TO: Consensus Standards Approval Committee (CSAC)

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RE: Patient-reported Outcomes in Performance Measurement – Comments Received

DA: December 7, 2012

The CSAC will review recommendations from the *Patient-reported Outcomes in Performance Measurement* project at its December 10 conference call.

This memo includes a summary of the project, recommendations, and themes identified from and responses to the public and member comments.

The draft report was posted for a 30-day comment period from October 24 through November 23, 2012. There is no voting. The recommendations need to be approved by the CSAC and if appropriate, the Board.

Accompanying this memo are the following documents:

1. **Patient-Reported Outcomes in Performance Measurement Draft Report.** The draft report has been updated to reflect the changes made following the Expert Panel discussion of public and member comments. The draft report posted for comment and supplemental materials are available on the project page (available here).
2. **Comment table**. The comment table is posted on SharePoint (available here). This table lists 34 comments received and the NQF/Expert Panel responses.

CSAC ACTION REQUIRED

- Approve report and recommendations
- Follow-up on recommendations that require CSAC action

BACKGROUND

Patient and family engagement is increasingly acknowledged as a key component of a comprehensive strategy, including performance improvement and accountability, in achieving a high quality, affordable health system. Emerging evidence affirms patients who are engaged in their care tend to experience better outcomes and choose less costly but effective interventions, such as physical therapy for low back pain, after undergoing a process of share decision-making. Promising approaches to authentically involve patients and their families at multiple levels are being implemented across the country including serving on governance boards at hospitals and contributing to system and practice redesign to make care safer and more patient-centric.

Historically, with the exception of collecting feedback on satisfaction or experience with care, patients remain an untapped resource in the assessment of the quality of care and that of long-term

support services. Patients are a valuable and arguably the authoritative source of information on other outcomes beyond experience including: health-related quality of life, symptom and symptom burden, and health-related behaviors. Therefore, interest in performance measures based on patient- reported outcomes is increasing.

The project goals were to:

- Identify key characteristics for selecting PRO instruments (PROMs) to be used in performance measures (PRO-PMs);
- Identify any unique considerations for evaluating PRO-PMs for NQF endorsement and use in accountability and performance improvement applications; and
- Lay out the pathway to move from PROMs to NQF-endorsed PRO-PMs.

DRAFT REPORT

The key points included:

- Defining and distinguishing PRO (outcome concept), PROM (instrument to measure the PRO), PRO-PM (PRO-based performance measure)
- NQF endorses the Pro-PM, not the PROM
- Pathway from PRO to endorsed PRO-PM
- PROs relevant for supportive services not just acute healthcare
- Some unique challenges with PRO-PMs (also expanded discussion in accompanying commissioned papers): cost, proxies, effort required of patients, response rate, two levels of methodological issues – PROM and PRO-PM
- Two areas of controversy: (1) evidence that the outcome is amenable to change requiring a reexamination of existing NQF criteria for all outcome measures; and (2) exceptions to endorsing PRO-based performance measures that are process measures focused on administering the PROMs

Recommendations

Recommendation 1. Those developing PRO-PMs to be considered for NQF endorsement should follow the basic steps shown in the pathway in Figure 2. Doing so will help ensure that the eventual PRO-PM and its supporting documentation conform to NQF endorsement criteria.

Recommendation 2. The NQF criterion or guidance for importance to measure and report should require evidence that the target population values the measured PRO and finds it meaningful.

Recommendation 3. The NQF criterion and guidance regarding evidence should require identification of the causal pathway linking the relevant structures;, (processes, interventions, or services); intermediate outcomes; and outcomes.

Recommendation 4. NQF should consider applying the existing criterion and guidance regarding evidence for a process performance measure to health outcome performance measures, including PRO-PMs – i.e., *a systematic assessment and grading of the quantity, quality, and consistency of the body of*

empirical evidence that at least one of the identified healthcare structures, processes, interventions, or services influences the outcome.

Recommendation 5. NQF should provide explicit guidance when a performance measure focused on an assessment, including administering a PROM, meets the exception for the evidence criterion.

In such exceptions, he following additional conditions should be required before it is considered for endorsement.

- The process performance measure is specified so that it requires providers to administer a specific PROM at designated intervals and record the PROM value in the health record, not merely check off that it was administered.
- The developer submits a credible plan to implement the process performance measure, collect data, and develop and test the outcome performance measure.

Recommendation 6. NQF should require measure specifications for PRO-PMs that include all the following: the specific PROM(s); standard methods, modes, and languages of administration; whether (and how) proxy responses are allowed; standard sampling procedures; the handling of missing data; and calculation of response rates to be reported with the performance measure results.

Recommendations 7. NQF should require testing for PRO-PMs that demonstrates the reliability of both the underlying PROM in the target population and the performance measure score.

Recommendation 8. NQF should require testing for PRO-PMs that demonstrate the validity of both the underlying PROM in the target population and the performance measure score. Empirical validity testing of the performance measure is preferred. If empirical validity testing of the performance measure is not possible, a systematic assessment of face validity should be accomplished with experts other than those who created the measure, including patients reporting on the PROM, and this assessment should specifically address the approach to aggregating the individual PROM values.

Recommendations 9. NQF should require analysis of missing data and response rates to demonstrate that potential problems in these areas do not bias the performance measure results.

Recommendation 10. NQF's feasibility criterion should consider the burden to both individuals providing PROM data (patients, service recipients, respondents) and the providers whose performance is being measured. The electronic capture criterion needs to be modified to include PROM data, not just clinical data.

COMMENTS AND THEIR DISPOSITION

NQF received 34 comments from 11 organizations and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments (available here) submitted during the comment period, with the draft responses to each comment and the actions taken by the Expert Panel, is posted to SharePoint.

Comment Themes and Expert Panel Responses

The Expert Panel reviewed the comments received via conference call on December 3, 2012. The comments focused on three major themes.

Theme 1 – Concern that requiring evidence that the PRO was amenable to change (actionable) would hold PRO-PMs to a higher standard than health outcome performance measures

Some commenters objected to the recommendation requiring evidence that the outcome was amenable to change when NQF criteria for health outcomes requires "a rationale that supports the relationship of the health outcome to processes or structures of care."

Related to this concern, some commenters also objected to the guiding principle of "actionability" because it seemed to be a new criterion only applied to PRO-PMs.

Expert Panel Response: The Expert Panel agreed that PRO-PMs should be treated the same as health outcome measures. The original recommendation was that the same requirement for evidence should be applied to all health outcome measures. The Panel recognized that this has broader policy implications for NQF evaluation criteria in "raising the bar" for all health outcome performance measures and will require further exploration by the CSAC and if recommended, a phased implementation.

Staff Note: The NQF guidance from the Evidence Task Force report provides for an exception to the requirement for a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence for health outcomes:

> "**Exception to Empirical Body of Evidence for Health Outcome -** For a health outcome measure: A rationale supports the relationship of the health outcome to at least one healthcare structure, process, intervention, or service."

Such a rationale would usually be grounded in evidence, although developers are not required to provide the quantity, quality, and consistency of the body of evidence. Should NQF require more than a rationale of the relationship to structures and processes of care, and if so to what extent?

The draft report was modified by:

- clarifying that PRO-PMs should be treated the same as other health outcome measures;
- recommending that NQF consider requiring evidence for all health outcome measures;
- removing the use of "actionable" and relating it to current NQF criteria for evidence; and
- noting the two viewpoints on evidence that an outcome is amenable to change.

Theme 2 – Endorsing performance measures focused on administering a PROM only under exceptional circumstances

Some commenters objected to an alternate pathway that included process performance measures focused on administering a PROM rather than the outcome performance measure. They were concerned it would divert resources and delay the goal of endorsing the outcome performance measures.

Expert Panel Response: The panel did not intend the "alternate" pathway to be viewed as equivalent to the primary pathway of creating outcome performance measures. The original report clearly indicated

that such a performance measures must require more than merely checking off that a PROM had been administered. Although the Panel agreed that a performance measure focused only on administering a PROM is not desirable, in some circumstances it may be a necessary first step. More specificity is needed on what types of circumstances would allow for this exception to be deemed necessary and thus CSAC guidance is needed on this type of policy decision.

Staff Note: This is another area that has broader implications for NQF criteria than just for PRO-PMs. A performance measure focused on administering a PROM is similar to any performance measure focused on conducting some assessment (e.g., taking a BP, performing a lab test, asking about smoking). Conducting an assessment is quite distal to the outcome of interest and typically does not have evidence that it influences the outcome. Performance measures focused on intervention, intermediate outcomes, or health outcomes are preferred over "assessment" performance measures. If they are recommended for endorsement

The draft report was modified by:

- removing reference to an "alternate pathway" and moving the discussion of a performance measure on administering a PROM under recommendations related to exceptions to NQF's evidence criterion; and
- recommending that NQF identify when a performance measure focused on administering a PROM would be considered and requirements for how it must be specified.

Theme 3 – Concern that there is too much emphasis on psychometric soundness

Some commenters thought the report emphasized measurement properties over the perspective of patients.

Expert Panel Response: The pathway begins with patients participating in identifying the quality performance issue and identifying outcomes that are meaningful to them. The Panel further emphasized the role of patients by recommending that for PRO-PMs NQF should require evidence that patient value the PRO and find it meaningful. NQF criteria for all performance measures require evidence of reliability and validity. PRO-PMs are more complex in that there are two levels: reliability and validity of the PROM and reliability and validity of the performance measure. NQF-endorsed measures are intended for use in accountability applications as well as performance improvement and if not reliable and valid, will not be useful.