To: Person and Family Centered Care Standing Committee
From: NQF Staff
RE: PFCC Off-Cycle Webinar: PRO-PMs
Date: May 16, 2017

Introduction

For the first off-cycle webinar of 2017, NQF would like to seek the PFCC Committee's input on categorization of instrument-based measures and Patient Reported Outcome Performance Measures (PRO-PMs). There are a variety of ways to capture patient-reported data, such as instruments that may be completed directed by patients OR administered by providers. In addition, although they are currently classed as such, not all patient-reported measures are outcome measures.

NQF currently recognizes four key PRO domains: health-related quality of life (including functional status), symptoms and symptom burden (e.g. pain, fatigue), experience with care, and health behaviors (e.g., smoking, diet, exercise)—but these domains do not currently impact evaluation. NQF would like the PFCC Committee to provide input on how we might accurately and consistently categorize these PRO measures and what impact this could or should have on measure evaluation.

A set of example measures is included at the end of this memo in Appendix A.

Dial-In & Webinar Information

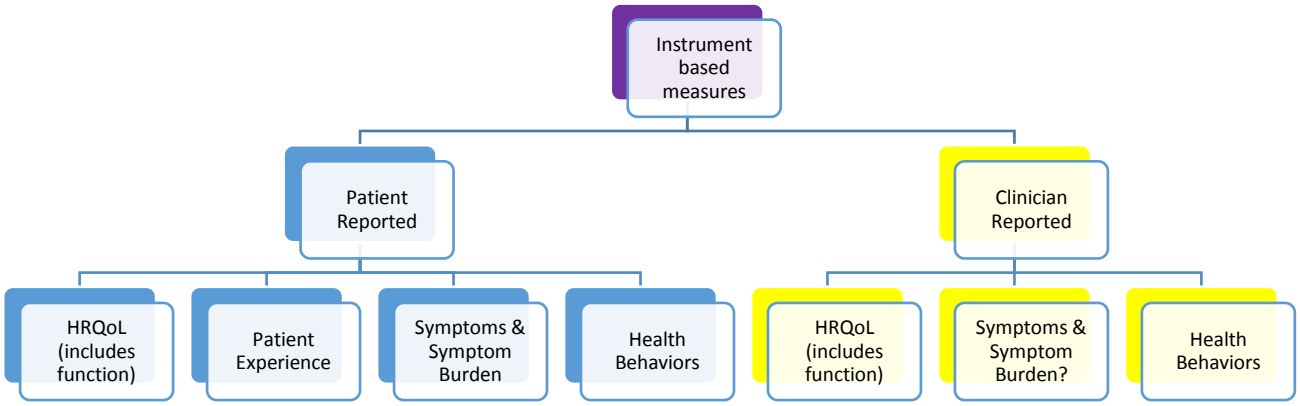
- **June 1, 2017, 2:00-4:00pm ET**
- Public Dial-In Line: 877-315-9042
- Web Link: http://nqf.commpartners.com/se/Rd/Mt.aspx?184223
- Registration Link: http://nqf.commpartners.com/se/Rd/Rg.aspx?184223

Discussion Questions

- Which instrument-based measures should be considered PRO-PMs?
    - Should provider-administered PROM measures be classified as PRO-PMs?
    - Do we need to differentiate between provider-solicited information and patient provided information?
    - Should patient self-report (e.g., a measure that asks a patient to report on whether a particular process was done) process measures be considered PRO-PMs? (These measures are currently evaluated as PRO-PMs. Are these still PRO-PMs or do they need to be classified differently)?
- Should the evaluation differentiate between PRO-based outcome and process measures? If so, what are the implications in terms of NQF's evaluation criteria? Would patient-reported process measures be held to the criteria for process measures (e.g., a more stringent evidence requirement for quantity, quality, and consistency of the body of evidence rather than a rationale, but no requirement for score-level reliability and validity testing)?

- Is it important to label PRO-PMs (or other instrument-based measures) according to PRO domains? Why or why not?
- Are there additional PRO domains that we should consider?
- What should be the implications (if any) of PRO domain on the evaluation criteria?
- There are two diagrams below: our current classification of instrument-based measures and a proposed classification. Are there concepts or items missing from the diagram below that would be helpful for NQF to know about and/or incorporate?
- If there is time on the call after discussing the previous questions, NQF staff would like the Committee to discuss these two questions:
    - What are the implications for Feasibility and Usability & Use, particularly with eMeasures?
    - Are there any considerations specific to eMeasures?

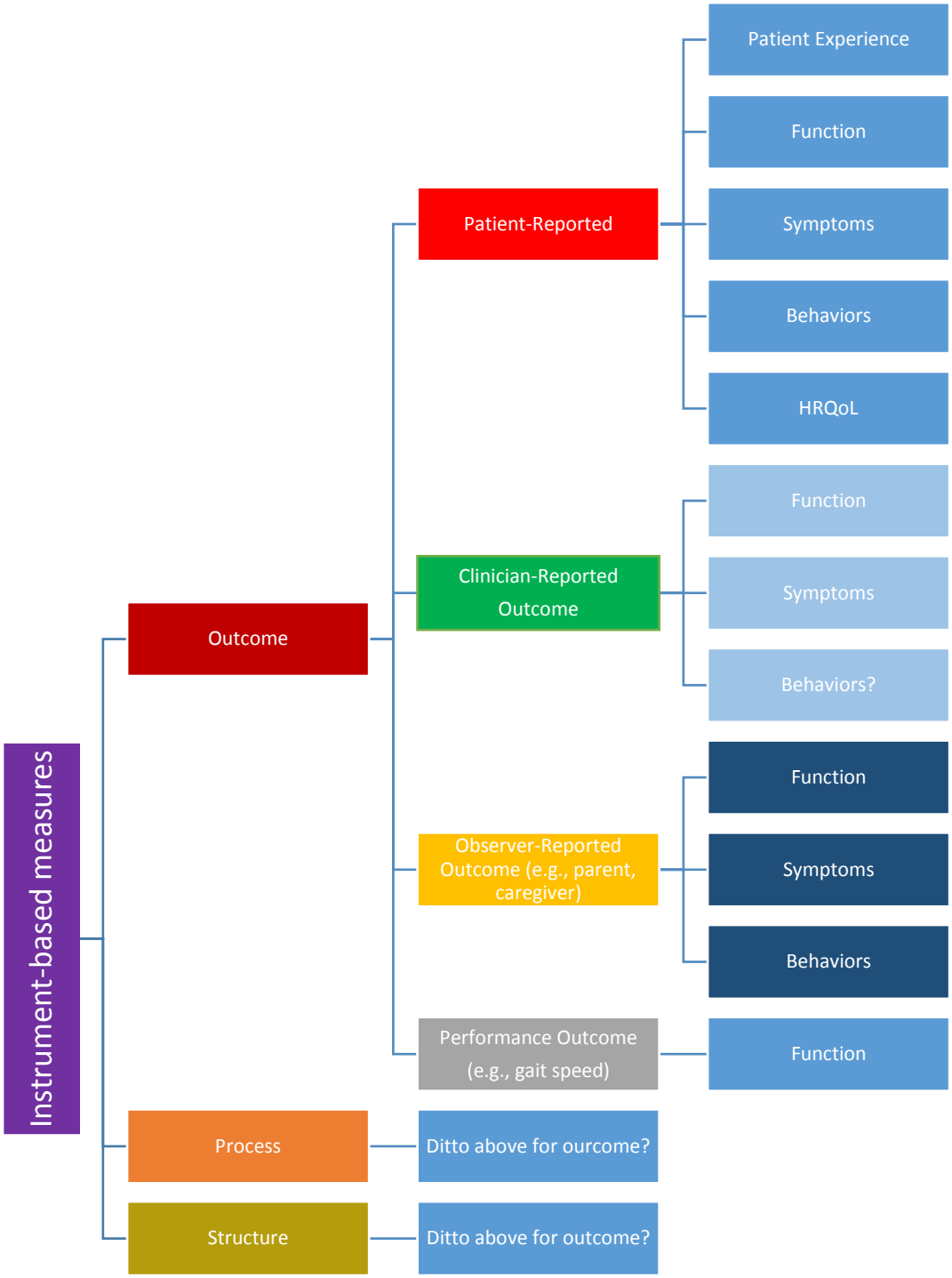
Current Classification



NATIONAL QUALITY FORUM

Proposed Classification

(See below for definitions)



Background Information

Definitions from NQF's 2013 report on Patient Reported Outcomes in Performance Measurement

Performance measure: Numeric quantification of healthcare quality for a designated accountable healthcare entity, such as hospital, health plan, nursing home, clinician, etc.

Patient-reported outcome (PRO): "Any report of the status of a patient's (or person's) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."

PRO measure (PROM): Instrument, scale, or single-item measure used to assess the PRO concept as perceived by the patient, obtained by directly asking the patient to self-report (e.g., PHQ-9).

PRO-based performance measure (PRO-PM): A performance measure that is based on PROM data aggregated for an accountable healthcare entity (e.g., percentage of patients in an accountable care organization whose depression score as measured by the PHQ-9 improved).

The report also notes that "PRO" has become an international term of art; the word "patient" is intended to be inclusive of all persons, including patients, families, caregivers, and consumers more broadly. It is intended as well to cover all persons receiving support services, such as those with disabilities. Key PRO domains include:

- Health-related quality of life (including functional status);
- Symptoms and symptom burden (e.g. pain, fatigue);
- Experience with care; and
- Health behaviors (e.g., smoking, diet, exercise).

Definitions from the FDA Clinical Outcome Assessment Qualification Program (2016)

Clinician-reported outcome (ClinRO) — A ClinRO is based on a report that comes from a trained health-care professional after observation of a patient's health condition. A ClinRO measure involves a clinical judgment or interpretation of the observable signs, behaviors, or other physical manifestations thought to be related to a disease or condition. ClinRO measures cannot directly assess symptoms that are known only to the patient (e.g., pain intensity).

Observer-reported outcome (ObsRO) — An ObsRO is a measurement based on an observation by someone other than the patient or a health professional. This may be a parent, spouse, or other non-clinical caregiver who is in a position to regularly observe and report on a specific aspect of the patient's health. An ObsRO measure does not include medical judgment or interpretation. Generally, ObsROs are reported by a parent, caregiver, or someone who observes the patient in daily life. For patients who cannot respond for themselves (e.g., infants or cognitively impaired), we encourage observer reports that include only those events or behaviors that can be observed. As an example, observers cannot validly report an infant's pain intensity (a symptom) but can report infant behavior thought to be caused by pain (e.g., crying). For example, in the assessment of a child's functioning in the classroom, the teacher is the most appropriate observer. Examples of ObsROs include a parent report of a child's

vomiting episodes or a report of wincing thought to be the result of pain in patients who are unable to report for themselves.

Patient-reported outcome (PRO) — A PRO is a measurement based on a report that comes from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's report by a clinician or anyone else. A PRO can be measured by self-report or by interview, provided that the interviewer records only the patient's response. Symptoms or other unobservable concepts known only to the patient (e.g., pain severity or nausea) can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others.

Performance outcome (PerfO) — A PerfO is a measurement based on a task(s) performed by a patient according to instructions that is administered by a health care professional. Performance outcomes require patient cooperation and motivation. These include measures of gait speed (e.g., timed 25 foot walk test), memory recall, or other cognitive testing (e.g., digit symbol substitution test).

Table 1. Distinctions among PRO, PROM, and PRO-PM: Two Examples
(From Patient Reported Outcomes in Performance Measurement)

Concept	**Patients With Clinical Depression**	**Persons with Intellectual or Developmental Disabilities**
PRO (patient-reported outcome)	Symptom: depression	Functional Status-Role: employment
PROM (instrument, tool, single-item measure)	PHQ-9©, a standardized *tool* to assess depression	Single-item measure on National Core Indicators Consumer Survey: *Do you have a job in the community?*
PRO-PM (PRO-based performance measure)	Percentage of patients with diagnosis of major depression or dysthymia and initial PHQ-9 score >9 with a follow-up PHQ-9 score <5 at 6 months (NQF #0711)	The proportion of people with intellectual or developmental disabilities who have a job in the community

Main Characteristics of Patient-Reported Outcomes

(From *Patient-Reported Outcomes in Performance Measurement*. Cella et al, 2015.)

PRO Category	Main Characteristics
Health-Related Quality of Life: HRQL is a multidimensional19 construct encompassing physical, social, and emotional well-being associated with illness and its treatment.	• Is multi-dimensional • Can be generic or condition-specific
Functional Status: Functional status refers to a patient's ability to perform both basic and more advanced (instrumental) activities of daily life.41 Examples of functional status include physical function, cognitive function, and sexual function.	Reflects ability to perform specific activities
Symptoms and Symptom Burden: *Symptoms* such as fatigue and pain intensity are key domains for PROMs. Symptoms are typically negative, and their presence and intensity are best assessed through patient report. *Symptom burden* captures the combination of both symptom severity and impact experienced with a specific disease or treatment.	• Are specific to type of symptom of interest • May identify symptoms not otherwise captured by medical work-up
Health Behaviors: Although health behaviors may be considered predictors of health outcomes, they are also health outcomes in their own right in the sense that health care interventions can have an impact on them.	• Are specific to type of behavior • Typically measure frequency of behavior
Patient Experience: Measurement of patient ratings is a complex concept that is related to perceived needs, expectations of care, and experience of care. Patient ratings can cover the spectrum from patient engagement, to experience, to shared decision making, to self-management to full activation.	• Concerns satisfaction with health care delivery, treatment recommendations, and medications (or other therapies) • Reflects actual experiences with health care services • Fosters patient activation

Evolving Evaluation Requirements

As the number of PRO-PMs in the NQF portfolio has grown and the complexity of measures has increased, NQF staff and committees, including the PFCC Committee, have identified areas where the existing endorsement criteria may need refinements. For process and outcome measures, the NQF

criteria allow testing at either the item (scale) level OR measure score level. PRO-PMs require both levels of testing. Tool-based measures—those measures that derive data from surveys, assessments, and other instruments—also require evaluation of reliability and validity testing results at the performance measurement level. Requiring performance score level testing allows evaluation to ensure variability in performance and the ability to differentiate between the facilities whose performance is being assessed.

Although measure developers have made great strides in submitting data to support the reliability and validity of their measures under consideration, Committees have encouraged NQF and the developer community to consider additional testing approaches to ensure that measures meet scientific acceptability criteria. In addition, the PFCC Committee has identified an interest in seeing results of cognitive testing to further support the validity of proposed measures that are based on patient reports; the Committee expects that this will lead to measures that include a patient's perspective on the design and selection of questions to make sure that the questions are understood, meaningful, and impactful.

Under Importance, the criterion (1c.5) requires: "If a PRO-PM (e.g., HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), evidence should demonstrate that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)" Past Committees, including the PFCC Committee, have encouraged NQF to require this criterion in the evaluation of any type of measure. With a national focus trending toward person- and family-centeredness, this criterion becomes extremely important. NQF may find opportunities not only to require the criterion for all measures, but also to focus education on the importance of the patient-centeredness concept. Currently, many developers of PRO-PMs leave this section blank, indicate it does not apply, or identify peer-reviewed literature to support it.

The 2013 NQF report also detailed a number of recommendations for PROs, many of which have been implemented, including:

- Evidence that the PRO is of Value to the Target Population: 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.
- 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.
- 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.
- 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.
- 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.

- 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.

The one remaining recommendation still to be implemented is:

- Evidence that the Measured PRO is Responsive to Intervention

Appendix A: Sample Measures

Potential Patient-Reported Process Measures/Current Process Measures

The measures below were submitted as process measures. The common denominator is that they are based on a PRO and appear, from a measurement perspective, to be process measures.

0030: Management of Urinary Incontinence in Older Adults (MUI)

The following components of this measure assess the management of urinary incontinence in older adults.

- Discussing Urinary Incontinence. The percentage of Medicare members 65 years of age and older who reported having urine leakage in the past six months and who discussed their urinary leakage problem with a health care provider.
- Treatment of Urinary Incontinence. The percentage of Medicare members 65 years of age and older who reported having urine leakage in the past six months and who discussed treatment options for their current urine leakage problem.
- Impact of Urinary Incontinence. The percentage of Medicare members 65 years of age and older who reported having urine leakage in the past six months and who reported that urine leakage made them change their daily activities or interfered with their sleep a lot.

0035: Fall Risk Management (FRM)

Assesses different facets of fall risk management:

- Discussing Fall Risk. The percentage of adults 75 years of age and older, or 65–74 years of age with balance or walking problems or a fall in the past 12 months, who were seen by a practitioner in the past 12 months and who discussed falls or problems with balance or walking with their current practitioner.
- Managing Fall Risk. The percentage of adults 65 years of age and older who had a fall or had problems with balance or walking in the past 12 months, who were seen by a practitioner in the past 12 months and who received fall risk intervention from their current practitioner.

0260 Assessment of Health-related Quality of Life in Dialysis Patients

Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.

Measures Submitted as PRO-PMs that Could Be Patient Reported Process or Observer Reported Process

2844: Family Experiences with Coordination of Care (FECC) -5: Care coordinator asked about concerns and health

Caregivers of CMC who report having a care coordinator and who report that their care coordinator has contacted them in the last 3 months should also report that their care coordinator asked them about the following:

- Caregiver concerns
- Health changes of the child

2846: Family Experiences with Coordination of Care (FECC)-8: Care coordinator was knowledgeable, supportive and advocated for child's needs

Caregivers of CMC who report having a care coordinator should also report that their care coordinator:

- Was knowledgeable about their child's health
- Supported the caregiver
- Advocated for the needs of the child

0027: Medical Assistance with Smoking and Tobacco Use Cessation

Assesses different facets of providing medical assistance with smoking and tobacco use cessation:

- Advising Smokers and Tobacco Users to Quit: A rolling average represents the percentage of patients 18 years of age and older who were current smokers or tobacco users and who received advice to quit during the measurement year.
- Discussing Cessation Medications: A rolling average represents the percentage of patients 18 years of age and older who were current smokers or tobacco users and who discussed or were recommended cessation medications during the measurement year.
- Discussing Cessation Strategies: A rolling average represents the percentage of patients 18 years of age and older who were current smokers or tobacco users and who discussed or were provided cessation methods or strategies during the measurement year.

PRO-PMs that could be Observer-Reported Outcomes

0693: Consumer Assessment of Health Providers and Systems (CAHPS®) Nursing Home Survey: Family Member Instrument

The CAHPS Nursing Home Survey: Family Member Instrument is a mail survey instrument to gather information on the experiences of family members of long stay (greater than 100 days) residents currently in nursing homes. The Centers for Medicare & Medicaid Services requested development of this questionnaire, which is intended to complement the CAHPS Nursing Home Survey: Long-Stay Resident Instrument and the Discharged resident Instrument. The Family Member Instrument asks respondents to report on their own experiences (not the resident's) with the nursing home and their perceptions of the quality of care provided to a family member living in a nursing home. The survey instrument provides nursing home level scores on 4 topics valued by patients and families: (1) Meeting Basic Needs: Help with Eating, Drinking, and Toileting; (2) Nurses/Aides' Kindness/ Respect Towards Resident; (3)Nursing Home Provides Information/Encourages Respondent Involvement; and (4) Nursing Home Staffing, Care of Belongings, and Cleanliness. In addition, the survey provides nursing home scores on 3 global items including an overall Rating of Care.

2548: Child Hospital CAHPS (HCAHPS)

The Consumer Assessment of Healthcare Providers and Systems Hospital Survey – Child Version (Child HCAHPS) is a standardized survey instrument that asks parents and guardians (henceforth referred to as

parents) of children under 18 years old to report on their and their child's experiences with inpatient hospital care.

The performance measures of the Child HCAHPS survey consist of 39 items organized by overarching groups into the following 18 composite and single-item measures:

Communication with Parent

1. Communication between you and your child's nurses (3 items)
2. Communication between you and your child's doctors (3 items)
3. Communication about your child's medicines (4 items)
4. Keeping you informed about your child's care (2 items)
5. Privacy when talking with doctors, nurses, and other providers (1 item)
6. Preparing you and your child to leave the hospital (5 items)
7. Keeping you informed about your child's care in the Emergency Room (1 item)

Communication with Child

8. How well nurses communicate with your child (3 items)
9. How well doctors communicate with your child (3 items)
10. Involving teens in their care (3 items)

Attention to Safety and Comfort

11. Preventing mistakes and helping you report concerns (2 items)
12. Responsiveness to the call button (1 item)
13. Helping your child feel comfortable (3 items)
14. Paying attention to your child's pain (1 item)

Hospital Environment

15. Cleanliness of hospital room (1 item)
16. Quietness of hospital room (1 item)

Global Rating

17. Overall rating (1 item)
18. Recommend hospital (1 item)

We recommend that the scores for the Child HCAHPS composite and single-item measures be calculated using a top-box scoring method. The top box score refers to the percentage of respondents who answered survey items using the best possible response option. The measure time frame is 12 months. A more detailed description of the Child HCAHPS measure can be found in the Detailed Measure Specifications (Appendix A).