Steering Committee Members Present: Scott Gazelle, MD, PhD, MPH (Co-Chair); Eric Peterson, MD, MPH (Co-Chair); Jacqueline Bello, MD, FACR; Stephen Cantrill, MD, FACEP; Carl D’Orsi, MD; Howard Forman, MD, MBA; Raymond Gibbons, MD; Donald Rucker, MD, MBA; Rebecca Smith-Bindman, MD; Roger Snow, MD, MPH

NQF Staff Present: Helen Burstin, MD, MPH; Ian Corbidge, RN, MPH; Sarah Fanta; Sally Turbyville, MA, MS

Measure Steward Representatives Present: Joe Allen, American College of Cardiology; Susan Arday, Centers for Medicare and Medicaid; Judy Burleson, American College of Radiology; Jeremiah Schuur, Brigham and Women’s Hospital; Sharman Stephens, The Lewin Group

WELCOME AND INTRODUCTIONS

NQF staff provided a project overview and updated the Committee on the project’s current status. From the initial in-person meeting on February 23-24, 2010, the Steering Committee elected to not approve four measures for further endorsement consideration because they do not meet the threshold criterion of importance to measure and report. Of the 17 measures submitted to the project, 12 were returned to the measure developers to respond to conditions that the Committee stipulated for further endorsement consideration. Of these measures, four were initially not approved for further endorsement consideration; however, the vote at the initial in-person meeting was close (9 for and 11 against), and therefore the Committee decided to include them among the other measures with conditions. This process allowed measure developers an opportunity to respond to the Committee's conditions, both as a learning exercise for the measure developers and as a measure gap identification process.

NQF staff updated the Committee about the upcoming voting process. The final vote will occur after the webinar and will be on the measures as they currently stand (i.e., the responses from measure developers to the conditions stipulated by the Committee). The Steering Committee will vote using an online survey tool, and the results will be sent to the Committee.

NQF staff summarized two additional important points related to the current measures under review: one relating to the measure harmonization efforts for measure IEP-008-10 and another relating to the appeal of a measure (IEP-006-10). The issues were discussed in full (see discussion below).

MEASURE REVIEW

Measure IEP-014-10
Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients (ACC): Page# 4
The measure developer was unwilling to meet the Committee’s initial condition to expand the sampling period to 12 months. The measure developer indicated its decision to not adjust the sample size was based on feasibility and the timeliness of feedback reports. The Committee expressed concerns about the sampling period, in particular if the limited sampling period would allow for sufficient sample size among most facilities across the nation. The measure developer responded that substantial testing had been conducted and that there should be enough facilities meeting sample size requirements for reported results to be representative across the United States, not just within a selective number of practices (original testing in private practices). The measure developer agreed to provide its filed test report or manuscript that contains information about sample size needs for this measure.

The following is the measure developer’s response to a question raised during the conference call on April 22, 2010 (supporting information can be found in the SPECT MPI Pilot Manuscript attached to the e-mail dated April 27, 2010):

“Six sites participated in this pilot study; 3 urban, 2 suburban, and 1 rural location. Practices were located in Florida, Wisconsin, Oregon, and Arizona, and the number of cardiologists at each site ranged from 7 to 20 physicians. The number of SPECT MPI patients submitted from each site varied from 328 to 1,597 patients.”

The smaller number reported by a practice was for a group that participated only for a few months of the pilot.

The measure developer agreed to the additional conditions: 1) remove “patients without sufficient patient selection criteria recorded” and 2) add stress MRI and CTA (the measure developer does not anticipate large numbers of cases for these imaging modalities). The measure developer initially indicated that it would align its list of “low-risk surgeries” with that of the Centers for Medicare & Medicaid Services (CMS). During the call, the measure developer clarified its intent to use the same list of “low-risk surgeries” as CMS, plus additional procedures deemed to be low risk. The Steering Committee did not consider this to be a harmonized approach and questioned the potential subjectivity that the measure developer’s additional low-risk procedures would add. Specifically, the measure developer wanted to include low-risk surgeries with less than 1 percent mortality. During the conference call, the measure developer verbally agreed to remove the additional surgeries from the list and to present a measure with a list that is harmonized with the CMS list.

The measure developer elected to not change the measure name, which concerned at least one Committee member. However, there was little other discussion or objection to the original name, although the concern was noted.

<table>
<thead>
<tr>
<th>Online Survey Results (real numbers)</th>
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<tr>
<td>Criterion</td>
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<td>H = High Rating</td>
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Measure IEP-015-10
Cardiac stress imaging not meeting appropriate use criteria: Routine testing after percutaneous coronary intervention (PCI) (ACC): Page# 1

During the in-person meeting, the Committee asked the measure developer to provide further information pertaining to the reliability and validity data for the measure. The measure developer responded to this condition by stating that it had already demonstrated reliability and validity testing of the measure, which was confirmed during the conference call by a review of the measure submission form. Committee members were agreeable to the level of testing as discussed on the call. After the conference call, NQF staff discovered that the measure developer had accidently indicated that the measure was not fully tested when in reality it was. Currently, the measure is considered to have been tested, with reliability and validity data provided. The measure is eligible for “full endorsement.”

The measure developer agreed to meet two of the Committee’s conditions for recommendation: 1) expand the measure to include MRI and CTA (the measure developer notes that this addition will capture only a small number of imaging modalities) and 2) remove the denominator exclusion criteria, “patients without sufficient patient selection criteria recorded” (the measure developer notes that this change may inflate the denominator). The measure developer was unwilling to add CABG to the denominator population or change the title. Neither of these two decisions to not satisfy the initial conditions seemed to cause issues with the Committee.

Measure IEP-016-10
Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low risk patients (ACC): Page# 2

Committee members recognized that the measure developer is willing to meet the following conditions: 1) add CTA and MRI (the measure developer does not anticipate large numbers for these imaging modalities) and 2) remove the denominator exclusion criteria, “patients without sufficient patient selection criteria recorded” (the measure developer notes that this change may inflate denominator). The Committee was satisfied with these decisions.

During the in-person meeting, the Committee asked the measure developer to consider the need for risk-adjustment. The measure developer responded that further risk-adjustment is not needed because the measure already accounts for risk. The measure developer elaborated further during the conference call, explaining that the measure uses a risk calculator model to assess for risk. The measure is currently in use, and entities are subject to risk audits. This measure has been fully tested. The Committee reached a consensus about the issue of risk assessment and considered the measure developer’s response to be adequate.
Measure IEP-010-10
Preoperative evaluation for low-risk non-cardiac surgery risk assessment (CMS): Page# 23

The Committee acknowledged that the CMS measure (IEP-010-10) and the ACC measure (IEP-014-10) are very similar in their constructs but differ in their perspectives, with the CMS measure focusing only on the Medicare population. During the in-person meeting, the Committee stipulated the condition that CMS harmonize its list of “low-risk surgeries” with that of ACC. CMS agreed to work with ACC to harmonize the list.

During the discussion of the CMS measure it came to light that ACC added a rider to its list of “low-risk surgeries” (as noted above in the discussion of measure IEP-014-10). The Committee reaffirmed its initial condition that the lists of “low-risk surgeries” be harmonized. During the conference call, ACC verbally agreed to remove the additional surgeries from the list and to present a measure with a list that is harmonized with the CMS list.

Online Survey Results (real numbers)

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<th>Criterion</th>
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<th>Scientific Acceptability</th>
<th>Usability</th>
<th>Feasibility</th>
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<tr>
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Measure IEP-011-10
Use of stress echocardiography, SPECT MPI, and cardiac stress MRI post CABG (CMS): Page# 21

The Committee had initial reservations regarding the measure and elected to review and vote on the measure after the measure developer responded to the initial conditions. The measure developer did not meet the Committee’s conditions to: 1) remove the six-month exclusion criteria, 2) expand the measure to include PCI, but report CABG and PCI separately, and 3) expand the sample size. The measure developer and steward stated that they did not meet the conditions stipulated by the Committee because it “is not feasible within the timeframe given to fully test and specify these new specific conditions,” with CMS indicating that it would have to go back to its technical advisory panel (TAP) and rerun its statistical data analyses. Overall, the lack of response from CMS was related to the issue of time constraints. The Committee agreed that there is no rationale for the six-month exclusion criteria and that none had been provided. Furthermore, the Committee believed that the six-month exclusion criterion does not add value. Overall the Committee expressed concern with the measure as it currently stands and was not satisfied with the medical reasonability of the measure.

CMS pushed back, stating that its TAP had fully vetted the measure and believed the six-month exclusion criterion was appropriate for the measure. CMS has not taken the Committee’s suggestions back to its TAP.

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Overall the Committee had significant concerns with the measure as it currently stands. The predominant concern relates to the fact that the measure developer has submitted a single measure looking at recall rates without having an additional measure targeting cancer detection rates. There were concerns that an entity could have a low recall rate, but miss a lot of cancers. Committee members acknowledged that the measure developer had appropriately addressed its conditions. During the conference call, some members stated that they accepted the measure as a stand-alone measure, while others stated that they preferred the measure to be coupled with a companion measure. However, at this point in the process there is not enough time to develop a companion measure.

During the in-person meeting, the Committee stipulated as a condition for recommendation that the CPT codes used to generate the measure be validated. The measure developer indicated that it has completed the validation of the CPT codes. Committee members stated that they were not particularly concerned with whether the codes were valid, but rather with whether the “generation of the measure reflects recall rates.”

Paired Measures IEP-001-10, IEP-003-10, and IEP-004-10
Cancer detection rate
Diagnostic mammography positive predictive value 2 (PPV2 – biopsy recommended)
Abnormal interpretation rate of screening mammography exams (recall rate) (ACR): Page# 6

During the in-person meeting, the Committee voted down each of the three measures as stand-alone measures. The Committee then discussed the merits of the measures as a paired suite of measures. The initial vote for the suite was 9 for and 11 against further endorsement consideration. Given the closeness of this vote and that the topic consumed a significant portion of the first day’s discussions, the Committee decided to allow the measure developer an opportunity to respond to its conditions.

Committee members noted that the measure developer did not support adding age stratification to the measures. The measure developer explained that it would make the N too small and that few, if any, facilities would have enough volume to even report the unstratified results publicly, making the collective measures essentially meaningless.

The ACR paired measures are similar to the CMS stand-alone measure, but with different concerns. ACR agreed that the measures should be presented as a paired suite, but it did not offer guidance on what the reporting of the suite should look like. Furthermore, the possibility that age stratification could lower the N to a noninformative state created a futile effort to combine the measures as a suite. The Committee acknowledged a need for measures targeting this realm, but it determined that the current measures submitted to the project may not be mature enough for public reporting.

Measure IEP-013-10
Use of brain computed tomography (CT) in the emergency department (ED) for atraumatic headache (CMS): Page# 22

As requested by the Committee, the measure developer submitted additional implementation instructions. The Committee noted that the instructions had been submitted, and it was ready to move forward. However, no further discussion on this measure occurred.

Measure IEP-005-10
Appropriate pulmonary CT imaging for pulmonary embolism (BWH): Page# 9

The Committee reiterated its recommendation to remove “intermediate probability” from the specification. During the webinar conference call, the measure developer verbally agreed to remove “intermediate probability” from the measure specification. The measure developer mentioned some initial confusion as to whether the removal of the intermediate probability was a separate condition or if it had been adequately addressed consequent to other specification changes made stemming from Committee input. The Committee clarified that there was still a request to remove “intermediate probability,” to which the measured developer readily agreed.

The measure developer’s follow-up response to a question posed during the conference call on April 22, 2010 is as follows:

“I apologize that our response to the original questions for measure #IEP-005-10 (PE CT) did not address the issue of low vs. medium probability. We agree with the request to change this. I have edited our response and the full measure specs and am attaching them. The only change we have not incorporated from the committee’s recommendation are that we use ‘negative D-Dimer’ rather than ‘high sensitivity D-Dimer’ for the measure numerator. The literature behind PE consensus recommendations does not support limiting the use of D-Dimer in low risk patients to high sensitivity D-Dimer.

Wording changes:

The numerator now reads: ‘Number of hemodynamically stable patients who receive CT pulmonary angiograms for suspected pulmonary embolism who have either†:

- a low clinical probability* of PE and a negative D-Dimer
OR
- a low clinical probability* of PE and no D-Dimer performed
OR
- No documentation of a pre-test probability
  a. We believe that it is important to require a pretest probability score as part of the pre-test assessment, otherwise clinicians who do not assess pretest risk will not be measured. We have not specified that this needs to be a high-sensitivity D-Dimer,
as the literature on using D-Dimer for patient at low clinical risk of PE strongly supports the use of qualitative and quantitative tests.”

There was discussion about the paper data collection tool and whether it would truly be a useful (and useable) tool. The measure, if endorsed, would receive time-limited endorsement—testing would continue within the next 12 months.

**Measure IEP-007-10**
Appropriate head CT imaging in adults with mild traumatic brain injury (BWH): Page# 11

There was a recurrent discussion regarding the paper data collection tool and whether it would truly be a useful (and useable) tool. The measure, if endorsed, would receive time-limited endorsement—the measure developer committed to conducting testing that includes the paper-based tool within the next 12 months.

The Committee had requested the measure developer to consider changing the specification to a GCS of greater than or equal to 13. However, the Committee’s primary reviewer for this measure discussed the GCS level and commented that the current specification of a GCS greater than 13 and the measure developer’s rational for not specifying a GCS greater than or equal to 13 was sufficient. The reviewer was comfortable with the measure specifications put forth by the measure developer, which specified and included a rationale for a GCS level of greater than 13.

**Measure IEP-008-10**
Appropriate cervical spine CT imaging in trauma (BWH): Page# 12.

(Measure merging efforts underway–more information will be forthcoming.)

This measure was taken off line to encourage the measure developer to work with Harborview Medical Center, the steward for an NQF-endorsed measure on cervical spine radiographs, to include CT imaging of the cervical spine in the measure. The NQF-endorsed measure follows very similar constructs to the candidate standard but focuses on radiographs rather than on CT. The measure developers have been in contact with one another and are exploring the use of an “OR” statement (radiographs or CT) to produce a single measure that would examine plain films and CT scans of the neck. The amended measure will be brought back to the Steering Committee when available for review. No further action is required at this time.

**Appealed Measure—Measure IEP-006-10**
Appropriate head CT imaging in adults with acute atraumatic headache (BWH): Page# 13

At the time of the in-person meeting, the Committee did not move the measure forward due to concerns with the level of evidence supporting the measure focus and the measure’s failure to meet the threshold criterion of importance to measure and report. The measure developer appealed the Committee’s decision on the grounds that the Committee endorsed a measure that addresses an identical clinical area, but with an even older level of evidence. (Please refer to the appeal letter [Attachment C]) as part of the measure developer response document.)

During the conference call, Committee members expressed appreciation for the insight provided in the appeal letter and acknowledged the need to review the new information presented in the
letter and revote on the measure. If you do not believe that the measure meets the importance criterion (i.e., in the survey, L = Low rating), then you may submit your vote for the importance criterion only. However, if you agree with the measure developer’s assertions and believe that the measure meets the importance criterion (i.e., in the survey, High or Middle rating) then vote for all four of the NQF measure criteria.