



# Patient Reported Outcome Measures

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This document provides information about patient-reported outcome measures (PROMs)<sup>①</sup>. These measures<sup>①</sup> have special considerations outside the more common structure<sup>①</sup>, process<sup>①</sup>, and outcome measures<sup>①</sup>. This information supplements the information found in the Blueprint, Chapter 5, Measure Specifications.

## 1 PATIENT-REPORTED OUTCOME MEASURES (PROMs)

PROMs are quality measures derived from outcomes reported by patients<sup>1</sup> and are a high priority for CMS and other organizations. PROMs present some design challenges. In this section, we describe some of these challenges and approaches to address them.

Ensuring that patients and families are engaged as partners in their care—one of the CMS priorities—can also be an effective way to measure the quality of patient care. Although patient reports of their health and experience with care are not the only outcomes that should undergo measurement, they are an important component. Historically CMS used surveys to collect patient-reported data, but the development of the infrastructure to collect these data more timely and in other ways (e.g., using mobile devices) continues. Most use and testing of tools to collect these data has been in academic settings for clinical application. [Figure 1](#) depicts the relationship between patient-reported outcomes (PROs)<sup>①</sup>, PROMs, and patient-reported outcome-based performance measures (PRO-PMs)<sup>①</sup>.

<sup>1</sup> The Blueprint uses the terms *persons* and *patients* interchangeably.

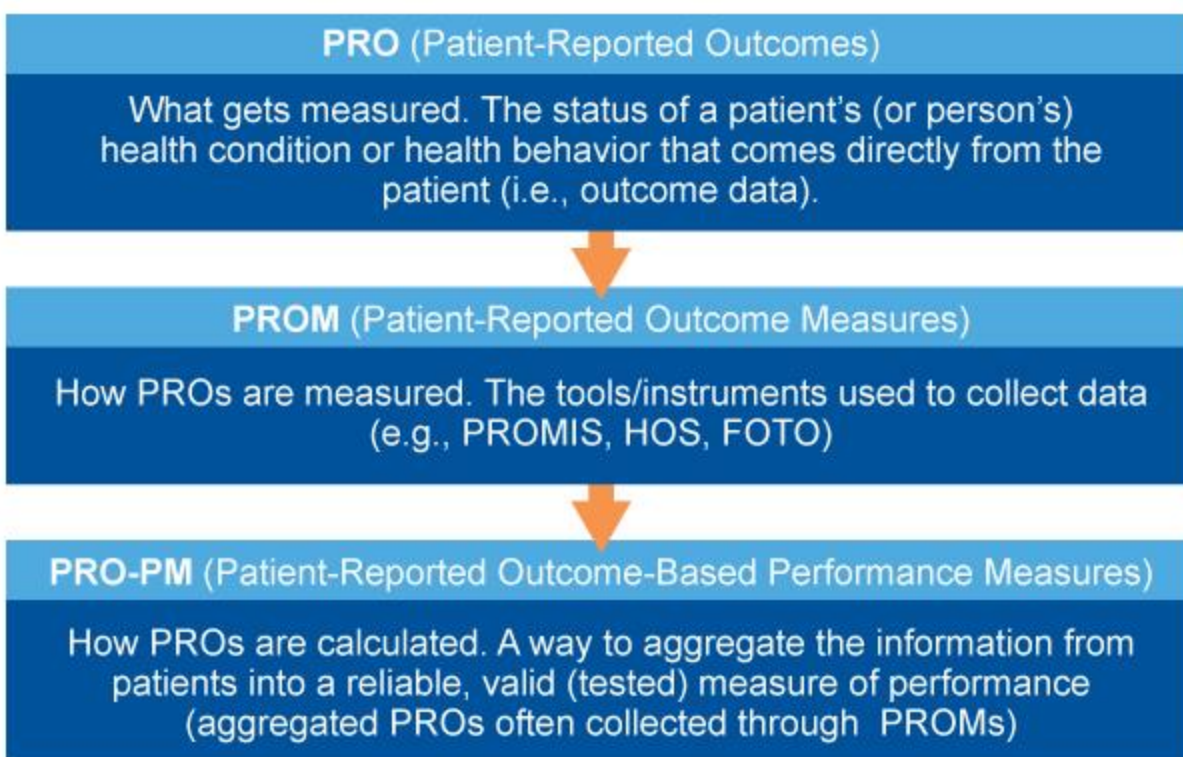


Figure 1. Relationship between PROs, PROMs, and PRO-PMs

## 1.1 PATIENT-REPORTED OUTCOMES (PROs)

CMS defines a PRO as any report of the status of a patient's health condition or health behavior that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. Self-reported patient data provide a rich [data source](#)<sup>①</sup> for outcomes. This definition reflects the key domains:<sup>2</sup>

- health-related quality of life (including functional status)
- symptoms and symptom burden (e.g., pain, fatigue)
- health behaviors (e.g., smoking, diet, exercise)

## 1.2 PATIENT-REPORTED OUTCOME MEASUREMENT (PROM) TOOLS

PROMs are tools used to collect patient-reported outcomes. Some examples of patient self-reported data collection tools include

- [Patient-Reported Outcomes Measurement Information System \(PROMIS\)](#)<sup>②</sup> —Funded by the National Institutes of Health (NIH), these tools measure patient self-reported health status.
- [Medicare Health Outcomes Survey](#)<sup>③</sup> (HOS)—The HOS was the first outcome measure used in Medicare Advantage plans. The goals of the Medicare HOS program are to gather valid and reliable health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and health improvement. All managed care plans with Medicare Advantage contracts must participate.

<sup>2</sup> Note that CMS and other HHS agencies define and use the term “domain” differently from one another. Therefore, the Blueprint defines the term “domain” differently in different contexts, depending on the relevant agency within the discussion.

- [Focus on Therapeutic Outcomes](#) (FOTO)—This tool measures the functional status of patients who received outpatient rehabilitation through the use of self-reported health status questionnaires. The FOTO tool assesses change in functional status by comparing measurements taken at intake, during, and at discharge from rehabilitation.

However, the outcomes collected by the tools are insufficient individually for measuring performance and accountability programs cannot use directly. Measure developers should construct quality measures that apply the outcome data collected by the tools to measure the quality of care.

### 1.3 PATIENT-REPORTED OUTCOME-BASED PERFORMANCE MEASURES (PRO-PMs)

A PRO-PM is a way to aggregate the information from patients into a reliable, valid measure of performance at the measured entity, level, e.g., clinician. NQF only endorses use of PRO-PMs in performance improvement and accountability. The same measure evaluation criteria and justification principles that apply to other outcome measures also apply to PRO-PMs.

Several PRO-PMs are available. Examples include

- Back Pain After Lumbar Discectomy/Laminotomy ([CMIT Reference Number 5597](#))
- Functional Status After Total Knee Replacement Surgery ([CMIT Reference Number 5876](#))

### 1.4 APPROACHES TO DEVELOPING PATIENT-REPORTED OUTCOME-BASED PERFORMANCE MEASURES

Although PROs are a special type of outcome measure, the principles for development are the same. The supplemental material, [Risk Adjustment in Quality Measurement](#), details the procedure for risk-adjusting outcome measures. NQF outlined a pathway for PROs ([Patient Reported Outcomes \(PROs\) in Performance Measurement](#)) to move from simple patient-reported data to measurement, to performance measurement, and finally to endorsed measures in use for reporting and accountability.

#### 1.4.1 Choose and Define a Patient-Reported Outcome

Patients report many kinds of data and some collected directly from patients without clinician interpretation. To choose patient-reported outcomes that will become quality measures, measure developers must first identify quality issues for a target/initial population. An appropriate outcome has clinical or policy relevance. For example, whether the patient did or did not develop a surgical site infection after cataract surgery would not be a good PRO. A patient could report redness, swelling, and drainage, but not actually whether they have an infection. A better outcome measure in this instance might be a clinically meaningful measure of improvement in vision.

Outcome quality measures must also be meaningful to the target population and usable by the accountable measured entities. Whenever possible, measure developers should consult clinical experts to help them define appropriate and meaningful outcomes.

#### 1.4.2 Determine the Appropriate Way to Collect the PRO Using a PROM (Tool)

Measure development always begins with an environmental scan and literature review to identify whether there are existing tools to collect the outcome in the target population. Measure developers may consider tools with established psychometric properties (e.g., adequate data element and tool reliability and validity). While the tools are not themselves measures, with further testing in clinical settings, measure developers may use the information from these tools to develop and test the

construct of a PROM. To help determine if the tool provides quality performance data, the measure developer should test [feasibility](#) for the relevant clinical applications.

It is important to test these tools with the population on which the measure focuses. Also note that there may be differences between the reliability and validity of a PRO tool in more controlled settings (e.g., clinical trials, academic research projects) compared to use in real-world practice settings, but testing of most PRO tools has only been in controlled settings.

### 1.4.3 Determine the Appropriate Performance Measure: the PRO-PM

The measure developer should report the outcomes for target/initial populations as average change or percentage improvement determined by the topic of interest. The measure developer must test all measures for reliability, [usability and use](#), [feasibility](#), validity, and threats to validity, including how to handle missing data and appropriate [risk adjustments](#). To appropriately distinguish variations in performance between measured entities, the outcome must capture the results of the care given and not the influence of comorbidities or other extraneous variables. However, as in any other outcome measurement, the measure developer should not allow risk adjustment to mask disparities. The supplemental material, [Risk Adjustment in Quality Measurement](#), contains a discussion on determining the need for risk adjustment and development, and evaluation of risk adjustment models.

## 2 PATIENT-REPORTED, OUTCOME (PRO)-BASED PERFORMANCE MEASURE EVALUATION

The measure developer should evaluate outcome measures, including those based on PROs, against standard criteria in the same way that measure developers evaluate all measures under development.

Some of the unique considerations (in addition to the others in each category) that apply to evaluating PRO-PMs include

- [Importance](#)—The measures must be patient-centered. Patients must be involved in identifying the PROs used for performance measurement.
- [Scientific Acceptability](#)—[Specifications](#) must include methods of administration, handling of proxy responses, response rate calculations, and how the responses affect results. The measure developer must establish reliability and validity not only for the data measurement instrument (i.e., PROM) but also for the derived performance measurement (i.e., PRO-PM).
- [Feasibility](#)—Minimize burden to respondents. Illness may complicate accessibility issues. Measure developers should consider language, literacy, and cultural issues.
- [Usability and Use](#)—Not only must patients find the results of PRO-PMs useful, but measured entities must also be able to use the information to improve quality of care.

The NQF enumerates endorsement criteria for PRO-PMs in their final report, [PROs in Performance Measurement](#).

Evaluation for PRO-PMs is a special case of overall outcome measure evaluation. In its January 2013 report, [PROs in Performance Management](#), NQF outlined criteria specific to PRO-PMs. Their overarching principle was that these measures should consider the patient foremost. Quality measures designed to capture performance on PROs should be

- Psychometrically sound—In addition to the usual validity and reliability criteria, the measure developer should consider cultural and language considerations, and patients’ burden of responding.
- Person-centered—Quality measures should reflect collaboration and shared decision-making with patients. Patients become more engaged when they can give feedback on outcomes important to them.
- Meaningful—Quality measures should capture impact on health-related quality of life, symptom burden, experience with care, and achievement of personal goals.
- Amenable to change—Outcomes of interest must be responsive to specific healthcare services or intervention.
- Implementable—Data collection directly from patients involves challenges of burden to patients, health literacy of patients, cultural competence of measured entities, and adaptation to computer-based platforms. Evaluation should address how to manage these challenges.

### 3 KEY POINTS

PROMS are quality measures derived from patient-reported outcomes and are a high priority for CMS and other organizations. These measures present some design challenges and require measure developers to construct PRO-PMs that apply patient outcome data to measure quality of care. PRO tools measure developers can use include [PROMIS](#), [\(HOS\)](#), and [FOTO](#). The same measure evaluation criteria and justification principles that apply to other outcome measures also apply to PRO-PMs. It is important that PROMs are patient-centered and produce data that measured entities can use to improve quality of care.

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