NATIONAL QUALITY FORUM

Memo

TO: NQF Members and Public

FR: NQF Staff

RE: Review of *Patient Reported Outcomes in Performance Measurement*

DA: October 24, 2012

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.

Review and Comment

The Expert Panel's recommendations are included in the draft document, *Patient Reported Outcomes in Performance Measurements*. The draft report is posted on the NQF web site for review and comment only—not voting. The recommendations include a suggested pathway to move from PRO concept to an endorsed PRO-PM and some modifications related to NQF criteria for evaluating performance measures when considering PRO-PMs for NQF endorsement. Of particular note are recommendations to require: evidence that persons form the target population find the PRO meaningful; evidence that a PRO is responsive to intervention; and reliability and validity testing of both the PROM and the PRO-PM.

You may post your comments and view the comments of others on the NQF website.

NQF Member and Public comments must be submitted no later than 6:00 PM ET, November 23, 2012.

NQF is now using a program that facilitates electronic submission of comments on this draft report. **All comments must be submitted using the online submission process.**

Supporting documents related to your comments may be submitted by e-mail to pro@qualityforum.org with "PRO Report" in the subject line and your contact information in the body of the e-mail.

Thank you for your interest in the NQF's work. We look forward to your review and comments.

National Quality Forum

Patient Reported Outcomes (PROs) in Performance Measurement

Draft Report for Comment

10/24/12

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INTRODUCTION

US Healthcare: Performance Improvement & Accountability

Widespread variation in the quality of healthcare in the United States is well documented.[1,2,3,4,5,6] Although there are many laudable examples across the country where safe, effective, affordable care and support services are consistently provided serious gaps persist. Coupled with the need to constrain escalating healthcare costs—threatening the livelihoods of individuals and families and the overall national economy— intense focus is being placed on performance improvement and holding providers accountable to tackle the double edged sword of achieving the highest quality care at the lowest possible costs. The Affordable Care Act has several provisions targeting this challenge including the creation of a National Quality Strategy (NQS) to serve as a blueprint to *improve the delivery of health care services, patient health outcomes, and population health.*[7] Released in March 2011 and updated yearly, the NQS identifies three overarching aims of better care, healthy people and communities, and affordable care and six priority areas[8] for collective action to ultimately drive towards a high-value health system.[9,10]

Achieving Performance Improvement & Accountability through Patient Reported Outcomes

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[11] and choose less costly but effective interventions, such as physical therapy for low back pain, after undergoing a process of share decision-making.[12] 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.[13,14]

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, functional status, symptom and symptom burden, and health-related behaviors. For example, in the case of long- term support services for persons with disabilities, asking about valued outcomes such as increased communication and self help skills, and improved social interactions. Hence, it is critically important to engage patients by building capacity and infrastructure to routinely capture patient-reported outcomes and then use this data to develop performance measures to allow for accurate appraisals of quality and efficiency.

NQF Role in Promoting Accountability & Performance Improvement

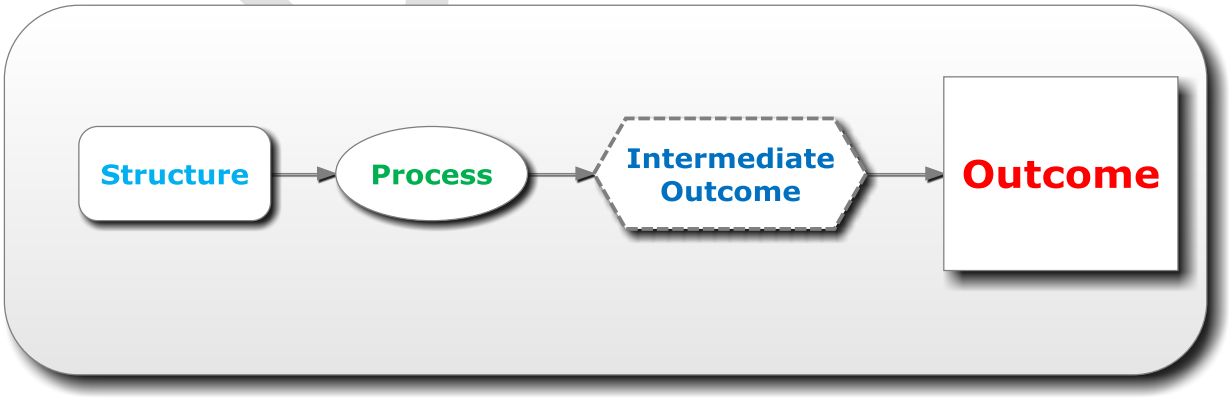
Valid, reliable measures are foundational for evaluating and monitoring performance and fostering accountability. The National Quality Forum (NQF) is a voluntary consensus standard setting organization recognized under the National Technology Transfer and Advancement Act.[15] In this role NQF endorses performance measures as consensus standards to assess the quality of healthcare for use in accountability applications such as public reporting and payment as well as performance improvement. NQF is a neutral evaluator of performance measures but is not a measure developer. NQF convenes diverse stakeholders to evaluate measures based on the well-vetted criteria (available here).

The field of performance measurement is evolving to meet the demands of increased accountability to improve outcomes in both quality and costs. In tandem, the direction for NQF-endorsed performance measures includes:

- a drive toward higher performance reflected in more outcome measures rather than very basic processes such as assessment;
- measuring disparities;
- a shift toward composite measures that summarize multiple aspects of care;
- harmonization of measures across sites and providers; and
- measurement across longitudinal patient-focused episodes including outcome measures, process measures with direct evidence of impact on desired outcomes; appropriateness measures; and cost/resource use measures coupled with quality measures, including overuse.

Figure 1 depicts the relationship between structure, process, and outcome. For NQF endorsement, there is a hierarchical preference for performance measures of health outcomes that are linked to evidence-based processes or structures; or outcomes of substantial importance with a plausible link to healthcare processes. Next in the preferred hierarchy are measures of intermediate outcomes and processes closely linked to desired outcomes. Measures of processes that are distal to desired outcomes (e.g., assess patient) and those that are satisfied by a "checkbox" are considered to have the least impact on the goal of improving healthcare and health.

Figure 1. Structure-Process-Outcome



Patient-Reported Outcomes Tools & Performance Measures

Patient-reported outcomes (PROs) are defined as "any report of the status of a patient's (or person's) health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[16] PRO has become an international term of art; use of term "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 supportive services, such as those with disabilities. The domains of patient-reported outcomes include:

- Health-related quality of life including functional status;
- Symptoms and symptom burden;
- Experience with care; and
- Health-related behaviors.

Various tools (e.g., instruments, scales, single-item measures) that enable assessment of patient-reported health status for physical, mental, and social well-being are referred to as PRO measures (PROMs). To include patient-reported outcomes more systematically as an essential component of assessing the quality of care or services provided, and as part of accountability programs such a value-based purchasing or public reporting, distinguishing between PROMs (i.e., tools) and aggregate-level performance measures is important.

A PRO-based performance measure (or PRO-PM) is based on patient-reported outcome data aggregated for an entity deemed as accountable for the quality of care or services delivered. Such entities can include (but would not be limited to) supportive services providers, hospitals, physician practices, or accountable care organizations (ACOs). NQF endorses performance measures (PRO-PMs) for purposes of performance improvement and accountability; NQF does not endorse the tools to measure PROs (PROMs). Table 1 illustrates the distinctions among PRO, PROM, and PRO-PM. Full definitions are in the glossary (Appendix C).

Table 1. Distinctions among PRO, PROM, and PRO-PM: Two Examples

Target Population	Patients with clinical depression	Persons with intellectual or developmental disabilities
PRO (concept)	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?** *A community job refers to paid work - either competitive or supported employment (includes both individual and group employment, such as a work crew or enclave). It does not include work done in facility-based settings like sheltered workshops. It also does not include volunteer work.*
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) and at 12 months (NQF #0710)	The proportion of people who have a job in the community

PRO-PMs Applications: Benefits and Challenges

Interest and appreciation of the value of using PROMs in performance measurement as part of the broader accountability and performance improvement landscape is mounting. To accelerate the adoption of PROMS to PRO-PMs that can be used for quality improvement and accountability two challenges must be addressed. First, PROMs have not been widely adopted for clinical use outside research settings in the United States and therefore may be unfamiliar to many health professionals, payers, and provider institutions. Second, more research is needed on best practices for aggregating patient data on PROMs to measure performance at multiple levels of analysis (e.g., individual, group practice, organization).

Foundational work is needed to address these challenges. In response, NQF with funding from the Department of Health and Human Services is conducting the *PROs in Performance Measurement* project. The project goals are to:

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

This project is purposively designed to bring together stakeholders who could facilitate the groundwork for developing, testing, endorsing and implementing PRO-PMs. Those stakeholders included researchers, health professionals, performance measure developers, and consumer and purchaser representatives (see Appendix A). We convened two workshops with an expert panel and commissioned two papers to achieve the goals of the project and help accelerate progress. The papers focused on the methodological issues and served as background for the workshops – the first focused on selecting PROMs for use in performance measurement (available here) and the second on the reliability and validity of PRO-PMs (available here).

Encouraging, are the national and international examples on whose successful experiences we can build. At the workshop valuable insights were gleaned on approaches to data collection/aggregation and practical pointers around implementation (e.g., getting buy-in from providers). At the first workshop, colleagues from the Dartmouth Spine Institute and Massachusetts General Hospital presented on their experiences with using PROMs in patient care and performance improvement (available here). At the second workshop, representatives from the Centers for Medicare and Medicaid Services Health Outcomes Survey; England, and Sweden presented on their initiatives to publicly report PRO-PMs (available here). These discussions informed the recommendations found later in this report and the path forward. Additionally, there is also a large body of knowledge on using experience with care measures as PRO-PMS from which lessons can be learned (e.g., performance measures based on CAHPS).

This report captures the insights from this effort to date and provides recommendations to move the field of performance measurement forward. The remaining sections of this report cover: guiding principles, a detailed pathway from PROs to PRO-PMs, key implications and recommendations related to NQF endorsement criteria, and future directions.

GUIDING PRINCIPLES

During the first workshop the Expert Panel discussed key characteristics for identifying PROMs most suitable for developing and testing PRO-based performance measures (PRO-PMs). They conceptualize these ideas as "guiding principles" for using PROMs in the context of performance measurement: they are not NQF endorsement criteria per se, but served as foundational constructs for their recommendations on the pathway form PRO to PRO-PM and related NQF endorsement criteria. PROM developers and PRO-PM measure stewards should also take these into account in preparing submissions and documentation for NQF consideration for endorsement.

The guiding principles, described below, place the patient front and foremost— and serve as the underpinning of the thinking that shaped the pathway from PROs to PRO-PMs discussed in the next section of this report. The word "patient" is often used as shorthand to comprise patients, families, caregivers, and consumers more broadly. It warrants emphasizing that this term is meant to be inclusive of persons receiving supportive services, such as those with disabilities. With this in mind, moving

forward NQF must ensure that the emerging portfolio of PRO-PMs addresses a range of health care services that expand outside the walls of a particular clinical setting of care.

The five guiding principles encompass the following: meeting technical psychometric standards; being person-centered; having meaning to individuals responding to PROMs; being actionable; and being implementable.

Psychometric Soundness

Workshop participants agreed on several psychometric properties as a baseline set of requirements to be considered in selecting PROMs for use in PRO-PMs. These are delineated in Box 1 and are derived from the first commissioned paper. Appendix B provides the expanded explanations for these scientific properties of instruments or tools to measure them. The remaining three sets of principles below presume that the main elements of reliable, valid, responsive and feasible PROMs are adequately covered and demonstrated.

Box 1. Characteristics for Selecting PROMs Identified in Commissioned Paper

1. Conceptual and Measurement Model Documented 2. Reliability 2a. *Internal consistency (multi-item scales)* 2b. *Reproducibility (stability over time)* 3. Validity *3a. Content Validity* *3b. Construct and Criterion-related Validity* *3c. Responsiveness* 4. Interpretability of Scores 5. Burden 6. Alternatives modes and methods of administration 7. Cultural and language adaptations 8. Electronic health record (EHR) capability

Person-Centered

Resoundingly, "person-centeredness" was the overarching theme that arose from the workshop discussions. In this context, using PROMs is viewed as an important step towards engaging patients, health professionals and other entities in creating a person-centered health system. The workshop participants also identified the opportunity for PROMs to facilitate shared decision-making (SDM), another strategy for engaging patients. SDM is defined as *a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences*.[17] For SDM, clinicians and other health care staff can use the instrument, scale, or single-item measure (PROM) to engage patients in their own preferred self-management and goal attainment by identifying outcomes important to them and tracking change over time. An important caveat to this discussion is not all patients want to engage in

formal SDM activities. Therefore, although contributing to SDM efforts is desirable, not all PROMs need to enable SDM.

Importantly, as a final consideration of person-centeredness, as patients become more engaged in their care by providing systematic feedback on outcomes such as their functional or health status, the flow of information between clinicians and patients must be bi-directional. This may mean that health professionals interpret PROM information back to their patients; it may mean that mechanisms are established to give patients their own information directly (displayed in easy-to-understand ways). With steps such as these, respondents to PROMs can benefit from seeing results in a timely way, and this type of service can balance any perceived burdens they may feel about completing data-collection activities. Although these considerations may not affect NQF endorsement efforts directly, the Expert Panel wished to emphasize that having PRO-PMs that can be used in this manner is desirable.

Meaningful

Closely intertwined with person-centeredness is the concept of "meaningfulness." Meaningfulness encompasses the relevance and degree of importance of the concepts measured by the PROM from the perspective of patients, their families, and caregivers—as well as clinicians and other health professionals who serve them. Among the concepts that PROMs would ideally capture are the following: the impact of health-related quality of life (including functional status); symptom and symptom burden; experience with care and satisfaction with the services; perceived utility of the services for achieving personal goals; or health-related behaviors. As suggested above, the focus comprises both "traditional" health care services broadly defined and supportive services for persons with disabilities.

Workshop participants debated how best to demonstrate evidence that stakeholders think a particular PROM is meaningful. The following framework, coined as the three "Cs", can serve as a starting point for thinking about how to operationalize the construct of being meaningful:

- Conceptual – the first step is to engage people in the dialogue of what matters most to them to define the concepts to be covered within PROs.

- Contextual – the second step is to learn how individuals use the information derived from either a PROM or a PRO-PM. Individuals here are defined very broadly to include not just "patients" (however construed for the application at hand) but also clinicians, other health professionals, administrators, and perhaps even policymakers. For example, does such information facilitate their participation managing their own health care? Does it help people to select a high- quality provider of health or supportive services? Does such data contribute to the discourse on larger social issues such as achieving high- quality care at acceptable costs?

- Consequential – the third step is determining what happens when the information (from a PRO-PM) is used in accountability programs (e.g., value-based purchasing) or performance improvement to assess and assure the availability of high quality of care and impact on availability of services. This step also needs to consider if the PRO-PM is consequential to the individual or family member.

Actionable

Actionability refers to evidence that the outcome of interest (i.e., PRO) is responsive to a specific health service or intervention. The guiding principle of "actionability" is that performance measures (i.e., PRO-PMs) intended for both accountability and improvement should be supported by evidence that the health care providers being measured can influence the person's short- or long-term outcomes. The position held by the majority of workshop participants was that without such evidence, a PRO-PM is not a valid indicator of quality.

From the workshop discussions emerged a spectrum of actionability for identifying the highest leverage PROs to accelerate on the path to PRO-PMs. This continuum had three levels:

- Highly actionable: evidence that the PRO is responsive to intervention as demonstrated in clinical studies and the intervention has been implemented in practice. Initial efforts for developing PRO-PMs should be focused here.

- Moderately actionable: evidence of responsiveness to intervention in clinical studies but there is limited experience with the intervention in practice. Moderately actionable PROs can be used for accountability but with caution. This is the next tier for consideration of accountability and performance measurement.

- Weakly or not actionable: evidence of responsiveness to intervention is weak in clinical studies and the intervention has not been implemented in practice. These PROs should not be considered for accountability or performance improvement purposes at this time (and thus not for NQF endorsement of PRO-PMs).

Some workshop participants offered a counter argument to the idea that all PROs considered for purpose of accountability or performance measurement must be actionable. The rationale presented was some outcomes are worth measuring even though they may not be amenable to change by providers—but are used by patients and clinicians to make informed decisions. Although not resolved at the workshop this is worthy of further exploration.

Implementable

The guiding principle that a PROM should be "implementable" acknowledges that many diverse factors affect implementation. Most of these factors relate to barriers to adopting such tools (PROMs) or collecting data and reporting on PRO-PMs in many practices, institutions or other settings. There were many implementation issues raised during the workshop discussions. Although not exhaustive, the workshop participants emphasized the following list: administering PROMs in real-world situations; addressing literacy and health literacy of respondents; addressing cultural competency of clinicians and other service providers; dealing with the potential for unintended consequences related to patient selection; covering costs associated with using PROMS (especially those not available in the public domain); and adapting PROMs to computer-based platforms or other alternate formats.

PATHWAY FROM PRO TO NQF-ENDORSED PRO-PM

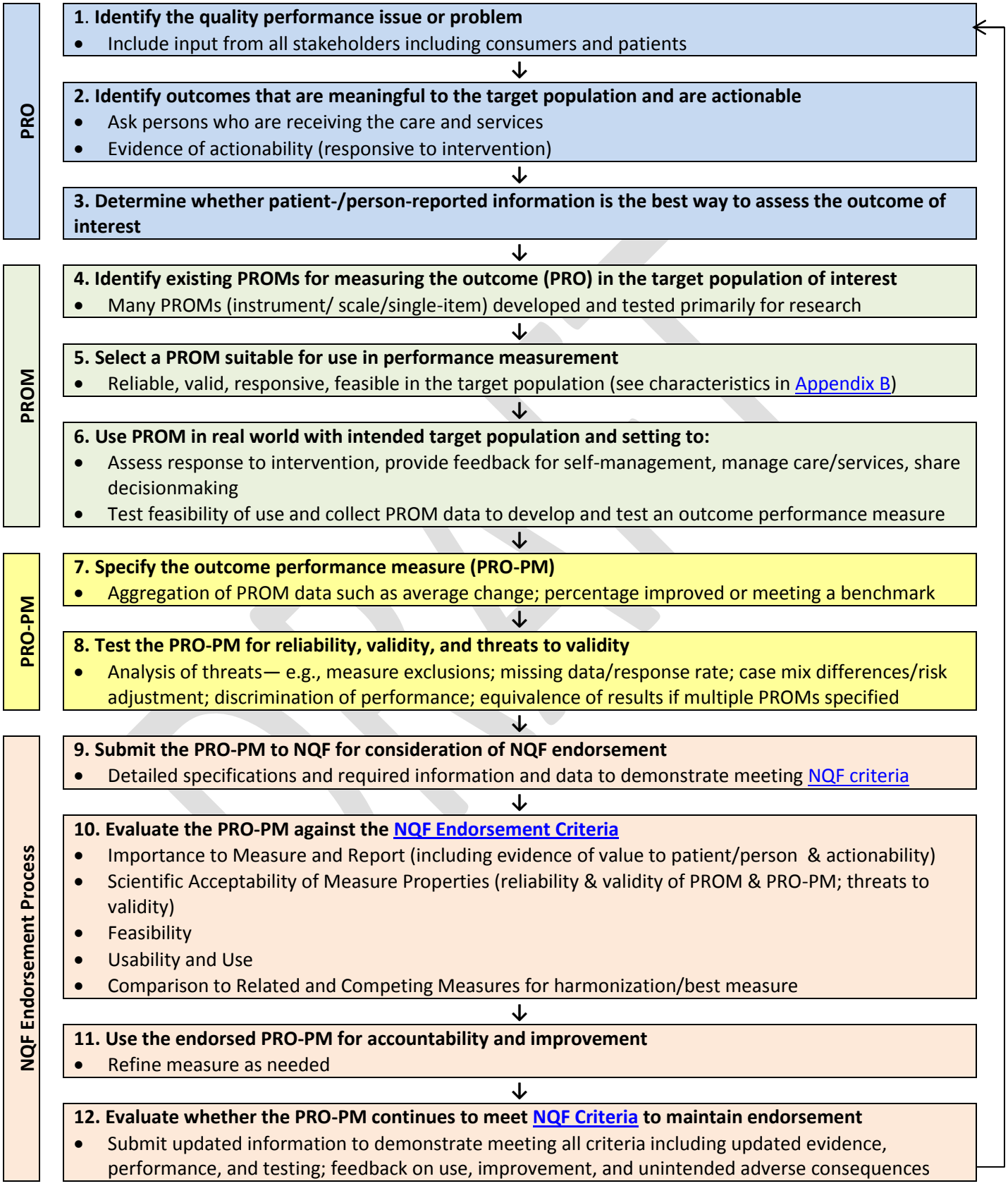
The pathway displayed in Figure 2, and described in detail below, lays out the critical steps in developing a PRO-based performance measure suitable for endorsement by NQF. It begins with the conceptual basis for identifying a PRO for performance measurement and proceeds through selecting a PROM and developing and testing a performance measure to achieving NQF-endorsement of a PRO-PM and using the performance measure for accountability and performance improvement. This pathway does not replace the existing NQF measure evaluation criteria, but rather describes how a PROM may form the basis of a PRO-PM that could be eventually endorsed by NQF. The existing NQF criteria *are* applicable to PRO-PMs, as well as the PROM used in the performance measure. Some recommendations for minor modifications to the NQF endorsement criteria to address the unique considerations of PRO-PMs are discussed in the next section.

Although NQF involvement occurs in the last section of the pathway, the earlier steps have implications for whether a performance measure will be suitable for NQF endorsement and are intended to serve as a guide and best practices to help ensure that PRO-PMs will meet NQF criteria. For example, steps 1 and 2 in the pathway indicate that patients (broadly defined as above) should be involved in identifying quality issues and outcomes that are meaningful to those receiving the care and supportive services. If patients are involved at those steps, then developers will have amassed the information needed to demonstrate that the outcome is of value to patients . In the context of using this pathway leading to an NQF-endorsed performance measure, step 2 also suggests identifying outcomes with evidence that the outcome is responsive to intervention.

Our first recommendation is stated in the box below. The steps shown in Figure 2 and described below are intended to help ensure that a proposed performance measure will meet NQF criteria for endorsement.

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.

279 Figure 2. Pathway from PRO to NQF-endorsed PRO-PM



Pathway Section Related to the PRO

The pathway begins with the conceptual basis for identifying a PRO for performance measurement.

1. Identify the quality performance issue or problem.

Before resources are devoted to performance measurement, a clear understanding of the quality performance issue or problem related to healthcare or supportive services for a target population will direct the focus and establish the need for a performance measure. Input from all stakeholders including the recipients of the care and services, providers whose performance will be measured, payers, purchasers, and policy makers are critical to identifying priorities for performance measurement.

2. Identify outcomes that are meaningful to the target population and are actionable by providers of care and services.

After identifying the quality performance issue, the specific outcomes that are valued and meaningful to the target population should be identified. That is, the people receiving the healthcare or supportive services should be asked for their input. At this stage, all relevant desired outcomes should be identified even if they might not be assessed through patient-reported data.

As discussed previously, the Expert Panel suggested focusing performance measures on outcomes that are actionable, i.e., responsive to intervention by healthcare and service providers. Therefore, outcomes with evidence that they are influenced by at least one structure, process, intervention, or service should be identified.

3. Determine whether patient-/person-reported information is the best way to assess the outcome of interest.

Patient-/person-reported data is not necessarily the best way to assess every desired outcome identified in the prior step. The domains of health-related quality of life including functional status, symptoms and symptom burden, and health-related behaviors have been identified as outcomes for which individuals receiving healthcare and services may be the best or only source of information. However, other meaningful outcomes such as survival/mortality and hospital readmission could be assessed using another data source.

Pathway Section Related to the PROM

After the PRO of interest is identified, the pathway addresses the steps to select a PROM suitable to use in a performance measure.

4. Identify existing PROMs for measuring the outcome (PRO) in the target population of interest.

Many PROMs already exist and should be searched to identify any that measure the outcome of interest in the target population. PROMs that were developed years ago may not have benefited from patient input; therefore, it is important to include patients in selecting PROMs

5. Select PROM suitable for use in performance measurement.

The scientific (psychometric) characteristics that should be used in selecting a PROM for performance measurement were summarized above and appear in detail in Appendix B. Of great importance is that PROMs be reliable, valid, and responsive in the target population. If there isn't an existing PROM for the target population suitable for use in a performance measure, then another existing PROM must be tested in the target population or a new PROM developed and tested before a performance measure can be developed. The commissioned paper on methodological issues related to PROMs provides a resource on considerations for selecting the PROM (available here).

6. Use the PROM in the real world with the intended target population and setting.

The Expert Panel agreed that PROMs should be used with the target population and in the settings for which performance measures are proposed before a PRO-PM is developed. Many PROMs were developed for research studies. This real-world application will identify feasibility issues related to administration, data capture, and workflow to use the PROM to assess individuals' responses to health care or supportive services intervention, provide feedback for self-management, and (as desired) facilitate shared decisionmaking.

Actual use of the PROM also generates the data needed to develop and test a PRO-PM for reliability and validity. The PROM could be used in a pilot or through more broad-based adoption. This step does not require an endorsed performance measure focused on administering the PROM. However, in some circumstances, adding steps for such a process measure may be considered and is discussed after the main pathway.

Pathway Section Related to the PRO-PM

After the PROM is selected and used in practice and sufficient data are available for testing, the pathway addresses specifying and testing a PRO-PM.

7. Specify the outcome performance measure (PRO-PM).

Developers specify how the outcome performance measure will be constructed. The metrics may be, for instance, an average change; percentage of patients improved; percentage of respondents meeting a specific benchmark value. The performance measure needs to be fully specified including the specific PROM, administration, and scoring; the target population and any exclusions; time frames for PROM administration as well as performance measurement; and risk adjustment.

8. Test the PRO-PM for reliability, validity, and threats to validity.

Developers need to test the performance measure for reliability and validity. They explicitly need to address a variety of threats to validity or other technical issues; these include the need for risk adjustment or stratification and options for doing this; appropriateness of potential exclusions; and options for dealing with missing data. A further challenge is explaining the level of equivalence of results when multiple PROMs are used.

Testing of the PRO-PM is distinct from testing the PROM. Using a PROM with sound psychometric properties is necessary but not sufficient to assure a reliable and valid PRO-PM. The commissioned paper on methodological issues for PRO-PMs provides a resource on considerations and approaches to reliability and validity of the performance measure (available here).

Pathway Section Related to the NQF Endorsement Process

The last section of the pathway focuses on the NQF endorsement process.

9. Submit the PRO-PM to NQF for consideration of NQF endorsement.

The NQF endorsement process begins when developers submit a measure to NQF for consideration. Developers submit required information in NQF's standard form so that all the information needed to evaluate the measure is available to reviewers.

10. Evaluate the PRO-PM against the NQF Endorsement Criteria.

NQF evaluates measures against four main endorsement criteria listed here and described and discussed in more detail below.

1. Importance to Measure and Report
2. Scientific Acceptability of Measure Properties
3. Feasibility
4. Usability and Use

In addition, NQF has criteria and processes to address measure harmonization and selection of the best measure form among competing measures, which also would apply to PRO-PMs.

11. Use the endorsed PRO-PM for accountability and improvement.

Once endorsed, NQF expects the measure to be used for accountability and performance improvement applications. Implementation of the performance measure facilitates improvement and measuring and tracking improvements. Use of the performance measure provides data on performance and improvement.

12. Evaluate whether the PRO-PM continues to meet NQF Criteria to maintain endorsement.

NQF reviews endorsed measures every three years to evaluate whether it continues to meet NQF criteria. In making its decision at this stage, NQF evaluates the measure on all criteria and considers information on actual use, improvement, and unintended adverse consequences. This information and results of the NQF endorsement maintenance decision also provide feedback to the beginning of the pathway and considerations for performance measurement.

Alternate Pathway

The main pathway depicted in Figure 2 and discussed above focuses on moving from a PRO to a PRO-PM – with the core construct an outcome that is meaningful to patients (broadly defined) and measured by a PROM that meets other desirable characteristics discussed in the guiding principles above. However, in some circumstances beginning to measure performance related to the administration and data capture of the PROM itself may be considered before moving straight to using the PRO data themselves. Ultimately, however, the goal is for outcome performance measures.

The primary purpose of a process performance measure focused on administration is to facilitate use of the PROM as described in step 6 of the main pathway and prepare the field for outcome performance measurement. Another potential reason for a process performance measure is concern that although the PRO is valued, it is not currently thought to be influenced by health care – but could be in the future. However, in this case, the PRO may not be a priority for performance measurement as indicated in step 2.

The alternate pathway entails developing, testing, endorsing, and implementing such a process measure before developing the outcome measure; therefore, it has implications for time and resources. Some questions to consider before pursuing the additional steps related to a process performance measure include:

- *Is there another mechanism in place to facilitate use of a PROM?* If use of a PROM is achieved through other requirements such as regulations or accreditation, or accepted guidelines then a performance measure may not appreciably impact the extent of use.
- *Will the process performance measure result in having the data needed to develop and test an outcome performance measure?* The process performance measure should be specified so that it requires that a specific PROM is administered at designated intervals, with recording of the PROM value in the health record — not merely checking that it was administered. Alternatively a more substantive process measure focused on an evidence-based intervention in response to a specific value of a PROM could be constructed so that use of the PROM is required.
- *Is there a credible plan to implement the process performance measure and collect data?* If the process performance measure is not implemented so that providers are accountable for performance on using the PROM and capturing PROM data, it less likely to affect adoption of the PROM and advance development of an outcome measure.

KEY IMPLICATIONS AND RECOMMENDATIONS RELATED TO NQF CRITERIA

Overview

The NQF endorsement criteria and guidance on evaluating all performance measures also apply to PRO-based performance measures (PRO-PMs). The four main endorsement criteria were mentioned previously (importance to measure and report, scientific acceptability of measure properties, feasibility, and usability and use). NQF committee members use the criteria to evaluate measures submitted for

potential endorsement. When these criteria are met and measures are endorsed they are considered suitable for accountability and performance improvement. Potential submitters (i.e., developers) also need to be very familiar with the NQF criteria so as to be able assemble the required documentation as part of their submission.

PRO-PMs may, however, have some special or even unique aspects that warrant special consideration. Table 2 lists these factors, in the context of the main NQF endorsement criteria. The left column provides an abbreviated description of the criteria. The middle column identifies special considerations for evaluating PRO-PMS, but they are not unique to PRO-PMs. Several unique aspects about PRO-PMs are identified in the right column and may warrant some modifications to the NQF criteria to ensure they are suitable for endorsement. This section provides recommendations and rationales for modifying the NQF criteria or guidance.

Table 2. NQF Endorsement Criteria and Special Considerations Related to PRO-PMs

Abbreviated NQF Endorsement Criteria	**Special Considerations For Evaluating PRO-PMs that are relevant to other performance measures**	**Unique Considerations for Evaluating PRO-PMs**
Importance to Measure and Report a. High impact b. Opportunity for improvement c. Health outcome OR evidence-based process/structure of care		• Patient/person must be involved in identifying PROs for performance measurement (person-centered; meaningful). • Evidence supports that the PRO is responsive to intervention (actionable).
Scientific Acceptability of Measure Properties a. Reliability 1. precise specifications 2. reliability testing for either data elements or performance measure score b. Validity 1. specifications consistent with evidence 2. validity testing for either data elements or performance measure score 3. exclusions 4. risk adjustment 5. identify differences in performance 6. comparability of	• Data collection instruments/tools should be identified (e.g., specific PROM instrument, scale or single-item) • If multiple data sources (i.e., PROMs, methods, modes, languages) comparability/equivalency of performance scores should be demonstrated.	• Specifications should include standard methods, modes. 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. • Reliability and validity should be demonstrated for both the data (PROM) and the PRO-PM performance measure score. • Response rates can affect validity and should be addressed in testing. • Differences in individuals' PROM values related to PROM instruments or methods,

Abbreviated NQF Endorsement Criteria	Special Considerations For Evaluating PRO-PMs that are relevant to other performance measures	Unique Considerations for Evaluating PRO-PMs
multiple data sources		modes, and languages of administration need to be analyzed and potentially included in risk adjustment.
Feasibility a. Data generated and used in care delivery b. Electronic data c. Data collection strategy can be implemented	• The burden of data collection, including those related to use of proprietary PROMs, are minimized and do not outweigh the benefit of performance measurement.	• The burden to respondents (people providing the PROM data) should be minimized (e.g., availability/accessibility enhanced by multiple languages, methods, modes). • Infrastructure to collect PROM data and integrate into workflow.
Usability and Use a. Accountability and transparency b. Improvement c. Benefits outweigh unintended negative consequences	• Adequate demonstration of the criteria specified above supports usability and ultimately the use of PRO-PM for accountability and performance improvement.	

Evidence that the PRO is of Value to the Target Population

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.

Person-centeredness is a key principle for developing PRO-PMs. As shown in Figure 2, identifying outcomes of value to the target population is a critical early step in the pathway to endorsement of a PRO-PM. NQF's current criteria require evidence that the measured aspect of care is of value to the patient for measures of experience with care. Experience with care is considered one type of patient-reported outcome; therefore, the requirement for having evidence of the value to the patient can be expanded to apply to all patient-reported outcomes.

Evidence that the Measured PRO is Responsive to Intervention

Recommendations 3-5.
3. The NQF criterion regarding evidence should require identification of the causal pathway linking the PRO and healthcare structures, processes, interventions, or services (i.e., process –PRO).

4. NQF should apply the existing criterion and guidance regarding evidence for a process performance measure to 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 health care structures, processes, interventions, or services influences the PRO.

5. NQF should consider adopting this approach for all health outcome performance measures regardless of whether the data are self-reported by patients (or acceptable proxy respondents) or by clinicians.

Actionability was a key principle identified for developing PRO-PMs. The Expert Panel suggested that evidence that the PRO is responsive to intervention be required for NQF endorsement of a PRO-PM. This represents a departure from NQF's current NQF guidance regarding evidence for performance measures of health outcomes.

For health outcome measures, NQF requires only a rationale linking the outcome to at least one health care structure, process, intervention, or service; it does not require submitting and evaluating information on systematic reviews of the empirical body of evidence as required for other types of performance measures. NQF's position on evidence for health outcomes is based on the following reasoning:

- Health outcomes such as survival, physical or cognitive function, relief of symptoms, or prevention of morbidity are the reasons for seeking care and the goal of providing care. Therefore, these outcomes are central to measuring the performance of those rendering health care or supportive services.
- Health outcomes are often integrative. As such, they may reflect the influence of multiple clinicians and care processes and therefore are based on multiple bodies of evidence. Submitting information on multiple bodies of evidence could be burdensome and a disincentive for submitting outcome performance measures for NQF endorsement.
- Measuring health outcomes to identify variability in performance is a key driver to identifying strategies for improvement, even for outcomes previously thought to not be modifiable such as central line-associated bloodstream infections.

The current environment in which penalties may be associated with performance measure scores, has increased concern about using outcome performance measures for accountability. To mitigate that concern to some extent, the Expert Panel suggested focusing performance measurement on PROs that are meaningful to patients *and* with evidence that they are responsive to intervention. England and Sweden are leaders in the area of measuring PROs for performance measurement and appear to have taken this approach. England measures and reports performance PROMs focused on specific surgical procedures to ameliorate problems with function and symptoms-hip and knee replacement and varicose vein surgery (access reports here). Sweden measures and reports performance on PROMs related to surgical procedure outcomes and complications (access report here). Sweden also reports performance on PROMs for a few medical conditions such as function 3 months after stroke and improvement after initiation of biological drug therapy for rheumatoid arthritis.

The Expert Panel acknowledged the trade-offs to a condition-specific approach. First, it does not include much of the population receiving healthcare and supportive services. Second, even for a specific

condition, limiting performance measurement to those who received only one possible intervention (i.e., surgery) does not provide a complete picture on performance related to the condition. A related question is whether to measure the PRO with generic or condition-specific PROMs. Condition-specific PROMs may be more responsive to change. However, generic measures offer more breadth, which is relevant given that many patients have more than one condition. Using both generic and condition-specific PROMs affords the opportunity to better understand the benefits and drawbacks of both. These issues will need to be considered and revisited as we gain experience with PRO-PMs.

Specification of the PRO-PM

Recommendation 6.
NQF should require measure specifications for PRO-PMs that include 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.

Performance measures used in accountability applications must be standardized. Therefore, developers must specify them in ways to ensure consistent implementation across providers. No unlike other performance measures, specifications should identify the data collection tool – i.e., the specific PROM(s) used to obtain the data for each patient (respondent). Specifications that are unique to PRO-PMs include 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.

Reliability and Validity of Both the PROM and the PRO-PM

Recommendations 7-8.
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 must be demonstrated.

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 specifically addresses the approach to aggregating the individual PROM values.

As already noted, NQF endorses performance measures; it does not endorse instruments or scales (i.e., the PROM). However, the PROM values are the data used in the performance measure, so the psychometric soundness of the PROMs specified for use in the performance measures is crucial to the reliability and validity of the PRO-PM. The Expert Panel agreed that reliability and validity of the PROM is necessary but not sufficient to ensure reliability and validity of the PRO-PM; therefore it recommended that testing for both the PROM and the PRO-PM are needed. Approaches to reliability and validity

testing, risk adjustment, and analyses of potential threats to validity were discussed in a commissioned paper on methodological issues related to PRO-PMs. (available here)

NQF criteria currently allow for testing reliability and validity for either the critical data elements used in the performance measure or for the computed performance measure score. In the case of the PRO-PM, a critical data element is the PROM value.

PROMs have traditionally been developed for group comparisons in research rather than for decisions about individual patients or service recipients. In a research context, investigators usually assign subjects randomly to treatment and control groups; whereas patients are not randomly assigned to provider of healthcare and support services. The primary question is whether demonstrated reliability and validity of the PROM is sufficient in itself to assume reliability and validity of the performance measure. NQF can consider two approaches to deal with this issue.

1. Accept reliability and validity of the PROM in the target population as meeting NQF criteria for reliability and validity testing at the data element level as long as the additional issues related to threats to validity are tested and analyzed for the performance measure score (i.e., exclusions, risk adjustment, discriminating performance comparability if multiple PROMs are used).

2. Require reliability and validity testing of the computed performance measure score *in addition to* providing evidence of reliability and validity of the PROM in the target population. The related threats to validity must also be addressed (i.e., exclusions, risk adjustment, discriminating performance comparability if multiple PROMs are used).

The primary advantage of the first approach is that measure developers can expend fewer resources for measure testing. The primary disadvantage of the first approach is less confidence in the results of the performance measure. The advantages and disadvantages of the second approach are the opposite.

The Expert Panel agreed that the second approach is most appropriate in the context of performance measures endorsed by NQF for accountability and performance improvement. Further, the impact on resources for testing is not substantial, given the need to develop and test risk adjustment with either approach.

The data needed for the required testing and analysis related to the threats to validity (e.g., development and testing of risk adjustment and analysis of comparability if specified with multiple PROMs) could also be used to conduct reliability testing of the performance measure such as a signal-to-noise analysis. Therefore, a requirement for reliability testing of the performance measure would not present an undue burden.

Validity testing of the performance measure score would require additional data to test hypothesized relationships such as data on another performance measure or information to compare groups known to differ on quality. NQF criteria currently allow a systematic assessment of face validity of the performance measure score as an indicator of quality. Because there are a variety of ways that the individual values on the PROM could be aggregated, there could be differences in the validity of the

results for indicating quality. Ideally, empirical validity testing would be conducted. If that is not possible, then face validity should be evaluated systematically with experts, including patients reporting on the PROM other than those who created the measure.

Missing Data and Response Rates

Recommendations 9.
NQF should require analysis of missing data and response rates to demonstrate they do not bias the performance measure results

Missing data is an important consideration when using PROM data for performance measurement. This issue encompasses missing responses on a multi-item scale; missing responses from eligible patients and its impact on potential response bias; missing information due to exclusions; and using proxies in the face of missing responses. Systematic missing data affects validity. Processes must be in place to safeguard against these exclusions and biases, and more robust engagement strategies are needed over time to prevent these gaps in response rates. NQF criteria for validity currently address exclusions and missing data is often an explicit or implicit exclusion. Because missing data is likely to be more prevalent with PRO-PMs it should be addressed explicitly in measure specifications as identified above and in analysis and evaluation of the PRO-PM.

Feasibility

Recommendation 10.
NQF's feasibility criterion should consider both individuals providing PROM data (patients, service recipients, respondents) and the providers whose performance is being measured.

The general principles of feasibility for a performance measure apply to PRO-PMs. Burden of data collection usually applies to the healthcare or service provider whose performance is being measured; however, the unique issue that needs to be considered with PRO-PMs is the potential burden to the individuals who are providing the PROM data. Burdens to both individuals and the providers delivering health or support services will influence response rates, missing data, and ultimately the reliability and validity of a performance measure. Flexibility to decrease burden such as collecting PROM data through tools developed in multiple languages and applying different methods, and modes of administration is desirable.

As with all performance measures, data collection and reporting for PRO-PMs may present a variety of costs to the providers whose performance is being measured. Such costs may involve expenditures on infrastructure such as computers and programming and in some cases, the need to pay licensing or other fees for proprietary instruments or measures. A potential difference between PRO-PMs and other performance measures regarding infrastructure is that currently PROMs are not widely in use and an information technology infrastructure is less advanced than electronic health records.

When considering burdens, it is important to weigh them against benefits. Obtaining PROM data is not merely a process to collect data for performance measurement; rather the PROM is used to assess patient status or response to intervention; provide feedback for self-management; and engage patients in shared decisionmaking (as desired). The benefits of performance measurement and reporting are widely accepted. As with other performance measures, the burden of data collection does not stop performance measurement; rather, it should serve as an impetus to find more efficient ways to collect PROM data and to use resources for performance measurement on PRO-PMs that meet NQF criteria.

Usability and Use

As with any NQF-endorsed measure, an NQF-endorsed PRO-PM is intended for use in both accountability and improvement applications. The primary factors of whether a performance measure is usable are whether it is in use and is making a difference. At the time of initial NQF endorsement, of course, usability may be only theoretical. The performance measure may have a rationale and plans for use in accountability and improvement activities. On subsequent review for endorsement maintenance, however, NQF requires information on use and data on improvement. NQF also requests public comment on experiences with using the performance measure.

FUTURE DIRECTIONS

This project provided a forum for dialogue across numerous stakeholders to address difficult conceptual and methodological issues. The aim was to hasten the endorsement and ultimately the implementation of PRO-based performance measures for use in accountability programs and performance improvement initiatives. The guiding principles articulated above and the detailed pathway (Figure 2) of taking a PRO to PRO-PM are intended to steer work in the field in ways to ensure a more person-centered approach. This report begins to lay a roadmap to get us there.

Nevertheless, some pressing methods issues require further examination. The examples given here are high-priority needs to fill. First, identifying and evaluating best practices for using proxy respondents are important next steps; the goal is not to exclude from our assessments various disadvantaged populations, such as frail elders or children, who may be unable to respond to PROMs on their own. Second, PROs may be evaluated through different PROMs (tools); demonstrating the equivalency of the data from different PROMs warrants careful attention. Of particular concern is the trade-off between allowing implementers as much flexibility as possible without sacrificing validity and the ability to do meaningful comparisons. Third, viable solutions are needed to overcome barriers to calibrating multiple individual-level PROMs (i.e., “disparate” data sources) to a standard scale. Finally, some considerations will arise as use of PROMs and PRO-PMs expands and evolves. These include the advisability and utility of calculating composite endpoints or combining PRO-PMs salient to a particular domain such as health related quality of life or health related behaviors. Having such a broad picture of the outcomes reflected in the PRO-PMs strongly appeals to consumers who want a complete picture of health and well-being.

Using information technology to enable the widespread collection and use of PRO-based performance measures requires further exploration to capitalize fully on existing and future infrastructure. Technology can increase response rates by allowing individuals or their proxy respondents to provide responses from home or elsewhere via telephone, computer tablet or through web-based PRO measurement systems. Technology permits scanning of paper and pencil responses and it allows for quick scoring and giving feedback to respondents. Computers are an essential technology for real-time application of item response theory in computer adaptive testing, which allows more efficient administration of PROMs and calibration of multiple instruments to a standard scale.

Integrating PROMs into electronic health records (EHRs) can facilitate their use for patient-centered care management and also provide data for performance improvement, but implementers must take account of several factors. Data standards are needed before PROM data can be fully incorporated into EHRs. Formulating such standards requires making decisions about aspects of capturing PROM data such as the following: source of the information (e.g., self or proxy); specific PROM instrument; method and mode of data collection; PROM value or response; and dates on which information was captured and scores were computed. In addition, how PROM data might be used in clinical practice needs to be clearly specified. These features include how to best display results, and when and how alerts should appear.

Incorporating data provided by patients into the health record may increase their sense of ownership of the record; doing so may also raise demands for extracting information and for providing data. This is an opportune time to include PROMs in EHRs and leverage the resources being directed to adoption of EHRs through the Medicare EHR Incentive Program referred to as "Meaningful Use." Nevertheless, some PROMs, such as those focused on people's experience with care, may not be appropriate to include in EHRs because current tools and approaches are based on the premise of anonymity.

In closing, the path forward toward NQF endorsement of PRO-based performance measures (PRO-PMs) is promising. This project has built on many years of exemplary work in the field of patient-reported outcomes and it attempts to lay out concrete steps to advance measurement and use of such data to the forefront of accountability and performance improvement.

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APPENDICES

Appendix A—Expert Panel Roster

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Appendix B—Characteristics for Selecting PROMs

Table 4[1]. Important characteristics and best practices to evaluate and select PROs for use in performance measures[279,284]

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[354] for use in hip arthroplasty
1.	**Conceptual and Measurement Model**		
	A PRO measure should have documentation defining and describing the concept(s) included and the intended population(s) for use.	• Target PRO concept should be a high priority for the health care system and patients. Patient engagement should define what is an important concept to patients. • Target PRO concept must be actionable in response to the healthcare intervention.	• Factorial validity of the physical function and pain subscales has been inadequate.[355]
	There should be documentation of how the concept(s) are organized into a measurement model, including evidence for the dimensionality of the measure, how items relate to each measured concept, and the relationship among concepts.		
2.	**Reliability**		
	The degree to which an instrument is free from random error.		
2a.	***Internal consistency*** *(multi-item scales)*	Classical Test Theory (CTT): ▪ reliability estimate ≥ 0.70 for group-level purposes ▪ reliability estimate ≥ 0.90 for individual-level purposes Item Response Theory: • item information curves that demonstrate precision [181] • a formula can be applied to estimate CTT reliability	• Cronbach alphas for the three subscales range from 0.86 to 0.98.[356-358]
2b.	***Reproducibility*** *(stability over time)* ▪ type of test-retest estimate depends on the response scale (dichotomous, nominal ordinal, interval, ratio)		• Test-retest reliability has been adequate for the pain and physical function subscales, but less adequate for the stiffness subscale.[358]
3.	**Validity**		
	The degree to which the instrument reflects what it is	• There are a limited number of	

[1] This table is adapted from recommendations contained within a report from the Scientific Advisory Committee of the Medical Outcomes Trust and a report submitted to the PCORI Methodology Committee. The recommendations from these sources have been adapted to enhance relevance to PRO selection for performance measurement.

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[354] for use in hip arthroplasty
	supposed to measure.	PRO instruments that have been validated for performance measurement. • PRO instruments should include questions that are patient-centered.	
3a.	***Content Validity***		
	The extent to which a measure samples a representative range of the content.		
	A PRO measure should have evidence supporting its content validity, including evidence that patients and/or experts consider the content of the PRO measure relevant and comprehensive for the concept, population, and aim of the measurement application.		• Development involved expert clinician input, and survey input from patients,[359] as well as a review of existing measures.
	Documentation of qualitative and/or quantitative methods used to solicit and confirm attributes (i.e., concepts measured by the items) of the PRO relevant to the measurement application.		
	Documentation of the characteristics of participants included in the evaluation (e.g., race/ethnicity, culture, age, socio-economic status, literacy).		
	Documentation of sources from which items were derived, modified, and prioritized during the PRO measure development process.		
	Justification for the recall period for the measurement application.		
3b.	***Construct and Criterion-related Validity***		
	A PRO measure should have evidence supporting its construct validity, including: • documentation of empirical findings that support predefined hypotheses on the expected associations among measures similar or dissimilar to the measured PRO • documentation of empirical findings that support predefined hypotheses of the expected differences in scores between "known" groups		• Patient ratings of satisfaction with arthroplasty were correlated with WOMAC scores in the expected direction.[22,360,361]
	A PRO measure should have evidence that shows the extent to which scores of the instrument are related to a criterion measure.		
3c.	***Responsiveness***		
	A PRO measure for use in longitudinal initiatives should have evidence of responsiveness, including empirical evidence of changes in scores consistent with predefined hypotheses regarding changes in the target population.	• If a PRO measure has cross-sectional data that provides sufficient evidence in regard to the reliability (internal consistency), content validity, and construct validity but has no data yet on responsiveness over time (i.e., ability of a PRO	• Demonstrates adequate responsiveness and ability to detect change in response to clinical intervention.[362]

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[354] for use in hip arthroplasty
		measure to detect changes in the construct being measured over time), would you accept use of the PRO measure to provide valid data over time in a longitudinal study if no other PRO measure was available?	
		• Important to emphasize responsiveness because there is an expectation of consequences. Need to be able to demonstrate responsiveness if action is to be taken.	
		• PRO must be sensitive to detect change in response to the specific healthcare intervention	
4.	**Interpretability of Scores**		
	A PRO measure should have documentation to support interpretation of scores, including: • what low and high scores represent for the measured concept • representative mean(s) and standard deviation(s) in the reference population • guidance on the minimally important difference in scores between groups and/or over time that can be considered meaningful from the patient and/or clinical perspective	• If different PROs are used, it is important to establish a link or cross-walk between them. • Because the criteria for assessing clinically important change in individuals does not directly translate to evaluating clinically important group differences, [327] a useful strategy is to calculate the proportion of patients who experience a clinically significant change[271,327]	• Availability of population-based, age- and gender-normative values[363] • Availability of minimal clinically important improvement values[364] • Can be translated into a utility score for use in economic and accountability evaluations[365]
5.	**Burden**		
	The time, effort, and other demands on the respondent and the administrator.	• In a busy clinic setting, PRO assessment should be as brief as possible, and reporting should be done in real-time. • Patient engagement should inform what constitutes "burden."	• Short form available[366] • Average time to complete mobile phone WOMAC = 4.8 minutes[367]
6.	**Alternatives modes and methods of administration**	• The use of multiple modes and methods can be useful for diverse populations. However, there should be evidence regarding their equivalence.	• Validated mobile phone and touchscreen based platforms[368,369]

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[354] for use in hip arthroplasty
7.	**Cultural and language adaptations**	• The mode, method and question wording must yield equivalent estimates of PRO measures.	• Available in over 65 languages[370]
8.	**Electronic health records (EHR)**	Critical features: ▪ interoperability ▪ automated, real-time measurement and reporting ▪ sophisticated analytic capacities	▪ Electronic data capture may allow for integration within EHR[367]

Appendix C—Glossary

Patient-reported outcome (PRO): The concept of any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. PRO domains included in this project encompass:

- health-related quality of life including functional status;
- symptom and symptom burden;
- experience with care; and
- health-related behaviors.

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).

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

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