



TO: Consensus Standards Approval Committee
FR: Helen Burstin, MD, MPH, Senior Vice President, Performance Measurement
DA: July 2, 2013
RE: Colonoscopy Quality Index measure review

During the recent comment period for the GI/GU Stage 2 recommendations six consumer and purchaser organizations submitted comments voicing support for candidate measure concept **C 2056 Colonoscopy Quality Index** submitted by Quality Quest for Health of Illinois. This measure concept was not recommended for Stage 2 review or endorsement. Additionally, the measure developer has voiced multiple concerns regarding the process and decisions of the Steering Committee. The CSAC chair and co-chair agreed to review the evaluation process for this measure at the in-person CSAC meeting on July 10-11, 2013.

To assist the CSAC, Ann Monroe requested answers to the following questions to inform the CSAC discussion:

1. *What was the structure of the review process?*

- a. Two-stage process. The measure was submitted as a measure concept during Stage 1 of the 2-stage GI/GU pilot project. The 2-stage project tested a two-stage version of the CDP process in which all measure concepts were evaluated against the “Importance to measure and Report” criteria first (Stage 1). Concepts that passed the Stage 1 review were eligible to submit the full measure for Stage 2 review several months later. Part of the 2-stage pilot included a checklist of recommendations by the Steering Committee that required responses in order to move to Stage 2. The CSAC reviewed and approved the checklist requirements at the November 2012 in-person meeting. Attachment 1 describes the 2-stage process.

- b. Who was on the steering committee? The 17-member Steering Committee was co-chaired by Andy Baskin and Chris Saigal, a urological oncologist from UCLA. The Committee reflected broad stakeholder balance, with approximately one-third representation from the GI community, 1/3 representation from the GU community, and 1/3 broad representation, including primary care, gerontology, health plan, and consumer representation. [Full roster and bios on project page.](#) All Committee members completed disclosure of interest disclosures. Two Committee members indicated involvement with development of measures under consideration. Andy Baskin noted that ActiveHealth Management is part of Aetna and he recused himself from discussion and voting on measures from ActiveHealth. At the time he was selected for the Committee Richard Luetkemeyer indicated that he was involved in the development of the CQI measure and agreed to recuse himself from discussion and voting on the measure.

- c. What data was expected to be provided for the committee’s review in Stage 1? The information required in Stage 1 addressed the *Importance to Measure and Report* criteria: evidence, performance gap and impact. As for all composite measures, a description of the evidence for each component of the composite measure was required as well as data on the performance gap.
- d. What data was provided for the committee’s review? At the first Stage 1 review during the in person meeting, the committee noted that the information provided for the evidence was insufficient to evaluate against the criteria and did not recommend the concept move forward.

During the comment period, the developer requested that the Committee reconsider the concept in light of an updated submission which provided clearer evidence to support the components of the composite. During the re-consideration of the measure concept, the committee reviewed a new document that presented evidence for each of the nine components. Following re-review, the Committee reaffirmed its view that multiple components did not meet the threshold of importance to measure and report, while other components lacked the evidence to support the measure focus.

- e. What was the conclusion of the committee’s review in Stage 1 about this measure? Complete summary of the concept evaluation is included as attachment 2.

The committee concluded that the evidence criteria were met for six of the nine components. Three components did not meet the evidence criteria:

- Item 2. Standardized Medical Risk Assessment - documentation only and does not include any conclusions or actions taken based on the score
- Item 3. Standardized Assessment of Bowel Prep – documentation only and does not include any conclusions or actions taken based on the assessment
- Item 7. Withdrawal Time was Recorded – documentation of time only, does not include assessment of timeframe that is known to be related to highest abnormality detection rate

Committee members noted that there is no evidence that documentation of these three items indicates that a high quality colonoscopy was performed.

The final vote after reconsideration of the evidence was:

- 5 –Yes, as specified with all nine components;
- 6 – Yes, if only the 6 evidence-based components are included
- 3 -No

Based on the Committee’s discussion and vote on each component, the following components of the composite were determined to have met the evidence subcriterion and were recommended by the Committee for approval for stage 2 review:

- Item 1: Appropriate Indication for Colonoscopy
- Item 4: Complete Examination
- Item 5: Cecal Photo Taken
- Item 6: All Essential Polyp Information Recorded
- Item 8: Free of Serious Complications
- Item 9: Appropriate Follow-up Recommendation

The CSAC approved the Committee recommendation: Yes – 11, No-0, Abstain -0
During the discussion, the CSAC emphasized that meeting the Stage 2 checklist requirements for all Stage 1 concepts was a clear expectation of CSAC.
The Board ratified the CSAC recommendation.

- f. What were the criteria which needed to be met for advancement to Stage 2 The checklist for advancement to Stage 2 for the Colonoscopy Quality Index included:
- the evidence attachment in the submission must be updated to reflect the evidence submitted for the reconsideration process;
 - components 2,3,7 be removed from the composite; and
 - Component 6 should include whether or not an adenoma was detected.
- g. What was the committee’s decision about this measure meeting those criteria?
After review of the Stage 2 measure submission, the committee concluded that the developer had not met the requirements of the checklist because components 2, 3, and 7 were not removed from the measure. The committee voted on two issues:
- Checklist items satisfactorily addressed: Yes –3; No – 9; Abstain -2
 - Concept moves forward to Stage 2: Yes -2; No-10; Abstain -2
- h. What information did they provide to the developer regarding their decision? The Committee met by public conference call to discuss whether the checklist requirements were met for all measures submitted for Stage 2. The developer heard the committee discussion and responded at length. The committee voted using Survey Monkey after the call. The voting results were sent to the developer by email from NQF staff.
- i. What options were given to the developer in terms of how to qualify for stage 2? The pilot design included the checklist that “summarizes the Committee’s recommendations for improving the concept(s) and considerations for specifying and testing the measure that must be addressed prior to submission to stage two.” At the November CSAC meeting, NQF staff was instructed that CSAC approval of the Stage 1 recommendations and checklist requirements for Stage 2 were expectations rather than recommendations. No other options were offered to the developer.
- j. What was the developer’s response to these options?
The developer did not meet the requirements of the checklist. Of note, NQF staff had multiple conversations with the measure developers to clarify the expectations on the checklist and provided significant technical assistance on the testing required for Stage 2.

2. *What are the concerns raised by the developer and others about this process?*

- a. “Muzzling” of supporters’ participation on the steering committee.
- i. The developer stated “the sole GI/GU Steering Committee who understood the Colonoscopy Quality Index measure was Dr. Rick Luetkemeyer. He was forbidden to make any comment about the measure during the proceedings.”
 - ii. The attendance records and transcripts of the committee meetings and calls:

- At the time he was selected for the Committee Richard Luetkemeyer indicated that he was involved in the development of the CQI measure and agreed to recuse himself from discussion and voting on the measure. His written disclosure of interest form clearly detailed his involvement in the development of the CQI measure.
- **Stage 1 In-Person Meeting – 8/27-28/12** – Did Not Attend – Listened on phone but did not speak
- **Stage 1 Post Comment Call in which evidence was re-considered-10/31/12** – Attended – Reiterated his decision to recuse himself from the CQI discussion - *“I was also involved in the committee that came up with the development and the implementation of the colonoscopy quality index that is before you. So, there is a conflict of interest.”*
- **Stage 2 Orientation Call (1) – 3/19/13** – Did Not Attend – Committee members voted on Checklist Recommendations for inclusion in Stage II Evaluation
- **Stage 2 Orientation Call (2) – 3/22/13** – Attended – Committee members voted on Checklist Recommendations for inclusion in Stage 2 Evaluation - Reiterated his decision to recuse himself from the discussion and voting on CQI - *“Yes, good morning, I’m a general internist and I do have a disclosure of a potential conflict of interest. I was on the (inaudible) team that helped developed and implement the quality quest report that will be in front of you later today. I will not be voting and I will not be part of the conversation.”*

b. Differences concerning the level of evidence reached by the measure

i. What does the developer claim?

In the submissions for Stages 1 and 2 the developer stated “EVIDENCE = LOGICAL ARGUMENT” and “The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].”

ii. What does the record from the committee show?

The Stage 1 measure concept submission form included 104 pages of guidelines and recommendations and a large slide deck in addition to the comments above. During technical review, the developer was asked to submit the evidence for each component separately; however, the submission did not respond to the standard questions about systematic reviews of the evidence. The committee initially noted that the information provided for the evidence was insufficient to evaluate against the NQF criteria for evidence (quality, quantity and consistency of the studies).

The information provided from the developer during re-consideration was not provided in the standard format and included only summary paragraphs and references. The Committee determined that six of the components met the evidence criteria, but three were simple documentation measures that did not meet the criteria. See attachment 2 for summary of committee’s evaluation of the evidence for each component. NQF’s composite measure evaluation criteria require that all components meet the evidence criterion for endorsement.

c. Claims of inappropriate treatment of the measure or the developer

i. *Comments from measure supporters:*

The Consumer Purchaser Disclosure Project (CPDP) submitted the following comment: “We have reviewed the transcripts from the Steering Committee meetings at which it was discussed and believe that the Steering Committee did not understand the measure and that the measure developer provided satisfactory responses to all the suggestions that were made.” “We are concerned that clinician opposition to the measure may have been based in part on the “high bar” nature of the measure, which, of course, is a reason for our strong support.”

--CPDP also commented: “The measure summarizes in a single composite whether the procedure met guidelines for appropriateness, whether it was conducted in the right way, and whether there were any immediate adverse outcomes. Because it is based on the “all-or-none concept” and uses actual clinical data to populate its elements, it is truly patient-centered and represents a high bar against which to hold the providers accountable.”

ii. What is the staff/committee perspective?

The Steering Committee approved the concept of an all-or-none colonoscopy composite performance measure, just not 3 of the proposed 9 components. All-or-none composite measures are based on the concept that all of the components are necessary to achieve the desired quality and outcomes. The evidence will indicate what is necessary and the evidence subcriterion applies to each component just as it does for single-topic performance measures. This requirement for evidence was recently affirmed in the latest guidance for composite performance measures. The Steering Committee correctly applied the evidence subcriterion as well as the CSAC guidance on measure construction, which advises against “documentation” measures. Steering Committees do have the option to make an exception to the evidence criterion and decided not to do so.

In terms of the issue of “appropriate care” it seems that is what the SC addressed in that documenting medical risk, bowel prep, and time do not provide information on appropriateness of the procedure. The denominator is only those receiving the colonoscopy so if bowel prep was inadequate was the colonoscopy performed anyway? There is no discrimination if the amount of time was too short for adequate detection. If the medical risk was high, what was done to mitigate the risk?

The committee evaluated this measure on multiple occasions and was frustrated by the lack of response from the developer after lengthy discussions and careful recommendations on behalf of the committee.

The primary reviewer assigned to the measure (Dr. Phil Schoenfeld) is an academic leader in gastroenterology whose research was included in the developer’s evidence review in the measure submission and who spent considerable time reviewing the extensive amount of material submitted by the developers. His review of the measure included a one-on-one phone call with one of the stewards to ensure he fully understood the measure and accurately represented the specifications during his presentation to the Committee.

Staff provided significant technical support to the developer to ensure that that the requirements for the checklist and Committee evaluation on testing if the measure moved onto Stage 2 review. Helen Burstin and Andy Baskin also had an extended conversation with the lead developer.

d. Articulation of any difference in review process/criteria if this were not in the Stage 2 pilot but rather had come through in the historical review process.

- The *Importance* criteria used in the Stage 1 pilot review is the same *Importance* criteria used in all projects. The initial assessment of insufficient evidence and re-consideration after the comment period would have occurred in the usual process. However, in the usual process the Committee would have determined the evidence evaluation based on the measures as submitted with all nine components without the option to recommend changes to the measure. It is unlikely that those Committee members who approved the concept “only if it included the six components” would have approved the nine component measure on evidence.
- The checklist requirements are unique to the 2-Stage pilot and not part of the usual CDP. The 2 Stage process and the checklist review offered an opportunity for the developer to revise the measure to meet the criteria. This is not available in the usual process.
- In the usual CDP, after passing the evidence criteria the measure would have been evaluated on the *Scientific Acceptability – Testing for Reliability and Validity* criteria.
 - Of note, the information submitted during Stage 2 for testing for reliability and validity underwent Technical Review by NQF staff who noted “The measure submission is partially incomplete, particularly in regards to required testing. If testing cannot be completed by the time of submission deadline, the measure is not ready for consideration for NQF endorsement. The measure has not been modified according to the stage 1 checklist.” The developer was given another opportunity to provide information on testing. The second Stage 2 submission indicated that there was testing for validity of the critical data elements and empiric testing of the measure score, however no description of the testing nor any data or results were provided. Face validity was not addressed. Though discussed with the measure developer, analysis to demonstrate that the components in question added to the value of the composite was not completed. The developer did not provide empirical evidence that the composite was better with the components recommended for removal than without them.

3. What options exist for the next step?

- a. The CSAC chairs could agree with the recommendation of the steering committee that the measure failed to comply with the Stage 1 checklist.
 - i. The CSAC could couple this recommendation with CDP process improvements to avoid this situation in the future. The CSAC/HITAC subcommittee on evidence and testing will provide recommendations at the in-person CSAC meeting.
- b. The CSAC chairs can request additional expert input.
- c. The CSAC chairs could ask the Committee to reconsider, though it is not clear how this would change the Committee’s initial recommendation without further guidance from the CSAC. This would be a challenge given that multiple Committee members commented that the measure appeared to be given more opportunities for re-review than other measures they reviewed in this and other projects.
 - i. Note: The measure has only been evaluated on importance to measure and report; if returned to the Committee for further deliberations, the Committee would need to reconsider importance and potentially consider the remaining criteria.

- C 2056 Colonoscopy Quality Index remains an approved concept. The developer may submit the full measure at the next call for GI measures. The developer should address the feedback on required information regarding testing provided during the Technical Review. The developer will have the opportunity to re-submit the approved concept in a future project when this measure could be considered.