgery patients with controlled postoperative blood glucose
CSAC Approval: Board Endorsement:

0127 Preoperative beta blockade
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percent of patients aged 18 years and older undergoing isolated CABG who received beta blockers within 24 hours preceding surgery. Numerator Statement: Number of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery Denominator Statement: All patients undergoing isolated CABG Exclusions: Cases are removed from the denominator if preoperative beta blocker was contraindicated. Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Clinicians: Group, Clinicians: Individual, Facility/ Agency, Population: Community, Population: Counties or cities, Population: National, Population: Regional/ network, Population: States Type of Measure: Process Data Source: Registry data Measure Steward: Society of Thoracic Surgeons | 633 North Saint Clair Street, Suite 2320 | Chicago | Illinois | 60611
Steering Committee Recommendation for Endorsement: Y-23; N-0; A-1 Rationale: There was strong evidence to support this measure and it demonstrated a clear performance gap.
If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-Up: This was one of four related measures considered for potential harmonization. The four included: e*ndorsed measure 0235*: Pre-op beta blocker in patient with isolated CABG; m*aintenance measure 0127*: Pre-operative beta blockade; e*ndorsed measure 0236*: Pre-op beta blocker in patient with isolated CABG; and m*aintenance measure 0284*: Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period. Discussion of the four measures is included here. The Steering Committee stated that measure 0284 is unique and harmonization will not be pursued at this time since it applies beyond CABG to other surgical patients receiving beta blocker therapy prior to admission. The Steering Committee identified measures 0235 and 0127 as similar and should be combined into a single measure. The measure developer confirmed that the measures are similar with the exception of the level of measurement and indicated that they would combine them into a single measure from which information at the individual or facility level can be drawn. The developer also noted that measures 0235 and 0236 are identical in their specifications and are two components of a Physician Quality Reporting System (PQRS) measure. The Steering Committee stated that they considered the measures derived from registry data (measures 0235 and 0127) and administrative claims data (measure 0236) to be similar but not competing since the two data sources result in capture of information about different populations; both measures are useful and valid. On the September 13 conference call, the measure developer confirmed that measures 0127 and 0235 had been combined into this single measure that includes a level of analysis for both facilities and individual clinicians.
1. Importance to Measure and Report: Y-21, N-0; A-0 (1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence) Rationale: There was strong evidence to support this measure and it demonstrated a performance gap of 86.6 percent.
2. Scientific Acceptability of Measure Properties: C-16; P-5; M-0; N-0 (2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities) Rationale: Questions regarding number of patients excluded by the measure and concerns over contraindications to preoperative beta blockers were satisfactorily addressed by additional information from the developer. Evidence in support of the measure demonstrates its value.
3. Usability: C-17; P-4; M-0; N-0 (3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures) Rationale: The measure as specified is usable; there may be opportunities for harmonization with other beta blocker measures. At the request of the Committee, the developer combined measures 0127 and 0235 into a single measure.
4. Feasibility: C-17; P-4; M-0; N-0 (4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented) Rationale: The measure is meaningful for public reporting and quality improvement; though, the cost of data extraction is of some

0127 Preoperative beta blockade
concern.
Public and Member Comments Commenters suggested that it be used as a composite with 0126. The developer stated that the denominator of measure 0127 differs from the denominator of 0126. The Committee did not change its recommendation but noted that endorsement as an individual measure does not preclude use in a composite.
Voting: Total Approval: 83% Comments received: "Good measure, but should be harmonized and made into a composite measure with #117, 127 and 284." CSAC Approval: Board Endorsement:

0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period. To be in the denominator, the patient must be on a beta-blocker prior to arrival. The case is excluded if the patient is not on a beta-blocker prior to arrival, as described below in 2a4. Numerator Statement: Surgery patients on beta blocker therapy prior to admission who receive a beta blocker during the perioperative period Denominator Statement: All surgery patients on beta blocker therapy prior to arrival Data Element Data Collection Question: Is there documentation that the patient was on a daily beta-blocker therapy prior to arrival? Yes/No Notes for Abstraction: • If there is documentation that the beta-blocker was taken daily at "home" or is a "current" medication, select "Yes". • If a beta-blocker is listed as a home medication without designation of how often or when it is taken, select "Yes". • If there is documentation that the beta-blocker is a home/current medication and additional documentation indicates the beta-blocker was not taken daily, e.g., the medication reconciliation form lists a beta-blocker as a home/current medication, but documentation in the nurses notes state "patient denies taking beta-blocker every day", select "No". • If there is documentation that the beta-blocker is on a schedule other than daily, select "No". • If there is documentation that the beta-blocker was given on a "prn" basis for cardiac or non-cardiac reasons, select "No". Exclusions: • Patients less than 18 years of age • Patients who have a Length of Stay greater than 120 days • Patients enrolled in clinical trials • Patients whose ICD-9-CM principal procedure occurred prior to the date of admission • Patients who expired during the perioperative period • Pregnant patients taking a beta-blocker prior to arrival • Patients with a documented Reason for Not Administering Beta-Blocker-Perioperative • Patients with Ventricular Assist Devices or Heart Transplantation Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility/ Agency, Population: National, Population: Regional Type of Measure: Process Data Source: Electronic administrative data/ claims, Paper medical record/ flow-sheet Vendor tools (electronic) or CART. CART is available for download free at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093 Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Blvd, Mail Stop S3-02-01 | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-20; N-0; A-1 Rationale: The measure is meaningful for public reporting and quality improvement.
If applicable, Conditions/Questions for Developer: 1. 2a.4 Denominator Statement: Include definition of 'prior to arrival' and clarify the expected beta blocker dosing during the perioperative period (e.g., beyond homeopathic dose) – should be done to a specific parameter; i.e., hear rate or blood pressure. 2. 2a.9 Denominator Exclusions: Exclusion for laparoscopy verbally reported as removed effective January 1, 2012. Please confirm. 3. 2a.9 Denominator Exclusions: Consider exclusions for patients on beta blockers for non-cardiac reasons.

0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period

Developer Response:

1. To be in the measure denominator, the patient must be on a beta-blocker prior to arrival. The data collection question and relevant notes for abstraction for the data element Beta-Blocker Current Medication are listed below. The case is excluded if the answer to this data element is "no." We do NOT use specific parameters for dosing because this measure was designed to ensure that patients on beta-blocker therapy at home have continued therapy. It is not evaluating whether the dose is therapeutic. There is simply no way to define a "homeopathic dose" for the purposes of data collection.

   Suggested Data Collection Question: Is there documentation that the patient was on a daily beta-blocker therapy prior to arrival? Yes/No

   Notes for Abstraction:

   • If there is documentation that the beta-blocker was taken daily at "home" or is a "current" medication, select "Yes".
   • If a beta-blocker is listed as a home medication without designation of how often or when it is taken, select "Yes".
   • If there is documentation that the beta-blocker is a home/current medication and additional documentation indicates the beta-blocker was not taken daily, e.g., the medication reconciliation form lists a beta-blocker as a home/current medication, but documentation in the nurses notes state "patient denies taking beta-blocker every day", select "No".
   • If there is documentation that the beta-blocker is on a schedule other than daily, select "No".
   • If there is documentation that the beta-blocker was given on a "prn" basis for cardiac or non-cardiac reasons, select "No".
2. The data element Laparoscope has been removed from all SCIP measures for January 1, 2012 discharges. Major surgeries performed laparoscopically may be included if their ICD-9 Principal Procedure Code is included in the denominator (Table 5.10).

   Those exclusions are accounted for in the Notes for Abstraction for the data element Beta-Blocker Current Medication. See above. The abstractor is instructed to answer "no" to this data element which excludes them from the measure.

Steering Committee Follow-up:

1. 2a.4 Denominator Statement: Further define "prior to arrival" to specify "all surgery patients on daily beta blocker therapy prior to arrival".
2. This was one of four related measures considered for potential harmonization. The four included: e*ndorsed measure 0235*: Pre-op beta blocker in patient with isolated CABG; m*aintenance measure 0127*: Pre-operative beta blockade; e*ndorsed measure 0236*: Pre-op beta blocker in patient with isolated CABG; and m*aintenance measure 0284*: Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period. Discussion of the four measures is included here. The Steering Committee stated that measure 0284 is unique and harmonization will not be pursued at this time since it applies beyond CABG to other surgical patients receiving beta blocker therapy prior to admission. The Steering Committee identified measures 0235 and 0127 as similar and should be combined into a single measure. The measure developer confirmed that the measures are similar with the exception of the level of measurement and indicated that they would combine them into a single measure from which information at the individual or facility level can be drawn. The developer also noted that measures 0235 and 0236 are identical in their specifications and are two components of a Physician Quality Reporting System (PQRS) measure. The Steering Committee stated that they considered the measures derived from registry data (measures 0235 and 0127) and administrative claims data (measure 0236) to be similar but not competing since the two data sources result in capture of information about different populations; both measures are useful and valid.

1. Importance to Measure and Report: Y-21; N-0

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Performance is above 90 percent; however, discontinuation of beta blockers in the post-op period has the potential to affect large numbers and for that reason remains a concern. It was noted that beta blockers had to be titrated to a certain heart rate for them to provide a beneficial result to the patient.

2. Scientific Acceptability of Measure Properties: C-10; P-10; M-1; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: The evidence, construction and testing of the measure meets requirements. The Committee questioned the period of time that was considered as part of the perioperative period and why laparoscopic procedures were included in the exclusions and set conditions related to these concerns.

3. Usability: C-12; P-9; M-0; N-0

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: The measure is meaningful for public reporting and quality improvement.

0284 Surgery patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period

4. Feasibility: C-12; P-9; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The required data is readily available; the Committee questioned whether the measure would continue to rely on paper records. It is not included in the list for electronic health records (EHR) at present; however, the developer was encouraged to consider capturing titration to heart rate when it does move to EHR. They were also requested that the bradycardia exclusion be included.

Public and Member Comment

- Should apply at the clinician level of analysis; and
- Multiple data sources

The developer indicated that the measure could be applied at the clinician level but was developed specifically for the facility level. 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 is 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 going forward.

Voting: Total Approval: 94%
Comments received: "Good measure, but should be harmonized and made into a composite measure with #117, 127 and 284."
CSAC Approval:
Board Endorsement:

0117 Beta blockade at discharge

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percent of patients aged 18 years and older undergoing isolated CABG who were discharged on beta blockers
Numerator Statement: Number of patients undergoing isolated CABG who were discharged on beta blockers
Denominator Statement: All patients undergoing isolated CABG
Exclusions: Cases are removed from the denominator if there was an in-hospital mortality or if discharge beta blocker was contraindicated.
Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Clinicians: Group, Facility/ Agency, Population: Counties or cities, Population: National, Population: Regional/network, Population: States
Type of Measure: Process
Data Source: Registry data
Measure Steward: Society of Thoracic Surgeons | 633 North Saint Clair Street, Suite 2320 | Chicago | Illinois | 60611

Steering Committee Recommendation for Endorsement: Y-21; N-0; A-1
Rationale: The measure is important and shows a performance gap.

If applicable, Conditions/Questions for Developer:
Developer Response:
If applicable, Questions to the Steering Committee:

1. Importance to Measure and Report: Y-21; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The measure is important and shows a performance gap with a mean of 95.1 percent and a median of 96.9 percent compliance; however, performance drops off sharply indicating there is room for continued performance improvement.

2. Scientific Acceptability of Measure Properties: C-18; P-3; M-0; NA-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: Initial concern about patients with contraindications who were removed from the numerator and denominator and the clarity of the time window were resolved in conversation with the developer. There is a clear relationship of this measure to patient outcomes. The rationale for using eligibility and exclusion criteria in lieu of a risk model that would be difficult to construct was accepted.

3. Usability: C-17; P-4; M-0; NA-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The measure was considered usable; no concerns were expressed.

4. Feasibility: C-18; P-3; M-0; NA-0

0117 Beta blockade at discharge
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented) Rationale: While there were questions about potential gaming and costs associated with data abstraction, these issues are relatively common across many measures and were not believed to compromise the feasibility of this measure.
Public and Member Comment • Considers the measure to be topped out due to the mean value being at 95.1 percent; and • Should be combined with measure 0126 and 0127. Although the mean value is 95.1 percent, the distribution of values indicates there is opportunity for improvement. The denominator of measures 0117 and 0127 differ from measure 0126. In addition, two of the measures are included in the NQF-endorsed® measure 0696 The STS CABG Composite Score. Endorsement as a standalone measure does not preclude use in a composite.
Voting: Total Approval: 83% Comments received: "Good measure, but should be harmonized and made into a composite measure with #117, 127 and 284." CSAC Approval: Board Endorsement:

0273 Perforated appendix admission rate (PQI 2)
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of admissions for appendicitis within county with perforated appendix. Numerator Statement: All discharges with ICD-9-CM diagnosis code for perforations or abscesses of appendix in any field among cases meeting the inclusion rules for the denominator. Denominator Statement: All non-maternal discharges of age 18 years and older in Metro Area1 or county with diagnosis code for appendicitis in any field. Exclusions: Not applicable. Adjustment/Stratification: risk adjustment method widely or commercially available The predicted value for each case is computed using a logistic regression model and covariates for gender and age in years (in 5-year age groups). The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2007 (updated annually), a database consisting of 43 states and approximately 30 million adult discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., county, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate/Observed rates may be stratified by gender, age (5-year age groups), race/ ethnicity. Level of Analysis: Population: Counties or cities, Population: States Type of Measure: Outcome Data Source: Electronic administrative data/ claims Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850
Steering Committee Recommendation for Endorsement: Y-21; N-0; A-1 Rationale: This is a population-based measure that is scientifically valid and easy to implement with a significant performance gap. Adverse outcomes such as longer length of stay with the resulting increased resource utilization are associated with an appendix perforation.
If applicable, Conditions/Questions for Developer: Developer Response: If applicable, Questions to the Steering Committee:
1. Importance to Measure and Report: Y-19; N-2 (1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence) Rationale: The Committee indicated that the measure demonstrated that adverse outcomes are associated with an appendix perforation and disparity data suggested a gap in care. The measure is useful as a population prevention indicator.
2. Scientific Acceptability of Measure Properties: C-16; P-5; M-0; N-0 (2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities) Rationale: This measure has scientific validity.
3. Usability: C-18; P-2; M-0; N-1 (3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing

0273 Perforated appendix admission rate (PQI 2)
measures) Rationale: This measure is useful in looking at clinical management and is in use.
4. Feasibility: C-18; P-3; M-0; N-0 (4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented) Rationale: This measure uses claims data and is feasible to collect.
Public and Member Comment • Better performing center may have a higher percentage of discharges with perforated appendicitis; and • Expand the scope of the measure The developer stated that the measure was designed with the intent to measure ready access to care and the quality of care in an area such as a county. The Committee supported continued endorsement of the measure based on performance gap and measure intent.
Voting: Total Approval: 94% Comments received: "This measure is reflective only in part by the hospital team's management of the patient with abdominal pain. The low risk patients may be counted as 23 hour observation by some hospitals and inpatients by others. The results are also modified by the individual who presents late with a ruptured appendix." CSAC Approval: Board Endorsement:

0265 Hospital transfer/admission
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Numerator Statement: Ambulatory surgical center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC. Denominator Statement: All ASC admissions Exclusions: None Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility/ Agency Type of Measure: Outcome Data Source: Paper medical record/ flow-sheet Measure Steward: ASC Quality Collaboration | 5686 Escondida Blvd S | St. Petersburg | Florida | 33715
Steering Committee Recommendation for Endorsement: Y-18; N-3; A-1 Rationale: This measure focus is important and will encourage reporting and provide the ability to analyze transfer rates among ASCs.
If applicable, Conditions/Questions for Developer: 1. 1b.2 Summary of Measure Results Demonstrating Performance Gap: Rates and percentages presented in the measure are confusing. Please review and revise as appropriate 2. 1b.3 Data/Sample: There is a discrepancy between the data that was collected and publicly reported. In the usability section, it states that 1,185 ASCs submitted data for 2nd quarter 2010 on this particular measure; however, in section 1b.3, it states that only 526 ASCs submitted data on this measure. Please reconcile. 3. 2a.2 Numerator Time Window: Revise numerator statement from "…discharge from the ASC" to a more appropriate interval this will also reduce potential perverse incentives. Time window should be at least 24 hours, which would also reduce potential for the unintended incentive to discharge home when admission needed. 4. 2f.2. Methods to Identify Statistically Significant and Practical or Meaningful Differences in Performance: The statistical analysis does not specify a method; validity is questioned. Please reevaluate and in doing so, be specific about what is known about what transfer rates should be expected to be. 5. 2h. Disparities in Care: Please submit any subpopulation performance data that is available for the measures. The committee understands that ASCs do not have a quality reporting system requirement; however, assessment of subpopulation data is important and should be collected and reported for this and other measures. Developer Response: 1. Although data for 1,185 ASCs are included in the ASC QC database for this measure, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The rates for this measure are based on the 526 individually-reporting ambulatory surgery centers throughout the US for services provided during April to June 2010. The rate for unscheduled transfer or admission to a hospital ranged from a minimum of 0.0% to a maximum of 2.3%. The mean rate was 0.1% (SD: 0.2%), while the median rate was

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0.1%. The maximum transfer rate of 2.3% and a third quartile value of 0.2% demonstrate that there is an opportunity for improvement in this measure.

2. Although data for 1,185 ASCs are included in the ASC QC database for this measure, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The 526 individually-reporting ambulatory surgery centers represent a convenience sample of the ASC population were used to assess the opportunity for improvement for this measure. The centers were located throughout the US. Services from the second calendar quarter of 2010 were included in this portion of the study.
3. Based on our experience to date, we have no reason to believe that patients requiring admission or transfer to the hospital are being discharged home in order to improve the ASC's performance on this measure. The malpractice risk from substandard care carries much graver consequences than any potential outcome from slightly higher rates of transfer/admission related to this measure. After discussion with NQF staff and if the Committee wishes to see a measure of the hospital admission rate for a more extended timeframe, we will create a separate measure using a sampling protocol. We propose to develop this measure using the following draft numerator and denominator statements, which may be modified during the development phase:
   Numerator statement: Ambulatory surgery center (ASC) admissions experiencing a hospital admission in the 24 hour period following discharge from the ASC.
   Denominator statement: All selected ASC patients (sampling protocol to be developed and tested)
4. An individual ASC's transfer rate may be compared to the standard rate from the ASC Quality website (http://www.ascquality.org/qualityreport.cfm#Transfer). A statistically significant difference in performance may be detected by using a standard test of proportions as outlined in most standard statistical texts. Since each transfer may represent increased risk exposure for the patient, a rate higher than the standard of 1 per 1000 is also of practical significance. The null hypothesis for this test is that the sample proportion from the ASC is not different from the industry standard taken from the ASC Quality website. The alternative is that there is a statistically significant difference. We recommend that this test be performed in its two-sided form so that the ASC may determine if they are either statistically higher or lower than the standard. The recommended p-value for this test is the 0.05 level, but ASCs may have justification for different value. Using this statistical method for detecting significant variances from the industry standard will allow users to determine if differences may be due to sampling error or may indicate a true difference in performance.
5. The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by third quarter of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three months thereafter.
6. ADDITIONAL INFORMATION and Response from Measure Developer:
   We have also revised 2f1 for this measure #0265 Hospital Transfer to provide additional clarity:
   2f.1. Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)
   Although data for 1,185 ASCs are included in the ASC QC database, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 526 ASCs throughout the US. The rates for this measure were collected for the 526 individually-reporting ambulatory surgery centers throughout the US for services provided during April to June 2010.

Steering Committee Follow-up:

The Steering Committee agreed with and encourages the developer's plan to create a measure to be submitted to NQF in the future focused on hospital admission rates with an extended timeframe. They expressed reservations that the current measure may have the unintended consequence of patients who are sent home rather than admitted when admission appeared a likely outcome. The Committee was also concerned about the burden of data collection, but agreed that the measure was important and, through reporting across ASCs and to the public, should further encourage reporting by ASCs. They agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-15; N-5

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The Committee deems the focus of the measure important but has concerns about a) the potential for the unintended

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consequence of discharging a patient to home when potential need for admission is relatively high which argues for modification of the measure to include a time window for admission and b) the low admission rate reflected in the data provided does not demonstrate a meaningful performance gap. Modification of the measure with a broader time window could resolve the concerns.
2. Scientific Acceptability of Measure Properties: C-2; P-10; M-6; N-2 (2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities) Rationale: The measure does not provide concise parameters for measurement benchmarking, since it does not establish an appropriate target rate of transfer. Developer was asked to address this and did so to the satisfaction of the committee. See developer response above.
3. Usability: C-6; P-9; M-3; N-2 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The statistical analysis did not seem valid, since the outliers would vary by ambulatory surgical center. This measure may not be ready for public reporting since it does not have a specific target transfer rate. Developer was asked to address this and did so to the satisfaction of the committee. See developer response above.
4. Feasibility: C-13; P-7; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Data is derived from the patient medical record. The measure could have the unintended consequence of promoting a discharge to home rather than a transfer, since an admission would be viewed as "failing to meet the measure".
Public and Member Comment • Unsure if measure will generate valuable information; and • Timeframe should be specified Support for this measure within the Committee was based on the intent to improve the ASC reporting rate of less than 50 percent of eligible ASCs. 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."
Voting: Total Approval: 100% Comments received: "We support these measures from the ASCs and expect them to become stronger over time." CSAC Approval: Board Endorsement:

1519 Statin therapy at discharge after lower extremity bypass (LEB)
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of patients aged 18 years and older undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge. This measure is proposed for both hospitals and individual providers. Numerator Statement: Patients undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge. Denominator Statement: All patients aged 18 years and older undergoing lower extremity bypass as defined above who are discharged alive, excluding those patients who are intolerant to statins. Exclusions: Chart documentation that patient was not an eligible candidate for statin therapy due to known drug intolerance, or patient died before discharge. Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Can be measured at all levels, Clinicians: Group, Clinicians: Individual, Facility/ Agency Type of Measure: Process Data Source: Registry data Measure Steward: Society for Vascular Surgery | 633 N. Saint Clair St., 22nd Floor | Chicago | Illinois | 60611
Steering Committee Recommendation for Endorsement: Y-20; N-0 ; A-1 Rationale: The focus of the measure is important and while the evidence cited speaks to statin use for LDL control, use of statins without reference to LDL is the current trend and, per the developer, it is expected that it will be supported in future guidelines.
If applicable, Conditions/Questions for Developer: 1. 2a.2 Numerator Time Window: Timeframe lacks precision. Please address. 2. 2a.7 Denominator Time Window: Timeframe lacks precision. Please address.

1519 Statin therapy at discharge after lower extremity bypass (LEB)
Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization Developer Response: We have modified the form time window for all SVS measures as follows: Since hospitals have sufficient annual volume to generate accurate reporting levels, these are proposed for reporting every 12 months for hospital. Since surgeons have lower individual volume, we recommend annual reporting of the last 50 consecutive procedures, which may span more than one year, with suppression if < 10 procedures (i.e., reported as too low volume to report). Steering Committee Follow-up: 1. The Steering Committee agreed that the response from the developer was adequate. 2. This was one of two related measures considered for potential harmonization. The two included: m*aintenance measure 0118*: Anti-lipid treatment discharge and n*ew candidate measure 1519*: Statin therapy at discharge after lower extremity bypass (LEB). Discussion of the two measures is included here. The Steering Committee stated that measures 0118 and 1519 were related in terms of therapy used; however, they involve different procedures and different patient populations and are reasonably aligned thus no further action was recommended.
1. Importance to Measure and Report: Y-19; N-1 (1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence) Rationale: The measure is based on a guideline that focuses on statin use for LDL control while the measure focuses on statin use regardless of the LDL control; however, the current trend in practice to use of statin without reference to LDL. Performance rates have improved from 41 percent to 79 percent, still short of the 90 percent goal.
2. Scientific Acceptability of Measure Properties: C-8; P-11; M-1; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The Committee noted the numerator and denominator timeframes lacked precision. The developer revised the timeframes to 12 months.
3. Usability: C-14; P-5; M-1; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure, which relies on registry data, was considered usable.
4. Feasibility: C-13; P-7; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The feasibility of implementation was questioned since the data comes from a registry. For registry participants the measure is quite feasible; a non-registry participant would have to collect manually or develop an electronic system.
Public and Member Comment Commenters suggested replacement of this process measure with an outcome measure. The focus of the measure was determined by the Committee to be important and is guideline based. NQF will continue to seek outcome measures that can supplement or supplant process measures.
Voting: Total Approval: 83% Comments received: None CSAC Approval: Board Endorsement:

1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of patients age 18 or older without carotid territory neurologic or retinal symptoms within the one year immediately preceding carotid endarterectomy (CEA) who experience stroke or death following surgery while in the hospital. This measure is proposed for both hospitals and individual surgeons. Numerator Statement: Patients age 18 or older without preoperative carotid territory neurologic or retinal sympotoms within the one year immediately preceding CEA who experience stroke or death during their hospitalization following carotid endarterectomy Denominator Statement: Asymptomatic patients (based on NASCET criteria) on the within one year of CEA Exclusions: Exclude patients with neurologic symptoms within one year of procedure Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility/ Agency, Clinicians: Individual, Clinicians: Group Type of Measure: Outcome Data Source: Registry data

1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy

Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 22nd St. | Chicago | Illinois, 60611

Steering Committee Recommendation for Endorsement: Y-21; N-0; A-1

Rationale: The measure will help determine the incidence of adverse outcomes in the asymptomatic patient undergoing what is essentially a prophylactic procedure.

If applicable, Conditions/Questions for Developer:

1. 2a Measure Specifications: Provide information about type and accuracy of codes from registry data? Provide the codes. Diagnostic codes must be used and will need to ensure testing with these codes is complete.
2. 2h. Disparities in Care: Provide information about disparities or plans to be able to provide data.
3. 3a.2 Use in a Public Reporting Initiative: Please provide plans for public reporting (within 3 years).

Developer Response:

1. As indicated in the list of previously provided registry variables that was attached to the last submission, post-operative stroke (major or minor) and death are recorded in the SVS registry. These are not derived from ICD-9 codes, but rather are directly obtained by review of the medical record, usually during the time of admission by clinical personnel. Definitions for these variables were also reported. We are not certain which "codes" are being referred to, since this is a registry measure defined by clinical definitions within the registry, or any other available registry that records postoperative stroke (major or minor) and death in asymptomatic patients undergoing carotid endarterectomy.
2. Disparities have not been reported. As additional data are acquired from the SVS registry across a much larger and varied population, future disparities may be discovered.
3. SVS intends to request that all of these measures be included in PQRS, and expects CMS to begin publishing PQRS data in the near future. Independent of this, SVS plans to request permission from participating providers and hospitals to publish these measures on the SVS public website.

Steering Committee Follow-up:

The Steering Committee discussed the importance of the measure. Carotid endarterectomy may be over utilized in asymptomatic patients. The Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-20; N-1

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The Committee considered the outcomes resulting from the asymptomatic patient undergoing carotid endarterectomy important to measure.

2. Scientific Acceptability of Measure Properties: C-6; P-14; M-1; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: The Committee noted the need to define and specify methods to document (e.g., ICD-9 coding, potential development and use of CPT-II codes) asymptomatic and then to standardize the definition. There was concern about whether the measure is, in fact, measuring what is intended. With the information that definitions for the variables are reported and further discussion, the concern was adequately addressed.

3. Usability: C-5; P-14; M-1; N-1

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: The Committee was unclear about the details of the measure steward's plan for publicly reporting the measure. The developer indicated that they will request that the measure be included in PQRS.

4. Feasibility: C-4; P-13; M-3; N-1

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale: Concerns relate to capture of 'asymptomatic'. The Committee was interested in the potential of future CPT-II codes in this regard.

Public and Member Comment

It was suggested that the measure would be more meaningful if the measure scope included additional adverse outcomes. The Committee suggested in future updates of the measure, that the developer consider inclusion of additional adverse outcomes including myocardial infarction.

Voting: Total Approval: 94%

Comments received: "The timing of the period of being asymptomatic for measure 1540 and 1543 should be the same. However, I believe the measure should be enlarged to encompass all patients having the procedure so as not to bias the sample with healthier individuals who would have better outcomes. This also helps in revealing who are appropriate surgical candidates."

CSAC Approval:

1540 Postoperative stroke or death in asymptomatic patients undergoing carotid endarterectomy

Board Endorsement:

1543 Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percentage of patients 18 years of age or older without carotid territory neurologic or retinal symptoms within 120 days immediately proceeding carotid angioplasty and stent (CAS) placement who experience stroke or death during their hospitalization for this procedure. This measure is proposed for both hospitals and individual interventionalists.

Numerator Statement: Patients over age 18 without preoperative carotid territory neurologic or retinal sympotoms within one year of their procedure who experience stroke or death during their hospitalization following elective carotid artery angioplasty and stent placement

Denominator Statement: Patients over age 18 without preoperative carotid territory neurologic or retinal symptoms within one year immediately preceding carotid artery stenting

Exclusions: Exclude patients with neurologic symptoms within one year of procedure

Adjustment/Stratification: No risk adjustment necessary/No stratification is required for this measure.

Level of Analysis: Facility/ Agency, Clinicians: Individual, Clinicians: Group

Type of Measure: Outcome

Data Source: Registry data

Measure Steward: Society for Vascular Surgery | 633 N. St. Clair, 22nd floor | Chicago | Illinois, 60611

Steering Committee Recommendation for Endorsement: Y-21; N-0; A-1

Rationale: The measure will help determine the incidence of adverse outcome in the asymptomatic patient undergoing what is essentially a prophylactic procedure.

If applicable, Conditions/Questions for Developer:

The Committee suggested that measures related to carotid artery stenting be developed in conjunction with other specialties that perform the procedures; i.e., radiologists and cardiologists.

Developer Response:

1. The measure proposed for carotid artery stenting is identical to the measure proposed for carotid endarterectomy, two competing procedures used to treat the same disease. By limiting the measure to asymptomatic patients, we are eliminating the need for risk adjustment, since this is embodied in the decision to perform these prophylactic procedures to prevent future stroke, i.e., the operative risk of stroke and death must be certain to be low in order to justify these procedures. Stroke and death is the combined endpoint used in all randomized trials of these procedures, and we believe it is critically important that surgeons who perform carotid endarterectomy and stenting should report their outcomes for BOTH of these procedures. Since this is such a clean outcome measure, without need for risk adjustment, we do not believe that its approval should be withheld because it has not yet been proposed by other specialties. In fact, SVS VQI has surgeons and radiologists who participate and support an outcome measure for both carotid endarterectomy and stenting. We respectfully ask the committee to approve both of these important measures in parallel. The form has been updated to reflect relevant comments provided for other SVS measures.

Steering Committee Follow-up:

The Steering Committee agreed that the response from the developer was adequate and suggested that SVS work to develop measures with other specialties in the future.

1. Importance to Measure and Report: Y-21; N-0

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The Committee considered the outcomes resulting from the asymptomatic patient undergoing carotid artery stenting important to measure.

2. Scientific Acceptability of Measure Properties: C-6; P-14; M-1; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: The Committee noted the need to define and specify methods to document (e.g., ICD-9 coding, potential development and use of CPT-II codes) asymptomatic and then to standardize the definition. With the information that definitions for the variables are reported and further discussion, the concern was adequately addressed.

3. Usability: C-6; P-13; M-1; N-1

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: The Committee was unclear about the public reporting plan. The developer indicated that the measure is to be reported with 1540 and will request inclusion in PQRS.

1543 Postoperative stroke or death in asymptomatic patients undergoing carotid artery stenting (CAS)
4. Feasibility: C-6; P-11; M-3; N-1 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Concerns relate to capture of 'asymptomatic'. The Committee was interested in the potential of future CPT-II codes in this regard.
Public and Member Comment It was suggested that the measure would be more meaningful if the measure scope included additional adverse outcomes. The Committee suggested in future updates of the measure, that the developer consider inclusion of additional adverse outcomes including myocardial infarction.
Voting: Total Approval: 94% Comments received: "The timing of the period of being asymptomatic for measure 1540 and 1543 should be the same. However, I believe the measure should be enlarged to encompass all patients having the procedure so as not to bias the sample with healthier individuals who would have better outcomes. This also helps in revealing who are appropriate surgical candidates." CSAC Approval: Board Endorsement:

0339 RACHS-1 pediatric heart surgery mortality
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Risk-adjusted rate of in-hospital death for pediatric cases undergoing surgery for congenital heart disease, along with ratio of observed to expected in-hospital mortality rates. Numerator Statement: Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator with a code of pediatric heart surgery with ICD-9-CM diagnosis of congenital heart disease in any field. Denominator Statement: Discharges under age 18 with ICD-9-CM procedure codes for congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field. Exclusions: Exclude cases: • MDC 14 (pregnancy, childbirth and pueperium) • with transcatheter interventions (either 3AP, 3BP, 3CP, 3DP, 3EP with 3D, or 3FP) as single cardiac procedures, performed without bypass (5P) but with catheterization (6P) • with septal defects (4P) as single cardiac procedures without bypass (5P) • with diagnosis of ASD or VSD (5D) with PDA as the only cardiac procedure • heart transplant (7P) • premature infants (4D) with PDA closure (3D and 3EP) as only cardiac procedure; • age less than or equal to 30 days with PDA closure as only cardiac procedure • missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1 =missing) • transferring to another short-term hospital (DISP=2) • neonates with birth weight less than 500 grams (Birth Weight Category 1) Adjustment/Stratification: risk adjustment method widely or commercially available PDI: The predicted value for each case is computed using a logistic regression with Generalized Estimating Equations (GEE) to account for within hospital correlation containing RACHS-1 risk category; age category (<= 28 days, 29 to 90 days, 91 days to 1 year, 1 to 17 years); birth weight <2500 grams; non-cardiac structural anomaly (modified CCS 217); admission transferred in; and combination of congenital heart surgery procedures performed during admission. The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2008 (updated annually), a database consisting of 43 states and approximately 7 million pediatric discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate (standardized mortality ratio), multiplied by the reference population rate. The model includes additional covariates for RACHS-1 risk categories, and multiple congenital heart procedures during the admission. Required data elements: Age in days up to 364, then age years at admission; International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) principal and secondary diagnosis codes; admission type; admission source. The user has the option to stratify by gender, birth weight, age in days, age in years, race / ethnicity, primary payer, and custom stratifiers./ The user has the option to stratify by gender, birth weight, age in days, age in years, race/ ethnicity, primary payer, and custom stratifiers. Level of Analysis: Facility/ Agency Type of Measure: Outcome Data Source: Electronic administrative data/ claims

0339 RACHS-1 pediatric heart surgery mortality
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850
Steering Committee Recommendation for Endorsement: Y-24; N-0; A-0 Rationale: Measuring pediatric heart surgery mortality is important and the measure is valid and meets criteria RACHS is supported in the literature.
If applicable, Conditions/Questions for Developer: 1. This measure and Measure 0340 should continue to be reported as a pair. Developer Response: 1. AHRQ agrees to continue to note the Pediatric heart surgery mortality and volume (339 and 340 respectively) are to be reported as a paired measure in related AHRQ QI documents. Steering Committee Follow-up: At the Steering Committee's request, the developer explained that they were working to combine measures *0339: Pediatric heart surgery mortality (PDI 6) (risk adjusted)* and *PCS-021-09: Standardized mortality ratio for congenital heart surgery, risk adjustment for congenital heart surgery (RACHS-1) adjusted*) for submission by August 15, 2011. On the September 13 conference call, the Steering Committee reviewed this newly combined measure which represents the harmonization of the former 0339 and PCS-021-09. Members determined that it adequately addressed their request and met criteria. The developer indicated that this measure remains appropriate to be paired with measure *340: Pediatric Heart Surgery Volume (PDI 7)*,
1. Importance to Measure and Report: Y-22; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure was considered important and the performance gap suggests room for improvement. The Committee requested timely updated citations in the future.
2. Scientific Acceptability of Measure Properties: C-17; P-5; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure was considered scientifically acceptable.
3. Usability: C-17; P-5; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: This measure has been in wide use over a number of years and is considered usable.
4. Feasibility: C-19; P-3; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: This measure uses claims data thus was considered feasible.
Public and Member Comment • Should apply at the clinician level of analysis; and • No description of the risk adjustment model The developer has yet to have the opportunity to test the application of the measure at the clinician level. 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 is appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues.
Voting: Total Approval: 100% Comments received: None CSAC Approval: Board Endorsement:

0340 Pediatric heart surgery volume (PDI 7)
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Number of discharges with procedure for pediatric heart surgery Numerator Statement: Discharges under age 18 with ICD-9-CM procedure codes for either congenital heart disease (1P) in any field or non-specific heart surgery (2P) with ICD-9-CM diagnosis of congenital heart disease (2D) in any field. Denominator Statement: This measure does not have a denominator due to the fact it is a volume measure. Exclusions: Not applicable. This measure does not have a denominator due to the fact it is a volume measure. Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure.

0340 Pediatric heart surgery volume (PDI 7)

Level of Analysis: Facility/ Agency
Type of Measure: Structure/management
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: Y-17; N-1; A-3
Rationale: The measure was considered important, valid and meets criteria.

If applicable, Conditions/Questions for Developer:

1. This measure and Measure 0339 should continue to be reported as a pair.

Developer Response:

1. AHRQ agrees to continue to note the Pediatric heart surgery mortality and volume (339 and 340 respectively) are to be reported as a paired measure in related AHRQ QI documents.

Steering Committee Follow-up:
The Steering Committee agreed that the response from the developer was adequate.

1. Importance to Measure and Report: Y-14; N-5
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The Committee noted the performance gap, which showed that the risk-adjusted mortality is higher at hospitals with fewer than 100 cases per year. The Committee requested timely updated citations in the future.

2. Scientific Acceptability of Measure Properties: C-10; P-8; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: This reporting of pediatric heart surgery volume alone may not be valid since it occurs in small numbers. Additionally, pediatric heart surgery has become regionalized and is conducted at relatively few institutions.

3. Usability: C-10; P-8; M-1; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: This measure has been in wide use over a number of years and is considered usable.

4. Feasibility: C-13; P-6; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: This measure uses claims data thus was considered feasible.

Public and Member Comment

- Should apply at the clinician level of analysis; and
- Concerns of supporting volume as a stand-alone performance measure

The developer has yet to have the opportunity to test the application of the measure at the clinician level. 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 is appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues.

This measure was initially endorsed to be reported as a pair with measure 0339. The recommendation is that it be continued to be reported as a pair.

Voting: Total Approval: 88%
Comments received: "Volume that is not differentiated among types of surgical procedures or risk of patients may not provide an accurate representation of the facility. The skill and effort in repair of a VSD is not the same as required to repair a tetrology of fallot."
CSAC Approval:
Board Endorsement:

0352 Failure to rescue in-hospital mortality (risk adjusted)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percentage of patients who died with a complications in the hospital.
Numerator Statement: Patients who died with a complication plus patients who died without documented complications. Death is defined as death in the hospital.
All patients in an FTR analysis have developed a complication (by definition).
Complicated patient has at least one of the complications defined in Appendix B(see website

0352 Failure to rescue in-hospital mortality (risk adjusted)

http://www.research.chop.edu/programs/cor/outcomes.php). Complications are defined using the secondary ICD9 diagnosis and procedure codes and the DRG code of the current admission.
Comorbidities are defined in Appendix C (see website http://www.research.chop.edu/programs/cor/outcomes.php) using secondary ICD9 diagnosis codes of the current admission and primary or secondary ICD9 diagnosis codes of previous admission within 90 days of the admission date of the current admission.
*When physician part B is available, the definition of complications and comorbidities are augmented to include CPT codes.
Denominator Statement: General Surgery, Orthopedic and Vascular patients in specific DRGs with complications plus patients who died in the hospital without complications.
Inclusions: adult patients admitted for one of the procedures in the General Surgery, Orthopedic or Vascular DRGs (see appendix A http://www.research.chop.edu/programs/cor/outcomes.php)
Exclusions: Patients over age 90, under age 18.
Adjustment/Stratification: risk-adjustment devised specifically for this measure/condition Risk Adjustment: Model was developed using logistic regression analysis.
Associated data elements: age in years, sex, race, comorbidities, DRGs (combined with and without complications) and procedure codes within DRGs, transfer status.
Failure to rescue is adjusted using a logistic regression model where y is a failure and the total N is composed of patients who develop a complication and patients who died without a complication.
According to developer: The model adjustment variables can vary. We have found that FTR results are fairly stable, even with little adjustment, since all patients in an FTR analysis have developed a complication (by definition), they are a more homogeneous group of patients than the entire population. Hence severity adjustment plays somewhat less of a role than in other outcome measures/Complicated patient has at least one of the complications defined in Appendix B (http://www.research.chop.edu/programs/cor/outcomes.php) Complications are defined using the secondary ICD9 diagnosis and procedure codes and the DRG code of the current admission. When Physician Part B file is available, the definition of complications and comorbidities are augmented to include CPT codes.
Level of Analysis: Facility/ Agency, Health Plan, Integrated Delivery System, Population: Counties or cities, Population: National, Population: Regional/ network, Population: States
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
Measure Steward: The Children´s Hospital of Philadelphia | 3535 Market Street, Suite 1029 | Philadelphia | Pennsylvania | 19104

Steering Committee Recommendation for Endorsement: Y-19; N-1; A-1
Rationale: The measure provides information about how hospitals handle patients who develop complications; i.e., whether hospital systems are in place to prevent a patient complication from progressing to death.

If applicable, Conditions/Questions for Developer:

1. 2a.6 Target Population Age Range: Reevaluate upper age limit in terms of increasing and providing exclusions to capture limited future; e.g., DNR status. In future, consider development of a companion pediatric measure.
2. 2h. Disparities in Care: Provide information about disparities or plans to be able to provide data.
3. 3a.2 Use in Public Reporting Initiative: Provide plans and expected date (within 3 years) for public reporting.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization

Developer Response:

1. 2a.6 Target Population Age Range: We use 90 years as a cut-point because of our concern regarding the increased use of do-not-resuscitate at higher ages [Wenger et al. Epidemiology of Do-Not Resuscitate Orders. Disparity by Age, Diagnosis, Gender, Race, and Functional Impairment. Arch Intern Med. 1995; 155(19):2056-62, Hakim et al. Factors Associated with Do-Not-Resuscitate Orders: Patients', Preferences, Prognoses, and Physicians Judgments. Ann Intern Med.1996; 125:284-293.]. While we do adjust for admission severity when reporting FTR, and this includes age, we still thought it prudent to use an upper bound on age, since DNR status prior to the procedure is not well defined at hospitals [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] (See 2d.1 Measure Exclusions Explanation section in submission form). Currently, we are not considering developing a companion pediatric measure because in general the pediatric population has low mortality rates. However we are currently exploring the development of a pediatric FTR specifically for cardiothoracic surgery where mortality rates are higher.
2. 2h. Disparities in Care:
   2h.1. Disparities in care are shown in Silber et al Arch Surg 2009 where the results show white patients displayed a reduction in failure-to-rescue rates in the teaching intensive hospitals vs. non-teaching hospitals (OR, 0.94; 95% CI, 0.92-0.97), black patients displayed an increased failure-to-rescue rate (OR, 1.06; 95% CI, 1.00-1.12)(Results are based on 30 day mortality FTR however in-hospital showed similar results)

0352 Failure to rescue in-hospital mortality (risk adjusted)
2h.2 Failure to Rescue can be used to detect disparities in health outcomes across providers, shown in Silber et al. Arch Surg 2009. 3. 3a.2 Use in Public Reporting Initiative: FTR information is online for the public to access (http://stokes.chop.edu/programs/cor/outcomes.php). Consumers can access FTR results through the multiple research publications on the measure. In the future FTR could be reported on a wider scale, the same way that mortality rates are reported. Steering Committee Follow-up: 1. The Steering Committee agreed that the response from the developer was adequate. 2. This was one of three related measures considered for potential harmonization. The three included: m*aintenance measure 0352*: Failure to rescue in-hospital mortality (risk adjusted); m*aintenance measure 0351*: Death among surgical in-patients with serious, treatable complications (PSI 4); and m*aintenance measure 0353*: Failure to rescue 30-day mortality (risk adjusted). Discussion of the three measures is included here. It was noted that measures 0352 and 0353 were initially a single measure that were divided at request of the NQF steering committee that initially considered the measure. The Steering Committee discussed the in-hospital focused measures with the developers in some detail. They noted that while the measures have common elements, measure 0351 captures a broader list of procedures and that some measures of validity have a stronger association with that measure. They also noted that measure 0352 captures a broader group of complications and reliability measures higher than those of 0351 have been reported. Members commented that the measures, while conceptually similar, have different aims; i.e., capture of avoidable complications vs. failure to rescue. In reflecting on the question of whether measure similarities argue for consideration of whether one meets criteria better than the other, they agreed that the measures have different objectives and are complementary.
1. Importance to Measure and Report: Y-18; N-3 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure complements mortality and complication statistics. It provides additional insight into statistics by looking beyond crude mortality and assesses whether hospital systems are in place to prevent a patient complication from progressing to death. This measure is supported by the evidence.
2. Scientific Acceptability of Measure Properties: C-9; P-11; M-1; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure contains updated CPT codes. The measure is risk adjusted and the population captured includes patients with and without documented complications. It assumes that if patients die post-surgery, there was an undocumented complication.
3. Usability: C-7; P-12; M-2; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure is somewhat complicated and has not yet been used in public reporting.
4. Feasibility: C-8; P-12; M-1; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The measure will be relatively easy to collect since it uses administrative data.
Public and Member Comment • Should apply at the clinician level of analysis; and • Preference of capturing DNR orders The developer noted that failure to rescue has always been a hospital measure because: (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeeding 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. to rescue in the hospital setting involves many systems and professional disciplines making it infeasible to apply the measure at the clinician level. The Committee agreed with the developer that at present use of DNR status as an exclusion could result in hospital differences due to the DNR process.
Voting: Total Approval: 95% Comments received: None CSAC Approval: Board Endorsement:

0353 Failure to rescue 30-day mortality (risk adjusted)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percentage of patients who died with a complication within 30 days from admission.
Numerator Statement: Patients who died with a complication plus patients who died without documented complications. Death is defined as death within 30 days from admission.
All patients in an FTR analysis have developed a complication (by definition).
Complicated patient has at least one of the complications defined in Appendix B(see website http://www.research.chop.edu/programs/cor/outcomes.php). Complications are defined using the secondary ICD9 diagnosis and procedure codes and the DRG code of the current admission.
Comorbidities are defined in Appendix C(see website http://www.research.chop.edu/programs/cor/outcomes.php) using secondary ICD9 diagnosis codes of the current admission and primary or secondary ICD9 diagnosis codes of previous admission within 90 days of the admission date of the current admission.
*When physician part B is available, the definition of complications and comorbidities are augmented to include CPT codes.
Denominator Statement: General Surgery, Orthopedic and Vascular patients in specific DRGs with complications plus patients who died in the hospital without complications.
Inclusions: adult patients admitted for one of the procedures in the General Surgery, Orthopedic or Vascular DRGs (see appendix A http://www.research.chop.edu/programs/cor/outcomes.php)
Inclusions: adult patients admitted for one of the procedures in the General Surgery, Orthopedic or Vascular DRGs (see appendix A)
Exclusions: Patients over age 90, under age 18.
Adjustment/Stratification: risk-adjustment devised specifically for this measure/condition Risk Adjustment: Model was developed using logistic regression analysis.
Associated data elements: age in years, sex, race, comorbidities, DRGs (combined with and without complications) and procedure codes within DRGs, transfer status.
Failure to rescue is adjusted using a logistic regression model where y is a failure and the total N is composed of patients who develop a complication and patients who died without a complication.
According to developer: The model adjustment variables can vary. We have found that FTR results are fairly stable, even with little adjustment, since all patients in an FTR analysis have developed a complication (by definition), they are a more homogeneous group of patients than the entire population. Hence severity adjustment plays somewhat less of a role than in other outcome measures/Complicated patient has at least one of the complications defined in Appendix B (http://www.research.chop.edu/programs/cor/outcomes.php) Complications are defined using the secondary ICD9 diagnosis and procedure codes and the DRG code of the current admission. When Physician Part B file is available, the definition of complications and comorbidities are augmented to include CPT codes.
Level of Analysis: Facility/ Agency, Health Plan, Integrated Delivery System, Population: Counties or cities, Population: National, Population: Regional/ network, Population: States
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
Measure Steward: The Children´s Hospital of Philadelphia | 34th St. and Civic Center Blvd. | Philadelphia | Pennsylvania | 19104

Steering Committee Recommendation for Endorsement: Y-19; N-2; A-0
Rationale: The measure provides information about how hospitals handle patients who develop complications; i.e., prevent patient complications from progressing to death. It will also track difference in length of stay that could bias statistics associated with in-hospital mortality.

If applicable, Conditions/Questions for Developer:

1. 2a.6 Target Population Age Range: Reevaluate upper age limit in terms of increasing and providing exclusions to capture limited future; e.g., DNR status. In future, consider development of a companion pediatric measure.
2. 2h. Disparities in Care: Provide information about disparities or plans to be able to provide data.
3. 3a.2 Use in Public Reporting Initiative: Provide plans and expected date (within 3 years) for public reporting.
4. Please advise how 30 day data is collected and how post-hospital care with potential for affecting outcomes is handled.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization

Developer Response:

1. 2a.6 Target Population Age Range: We use 90 years as a cut-point because of our concern regarding the increased use of do-not-resuscitate at higher ages [Wenger et al. Epidemiology of Do-Not Resuscitate Orders. Disparity by Age, Diagnosis, Gender, Race, and Functional Impairment. Arch Intern Med. 1995; 155(19):2056-62, Hakim et al. Factors Associated with Do-Not-Resuscitate Orders: Patients', Preferences, Prognoses, and Physicians Judgments. Ann Intern Med.1996; 125:284-293.]. While we do adjust for admission severity when reporting FTR, and this includes age, we still thought it prudent to use an upper bound on age, since DNR status prior to the procedure is not well defined at hospitals [Tabak YP, Johannes RS, Silber

0353 Failure to rescue 30-day mortality (risk adjusted)
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] (See 2d.1 Measure Exclusions Explanation section in submission form) Currently, we are not considering developing a companion pediatric measure because in general the pediatric population has low mortality rates. However we are currently exploring the development of a pediatric FTR specifically for cardiothoracic surgery where mortality rates are higher. 2. 2h. Disparities in Care: 2h.1. Disparities in care are shown in Silber et al Arch Surg 2009 where the results show white patients displayed a reduction in failure-to-rescue rates in the teaching intensive hospitals vs. non-teaching hospitals (OR, 0.94; 95% CI, 0.92-0.97), black patients displayed an increased failure-to-rescue rate (OR, 1.06; 95% CI, 1.00-1.12)(Results are based on 30 day mortality FTR however in-hospital showed similar results) 2h.2. Failure to Rescue can be used to detect disparities in health outcomes across providers, shown in Silber et al. Arch Surg 2009. 3. 3a.2 Use in Public Reporting Initiative: FTR information is online for the public to access (http://stokes.chop.edu/programs/cor/outcomes.php). Consumers can access FTR results through the multiple research publications on the measure. In the future FTR could be reported on a wider scale, the same way that mortality rates are reported. 4. If one has administrative claims data that can be linked to post-discharge data, then one can report a 30-day from admission measure. The advantage of a 30-day measure is that it is unbiased with respect to the practice pattern of the hospital. All hospitals are judged with the same 30-day window whether they tend to discharge patients earlier than later. This is generally considered to be the gold standard for using mortality data. The FTR 30-day measure has the same advantages of the 30-day mortality measure. Analytic difficulties related to post-discharge care have the same likelihood of occurring across hospitals using the 30-day measure but would be more problematic if a uniform window would not be used. Steering Committee Follow-up: 1. The Steering Committee agreed that the response from the developer was adequate. 2. This was one of three related measures considered for potential harmonization. The three included: m*aintenance measure 0352*: Failure to rescue in-hospital mortality (risk adjusted); m*aintenance measure 0351*: Death among surgical in-patients with serious, treatable complications (PSI 4); and m*aintenance measure 0353*: Failure to rescue 30-day mortality (risk adjusted). Discussion of the three measures is included here. It was noted that measures 0352 and 0353 were initially a single measure that were divided at request of the NQF steering committee that initially considered the measure. The Steering Committee discussed the in-hospital focused measures with the developers in some detail. They noted that while the measures have common elements, measure 0351 captures a broader list of procedures and that some measures of validity have a stronger association with that measure. They also noted that measure 0352 captures a broader group of complications and reliability measures higher than those of 0351 have been reported. Members commented that the measures, while conceptually similar, have different aims; i.e., capture of avoidable complications vs. failure to rescue. In reflecting on the question of whether measure similarities argue for consideration of whether one meets criteria better than the other, they agreed that the measures have different objectives and are complementary.
1. Importance to Measure and Report: Y-17; N-3; A-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure complements mortality and complication statistics. It provides additional insight into statistics by looking beyond crude mortality and assesses whether hospital systems are in place to prevent a patient complication from progressing to death. This measure is supported by the evidence.
2. Scientific Acceptability of Measure Properties: C-6; P-12; M-2; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure contains updated CPT codes. The measure is risk adjusted and the population captured includes patients with and without documented complications. It assumes that if patients die post-surgery, there was an undocumented complication.
3. Usability: C-3; P-10; M-8; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure uses administrative data and has been shown to be useable; however, it may be complicated to track given the 30 day range.
4. Feasibility: C-3; P-10; M-7; N-1 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)*

0353 Failure to rescue 30-day mortality (risk adjusted)

Rationale: This measure has not yet been used in public reporting. There were questions regarding feasibility of use of this measure for non-Medicare patients.

Public and Member Comment

- Should apply at the clinician level of analysis; and
- Preference of capturing DNR orders

The developer noted that failure to rescue has always been a hospital measure because: (1) the sample size requirements at the physician level would generally be a problem; (2) attributing blame for not succeeding 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.

to rescue in the hospital setting involves many systems and professional disciplines making it infeasible to apply the measure at the clinician level. The Committee agreed with the developer that at present use of DNR status as an exclusion could result in hospital differences due to the DNR process.

Voting: Total Approval: 95%
Comments received: None
CSAC Approval:
Board Endorsement:

0351 Death among surgical inpatients with serious, treatable complications (PSI 4)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percentage of cases having developed specified complications of care with an in-hospital death.
Numerator Statement: All discharges with a disposition of "deceased" (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.
Denominator Statement: All surgical discharges age 18 years and older or MDC 14 (pregnancy, childbirth, and puerperium) defined by specific DRGs or MS-DRGs and an ICD-9-CM code for an operating room procedure, principal procedure within 2 days of admission OR admission type of elective (ATYPE=3) with potential complications of care listed in Death among Surgical definition (e.g., pneumonia, DVT/PE, sepsis, shock/cardiac arrest, or GI hemorrhage/acute ulcer).
Exclusions: Exclude cases:
• age 90 years and older
• transferred to an acute care facility (DISP = 2)
• missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1 =missing)
NOTE: Additional exclusion criteria is specific to each diagnosis (pneumonia, DVT/PE, sepsis, shock/cardiac arrest, or GI hemorrhage/acute ulcer). See 2a.10.
Adjustment/Stratification: risk adjustment method widely or commercially available The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, age in years (in 5-year age groups), modified CMS DRG and AHRQ Comorbidities. The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2007 (updated annually), a database consisting of 43 states and approximately 30 million adult discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate/User has an option to stratify by Gender, age (5-year age groups), race/ ethnicity, primary payer, and custom stratifiers.
Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
Measure Steward: Agency for Healthcare Research and Quality | 540 Gaither Road | Rockville | Maryland | 20850

Steering Committee Recommendation for Endorsement: Y-20; N-0; A-1
Rationale: This measure highlights specific complications, which presents opportunities for early interventions and action

If applicable, Conditions/Questions for Developer:

1. 2a.6 Target Population Age Range: Expand the age range to include a larger population.

Note: Discussion of Related and Competing measures may result in additional requests to developers specific to harmonization.

Developer Response:

1. There was an error in the NQF measure maintenance form, which noted age 75 years and older were excluded. The actual

0351 Death among surgical inpatients with serious, treatable complications (PSI 4)
exclusion is age 90 years and older. Steering Committee Follow-up: 1. The Steering Committee agreed that the response from the developer was adequate, but requested that the developer update the age specifications listed on their website. 2. This was one of three related measures considered for potential harmonization. The three included: m*aintenance measure 0352*: Failure to rescue in-hospital mortality (risk adjusted); m*aintenance measure 0351*: Death among surgical in-patients with serious, treatable complications (PSI 4); and m*aintenance measure 0353*: Failure to rescue 30-day mortality (risk adjusted). Discussion of the three measures is included here. It was noted that measures 0352 and 0353 were initially a single measure that were divided at request of the NQF steering committee that initially considered the measure. The Steering Committee discussed the in-hospital focused measures with the developers in some detail. They noted that while the measures have common elements, measure 0351 captures a broader list of procedures and that some measures of validity have a stronger association with that measure. They also noted that measure 0352 captures a broader group of complications and reliability measures higher than those of 0351 have been reported. Members commented that the measures, while conceptually similar, have different aims; i.e., capture of avoidable complications vs. failure to rescue. In reflecting on the question of whether measure similarities argue for consideration of whether one meets criteria better than the other, they agreed that the measures have different objectives and are complementary.
1. Importance to Measure and Report: Y-19; N-1 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: This goal of this measure is to capture information about a specific set of surgical complications that have been determined to provide opportunity for early intervention and improvement action.
2. Scientific Acceptability of Measure Properties: C-13; P-7; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: An advantage of this measure is that it focuses on a broad population, patients 18 and over.
3. Usability: C-13; P-7; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure is currently being widely reported to the public.
4. Feasibility: C-14; P-5; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The measure uses claims data and was considered feasible.
Public and Member Comment Commenters expressed concerns of using hierarchical risk modeling (HRM). The developer indicated that 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.
Voting: Total Approval: 100% Comments received: None CSAC Approval: Board Endorsement:

0515 Ambulatory surgery patients with appropriate method of hair removal
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of ASC admissions with appropriate surgical site hair removal. Numerator Statement: ASC admissions with surgical site hair removal with a razor or clippers from the scrotal area, or with clippers or depilatory cream from all other surgical sites Denominator Statement: All ASC admissions with surgical site hair removal Exclusions: ASC admissions who perform their own hair removal Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Paper medical record/ flow-sheet Measure Steward: ASC Quality Collaboration | 5686 Escondida Blvd S | St. Petersburg | Florida | 33715
Steering Committee Recommendation for Endorsement: Y-12 (active); Y-7 (reserve); N-2; A-1

0515 Ambulatory surgery patients with appropriate method of hair removal

Rationale: This measure has high performance in the reporting populations. It would be appropriate to consider reporting the measure as part of a surgical bundle.

Steering Committee Follow-up:
The measure developer requested that the Committee's recommendation of the measure be revised from reserve status to active endorsement. The Steering Committee noted that the 96 percent performance on the measure reflected a convenience sample of the 192 institutions that reported and may not accurately reflect performance within the larger ambulatory surgery community. Members agreed that continuing active endorsement of the measure could encourage reporting by those ASCs not currently participating. The developer stated that measure has been proposed for inclusion in the ASC measure set by CMS, and nationwide reporting is anticipated in the next year or so. The Committee agreed that, depending on the increase in reporting, this could allow for a more comprehensive review of the performance gap in the future.

1. Importance to Measure and Report: Y-6; N-13
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The evidence supports the measure; however, at a mean performance level of 96 percent and just over 7 percent of reporting centers with rates below 100 percent, the measure is at a high level of performance.

2. Scientific Acceptability of Measure Properties: C-5; P-13; M-0; N-1
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The Committee stated that the validity testing of the measure could be improved, and the measure did not present disparity data.

3. Usability: C-7; P-9; M-2; N-1
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The measure is in wide use. It was noted that this measure was harmonized with measure *0301: Surgery patients with appropriate hair removal.*

4. Feasibility: C-13; P-4; M-2; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: Required data is generated as part of care and does not require additional sources.

Public and Member Comment
Commenters were not in support of this measure because they believed that 100 percent compliance could occur with the removal of razors from the operating room. 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.

Voting: Total Approval: 81%
Comments received: "Measure #515 and 0301 should be harmonized into a single measure as the physiology does not change between ASC and in-patient hospital setting."
CSAC Approval:
Board Endorsement:

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: This measure estimates hospital risk-standardized complication rates (RSCRs) associated with primary elective THA and TKA in patients 65 years and older. The measure uses Medicare claims data to identify complications occurring from the date of index admission to 90 days post date of the index admission.
Numerator Statement: This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1c tests per year); thus, we are using this field to define the outcome (i.e. adverse events) following THA and/or TKA procedures. The outcome is one or more complications, including death, identified from the date of the index admission up to 90 days post date of the index admission, depending on the complication. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission.
The composite complication is a binary outcome (yes for any complication(s); no for no complications). Therefore, if a patient

experiences 1 or more complications, the outcome variable will get coded as a "yes." Complications are counted in the measure only if they occur during the index hospital admission or during a readmission.

The complications captured in the numerator are identified during the index admission or associated with a readmission up to 90 days post date of index admission, depending on the complication. The follow-up period for complications from date of index admission is as follows:

1) Mechanical complications - 90 days
2) Periprosthetic joint infection (PJI) - 90 days
3) Wound infection - 90 days
4) Surgical site bleeding - 30 days
5) Pulmonary embolism - 30 days
6) Death - 30 days
7) AMI - 7 days
8) Pneumonia - 7 days
9) Sepsis/septicemia - 7days

Denominator Statement: The target population for this measure includes admissions for patients at least 65 years of age undergoing elective primary THA and/or TKA procedures.

Exclusions: Patients will be excluded from the cohort if they meet any of the followed criteria*:

1. Patients with hip fractures

Presence of one of the following diagnosis codes: 733.1, 733.10, 733.14, 733.15, 733.19, 733.8, 733.81, 733.82, 733.95, 733.96, 733.97, 808.0, 808.1, 820.00, 820.01, 820.02, 820.03, 820.09, 820.10, 820.11, 820.12, 820.13, 820.19, 820.20, 820.21, 820.22, 820.30, 820.31, 820.32, 820.8, 820.9, 821, 821.0, 821.00, 821.01, 821.1, 821.10, 821.11

Rationale: Patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is not elective.

2. Patients undergoing revision procedures (with or without a concurrent THA/TKA)

Presence of one of the following diagnosis codes: 81.53, 81.55, 81.59, 00.70, 00.71, 00.72, 00.73, 00.80, 00.81, 00.82, 00.83, 00.84

Rationale: Revision procedures may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication and readmission rates.

3. Patients undergoing partial hip arthroplasty procedures (with or without a concurrent THA/TKA)

Presence of the following diagnosis code: 81.52

Rationale: Partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions.

4. Patients undergoing resurfacing procedures (with or without a concurrent THA/TKA)

Presence of one of the following diagnosis codes: 00.85, 00.86, 00.87

Rationale: Resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients.

5. Patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission*

Rationale: A complication coded in the principal field indicates it was present on admission, and these patients underwent an arthroplasty due to a complication related to a prior procedure. Furthermore, these patients may require more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications.

6. Patients who are transferred in to the index hospital

Rationale: If the patient is transferred from another acute care facility to the hospital where the index procedure occurs, it is likely that the procedure is not elective.

7. Patients who leave the hospital against medical advice (AMA)

Rationale: Hospitals and physicians do not have the opportunity to provide the highest quality care.

8. Patients with more than two THA/TKA procedure codes during the index hospitalization

Rationale: Patients with more than two procedure codes for THA/TKA are excluded because it is rare that a patient would have 3 arthroplasty procedures done at one time. This is likely to be a coding error.

9. Patients with multiple admissions for THA/TKA in the 12 months studied; one hospitalization per patient was randomly selected for inclusion after applying the other exclusion criteria

Rationale: Observations are not independent; a patient is not eligible for the death outcome during the first admission if admitted later in the year for another procedure

*Based on a medical record validation study of this measure, we also excluded patients with a mechanical complication coded in the *principal discharge diagnosis field of the index admission* because a complication coded in the principal field indicates it was present on admission. Furthermore, these patients represent more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications. Please refer to section 2c, Validity Testing for details regarding the validation study.

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)
Adjustment/Stratification: Risk-adjustment devised specifically for this measure/condition/ The measure estimates hospital-level RSCRs using hierarchical logistic regression models. In brief, the approach simultaneously models outcomes at two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals (Normand et al., 2007). At the patient level, the model adjusts the log-odds of a complication for age, sex, and selected clinical covariates. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of complication at the hospital, after accounting for case mix. If there were no differences among hospitals, then after adjusting for case mix, the hospital intercepts should be identical across all hospitals. The measure adjusts for key variables that were clinically relevant and had strong relationships with the outcome (e.g. demographic factors, disease severity indicators, and indicators of frailty). For each patient, covariates are obtained from Medicare claims extending 12 months prior to and including the index admission. The model adjusts for case mix differences based on the clinical status of the patient at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis and procedure codes. Conditions that may represent adverse outcomes due to care received during the index admission are not considered for inclusion in the risk adjusted model. Although they may increase the risk of mortality and complications, including them as covariates in a risk-adjusted model could attenuate the measure's ability to characterize the quality of care delivered by hospitals. Hence, these conditions are not adjusted for if they only appear in the index admission and not in the 12 months prior to admission. The risk adjustment model included 33 variables which are listed below: Demographic 1. Age-65 (years above 65, continuous) 2. Sex THA/TKA Procedure 3. THA procedure 4. Number of procedures performed Clinical Risk Factors 5. Skeletal deformities (ICD-9 code 755.63) 6. Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16) 7. Morbid obesity (ICD-9 code 278.01) 8. Metastatic cancer and acute leukemia (CC 7) 9. Cancer (CC 8-10) 10. Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13) 11. Diabetes and DM complications (CC 15-20,119,120) 12. Protein-calorie malnutrition (CC 21) 13. Bone/Joint/Muscle Infections/Necrosis (CC 37) 14. Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38) 15. Osteoarthritis of hip and knee (CC 40) 16. Osteoporosis and Other Bone/Cartilage Disorders (CC 41) 17. Dementia and senility (CC 49, 50) 18. Major psychiatric disorders (CC 54-56) 19. Hemiplegia, paraplegia, paralysis, function disability (CC 67-69, 100-102, 177-178) 20. Cardio-respiratory failure and shock (CC 79) 21. Chronic atherosclerosis (CC 83-84) 22. Stroke (CC 95, 96) 23. Vascular or circulatory disease (CC 104-106) 24. COPD (CC 108) 25. Pneumonia (CC 111-113) 26. Pleural effusion/ pneumothorax (CC 114) 27. End-stage renal disease or dialysis (CC 129, 130) 28. Renal Failure (CC 131) 29. Decubitus ulcer or chronic skin ulcer (CC 148, 149) 30. Trauma (CC 154-156,158-161) 31. Vertebral Fractures (CC 157) 32. Other injuries (CC 162) 33. Major complications of medical care and trauma (CC 164) Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226/ This measure is not stratified/

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

Level of Analysis: Facility/ Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/ claims
The datasets used to create the measures are described below.
1. 2008 Part A (inpatient) data
Part A inpatient data includes claims paid for Medicare inpatient hospital care, skilled nursing facility care, some home health agency services, and hospice care. For purposes of this project, Part A is used to refer to inpatient services only and includes data from 2 time periods:
a. Index admission: Index admission data are based on the inclusion/exclusion criteria for THA/TKA, and comorbidities (if any) are identified from the secondary diagnoses associated with the index admission.
b. Pre-index: 12 months prior to the index admission ("pre-index").
2. 2008 Part A (outpatient) data – 12 months pre-index
Hospital outpatient refers to Medicare claims paid for the facility component of surgical or diagnostic procedures, emergency room care, and other non-inpatient services performed in a hospital outpatient department or ambulatory surgical/diagnostic center.
3. Part B data – 12 months pre-index
Part B data refers to Medicare claims for the services of physicians (regardless of setting) and other outpatient care, services, and supplies. For purposes of this project, Part B services included only face-to-face encounters between a care provider and patient. We thus do not include services such as laboratory tests, medical supplies, or other ambulatory services.
4. 2008 Medicare Enrollment Database
This database contains Medicare beneficiary demographic, benefit/coverage, enrollment status on admission, and vital status information. These data have previously been shown to accurately reflect patient vital status (Fleming Fisher et al., 1992).
Fleming C., Fisher ES, Chang CH, Bubolz D, Malenda J. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs Hospitals. Medical Care. 1992; 30(5): 377-91.
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Blvd, Mail Stop S3-02-01 | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Y-20; N-0; A-2
Rationale: This is a high volume, costly procedure that has been increasingly performed and will be important to measure and report.

If applicable, Conditions/Questions for Developer:
Developer Response:
If applicable, Questions to the Steering Committee:

1. Importance to Measure and Report: Y-19; N-1
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: This is a high volume, costly procedure that has been increasingly performed. There are a number of complications associated with this procedure.

2. Scientific Acceptability of Measure Properties: C-11; P-8; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The measure is valid. The follow-up timing varies depending on the complication. There is a segment of patients that will not be counted with this measure based on the age range, which is limited to patients 65 and over. The risk adjustment is sophisticated. The Committee questioned why deep vein thrombosis (DVT) and urinary tract infections (UTIs) were considered exclusions and noted that the included complications are appropriate.

3. Usability: C-10; P-10; M-0; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The information relies on claims data and is useful for reporting even though timing for the complications may make it more complicated in that there are at different intervals; i.e., 7, 30, 90 days.

4. Feasibility: C-14; P-6; M-0; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The measure was considered feasible based on the use of administrative claims data.

Public and Member Comment
- Socioeconomic status (SES) should be included in risk adjustment models;
- Concerns of using hierarchical risk modeling (HRM);
- Level of analysis should include providers at all levels;

1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

- Expand to commercial population (ages 18-64); and
- Inadequate list of ICD-9-CM codes in the denominator exclusions

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.

HGLM was used 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. The Committee believes 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.

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 developer is 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.

The developer identified the denominator exclusions in consultation with an advisory group of orthopedic surgeons with experience in identifying relevant procedures in claims data.

Voting: Total Approval: 89%
Comments received: "Agree with this measure and hope that it can be expanded to include those 18 to 64 as welll as those 65 years and older."
"I wanted to vote approval for this measure, but could not as currently specified, particularly since it is on the CMS list for near-term use for reporting and payment released last week. It still contains complications present on index admission in the numerator of the measure even after the recent modification. This will distort hospital comparisons and perversely reward hospitals that do not admit patients with existing complications. I would vote approval if ALL POA complication diagnoses in any position (in index admission only) were removed from the numerator."
CSAC Approval:
Board Endorsement:

1551 Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: This measure estimates hospital 30-day RSRRs following elective primary THA and TKA in patients 65 years and older. The measure uses Medicare claims data to develop a hospital-level RSRR for THA and TKA and will include patients readmitted for any reason within 30 days of discharge date of the index admission. Some patients are admitted within 30 days of the index hospitalization to undergo another elective THA/TKA procedure. These are considered planned readmissions and are NOT counted in the measure as readmissions.
Numerator Statement: This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1c tests per year); thus, we are using this field to define readmissions.
The outcome for this measure is a readmission to any acute care hospital, for any reason occurring within 30 days of the discharge date of the index hospitalization. We do not count planned readmissions in the outcome (see numerator details).
Denominator Statement: The target population for this measure includes admissions for patients at least 65 years of age undergoing primary THA and/or TKA procedures.
Exclusions: Patients will be excluded from the cohort if they meet any of the followed criteria:
1. Patients with hip fractures
Presence of one of the following diagnosis codes: 733.1, 733.10, 733.14, 733.15, 733.19, 733.8, 733.81, 733.82, 733.95, 733.96, 733.97, 808.0, 808.1, 820.00, 820.01, 820.02, 820.03, 820.09, 820.10, 820.11, 820.12, 820.13, 820.19, 820.20, 820.21, 820.22, 820.30,

1551 Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

820.31, 820.32, 820.8, 820.9, 821, 821.0, 821.00, 821.01, 821.1, 821.10, 821.11
Rationale: Patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is generally not elective.
2. Patients undergoing revision procedures (with or without a concurrent THA/TKA)
Presence of one of the following procedure codes: 81.53, 81.55, 81.59, 00.70, 00.71, 00.72, 00.73, 00.80, 00.81, 00.82, 00.83, 00.84
Rationale: Revision procedures may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication, and readmission rates.
3. Patients undergoing partial hip arthroplasty procedures (with or without a concurrent THA/TKA)
Presence of the following procedure code: 81.52
Rationale: Partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions.
4. Patients undergoing resurfacing procedures (with or without a concurrent THA/TKA)
Presence of one of the following procedure codes: 00.85, 00.86, 00.87
Rationale: Resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients.
5. Patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission*
Rationale: A complication coded in the principal field indicates it was present on admission, and these patients underwent an arthroplasty due to a complication related to a prior procedure. Furthermore, these patients may require more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications.
6. Patients without at least 30-days post-discharge enrolment in Medicare
Rationale: The 30-day readmission outcome cannot be assessed for the standardized time period.
7. Patients who are transferred in to the index hospital
Rationale: If the patient is transferred from another acute care facility to the hospital where the index procedure occurs, it is likely that the procedure is not elective.
8. Patients who were admitted for the index procedure and subsequently transferred to another acute care facility
Rationale: Attribution of readmission to the index hospital would not be possible in these cases, since the index hospital performed the procedure but another hospital discharged the patient to the non-acute care setting.
9. Patients who leave against medical advice (AMA)
Rationale: Hospitals and physicians do not have the opportunity to provide the highest quality care for these patients.
10. Patients with more than two THA/TKA procedures codes during the index hospitalization
Rationale: Patients with more than two procedure codes for THA/TKA are excluded because it is rare that a patient would have 3 arthroplasty procedures done at one time. This is likely to be a coding error.
10. Patients who die during the index admission
Rationale: Patients who die during the initial hospitalization are not eligible for readmission.
Additional otherwise qualifying THA and/or TKA admissions that occurred within 30 days of discharge date of an earlier index admission are not considered as index admission. They are considered as potential readmissions. Any THA and/or TKA admission is either an index admission or a potential readmission, but not both.
*Based on a medical record validation study of the paired hospital risk-standardized complications measure, we also excluded patients with a mechanical complication coded in the *principal discharge diagnosis field of the index admission* because a complication coded in the principal field indicates it was present on admission. Furthermore, these patients represent more technically complex arthroplasty procedures, and may be at increased risk for readmission, particularly for mechanical complications.
Prior to this cohort exclusion, there were 295,224 patients in the readmission measure cohort (2008). After excluding from the measure cohort, the patients who had a mechanical complication coded in the principal discharge diagnosis field on the index admission, the number of patients in the cohort decreased by 930 patients to 294,292 (less than 0.5% decrease).
The hospital risk-standardized mean readmission rate prior to this cohort exclusion was 6.25% (range 3.03 to 50.97%). The hospital risk-standardized mean readmission rate after this cohort exclusion increased slightly to 6.27% (range 3.06 to 50.72%). Thus, the additional cohort exclusion has a minimal effect on the hospital risk-standardized mean readmission rate, but the range of the rate still shows significant variation in hospital readmission rates. Details regarding the validation study are provided in the NQF application for the paired hospital risk-standardized complications measure (section 2c, Validity Testing).
Adjustment/Stratification: Risk-adjustment devised specifically for this measure/condition The measure estimates hospital-level 30-day all-cause RSRRs using hierarchical logistic regression models. In brief, the approach simultaneously models outcomes at two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals (Normand et al., 2007). To model the log-odds of 30-day all-cause readmission at the patient level, the model adjusts for age, sex, and selected clinical covariates. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission at the hospital, after accounting for case mix. If there were no differences among hospitals, then after

adjusting for case mix, the hospital intercepts should be identical across all hospitals. The measure adjusts for key variables that are clinically relevant and have strong relationships with the outcome (e.g. demographic factors, disease severity indicators, and indicators of frailty). For each patient, covariates are obtained from Medicare claims extending 12 months prior to and including the index admission. The model adjusts for case mix differences based on the clinical status of the patient at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis and procedure codes. We do not risk-adjust for CCs that are possible adverse events of care and that are only recorded in the index admission. In addition, only comorbidities that convey information about the patient at that time or in the 12-months prior, and not complications that arise during the course of the hospitalization are included in the risk-adjustment. The risk adjustment model included 33 variables which are listed below:

Demographics

1. Age-65 (years above 65, continuous)
2. Sex

TKA/THA Procedure

3. THA procedure
4. Number of procedures (2 vs.1)

Clinical Risk Factors

5. History of Infection (CC 1, 3-6)
6. Metastatic cancer and acute leukemia (CC 7)
7. Cancer (CC 8-12)
8. Diabetes and DM complications (CC 15-20, 119, 120)
9. Protein-calorie malnutrition (CC 21)
10. Disorders of Fluid/Electrolyte/Acid-Base (CC 22, 23)
11. Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)
12. Severe Hematological Disorders (CC 44)
13. Dementia and senility (CC 49, 50)
14. Major psychiatric disorders (CC 54-56)
15. Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)
16. Polyneuropathy (CC 71)
17. Congestive Heart Failure (CC 80)
18. Chronic Atherosclerosis (CC 83-84)
19. Hypertension (CC 89, 91)
20. Arrhythmias (CC 92, 93)
21. Stroke (CC 95, 96)
22. Vascular or circulatory disease (CC 104-106)
23. COPD (CC 108)
24. Pneumonia (CC 111-113)
25. End-stage renal disease or dialysis (CC 129, 130)
26. Renal Failure (CC 131)
27. Decubitus ulcer or chronic skin ulcer (CC 148, 149)
28. Cellulitis, Local Skin Infection (CC 152)
29. Other Injuries (CC162)
30. Major Symptoms, Abnormalities (CC 166)
31. Skeletal Deformities (ICD-9 code 755.63)
32. Post Traumatic Osteoarthritis (ICD-9 codes 716.15, 716.16)
33. Morbid Obesity (ICD-9 code 278.01)/No stratification is required for this measure.

Level of Analysis: Facility/ Agency

Type of Measure: Outcome

Data Source: Electronic administrative data/ claims

We obtained index admission, readmission, and in-hospital comorbidity data from Medicare's Standard Analytic File (SAF). Comorbidities were also assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index admission. Enrollment and post-discharge mortality status were obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

1. 2008 Part A (inpatient) data

Part A inpatient data includes claims for Medicare inpatient hospital care, skilled nursing facility care, some home health agency

1551 Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)
services, and hospice care. For purposes of this project, Part A is used to refer to inpatient services only and includes data from 2 time periods: a. Index admission: Index admission data are based on the inclusion/exclusion criteria for THA/TKA, and comorbidities (if any) are identified from the secondary diagnoses associated with the index admission. b. Pre-index: 12 months prior to the index admission ("pre-index"). 2. 2008 Part A (outpatient) data – 12 months pre-index Hospital outpatient refers to Medicare claims paid for the facility component of surgical or diagnostic procedures, emergency room care, and other non-inpatient services performed in a hospital outpatient department or ambulatory surgical/diagnostic center. 3. Part B data – 12 months pre-index Part B data refers to Medicare claims for the services of physicians (regardless of setting) and other outpatient care, services, and supplies. For purposes of this project, Part B services included only face-to-face encounters between a care provider and patient. We thus do not include services such as laboratory tests, medical supplies, or other ambulatory services. Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Blvd, Mail Stop S3-02-01 | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-20; N-0; A-2 Rationale: This is a high volume, costly procedure that has been increasingly performed and will be important to measure and report.
If applicable, Conditions/Questions for Developer: Developer Response: If applicable, Questions to the Steering Committee:
1. Importance to Measure and Report: Y-20; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: This is a high volume, costly procedure that has been increasingly performed. There are a number of complications associated with this procedure.
2. Scientific Acceptability of Measure Properties: C-15; P-5; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This was considered valid and easier to measure than *1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)* since it focuses on all causes for readmission other than for elective procedures. There is a segment of patients that will not be counted within this measure based on the age range, which is limited to patients aged 65 years and over. The risk adjustment is sophisticated. The Committee questioned why deep vein thrombosis (DVT) and urinary tract infections (UTIs) were considered exclusions.
3. Usability: C-16; P-4; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure is in wide use.
4. Feasibility: C-14; P-6; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: This measure is based on administrative claims data.
Public and Member Comment • Socioeconomic status (SES) should be included in risk adjustment models; • Concerns of using hierarchical risk modeling (HRM); • Level of analysis should apply to providers at all levels; • Expand to commercial population (ages 18-64); and 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. HGLM was used 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. The Committee believes 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.

1551 Hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

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 developer is 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.

Voting: Total Approval: 95%
Comments received: "Agree with this measure and hope that it can be expanded to include those 18 to 64 as welll as those 65 years and older."
CSAC Approval:
Board Endorsement:

1536 Cataracts: Improvement in patient's visual function within 90 days following cataract surgery

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery
Numerator Statement: Patients 18 years and older in sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument
Denominator Statement: All patients aged 18 years and older in sample who had cataract surgery
Exclusions:
Adjustment/Stratification: no risk adjustment necessary/ A risk adjustment methodology is not necessary if the stratification schema is utilized, as described above./ This measure can be stratified into two major groups: those patients with ocular co-morbidities and those patients without ocular co-morbidities. An improvement in visual function after cataract surgery would be expected in both groups, however the magnitude of the difference would vary by group. The Cataract Patient Outcomes Research Team found that an important preoperative patient characteristic that was independently associated with failure to improve on one of the outcomes measured (including the VF-14) was ocular comorbidity. The authors explained that this was expected, because it is reasonable to assume that other diseases that impair visual function would be correlated with a reduced improvement in functional status. The National Eye Care Outcomes Network also found that there were differences in the mean postooperative VF-14 scores across groups of patients with and without ocular co-morbidities, as seen in the table below. The study involving the Rasch-scaled short version of the VF-14 also found differences between the preoperative and postoperative visual function test scores and differences between preoperative and postoperative visual function tests, as seen below.
National Eyecare Outcomes Network
Mean VF-14 (postoperative)
- Total 92.7
- With ocular comorbidity 89.9
- Without ocular comorbidity 94.6

Rasch-Scaled Short Version of the VF-14
Patients without Ocular Comorbidity - Preop VF-8R - 68.87
Postop VF-8R - 86.22
Mean Diff = 17.35
Patients with Ocular Comorbidity - Preop VF-8R - 67.71
Postop VF-8R - 81.58
Mean Diff = 13.87

A list of codes for comorbidities can be found in the AMA PCPI measure for 20/40 visual acuity after cataract surgery:

Acute and subacute iridocyclitis	364.00
Acute and subacute iridocyclitis	364.01
Acute and subacute iridocyclitis	362.02
Acute and subacute iridocyclitis	364.03
Acute and subacute iridocyclitis	364.04
Acute and subacute iridocyclitis	364.05
Amblyopia	368.01
Amblyopia	368.02
Amblyopia	368.03

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Burn confined to eye and adnexa	940.0				
Burn confined to eye and adnexa	940.1				
Burn confined to eye and adnexa	940.2				
Burn confined to eye and adnexa	940.3				
Burn confined to eye and adnexa	940.4				
Burn confined to eye and adnexa	940.5				
Burn confined to eye and adnexa	940.9				
Cataract secondary to ocular disorders	366.32				
Cataract secondary to ocular disorders	366.33				
Certain types of iridocyclitis	364.21				
Certain types of iridocyclitis	364.22				
Certain types of iridocyclitis	364.23				
Certain types of iridocyclitis	364.24				
Certain types of iridocyclitis	364.3				
Choroidal degenerations	363.43				
Choroidal detachment	363.72				
Choroidal hemorrhage and rupture	363.61				
Choroidal hemorrhage and rupture	363.62				
Choroidal hemorrhage and rupture	363.63				
Chorioretinal scars	363.30				
Chorioretinal scars	363.31				
Chorioretinal scars	363.32				
Chorioretinal scars	363.33				
Chorioretinal scars	363.35				
Chronic iridocyclitis	364.10				
Chronic iridocyclitis	364.11				
Cloudy cornea	371.01				
Cloudy cornea	371.02				
Cloudy cornea	371.03				
Cloudy cornea	371.04				
Corneal edema	371.20				
Corneal edema	371.21				
Corneal edema	371.22				
Corneal edema	371.23				
Corneal edema	371.43				
Corneal edema	371.44				
Corneal opacity and other disorders of cornea	371.00				
Corneal opacity and other disorders of cornea	371.03				
Corneal opacity and other disorders of cornea	371.04				
Degenerative disorders of globe	360.20				
Degenerative disorders of globe	360.21				
Degenerative disorders of globe	360.23				
Degenerative disorders of globe	360.24				
Degenerative disorders of globe	360.29				
Degeneration of macula and posterior pole	362.50				
Degeneration of macula and posterior pole	362.51				
Degeneration of macula and posterior pole	362.52				
Degeneration of macula and posterior pole	362.53				
Degeneration of macula and posterior pole	362.54				
Degeneration of macula and posterior pole	362.55				
Degeneration of macula and posterior pole	362.56				
Degeneration of macula and posterior pole	362.57				
Disseminated chorioretinitis and disseminated retinochoroiditis	363.10				
Disseminated chorioretinitis and disseminated retinochoroiditis	363.11				
Disseminated chorioretinitis and disseminated retinochoroiditis	363.12				

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Disseminated chorioretinitis and disseminated retinochoroiditis	363.13
Disseminated chorioretinitis and disseminated retinochoroiditis	363.14
Disseminated chorioretinitis and disseminated retinochoroiditis	363.15
Diabetic retinopathy	362.01
Diabetic retinopathy	362.02
Diabetic retinopathy	362.03
Diabetic retinopathy	362.04
Diabetic retinopathy	362.05
Diabetic retinopathy	362.06
Diabetic macular edema	362.07
Disorders of optic chiasm	377.51
Disorders of optic chiasm	377.52
Disorders of optic chiasm	377.53
Disorders of optic chiasm	377.54
Disorders of visual cortex	377.75
Focal chorioretinitis and focal retinochoroiditis	363.00
Focal chorioretinitis and focal retinochoroiditis	363.01
Focal chorioretinitis and focal retinochoroiditis	363.03
Focal chorioretinitis and focal retinochoroiditis	363.04
Focal chorioretinitis and focal retinochoroiditis	363.05
Focal chorioretinitis and focal retinochoroiditis	363.06
Focal chorioretinitis and focal retinochoroiditis	363.07
Focal chorioretinitis and focal retinochoroiditis	363.08
Glaucoma	365.10
Glaucoma	365.11
Glaucoma	365.12
Glaucoma	365.13
Glaucoma	365.14
Glaucoma	365.15
Glaucoma	365.20
Glaucoma	365.21
Glaucoma	365.22
Glaucoma	365.23
Glaucoma	365.24
Glaucoma	365.31
Glaucoma	365.32
Glaucoma	365.51
Glaucoma	365.52
Glaucoma	365.59
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.41
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.42
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.43
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.44
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.60
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.61
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.62
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.63
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.64
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.65
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.81
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.82
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.83
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.89
Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes	365.9
Hereditary corneal dystrophies	371.50

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Hereditary corneal dystrophies	371.51
Hereditary corneal dystrophies	371.52
Hereditary corneal dystrophies	371.53
Hereditary corneal dystrophies	371.54
Hereditary corneal dystrophies	371.55
Hereditary corneal dystrophies	371.56
Hereditary corneal dystrophies	371.57
Hereditary corneal dystrophies	371.58
Hereditary choroidal dystrophies	363.50
Hereditary choroidal dystrophies	363.51
Hereditary choroidal dystrophies	363.52
Hereditary choroidal dystrophies	363.53
Hereditary choroidal dystrophies	363.54
Hereditary choroidal dystrophies	363.55
Hereditary choroidal dystrophies	363.56
Hereditary choroidal dystrophies	363.57
Hereditary retinal dystrophies	362.70
Hereditary retinal dystrophies	362.71
Hereditary retinal dystrophies	362.72
Hereditary retinal dystrophies	362.73
Hereditary retinal dystrophies	362.74
Hereditary retinal dystrophies	362.75
Hereditary retinal dystrophies	362.76
High myopia	360.20
High myopia	360.21
Injury to optic nerve and pathways	950.0
Injury to optic nerve and pathways	950.1
Injury to optic nerve and pathways	950.2
Injury to optic nerve and pathways	950.3
Injury to optic nerve and pathways	950.9
Keratitis	370.03
Moderate or severe impairment, better eye, profound impairment lesser eye	369.10
Moderate or severe impairment, better eye, profound impairment lesser eye	369.11
Moderate or severe impairment, better eye, profound impairment lesser eye	369.12
Moderate or severe impairment, better eye, profound impairment lesser eye	369.13
Moderate or severe impairment, better eye, profound impairment lesser eye	369.14
Moderate or severe impairment, better eye, profound impairment lesser eye	369.15
Moderate or severe impairment, better eye, profound impairment lesser eye	369.16
Moderate or severe impairment, better eye, profound impairment lesser eye	369.17
Moderate or severe impairment, better eye, profound impairment lesser eye	369.18
Nystagmus and iother irregular eye movements	379.51
Open wound of eyeball	871.0
Open wound of eyeball	871.1
Open wound of eyeball	871.2
Open wound of eyeball	871.3
Open wound of eyeball	871.4
Open wound of eyeball	871.5
Open wound of eyeball	871.6
Open wound of eyeball	871.7
Open wound of eyeball	871.9
Optic atrophy	377.10
Optic atrophy	377.11
Optic atrophy	377.12
Optic atrophy	377.13
Optic atrophy	377.14

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Optic atrophy 377.15
Optic atrophy 377.16
Optic neuritis 377.30
Optic neuritis 377.31
Optic neuritis 377.32
Optic neuritis 377.33
Optic neuritis 377.34
Optic neuritis 377.39
Other background retinopathy and retinal vascular changes 362.12
Other background retinopathy and retinal vascular changes 362.16
Other background retinopathy and retinal vascular changes 362.18
Other corneal deformities 371.70
Other corneal deformities 371.71
Other corneal deformities 371.72
Other corneal deformities 371.73
Other disorders of optic nerve 377.41
Other disorders of sclera 379.11
Other disorders of sclera 379.12
Other endophthalmitis 360.11
Other endophthalmitis 360.12
Other endophthalmitis 360.13
Other endophthalmitis 360.14
Other endophthalmitis 360.19
Other retinal disorders 362.81
Other retinal disorders 362.82
Other retinal disorders 362.83
Other retinal disorders 362.84
Other retinal disorders 362.85
Other retinal disorders 362.89
Other and unspecified forms of chorioretinitis and retinochoroiditis 363.20
Other and unspecified forms of chorioretinitis and retinochoroiditis 363.21
Other and unspecified forms of chorioretinitis and retinochoroiditis 363.22
Prior penetrating keratoplasty 371.60
Prior penetrating keratoplasty 371.61
Prior penetrating keratoplasty 371.62
Profound impairment, both eyes 369.00
Profound impairment, both eyes 369.01
Profound impairment, both eyes 369.02
Profound impairment, both eyes 369.03
Profound impairment, both eyes 369.04
Profound impairment, both eyes 369.05
Profound impairment, both eyes 369.06
Profound impairment, both eyes 369.07
Profound impairment, both eyes 369.08
Purulent endophthalmitis 360.00
Purulent endophthalmitis 360.01
Purulent endophthalmitis 360.02
Purulent endophthalmitis 360.03
Purulent endophthalmitis 360.04
Retinal detachment with retinal defect 361.00
Retinal detachment with retinal defect 361.01
Retinal detachment with retinal defect 361.02
Retinal detachment with retinal defect 361.03
Retinal detachment with retinal defect 361.04
Retinal detachment with retinal defect 361.05

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Retinal detachment with retinal defect 361.06
Retinal detachment with retinal defect 361.07
Retinal vascular occlusion 362.31
Retinal vascular occlusion 362.32
Retinal vascular occlusion 362.35
Retinal vascular occlusion 362.36
Retinopathy of prematurity 362.21
Scleritis and episcleritis 379.04
Scleritis and episcleritis 379.05
Scleritis and episcleritis 379.06
Scleritis and episcleritis 379.07
Scleritis and episcleritis 379.09
Separation of retinal layers 362.41
Separation of retinal layers 362.42
Separation of retinal layers 362.43
Uveitis 360.11
Uveitis 360.12
Visual field defects 368.41

References:

1. Schein OD, Steinberg EP, Cassard SD et al. Predictors of outcome in patients who underwent cataract surgery. Ophthalmology 1995; 102:817-23.
2. Lum F, Schachat AP, Jampel HD.The development and demise of a cataract surgery database. Jt Comm J Qual Improv. 2002 Mar;28(3):108-14.
3. Gothwal VK, Wright TA, Lamoureux EL, Pesudovs K. Measuring outcomes of cataract surgery using the Visual Function Index-14. J Cataract Refract Surg 2010; 36:1181-8. no risk adjustment necessary

Level of Analysis: Clinicians: Individual
Type of Measure: Outcome
Data Source: Survey: Patient
Measure Steward: American Academy of Ophthalmology and Hoskins Center for Quality Eye Care | 655 Beach Street | San Francisco | California, 94109-1336

Steering Committee Recommendation for Endorsement: Y-16; N-4; A-1
Rationale: The Committee verified the importance of patient centered measures such as this one noting that the additional information that is provided from the patient perspective about visual function makes this an important and useful measure.

If applicable, Conditions/Questions for Developer:

Overarching comment: The numerator, denominator with the inclusions and exclusions should be refined to capture patients relevant to the measure focus and the measure should be tested with the changes that are made.

1. 2a.3 Numerator Details: a) Provide the method (e.g., scale or other method to demonstrate improvement quantatively pre- and post- surgery) to define "improvement"; b) It appears inappropriate to include, in the numerator, patients who do not complete visual function assessments; reevaluate how these cases should be handled; c) Indicate whether objective vs. subjective improvement by survey only; d) Specify whether patient is surveyed both pre-and post-surgery. If only post-surgery, is the patient asked to rate vision preoperatively and asked to rate vision post-operatively, or is the patient asked to rate the number of points of improvement?
2. 2a.9 Denominator Exclusions: Excluding patients who do not want to complete the survey inappropriately inflates the rate.
3. 2a.25 Data Source/Data Collection Instrument: a) Identify the specific tool(s) used for the measure and provide information about the use for which it/they have been validated (e.g., self-administration, provider facilitated administration, etc.); b) Include information about why the objective assessment of visual function/acuity should be supplement with such a measure; c) Define survey methodology: Is it a mail survey, phone survey, in office paper survey with questions asked by office staff? Is the survey of the entire population of those with cataract surgery or a sample? If a sample, please specify sampling methodology.
4. 3a.2 Use in Public Reporting Initiative: Provide plans and expected date (within 3 years) for public reporting.
5. 4e Data Collection Strategy: Clarify more specifically the burden on providers of data collection.

Developer Response:

1. 2a.3 Numerator Details: a) The method to define "improvement" used is the quantitative scale used pre and post surgery to measure visual function with the VF-8R instrument. The 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. Currently in the scientific literature, there is no well-established method to define a threshold or interval that indicates improvement on the VF-

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8R. The Rasch scale has found to be more sensitive to change than the VF-14 in longitudinal studies and has a different scale for scoring than the VF-14. The VF-14 is based on summative scoring, which has no rationale for how numerical values are assigned and how a summary score is produced, and does not give a sense of the degree of change. The Rasch model is 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. 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 pre-operative 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. b) Regarding the cases that do not complete visual function instruments; these will not be included in the numerator. c) This is subjective improvement by patient self-reporting by survey, as measured by the VF-8R instrument. d) The patient is surveyed both pre- and post-surgery. 2. 2a.9 Denominator Exclusions: We agree and will not exclude patients who do not want to complete the survey. 3. 2a.25 Data Source/Data Collection Instrument: a) The specific tool used for the measure is the VF-8R. The information about the use for which it has been validated is self- administration. There are at least two peer-reviewed studies in the literature reports demonstrating the validity and responsiveness of the self-administered VF-14. b) It is important to supplement the existing measure for objective assessment of visual acuity because this new measure centers on patient quality of life, ability to perform activities of daily living and is a patient-reported outcome. This is the outcome most critical and applicable to the patient. Visual acuity is an objective assessment of visual function but only describes one aspect of visual function. Visual function has multiple components in addition to central near, intermediate, and distance visual acuity. It also encompasses peripheral vision; visual search; binocular vision; depth perception; contrast sensitivity; perception of color; adaptation; and visual processing speed; all of which cannot be measured in a visual acuity test. This measure focuses on the functional disability caused by visual impairment, because many activities of daily living are affected by one or more of these components of visual function. c) The survey methodology is described as follows. The survey would be administered by a third party (a registry for reporting of PQRS measures) to prevent or minimize bias which might be introduced if it is an in-office paper survey with questions asked by the office staff. Options would be provided to the patient, either online survey, mail survey or phone survey, depending on their preferences and abilities. The survey would be of a sample of those individuals with cataract surgery. The sample size would be postulated at 30, because this is a well-accepted statistical sample and used by the CMS for reporting on measure groups in PQRS. Because visual function is reported at 90 days after surgery, this would allow physicians to identify 30 cases from January –August for reporting purposes. 4. 3a.2 Use in Public Reporting Initiative: This is planned for public reporting through the CMS PQRS within the next 3 years. 5. 4e Data Collection Strategy: The sampling strategy of 30 cases, and the use of a third party (a registry for reporting of PQRS measures initiated by the Academy) should significantly alleviate the burden on providers of data collection. Providers would not be responsible for collecting this data from patients and following up on their response. Steering Committee Follow-up: 1. The Steering Committee stated that the data collection strategy involving the use of a third party and registry initiated by the Academy would alleviate the burden on providers. The Steering Committee clarified that about 94 percent of practicing ophthalmology practices belong to the Academy but that non-members could also be included in the registry. 2. This was one of two related measures considered for potential harmonization. The two included: n*ew candidate measure 1536*: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery; and e*ndorsed measure 0565*: Cataracts: 20/40 or better visual acuity within 90 days following cataract surgery. Discussion of the two measures is included here. The Steering Committee noted that measures 1536 and 0565 are similar but not competing since one measures acuity and the other patient perception of visual function. Potential for harmonization was discussed in terms of numerator and denominator as well as data gathering strategies. It was determined that harmonization could result in the loss of valuable information. The group also liked the fact that measure 1536 measures patient satisfaction. Variation between the measures was considered acceptable since the measures are designed to capture different things/data.
1. Importance to Measure and Report: Y-18; N-1 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The Committee recognized the frequent occurrence of cataract surgery in the United States. They also affirmed the importance of patient-centered measures. In this measure, visual function is considered a more broad assessment than that of visual acuity.
2. Scientific Acceptability of Measure Properties: C-2; P-12; M-4; N-1 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The Committee was advised that the tool used for assessment of visual function had been validated. It was questioned how

1536 Cataracts: Improvement in patient's visual function within 90 days following cataract surgery
the measure defined visual improvement. The time window of the measure may need to be extended to take into account multi-focal implants, which are now being used to improve visual acuity. The Committee suggested measuring the improvement in visual function for patients with and without comorbidities.
3. Usability: C-1; P-15; M-1; N-2 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The tool is self-administered. The return rate has been 50 percent; which is considered a good rate for surveys. Some patient contact has been required to increase return rate. The Committee encouraged the developer to reconsider this practice. They did note the value to consumer decision making to have the type of information the measure provides.
4. Feasibility: C-1; P-12; M-4; N-2 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: It was questioned whether patients could accurately assess their visual acuity. In addition to potential bias introduced by calling patients to respond, they also mentioned that the exclusion criteria of "patient refused to participate" may bias the results. Additionally, conducting the survey will incur a cost and the burden on the provider was described as unclear.
Public and Member Comment Commenters note that this a good measure and suggested that the threshold of 'improvement' is needed to make the measure more objective. The developer indicated that 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. The Committee noted that with additional experience and evidence, categories reflecting amount of improvement may prove possible and encourages continued evolution of the measure.
Voting: Total Approval: 100% Comments received: "On the surface this appears to be intuitive; but it can also be used to judge those ophthalmologists who may have inappropriately selected individuals whose improvement may be minimal." CSAC Approval: Board Endorsement:

0528 Prophylactic antibiotic selection for surgical patients
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure). Numerator Statement: Surgical patients who received recommended prophylactic antibiotics for specific surgical procedures Denominator Statement: All selected surgical patients with no evidence of prior infection. Included Populations: An ICD-9-CM Principal Procedure Code of selected surgeries (as defined in Appendix A, Table 5.10 for ICD-9-CM codes). AND An ICD-9-CM Principal Procedure Code of selected surgeries (as defined in Appendix A, Table 5.01-5.08 for ICD-9-CM codes). Exclusions: Excluded Populations: Patients less than 18 years of age Patients who have a length of Stay greater than 120 days Patients who had a principal diagnosis suggestive of preoperative infectious diseases (as defined in Appendix A, Table 5.09 for ICD-9-CM codes) Patients whose ICD-9-CM principal procedure was performed entirely by Laparoscope Patients enrolled in clinical trials Patients whose ICD-9-CM principal procedure occurred prior to the date of admission Patients with physician/advanced practice nurse/physician assistant (physician/APN/PA) documented infection prior to surgical procedure of interest Patients who expired perioperatively Patients who were receiving antibiotics more than 24 hours prior to surgery (except colon surgery patients taking oral prophylactic antibiotics) Patients who were receiving antibiotics within 24 hours prior to arrival (except colon surgery patients taking oral prophylactic antibiotics) Patients who did not receive any antibiotics before or during surgery, or within 24 hours after Anesthesia End Time (i.e., patient did not

0528 Prophylactic antibiotic selection for surgical patients
receive prophylactic antibiotics) Patients who did not receive any antibiotics during this hospitalization Adjustment/Stratification: no risk adjustment necessary/The antibiotic prophylaxis measures are stratified according to surgery type. The tables are subsets of Table 5.10 (see link for Specification Manual and Appendix A, Tables 5.01 to 5.08. The specific procedures must be in the large table (Table 5.10) to be eligible for the SCIP measures. The measure specific tables for SCIP-Inf-2 are 5.01 to 5.08. Level of Analysis: Facility/ Agency, Population: National, Can be measured at all levels, Program: QIO Type of Measure: Process Data Source: Electronic administrative data/ claims; Electronic Health/ Medical Record; Paper medical record/ flow-sheet Most facilities use vendors to collect the data electronically. CMS provides a free, downloadable tool called CART. A paper tool modeled after the data collected electronically is provided as an attachment. CART downloads can be found on QualityNet.org at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093 Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard , Mail Stop S3-01-02 | Baltimore | Maryland | 21244-1850
Steering Committee Recommendation for Endorsement: Y-22; N-1; A-1 Rationale: This measure was described as appropriate and important to encourage continued focus on post surgical infection.
Steering Committee Follow-up: This was one of three related measures considered for potential harmonization. The three included: m*aintenance measure 0126*: Selection of antibiotic prophylaxis for cardiac surgery patients; e*ndorsed measure 0268*: Selection of prophylactic antibiotic: First or second generation cephalosporin; and m*aintenance measure 0528*: Prophylactic antibiotic selection for surgical patients. Discussion of the three measures is included here. The Steering Committee determined there were no competing measures in the group. Members made no recommendations for harmonization of measure 0126 which is limited to cardiac surgery and is derived from registry data. Members requested that measures 0268 and 0528 be combined into a single measure from which the cephalosporin data for individual clinicians required by 0268 could be reported as a subset. For the measure not within the current project (AMA-PCPI measure 0268), NQF staff will relay the request of the Committee for developer action as they update and test the measure. The combined measure is expected to be submitted for consideration under the next Surgery Endorsement Maintenance project scheduled to launch in 2013.
1. Importance to Measure and Report: Y-18; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure is strongly supported by evidence. While performance rates are relatively high, room for improvement remains.
2. Scientific Acceptability of Measure Properties: C-15; P-3; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The science behind the antibiotic selections is good but will need to continue to be harmonized with national guidelines as they come out. The Committee noted that including laparoscopic procedures will no longer be an exclusion effective January 1, 2012, which they supported.
3. Usability: C-16; P-2; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The Committee indicated that the measure will require ongoing harmonization with national guidelines as they are released.
4. Feasibility: C-15; P-3; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The Committee stated that the measure was feasible based on data source.
Public and Member Comment • Should be combined with measure 0527 to create a patient-centered all-or-none composite; and • Measure relies on a specific type of antibiotic used for compliance 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. The Committee noted that 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. The measure specifications are based on several guidelines and therefore have a variety of recommendations, not a single class of antimicrobials. 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 antibiotic selection for surgical patients
Voting: Total Approval: 81% Comments received: None CSAC Approval: Board Endorsement:

0126 Selection of antibiotic prophylaxis for cardiac surgery patients
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percent of patients aged 18 years and older undergoing cardiac surgery who received preoperative prophylactic antibiotics recommended for the operation. Numerator Statement: Number of patients undergoing cardiac surgery who received a first generation or second generation cephalosporin prophylactic antibiotic (e.g., cefazolin, cefuroxime, cefamandole) preoperatively or in the event of a documented allergy, an alternate antibiotic choice (e.g., vancomycin, clindamycin) was ordered and administered preoperatively. Denominator Statement: Number of patients undergoing cardiac surgery Exclusions: Exclusions include: - Patients who had a principal diagnosis suggestive of preoperative infectious diseases - Patients whose ICD-9-CM principal procedure was performed entirely by Laparoscope - Patients enrolled in clinical trials - Patients with documented infection prior to surgical procedure of interest - Patients who expired perioperatively - Patients who were receiving antibiotics more than 24 hours prior to surgery - Patients who were receiving antibiotics within 24 hours prior to arrival - Patients who did not receive any antibiotics before or during surgery, or within 24 hours after anesthesia end time (i.e., patient did not receive prophylactic antibiotics) - Patients who did not receive any antibiotics during this hospitalization This list will be provided in the STS Adult Cardiac Surgery Database Data Manager's Training Manual as acceptable exclusions. AbxSelect is marked "Exclusion" Adjustment/Stratification: no risk adjustment necessary N/A N/A Level of Analysis: Clinicians: Group, Facility/ Agency, Population: Counties or cities, Population: National, Population: Regional/ network, Population: States Type of Measure: Process Data Source: Registry data Measure Steward: Society of Thoracic Surgeons | 633 North Saint Clair Street, Suite 2320 | Chicago | Illinois | 60611
Steering Committee Recommendation for Endorsement: Y-22; N-1; A-1 Rationale: The Committee affirmed that the seriousness of infections following these procedures makes this measure and its focus important to track and agreed that 92 percent performance indicates room for continued improvement.
Steering Committee Comments: This was one of three related measures considered for potential harmonization. The three included: m*aintenance measure 0126*: Selection of antibiotic prophylaxis for cardiac surgery patients; e*ndorsed measure 0268*: Selection of prophylactic antibiotic: First or second generation cephalosporin; and m*aintenance measure 0528*: Prophylactic antibiotic selection for surgical patients. Discussion of the three measures is included here. The Steering Committee determined there were no competing measures in the group. Members made no recommendations for harmonization of measure 0126 which is limited to cardiac surgery and is derived from registry data. Members requested that measures 0268 and 0528 be combined into a single measure from which the cephalosporin data for individual clinicians required by 0268 could be reported as a subset. For the measure not within the current project (AMA-PCPI measure 0268), NQF staff will relay the request of the Committee for developer action as they update and test the measure.
1. Importance to Measure and Report: Y-19; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The evidence indicated that the use of prophylactic antibiotics can decrease the incidence of mediastinitis, which ranges between 0.25 percent and 4 percent. The seriousness of infection in the population measured suggests that even at 92 percent performance, additional improvement should be expected and sought.
2. Scientific Acceptability of Measure Properties: C-15; P-4; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure focus on prophylaxis and measure specifications were considered appropriate and valid.
3. Usability: C-17; P-2; M-0; N-0

0126 Selection of antibiotic prophylaxis for cardiac surgery patients

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: The measure has been in use since 2007 and is publicly reported on the STS and Consumers Union websites.

4. Feasibility: C-18; P-1; M-0; N-0

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale: The measure was considered feasible based on its continued use over time.

Public and Member Comment

- Considers the measure to be topped out due to the mean value being greater than 90 percent; and
- Should be combined with measure 0126 and 0127 to create a patient-centered all-or-none composite

Although the mean value is greater than 90 percent, the distribution of values indicates there is opportunity for improvement.

The denominator of measures 0117 and 0127 differ from measure 0126. In addition, two of the measures are included in the NQF-endorsed® measure 0696 The STS CABG Composite Score. Endorsement as a stand alone measure does not preclude use in a composite.

Voting: Total Approval: 83%
Comments received: None
CSAC Approval:
Board Endorsement:

0264 Prophylactic intravenous (IV) antibiotic timing

For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings

Description: Rate of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time
Numerator Statement: Number of ambulatory surgical center (ASC) admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection who received the prophylactic antibiotic on time
Denominator Statement: All ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection
Exclusions: ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of infections other than surgical site infections (e.g., bacterial endocarditis).
ASC admissions with a preoperative order for a prophylactic antibiotic not administered by the intravenous route.
Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure.
Level of Analysis: Facility/ Agency
Type of Measure: Process
Data Source: Paper medical record/ flow-sheet
Measure Steward: ASC Quality Collaboration | 5686 Escondida Blvd S | St. Petersburg | Florida | 33715

Steering Committee Recommendation for Endorsement: Y-18; N-1; A-3
Rationale: This measure was considered important to measure and report despite its small performance gap. The Committee wants to see disparities information prior to making any determination regarding continued reporting of the measure.

If applicable, Conditions/Questions for Developer:

1. 2a.1 Numerator Statement: Clarify 'on time.' Suggested modification-Instead of 'on time' change to 'one hour.'
2. 2h. Disparities in Care: Please submit any subpopulation performance data that is available for the measures. The committee understands that ASCs do not have a quality reporting system requirement; however, assessment of subpopulation data is important and should be collected and reported for this and other measures.

Developer Response:

In response to your suggestion, we are offering two items for your consideration:
1) Our rational for our current use of 'on time' and
2) What we will do if our rationale is not compelling to the Committee.
For clarification of "on time", please see Section 2a.3. Numerator Details on the measure submission form. The pertinent material is reproduced here:

2a.3. Numerator Details *(All information required to collect or calculate the numerator, including all codes, logic, and definitions)*
DEFINITIONS:
On time: antibiotic infusion is initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or a

fluoroquinolone is administered:

This approach was selected in order to allow a concise numerator statement that clearly conveys the performance expectation of the measure, which is that any prophylactic IV antibiotics ordered preoperatively will be given in a timely manner. Defining "on time" separately allows us to avoid inserting a parenthetical modification in the numerator statement to address the two-hour exception for vancomycin and fluoroquinolones. Defining "on time" separately also allows us to simultaneously address several issues pertaining to timeliness: 1) how the time interval is to be measured (from initiation of infusion to the initial surgical incision, 2) how the time interval is to be measured for procedures that do not involve an incision, or that involve the inflation of a tourniquet, and 3) the existence of two allowable timeframes, depending upon the type of antibiotic administered. The data collected using these specifications supports the reliability of this approach. This method has been well received by the facilities that use the measure and we would prefer to continue to specify the measure in this manner.

However, if the measure will not continue to be endorsed in the absence of the modification suggested above , we would then revise the numerator statement to read as follows, which more closely mimics the phrasing of the other related measures:

Number of ambulatory surgical center (ASC) admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection with prophylactic antibiotic initiated within one hour prior to surgical incision (two hours if initiating vancomycin or a fluoroquinolone)

We would also delete the current data element definition of "on time" and add a new statement regarding "surgical incision":

DEFINITIONS:

Surgical incision: For purposes of this measure, the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet).

{At this time, we have <u>not</u> made any changes regarding this specific issue to the measure currently on line. We will make the needed changes once we have direction from the steering committee.}

<u>2h. Disparities in Care</u>: Please submit any subpopulation performance data that is available for the measures. The committee understands that ASCs do not have a quality reporting system requirement; however, assessment of subpopulation data is important and should be collected and reported for this and other measures.

Response: The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by third quarter of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three months thereafter.

ADDITIONAL INFORMATION and Response from Measure Developer:

We have also revised 1b2/1b3/1b4/2f1/2f2/2f3 for this measure #0264 Antibiotic Timing to provide additional clarity:

1b.2. Summary of Data Demonstrating Performance Gap *(Variation or overall poor performance across providers)*

Although data for 671 ASCs are included in the ASC Quality Collaboration (ASC QC) database for this measure, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 349 ASCs throughout the US. The rates for this measure are based on the 349 individually-reporting ambulatory surgery centers, located throughout the US. The rate for timely administration of a pre-operative antibiotic ranged from a minimum of 0.2% to a maximum of 100%. The mean rate was 96% (SD: 14.6%), while the median rate was 100%. The minimum compliance rate of 0.2% demonstrates that there is a significant opportunity for improvement in this measure.

1b.3. Citations for Data on Performance Gap

Although data for 671 ASCs are included in the ASC QC database, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 349 ASCs throughout the US. The 349 individually-reporting ambulatory surgery centers represent a convenience sample that may be used to assess the opportunity for improvement for this measure. The centers were located throughout the US. Data collected for second calendar quarter of 2010 were included in this portion of the study.

1b.4. Summary of Data on Disparities by Population Group

This measure is currently collected at the ASC-level or at the level of the corporate parent of the ASC. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. The ASC QC is investigating a number of strategies that will make this type of data available and hopes to add this component in the near future.

2f.1. Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a

0264 Prophylactic intravenous (IV) antibiotic timing
sample, characteristics of the entities included) *Although data for 671 ASCs are included in the ASC QC database, many report at the corporate level and do not report data for individual ASCs. The ASC QC database includes center-level rates for this measure for 349 ASCs throughout the US. The rates for this measure were collected for the 349 individually-reporting ambulatory surgery centers throughout the US for services provided during April to June 2010.* 2f.2. Methods to Identify Statistically Significant and Practical or Meaningful Differences in Performance (Type of analysis and rationale) *An individual ASC's rate for timely administration of antibiotic may be compared to the standard rate from the ASC Quality website (http://www.ascquality.org/qualityreport.cfm#Antibiotic). A statistically significant difference in performance may be detected by using a standard test of proportions as outlined in most standard statistical texts. Since each delay in administration of the preoperative antibiotic may represent increased surgical site infection risk for the patient, a rate lower than the 94.4% is also of practical significance.* *The null hypothesis for this test is that the sample proportion from the ASC is not different from the industry standard taken from the ASC Quality website. The alternative is that there is a statistically significant difference. We recommend that this test be performed in its two-sided form so that the ASC may determine if they are either statistically higher or lower than the standard. The recommended p-value for this test is the 0.05 level, but ASCs may have justification for different value. Using this statistical method for detecting significant variances from the industry standard will allow users to determine if differences may be due to sampling error or may indicate a true difference in performance.* 2f.3. Measure Scores from Testing or Current Use (Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)The rate for timely administration of antibiotic ranged from a minimum of 0.2% to a maximum of 100%. The mean rate was 96.0% (SD: 14.6%), while the median rate was 100%. The maximum rates of 100% and a third quartile value of 100% demonstrate that there is an opportunity for improvement in this measure and that full compliance (100%) is achievable for all centers. Steering Committee Follow-Up: The Steering Committee agreed that the response from the developer was adequate.
1. Importance to Measure and Report: Y-17; N-2 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Performance on the measure is high; however disparities information is not presented. ASC noted that only about 900 of the eligible 5,200 institutions report.
2. Scientific Acceptability of Measure Properties: C-10; P-9; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The Committee questioned why the measure focused on antibiotics being provided in a one hour timeframe.
3. Usability: C-12; P-7; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The Committee described the measure as usable.
4. Feasibility: C-13; P-6; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The measure uses procedure codes, which makes it less burdensome for ambulatory surgical centers to collect.
Public and Member Comment Commenters showed support for the measure but recommended that ongoing assessment of the measure occur. 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.
Voting: Total Approval: 94% Comments received: "This is a good measure but measure #264 and 527 should be harmonized to become a single measure as place of service is irrelevant to this measure." CSAC Approval: Board Endorsement:

0527 Prophylactic antibiotic received within 1 hour prior to surgical incision
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received

0527 Prophylactic antibiotic received within 1 hour prior to surgical incision
vancomycin or a fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within two hours prior to surgical incision. Due to the longer infusion time required for vancomycin or a fluoroquinolone, it is acceptable to start these antibiotics within two hours prior to incision time. Numerator Statement: Number of surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision (two hours if receiving vancomycin, in Appendix C, Table 3.8, or a fluoroquinolone, in Appendix C, Table 3.10). Denominator Statement: All selected surgical patients with no evidence of prior infection. Table 5.10 is the complete table of selected major surgeries Exclusions: Patients less than 18 years of age Patients who have a Length of Stay greater than 120 days Patients who had a hysterectomy and a caesarean section performed during this hospitalization Patients who had a principal diagnosis suggestive of preoperative infectious diseases (as defined in Appendix A, Table 5.09 for ICD-9-CM codes) Patients whose ICD-9-CM principal procedure was performed entirely by Laparoscope Patients enrolled in clinical trials Patients whose ICD-9-CM principal procedure occurred prior to the date of admission Patients with physician/advanced practice nurse/physician assistant (physician/APN/PA) documented infection prior to surgical procedure of interest Patients who had other procedures requiring general or spinal anesthesia that occurred within 3 days (4 days for CABG or Other Cardiac Surgery) prior to or after the procedure of interest (during separate surgical episodes) during this hospital stay Patients who were receiving antibiotics more than 24 hours prior to surgery Patients who were receiving antibiotics within 24 hours prior to arrival (except colon surgery patients taking oral prophylactic antibiotics) Adjustment/Stratification: no risk adjustment necessary/The antibiotic prophylaxis measures are stratified according to surgery type. The tables are subsets of Table 5.10 (see link for Specification Manual and Appendix A, Tables 5.01 to 5.08. The specific procedures must be in the large table (Table 5.10) to be eligible for the SCIP measures. The measure specific tables for SCIP-Inf-1 are 5.01 to 5.08. Level of Analysis: Can be measured at all levels, Facility/ Agency, Population: National, Program: QIO Type of Measure: Process Data Source: Electronic administrative data/ claims, Electronic Health/ Medical Record, Paper medical record/ flow-sheet Most facilities use vendors to collect and submit the data electronically. CMS provides a free, downloadable tool called CART. A paper tool modeled after the data collected electronically is provided as an attachment. CART downloads can be found on QualityNet.org at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093 Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard , Mail Stop S3-01-02 | Baltimore | Maryland | 21244-1850
Steering Committee Recommendation for Endorsement: Y-21; N-2; A-1 Rationale: The measure focus and specifications are appropriate. Performance presents disparity data that demonstrates performance gaps across subpopulations.
Steering Committee Follow-up: This was one of five related measures considered for potential harmonization. The five included: m*aintenance measure 0125*: Timing of antibiotic prophylaxis for cardiac surgery patients; e*ndorsed measure 0269*: Timing of prophylactic antibiotics-administering physician; e*ndorsed measure 0270*: Timing of antibiotic prophylaxis-ordering physician; m*aintenance measure 0527*: Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-1; and e*ndorsed measure: 0472*: Prophylactic antibiotic received within one hour prior to surgical incision or at the time of delivery-cesarean section. Discussion of the five measures is included here. The Steering Committee requested that the developer of measures 0270 and 0269, neither of which are under consideration in this project, be approached by NQF staff to determine the current state of these measures and encourage them to consider combining them into a single measure that focuses on administration. Based on their opinion that timing of antibiotics administration prior to surgical incision, including for cardiac surgery, should not be different. Members asked that the developers of the five measures be asked to collaborate on the potential for combining the measures into a single measure that, to the extent possible, closely mirrors measure 0527. As part of that effort, they asked that the developer of measure 0472 provide information about any differences that would make administration of antibiotic at delivery unique. They did not view incision for cesarean unique. With respect to measure 0125, they asked that the developer provide information about whether registry data would provide significantly different outcomes than administrative/claims data across institutions. For the measures not within the current project (AMA-PCPI measure 0269 and 270 and Massachusetts General measure 0472), NQF staff will relay the request of the Committee for their action and feedback. The combined measure is expected to be submitted for consideration under the next Surgery Endorsement Maintenance project scheduled to launch in 2013.
If applicable, Conditions/Questions for Developer: Developer Response:

0527 Prophylactic antibiotic received within 1 hour prior to surgical incision
If applicable, Questions to the Steering Committee:
1. Importance to Measure and Report: Y-19; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure focus is supported by the evidence. While the performance gap has been reduced over time, the measure continues to demonstrate a performance gap that could be improved. It was also noted that the gap still exists for general surgeries compared with cardiac surgeries.
2. Scientific Acceptability of Measure Properties: C-13; P-6; M-0; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure focus and specifications are appropriate. The request that laparoscopic procedure be removed from the exclusions will become effective January 1, 2012.
3. Usability: C-14; P-5; M-0; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure has been widely used for some time; harmonization with the similar measures below should be considered: #0125: Timing of antibiotic prophylaxis for cardiac surgery patients #0269: Timing of prophylactic antibiotics - administering physician #0270: Timing of antibiotic prophylaxis- ordering physician #0472: Prophylactic antibiotic received within one hour prior to surgical incision or at the time of delivery – cesarean section.
4. Feasibility: C-18; P-1; M-0; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The Committee stated that the measure was feasible based on the data required and its record of use.
Public and Member Comment Commenters suggested the measure be combined with measure 0528 to create a patient-centered all-or-none composite. 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. The Committee noted that 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.
Voting: Total Approval: 83% Comments received: "This is a good measure but measure #264 and 527 should be harmonized to become a single measure as place of service is irrelevant to this measure." CSAC Approval: Board Endorsement:

Evaluation Summary—Candidate Consensus Standards Recommended for Endorsement and Placement in Reserve Status

0301 Surgery patients with appropriate hair removal
For More Information: Detailed Measure Specifications; Complete Measure Submission; Meeting/Call Proceedings
Description: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal. Numerator Statement: Surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal Denominator Statement: All selected surgery patients Include patients with an ICD-9-CM Principal Procedure Codes of selected surgeries. Exclusions: Excluded Populations: Patients less than 18 years of age Patients who have a length of Stay greater than 120 days Patients whose ICD-9-CM principal procedure was performed entirely by laparoscope. Patients enrolled in clinical trials Patients whose ICD-9-CM principal procedure occurred prior to the date of admission Patients who performed their own hair removal Adjustment/Stratification: no risk adjustment necessary/No stratification is required for this measure. Level of Analysis: Facility/ Agency, Can be measured at all levels, Population: National, Program: QIO Type of Measure: Process Data Source: Electronic administrative data/ claims, Electronic Health/ Medical Record: Electronic Provider Survey/ Paper medical record/ flow-sheet Most facilities use vendors to collect the data electronically. CMS provides a free, downloadable tool called CART. A paper tool modeled after the data collected electronically is provided as an attachment. CART downloads can be found on QualityNet.org at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138900279093 Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Blvd, Mail Stop S3-02-01 | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Recommended and placement in Reserve Status Y-14 (reserve); Y-5 (active); N-2; A-1 Rationale: This measure is at a high level of performance but should remain available in the event periodic surveillance demonstrates a drop in performance. It addresses the important concern of surgical site infections (SSI).
If applicable, Conditions/Questions for Developer: Developer Response: If applicable, Questions to the Steering Committee:
1. Importance to Measure and Report: Y-4; N-15 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: This measure is at a high level of performance. Medicare data indicates consistent high performance with a 99.6 percent appropriate rate of hair removal in the second quarter of 2010. Concern about discontinuing regularly reporting was centered on the potential to have performance drop (e.g., return of use of razors the operating room for economic reasons). The measure is on the list of CMS measures to be retired in 2013 or 2014. It would be appropriate to consider reporting the measure as a component of a surgical bundle. There is evidence from randomized trials and systematic review that support the measure focus; though, the Committee noted lack of "absolutely" clear evidence.
2. Scientific Acceptability of Measure Properties: C-10; P-8; M-0; N-1 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is supported by the literature thought it contains numerous exclusions. Both the number and some of the specific exclusions (self hair removal) were discussed in some length and accepted.
3. Usability: C-12; P-5; M-1; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure is part of a group of surgical site infection measures that are publicly reported widely.
4. Feasibility: C-13; P-5; M-1; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The data is drawn from patient health records and claims data.
Public and Member Comment Commenters were not in support of this measure because they believed that 100 percent compliance could occur with the removal of razors from the operating room. CMS is retaining the measure but has decided to suspend data collection requirements to address

0301 Surgery patients with appropriate hair removal
comments and concerns about the retirement of accountability measures. 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.
Voting: Total Approval: 71% Comments received: "Measure #515 and 0301 should be harmonized into a single measure as the physiology does not change between ASC and in-patient hospital setting." CSAC Approval: Board Endorsement:

SURGICAL QUALITY ALLIANCE

c/o American College of Surgeons

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Washington, DC 20007

July 6, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Request to suspend use of SCIP hair removal measure

Dear Acting Administrator Frizzera,

On behalf of the respective members of the undersigned societies representing specialties that provide surgical care, we are writing to express our concern about a widely adopted Surgical Care Improvement Project (SCIP) measure. Recent efforts to reduce surgical site infections have resulted in the development of a SCIP infection prevention measure titled, "Surgery Patients with Appropriate Hair Removal." The measure essentially characterizes razors as "never appropriate" for surgical skin preparation, and under the SCIP program, hospitals are encouraged to educate staff on the increased infection rates associated with preoperative shaving and to remove all razors from stock carts and surgical prep kits. The SCIP hair removal measure has been endorsed by the National Quality Forum (NQF) and is now included under Medicare's Reporting of Hospital Quality Data for Annual Hospital Payment Update (RHQDAPU) program. It was also identified as a national patient safety goal under The Joint Commission's hospital accreditation program, and starting on January 1, 2010, the Commission will consider shaving an "inappropriate" hair removal method. The Surgical Quality Alliance (SQA) is highly concerned about the widespread application of this measure, since it is supported by very limited evidence and inappropriately generalized across surgical specialties.

The specialty of neurosurgery is uniquely affected by this measure. Many neurosurgeons shave hair for cranial and spinal procedures and the infection rate among elective neurosurgery is very low. There is very little data from well-designed, properly powered, carefully controlled studies that demonstrates that removing hair through methods other than razors decreases surgical site infections for neurosurgical procedures. In fact, a review of the current literature found no studies that evaluate shaving versus clipping specifically related to spine surgery, and only one study specifically related to craniotomy, which was published in 1987 and found no differences between shaving and clipping.[1]

[1] Zentner J, Gilsbach J, Daschner F. Incidence of wound infection in patients undergoing craniotomy: influence of type of shaving. Acta Neurochir (Wien). 1987;86(3-4):79-82.

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Three more recent systematic reviews on surgical hair removal not specific to neurosurgery produced mixed findings, [2,3,4] one of which specifically recommended a large randomized controlled trial for evaluating preoperative hair removal before making further recommendations. Furthermore, a 2007 study commissioned by the Agency for Healthcare Research and Quality (AHRQ) and performed through the Stanford-UCSF Evidence-based Practice Center observed that:

> "No conclusion can be reached regarding the effectiveness of QI strategies at promoting perioperative glucose control, perioperative normothermia, or decreasing operative site shaving. We were unable to determine any strategies effective at reducing SSI rates. In studies that did not have important methodologic flaws, surgical site infection rates were not consistently reduced, even when process measurements were improved." [5]

Thus, despite increased compliance with quality improvement strategies such as appropriate hair removal, AHRQ found no statistically valid demonstration of the reduction of surgical site infections. **Appendix I** illustrates the varying quality of the references cited in AHRQ's 2007 evidence report.

The SCIP program references the Centers for Disease Control and Prevention's (CDC) 1999 Guidelines for Prevention of Surgical Site Infection[6] to justify its position that use of razors is inappropriate. However, the CDC's recommendation on pre-operative hair removal relies, in part, on the prevention of SSI following cardiac surgery by comparing razor shaving the night before surgery with electric clipping the morning of surgery. The SQA believes it is inappropriate for payers and accreditation agencies to draw broad generalizations about all surgical site preparation based on an improperly designed study that focuses on a single surgical specialty.

It is clear that many valid research questions regarding the appropriate timing and methods of hair removal, particularly for cranial and spinal procedures, remain unresolved. Given these gaps in the evidence, it is inappropriate to require hospitals to report on this measure in order to receive their full annual Medicare payment update. Although the RHQDAPU program is a voluntary reporting program, hospitals that fail to report this data are subject to an annual payment cut and data collected under this program are publicly reported on CMS's Hospital Compare Web site. consistent evidence. Where there is no reliable data to compel one practice over another, restrictive guidelines are inappropriate and the clinical choice should be left up to the physician.

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[2] Tanner J, Woodings D, Moncaster K. Preoperative hair removal to reduce surgical site infection. Cochrane Database Syst Rev. 2006 Jul 19;3:CD004122.
[3] Tanner J, Moncaster K, Woodings D. Preoperative hair removal: a systematic review. J Perioper Pract. 2007 Mar;17(3):118-21, 124-32.
[4] Niël-Weise BS, Wille JC, van den Broek PJ. Hair removal policies in clean surgery: systematic review of randomized, controlled trials. Infect Control Hosp Epidemiol. 2005 Dec;26(12):923-8.
[5] *Evidence Report/Technology Assessment,* Number 9, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies", Volume 6—Prevention of Healthcare-Associated Infections, http://www.premierinc.com/safety/safety-share/02-07-downloads/12-hainfgap.pdf, January 2007.
6 Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guidelines for prevention of surgical site infection,1999. Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol* 1999; 20:250-278.
[6] Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guidelines for prevention of surgical site infection,1999. Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol* 1999; 20:250-278.

The SQA respectfully requests that the CMS suspend use of the SCIP hair removal measure until such time as well-designed studies demonstrate that compliance with such a measure results in a clear benefit to patients and that such benefits are not accompanied by adverse effects on patients, medical practices, or health systems. Additional research should also evaluate the potential for unintended adverse effects, such as: the effect on patients when hair removal prolongs anesthesia time; the impact on patients with difficult to remove hair in emergency situations requiring rapid cranial surgery; and the impact on physician medical staff privileges and physician availability when surgeons are disciplined for choosing to bring their own razors to operating rooms.

The SQA appreciates the CMS considering our request and is available to speak in more detail with CMS regarding our concerns. Should you have any questions, please feel free to contact Rachel Groman, Senior Manager of Quality Improvement and Research, American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS), 202-628-2072 or rgroman@neurosurgery.org.

Sincerely,
American College of Surgeons
American Academy of Ophthalmology
American Association of Neurological Surgeons
Congress of Neurological Surgeons
American Urological Association
American Society of Colon and Rectal Surgeons
American Academy of Otolaryngology-Head and Neck Surgery
American Society of Plastic Surgeons
American Society for Metabolic and Bariatric Surgery
American Academy of Orthopaedic Surgeons
Society of Thoracic Surgeons
American College of Osteopathic Surgeons

cc: Carolyn Clancy, MD, Director, Agency for Healthcare Research and Quality
Mark R. Chassin, MD, MPP, MPH, President, The Joint Commission
Janet M. Corrigan, PhD, MBA, President and CEO, National Quality Forum

Enclosures

Appendix I. Compilation of references from AHRQ's 2007 evidence report, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies,"* including AANS/CNS estimate of the quality of each study.

Author (AHRQ reference #)	Setting And Hospital Type	Study pd	Length of follow-up	Preventive Interventions	QI Intervention	Results	Quality of Study
Gastmeier 2002 (66)	Germany Multiple hospitals of different types	10 mnths	2 yrs	Hand hygiene Appropriate use of perioperative antibiotics **<u>Decreasing use of preoperative shaving of the operative site</u>** Improving perioperative glucose control	*QI strategies: Clinician education, audit and feedback* Intervention hospitals introduced quality circles and surveillance activities. The quality circles consisted of at least 1 physician and 1 nurse from the surgical unit and ICU, and infection control personnel. The quality circles were structured groups that used continuous quality improvement (CQI) methodology to decide on a problem focus, reach a consensus on solving a given problem, and execute the solution. Each QC focused on hand hygiene, but otherwise each intervention	Infection rate prior to intervention: 2.6% of cases Infection rate after intervention: 2.0 % of Cases; p=NS	**Controlled studies**

					hospital individualized their focus. Thus, each hospital focused on different aspects of SSI, CAUTI or CLABSI prevention; the specific preventive interventions targeted appear to vary between hospitals, but generally belonged to CDC category I. After a 10-month period in which the quality circles were set up, outcomes were measured, and subsequently ongoing surveillance was performed by infection control nurses according to NNIS protocols. Outcomes were measured again after another 10 months.		
Greco 1991 (61)	Italy Multiple hospitals of different types	12/1988 – 6/1989	19 mnths	Appropriate use of perioperative antibiotics **<u>Decreasing use of preoperative shaving of the operative site</u>**	*QI strategies: Clinician education, audit and feedback, clinician reminder* Series of meetings with surgeons and nurses from each of participating wards. Data on	Infection rate prior to intervention: 7.8% of patients Infection rate after intervention: 6.2% of patients; p=NS	**Before-after studies with good methodologic quality**

				Audit and feedback of infection rates to hospitals or individual clinicians	infection incidence and practices were discussed and best practices reviewed including: appropriate use of perioperative antibiotics (pre-operative, limited duration, appropriate selection), **avoidance of preoperative shaving**, closed drainage of urinary catheters and surgical drains, implementation of respiratory exercises, use of hygienic measures for urinary catheters.		
Dellinger 2005 (19)	United States Multiple hospitals of different types	4/2002-2/2003	11 mnths	Appropriate use of perioperative antibiotics **Decreasing use of preoperative shaving of the operative site** Improving perioperative glucose control	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Collaboration among 56 hospitals to study implementation of 1 or more quality initiatives. Each facility created team of "clinical champion" - surgeon or anesthesiologist - along with day-to-day coordinators. Learning sessions	Infection rate prior to intervention: 2.28% of cases Infection rate after intervention: 1.65% of cases; p=NS Adherence to administering perioperative antibiotics for the appropriate duration: Before intervention: 72%	

					performed every 4 months. Subsequently, information was brought back to individual facilities. Exact means of diffusion of information for specific measures were not stated.	After intervention: 92%; p<0.01 Adherence to appropriate selection of perioperative antibiotics: Prior to intervention: 90% after intervention: 95%; p<0.01 Adherence to protocols for **perioperative shaving of the surgical site**: Prior to intervention: 59% after intervention: 95%; p<0.01 Adherence to protocols for perioperative normothermia: Prior to intervention: 57% after intervention: 74%; p<0.01 Adherence to protocols for perioperative glucose control: Prior to intervention: 46%	

						After intervention: 54%; p<0.01	
Borer 2004 (74)	Israel Tertiary care or university hospital	1997 - 9/2001	24 mnths	Hand hygiene Appropriate use of perioperative antibiotics **Decreasing use of preoperative shaving of the operative site** Improving perioperative glucose control	*QI Strategies: Clinician education* A check list of infection control items was devised. These consisted of hand hygiene, appropriate use of perioperative antibiotics, glycemic control, and **decreasing use of shaving of the operative site**. In addition to these interventions, there was strict aseptic techniques used to scrub the surgical site; staff couldn't wear fake nails or jewelry; staff received education and active surveillance was performed.	Infection rate prior to intervention: 4.2% of cases Infection rate after intervention : 0% of cases p<0.01	**Simple before-after studies of moderate methodologic quality**
Rao 2004 (85)	Tertiary care or university hospital	1/1999 – 4/1999	20 mnths	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Improving perioperative glucose	*QI Strategies: Clinician education, clinician reminder* ICP was assigned to the open heart Surgery program. ICP followed patient from admission	Infection rate prior to intervention: 2.1% Infection Rate after intervention: 1.5% p=NS Adherence to protocols for	**Simple before-after studies of moderate methodologic quality**

				control	to discharge and implemented the following program: prospective surveillance of superficial and deep chest and leg infections; post discharge follow up of patients readmitted within 30 days; chlorhexidine showers by pts the night before/morning of surgery; hair removal by clippers only; administration of antibiotics 2 hours before surgical incision; segregation of surgical instruments; improved glycemic control.	perioperative antibiotic prophylaxis: Before intervention: 70% After intervention: 92% p value not reported	
Schelenz 2005 (72)	UK Hospital type not specified	9/2000 – 12/2001	16 mnths	Hand hygiene Appropriate use of perioperative antibiotics **<u>Decreasing use of preoperative shaving of the operative site</u>** Audit and feedback of	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Investigators implemented a bundle of different interventions aimed at decreasing MRSA wound infections, using education, audit and feedback,	Infection rate prior to intervention: 4.1% of cases Infection rate after intervention: 2.1% of cases p=NS	**Simple before-after studies of poor method-ologic quality**

				infection rates to hospitals or individual clinicians	**improvements in surgical skin preparation**, improved antibiotic prophylaxis and several measures to limit the spread of MRSA.		
Haycock 2005 (69)	United States Hospital type not specified	4 mnths	1 yr	Hand hygiene Appropriate use of perioperative antibiotics **Decreasing use of preoperative shaving of the operative site** Perioperative normothermia Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Identified best practices for preventive practices and gaps in current practice. Formed process teams and implemented pilot protocol. Then implemented change and modified strategy based on results. Intervention targeted antibiotic prophylaxis, **skin preparation**, hand hygiene, blood glucose control, and wound case management for cardiac surgery patients.	Infection rate prior to intervention: 1.5% of cases Infection rate after intervention: 0.3%, p<0.05 Adherence to protocols for hand hygiene: Percentage change in compliance rate (post % - pre %): 11% Adherence to administering perioperative antibiotics for the appropriate timing: Before intervention: NR After intervention: 87% Adherence to Appropriate selection of perioperative antibiotics:	

						Before intervention: NR After intervention: 98% Adherence to protocols for perioperative shaving of the surgical site: Before intervention: NR After intervention: 100%	
McConkey 1999 (82)	United States Tertiary care or university hospital	4/1991-12/1994	3 yrs	Appropriate use of perioperative antibiotics **Decreasing use of preoperative shaving of the operative site** Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Audit and feedback, clinician reminder* Prospective effort to reduce SSI using comprehensive infection control program. The following interventions were instituted: 1) prospective surveillance; 2) quarterly reporting of surgeon and assistant specific SSI rates; 3) chlorhexidine shower by pt preoperative; 4) **Hair removal by clipping on morning of surgery**; 5) antibiotic prophylaxis 1/2		

					to 2 hours prior to incision; 6) elimination of open ice baths for cooling of cardioplegia solution; 7) limitation of OR traffic; 8) minimization of intraoperative flash sterilization; 9) elimination of tapwater wound bathing within 96 hours post-op; 10) sterile wound dressing for first 96 hours post-op; 11) use of dedicated infection control practitioner.		

* *Evidence Report/Technology Assessment,* Number 9, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies", Volume 6—Prevention of Healthcare-Associated Infections, http://www.premierinc.com/safety/safety-share/02-07-downloads/12-hainfgap.pdf, January 2007.

AHRQ Reference # and Study Quality Estimate

Controlled Study

66. Gastmeier P, Brauer H, Forster D, et al. A quality management project in 8 selected hospitals to reduce nosocomial infections: a prospective, controlled study. Infect Control Hosp Epidemiol. 2002 Feb;23(2):91-7.

Before-after studies with good methodologic quality

61. Greco D, Moro ML, Tozzi AE, et al. Effectiveness of an intervention program in reducing postoperative infections. Italian
PRINOS Study Group. Am J Med. 1991 Sep 16;91(3B):164S-9S.

Before-after studies with moderate methodologic quality

19. Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. Am J Surg. 2005 Jul;190(1):9-15.

74. Borer A, Gilad J, Hyam E, et al. Prevention of infections associated with permanent cardiac antiarrhythmic devices by implementation of a comprehensive infection control program. Infect Control Hosp Epidemiol. 2004 Jun;25(6):492-7.

85. Rao N, Schilling D, Rice J, et al. Prevention of postoperative mediastinitis: a clinical process improvement model. J Healthc Qual. 2004 Jan- Feb;26(1):22-7; quiz 8.

Simple before-after studies of poor methodologic quality

69. Haycock C, Laser C, Keuth J, et al. Implementing evidence-based practice findings to decrease postoperative sternal wound infections following open heart surgery. J Cardiovasc Nurs. 2005 Sep- Oct;20(5):299-305.

72. Schelenz S, Tucker D, Georgeu C, et al. Significant reduction of endemic MRSA acquisition and infection in cardiothoracic patients by means of an enhanced targeted infection control programme. J Hosp Infect. 2005 Jun;60(2):104-10.

82. McConkey SJ, L'Ecuyer PB, Murphy DM, et al. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. Infect Control Hosp Epidemiol. 1999 Aug;20(8):533-8.

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December 9, 2011

Janet Corrigan, PhD, MBA
CEO and President
The National Quality Forum
601 Thirteenth Street, NW
Suite 500 North
Washington, DC 20005

RE: Support for the Endorsement of Measure 1536: – Cataracts: Improvement in patient's visual function within 90 days following cataract surgery

Dear Dr. Corrigan:

On behalf of the over 78,000 members of the American College of Surgeons (ACS), we are pleased to support the nomination for National Quality Forum endorsement of Measure 1536 – Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. The measure was developed by the American Academy of Ophthalmology as part of the Surgery Endorsement Maintenance process and was recommended for endorsement by the CSAC at its November meeting.

Measure 1536 is a patient-reported outcome measure based on a visual function survey administered both before and after cataract surgery. The measure captures improvement in the patient's ability to perform activities of daily living from the patient perspective and serves as a compliment to clinical measures such as visual acuity after surgery. The measure will be paired with the Surgical CAHPS Survey developed by the Surgical Quality Alliance as part of the first ever outcomes-oriented group measure for ophthalmology for the 2012 Physician Quality Reporting System. Cataract is one of the most commonly billed procedures in Medicare, and the measure group has the potential to improve care and patient experience.

While objective clinical outcome measures are valuable indicators of surgical quality, the patient's perception of the outcome is a critical component to assessing the success of a surgical procedure. For this reason, measures of patient reported outcomes are a high priority for the surgery community. ACS supports this measure as an example of the more innovative and outcome-

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oriented measures that the surgery community has been advocating for over the past several years, and we believe that it clearly meets the NQF criteria for importance, scientific acceptability, usability, and feasibility. We strongly support CSAC endorsement for Measure 1536.

Sincerely,

David B. Hoyt

David Hoyt, MD FACS
Executive Director

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