Changes in Patient-Reported Outcomes (PROs) Following Non-Emergent Percutaneous Coronary Intervention (PCI)

MEASURES

The Centers for Medicare & Medicaid Services (CMS) seeks stakeholder comments on the following electronic clinical quality measure under development:

Title

Changes in Patient-Reported Outcomes (PROs) Following Non-Emergent Percutaneous Coronary Intervention (PCI)

Description

This measure assesses the percentage of patients age 18 or older who undergo a qualifying non-emergent PCI procedure with documented improvement in self-reported functional status, health-related quality of life (HRQoL), and symptoms based on a combination of disease-specific patient-reported outcome measures (PROMs). The selected PROMs are (1) the Seattle Angina Questionnaire Short Form (SAQ-7) and (2) the Rose Dyspnea Scale (RDS).

This document provides information about the measure's rationale, intent, and history. We seek comments from the public about (1) the measure specification and (2) the specific questions outlined in the Questions section of this document.

Measure rationale

An estimated 15.5 million Americans over the age of 20 have coronary heart disease (CHD), which was the underlying cause of about 1 in 7 deaths in the United States in 2011 (Mozaffarian et al. 2015). Including the cost of health care services, medications, and lost productivity, CHD costs the United States an estimated $108.9 billion each year, a number projected to increase by up to 100 percent between 2013 and 2030 (Centers for Disease Control and Prevention 2015; Mozaffarian et al. 2015; Heidenreich et al. 2011). CHD can lead to serious, often fatal acute coronary syndromes, in addition to chronic and debilitating heart conditions such as angina or heart failure (Mozaffarian et al. 2015).

Non-emergent PCI, one of the most commonly performed cardiovascular procedures, can be used to improve the HRQoL, functional status, and angina and dyspnea symptoms of patients with CHD (Levine et al. 2011; Weintraub et al. 2008; American College of Cardiology Foundation 2015). The benefits of PCI can be measured with disease-specific, validated tools that assess changes in HRQoL, functional status, and symptom burden (Spertus et al. 2004; Chan et al. 2014; McNamara et al. 2015). These patient-reported outcome measures (PROMs) are increasingly recognized as a valuable source of information about a patient's health status and are guiding more informed discussions about the management of their care (McNamara et al. 2015). Data obtained from the SAQ-7 and RDS about patient symptoms prior to and after PCI procedures can be used to inform clinical decision making as well as to increase quality of care.

Measure intent

This measure, as specified, is intended to assess and improve quality of care of non-emergent PCI procedures with respect to patient-centered outcomes by assessing patient-reported health status (that is, symptoms, HRQoL, and functional status) before and after a non-emergent PCI procedure. This can lead to the following:

- **Better quality of care associated with the treatment.** Implementation of the measure would incentivize clinicians to identify patients for PCI who are most likely to benefit from it and to seek additional training, which could increase provider performance of the procedure.

- **Enhanced communication between providers and patients.** Clinicians and patients would work together to determine areas for improvement in functional status, symptom burden, and quality of life. Then they could use this information as a factor in their joint decision about whether or not to perform a PCI on a patient.

- **Better alignment between patient goals and treatment decisions.** PROMs such as the SAQ-7 and RDS would help providers make more informed, patient-centered treatment decisions.

- **Improved patient outcomes.** Using PROMs to assess patient health status before and after non-emergent PCI may result in more patients achieving improved quality of life, symptom reduction, and improved functional status.

In alignment with the measure intent, this measure does not assess compliance with guidance on appropriate use criteria for performing non-emergent PCI, nor do the measure specifications exclude every clinical scenario in which PCI is indicated without the expectation of symptom improvement. Our exclusions instead remove cases of acute (emergent) PCI, specifically patients with acute coronary syndromes and patients with other acute processes, as well as patients undergoing PCI in anticipation of another procedure.

Measure history

There is substantial evidence that up to 30 percent of patients who receive PCI procedures continue to experience symptoms after the procedure (Weintraub et al. 2008). This evidence, in addition to the fact that PROMs are currently underutilized in clinical practice, provided a basis for our initial development of the measure. Our measure addresses these issues by incorporating use of PROMs to help providers understand patient health status and by using these outcomes to assess changes in health status post-PCI. Feedback from (1) interviews and surveys of clinical stakeholder organizations, (2) a panel of clinical experts, and (3) a technical expert panel made up of multiple stakeholders also informed the measure.

The Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (CORE) team developed a similar hospital-level measure under contract with CMS. Under CMS direction, our team has worked closely with the CORE team to align our measures where possible, including alignment of our measure specifications, cohort exclusions, PROM tools, and outcome definition (minimally important difference approach). The CORE team conducted research as well as various discussions with expert stakeholders and patients to define the aforementioned criteria, which our team incorporated into our measure. It should be noted

that although the measures are aligned, they are intended for use in different settings and are aggregated at different levels (i.e., our measure is calculated at the eligible clinician level and could include procedures taking place in hospitals as well as ambulatory surgical centers).

Next steps for measure development

After feedback is collected through the public comment period, we intend to review this information with a team of clinical experts to determine if revisions to the measure specification are necessary. At a later time, we intend to test the feasibility and reliability of the measure and explore and test the possibility and need for risk adjustment.

Questions

We are seeking feedback on all components of the proposed measure (for example, choice of denominator exclusions) as well as the following specific questions:

1. The measure's numerator includes patients who show an improvement of at least the MID for one of the two disease-specific PROMs: 5 points in the summary score for the short SAQ-7 or 1 point in the RDS. The SAQ-7 is derived from the full-length SAQ. Although it only contains 7 items compared to the full-length version's 19 items, it has comparable psychometric properties. The full-length SAQ has limited routine use in clinical practice because of its length.

   a. We seek comments on the importance of using these disease-specific PROMs (that is, the SAQ-7 and the RDS) to select patients in the numerator of this measure.

   b. If a site uses the long form of the SAQ when the measure specifies use of the SAQ-7, should the site be allowed to report this measure using the relevant portions of the SAQ or should the site be excluded from the measure?

   c. Is there any other feedback on the RDS or the SAQ-7 that we should be aware of when considering numerator inclusion?

2. The draft measure currently attributes measure performance to the interventional cardiologist (that is, the clinician performing the PCI). Often times, there may be another cardiologist who meets with patients and refers them to an interventional cardiologist to receive a PCI.

   a. We seek feedback about whether the measure attribution should be for the interventional cardiologist or the referring cardiologist.

3. As part of next steps in measure development, we plan to explore and test possible risk adjustment for body mass index (BMI), left ventricular ejection fraction (LVEF), glomerular filtration rate (GFR), age, and other patient characteristics.

   a. We seek feedback on our existing list of variables, as well as other suggested patient characteristics that should be considered for risk adjustment.

4. In some cases patients will have missing PROM data, due to not receiving a baseline or follow-up assessment from their provider, declining to complete or not completing a baseline or follow-up assessment or receiving a baseline or follow-up assessment from a different provider. Excluding patients with missing post-PCI assessments could result in

clinicians improving their score by administering the pre- and post-PCI PROM only to patients who responded well to the procedure.

    a. We seek feedback for handling patient data in the event that PROM pre- or post-PCI scores are missing. Should we exclude patients with a missing baseline or follow-up PROM score?

5.   To address concerns about missing data, we have considered dividing the measure into two measures: (1) one that assesses the percentage of patients who have received a pre- and post-PCI PROM assessment and (2) one that evaluates the percentage of patients from the first population who have experienced improvement in self-reported functional status, HRQoL, and symptoms.

    a. We seek feedback about whether this proposed measure revision seems feasible.

In addition to the questions above, we welcome your feedback on the following topics:

- The usefulness of the measure to assess and improve the quality of care for patients

- The feasibility of the measure to assess provider performance and any unintended consequences of implementing the measure

- Whether data elements related to this measure are available in structured, extractable fields in electronic health record systems

- Whether there are any additional exclusions that should be included in this measure

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