Public Comment Summary Report

Project Title:

Hospital- Level Patient-Reported Outcome-Based Performance Measure for Patients Undergoing Non-Emergent Percutaneous Coronary Intervention

Dates:

The Call for Public Comment ran from July 18, 2016 to August 17, 2016.
The Public Comment Summary was made on September 2, 2016.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) to develop a patient-reported outcome-based performance measure (PRO-PM) for patients undergoing non-emergent percutaneous coronary intervention (PCI). The contract name is Development, Reevaluation, and Implementation of Hospital Outcomes/Efficiency Measures. The contract number is HHSM-500-2013-13018I, Task Order HHSM-500-T0001. As part of its measure development process, CMS requests interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

The primary goal of this project is to develop a patient-reported outcome-based performance measure to assess hospital-level performance. The overarching purpose of the project is to develop a measure that can be used to enhance the quality of care provided to patients with ischemic heart disease undergoing PCI.

Information About the Comments Received:

Public comments were solicited by email notifications to CMS listserv groups, email notification to measure stakeholders including the Technical Expert Panel (TEP), Clinical Working Group, Patient Working Group, and web post on the CMS Public Comment website. Three responses were received on the measure from one hospital association, one individual cardiologist, and one not-for-profit purchaser organization.

Preliminary Recommendations

CMS appreciates the comments received for the PCI PRO-PM and will take all comments into consideration during measure reevaluation and the implementation process. CMS will continue to evaluate and refine the specifications of this measure, particularly risk adjustment, prior to implementation in a public reporting program.

Stakeholder Comments - General and Measure-Specific

Summary of general comments

- Two commenters were supportive of the measure.
    - One commenter praised the measure, stating the measure is very well designed and a valuable effort to advance the use of PRO-PMs.
    - The second commenter also provided support for the development of a PRO-PM, as PRO-PMs advance new opportunities for patient engagement and performance improvement. In addition, the commenter expressed support for focusing on PCI, noting that it is an important area for quality assessment.
- One commenter supported assessment of the impact of hospital care on patient outcomes, but questioned the need for a hospital-level PRO-PM for PCI patients.
- One commenter indicated the proposed measure is a good starting point for a PRO-PM, but recommended focusing on patient populations by diagnosis (such as the proportion of post myocardial infarction [MI] patients with significant angina) rather than by procedure.

Response:
Thank you for your comments and recommendations. CMS appreciates the support for the development of PRO-PMs and agrees that they represent a priority area for quality measurement. In response to the suggestion to focus measurement on populations defined by diagnosis instead of procedure, CMS believes that focusing on PCI patients represents a promising and appropriate initial step for incorporating PROs into quality measurement. CMS will take the suggestion to expand the portfolio of PRO-PMs to include additional patient populations under consideration.

Summary of specific comments – Measure Specifications

Cohort

- One commenter expressed concern that hospitals which primarily refer patients with severe angina for PCI will perform better on the measure than hospitals which refer patients with less severe angina for PCI.
- One commenter provided support for the current exclusion criteria, which remove patients who under PCI for acute processes and patients who undergo PCI in anticipation of another procedure (such as transcatheter aortic valve replacement [TAVR]). The commenter

emphasized that the current lists are not all inclusive, and suggested additional exclusion criteria be considered, and pointed to mitral interventions as an example.

Response:
In regards to the measure cohort, CMS appreciates the concern regarding hospitals performing better on the measure if they primarily refer patients for PCI only if they have severe angina. CMS believes that this unintended consequence is unlikely to occur given that the measure outcome is defined as the proportion of patients at a hospital who achieved a Minimally Important Difference (MID) in their symptoms following the PCI. Using a MID approach, the measure will not reflect differences in the magnitude of symptom improvement but instead reflect whether or not patients experienced a clinically meaningful improvement. As such, a patient with less severe angina at baseline who improves (for example, a patient with a baseline Seattle Angina Questionnaire Short Form [SAQ-7] summary score of 95 who scores a 100 on follow up) will count the same as a patient with severe angina at baseline who has no symptoms at follow up (for example, a patient with a baseline SAQ-7 summary score of 40 who scores a 100 on follow up). Nevertheless, CMS acknowledges the need to monitor this potential unintended consequence in the future.

In regards to the comment to expand the exclusion criteria for acute processes or procedures in which PCI is an adjunct to, the current measure cohort definition reflects the input of clinical experts, patients, and a Technical Expert Panel, consisting of a diverse group of stakeholders. CMS will continue to reevaluate the measure specifications on an annual basis and will update or alter the measure as indicated by changes in clinical practice. For example, it is our understanding that patients undergoing percutaneous mitral interventions do not routinely undergo PCI prior to their valve procedure, but CMS will explore additional exclusions in the future.

Patient-reported outcome measure (PROM) Selection

- One commenter supported the inclusion of a generic health status survey in addition to the disease-specific surveys since both day-to-day functioning related to cardiac status and overall health are important to patients.
- One commenter supported the choice of the SAQ-7, citing patient preference for shorter instruments which can result in greater response rates.
- One commenter expressed concern over the ability of the selected instruments to yield usable information, as well as the ability of some patients to accurately report their symptoms.

Response:
Thank you for your comments and recommendations. CMS carefully considered a number of patient-reported outcome measures (PROMs) for use in the measure outcome. The SAQ-7 and Rose Dyspnea Scale (RDS) were chosen based on their 1) excellent psychometric properties, including strong reliability and validity, 2) minimal burden to patients and providers, 3) acceptability among our Technical Expert Panel, Clinical Working Group, Patient Working Group, and 4) consistency with recommendations from key stakeholder organizations (including the International Consortium of

Health Outcomes Measures , Oxford Patient-Reported Outcome Measurement Group, and the United States Department of Veterans Affairs Patient Reported Health Status Assessment system). As supported by our literature review and environmental scan, these instruments are the best available PROMs to capture relevant symptoms and represent the most suitable instruments for the measure. CMS acknowledges that the selected PROMs may not capture all possible clinical manifestations of ischemic heart disease, but notes that this is a limitation of all PROMs.

CMS will continue to consider the inclusion of a generic health status PROM in the measure outcome in addition to the disease-specific PROMs in future iterations of the measure. Currently no appropriate data source has been identified by which a generic health status PROM can be tested in the target patient population. This represents a significant barrier for incorporating a generic health status PROM in the first iteration of the measure.

Outcome

- Two commenters provided feedback on using the MID approach to define the measure outcome.
    - One commenter felt the MID approach is appropriate for the measure outcome, but noted that the process of selecting a MID should be supported by strong science and not based solely on expert consensus.
    - The other cautioned against selecting an overly conservative MID, as there is variation in the outcomes of PCI and this variation should be reflected in the PROM results.

Response:
Thank you for your comments and recommendations. CMS did not select the MID on the basis of expert consensus alone. Rather, CMS conducted a rigorous evaluation that included a review of the literature, empiric testing of available data, and consultation with patients who had undergone PCI. Nevertheless, CMS will revisit the definition of the MIDs in measure reevaluation. This may include incorporation of an anchor question in future pilot testing to evaluate the specified MIDs further.

Risk adjustment

- Two commenters provided feedback on risk adjustment.
    - One commenter encouraged consideration of additional sociodemographic variables.
    - The other specifically noted that gender, vascular status, left ventricular function, diabetes, and history of prior stroke should be included in the risk-adjustment model, and stated that efforts should be made to define socioeconomic and disadvantaged populations.

Response:
Thank you for your comments and recommendations. CMS acknowledges that surveillance of disparities by key sociodemographic variables is important. During measure development, analyses

of available data (which included sociodemographic variables including age, gender, race, education, and insurance status) did not provide evidence that the proposed measure is likely to disadvantage vulnerable populations. Nevertheless, CMS will continue to evaluate the need to incorporate sociodemographic variables into the risk model in the future. CMS notes that all of the variables identified by the commenter were either included in the preliminary risk model (left ventricular function) or considered as candidate variables (gender, peripheral vascular disease, diabetes, and a history of cerebrovascular disease).

Summary of specific comments – Feasibility and Additional Testing

- Two commenters provided general support for a large-scale pilot test prior to implementation.
    - One commenter noted that a pilot test should be completed prior to implementation of the measure in incentive programs for hospitals and clinicians.
- One commenter noted that any pilot test should be representative of hospitals that would be included in the measure.
- One commenter noted that left ventricular ejection fraction (LVEF) values are challenging to collect and the feasibility of systematically collecting this variable for use in the measure must be further examined.

Response:
Thank you for your comments and recommendations. As noted in the Draft Measure Methodology Report, CMS is considering options for additional pilot testing of the measure prior to broader implementation. Such an effort could provide the opportunity for additional assessments of measure feasibility, reliability, and validity. If CMS conducts pilot testing, it will, to the extent possible, include a representative sample of hospitals and patients. Regarding the concern raised about collecting LVEF, CMS notes that there is evidence that LVEF values are feasible to collect. For example, abstraction of LVEF data from electronic health records (EHRs) has been shown to be highly accurate when compared to manual review[1].

- One commenter noted that additional feasibility, reliability, and validity assessments must be completed on the measure as a whole as well as the risk adjustment model specifically.

Reponses:
Thank you for your comment and recommendation. In regards to the comment on additional testing of the feasibility, reliability, and validity, CMS agrees with the need to reevaluate the measure in the future and will continue to evaluate the risk-adjustment model.

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[1] David W. Baker, MD, MPH; Stephen D. Persell, MD, MPH; Jason A. Thompson, BA; Neilesh S. Soman, MD, MBA; Karen M. Burgner, MD; David Liss, BA; and Karen S. Kmetik, PhD. Automated Review of Electronic Health Records to Assess Quality of Care for Outpatients with Heart Failure. *Ann Intern Med*. 2007;146(4):270-277.

Summary of specific comments – Implementation: Future Reporting

- One commenter urged the development of a physician-level measure as physicians play a central role in the quality of care for PCI patients. Clinician-level performance information can support quality improvement as well as public reporting and value-based purchasing programs.

Response:
Thank you for your comment and recommendation. CMS acknowledges that physicians play an important role in the quality of care and may consider a physician-level measure in this area.

- One commenter believed that the measure developer did not provide evidence to demonstrate that the care provided by a hospital following PCI directly impacts a patient's functional status and quality of life.

Response:
Thank you for your comment. All hospital-level quality measurement assumes that the care provided by a hospital directly impacts a patient's function status and quality of life. For the measure under consideration, hospitals are directly responsible for many critical aspects of PCI care that would be expected to impact patient outcomes following PCI including: case selection, procedural appropriateness, procedural success, adverse outcomes, discharge medications, and discharge processes.

- One commenter recommended a process measure that evolves into an outcome measure, such that the measure outcome could first assess the proportion of patients with coronary artery disease (CAD) undergoing non-emergent PCI who complete pre- and post-procedure PROMs. As compliance to collecting PROMs increases over time, the measure outcome could evolve to assess improvement rates and also account for missing data.

Response:
CMS will take the suggestion to implement a phased approach under consideration, including first reporting a process measure which incentivizes collection of PROMs in this population and then evolves to reporting of the outcome measure described in this public comment.

- One commenter urged CMS ensure uniformity of medical management across physicians and institutions during the 28-60 day follow-up time frame and standardization of collecting PROMs at the prescribed times.

Response:
Thank you for your comment. CMS appreciates the concern raised by this comment. However, ensuring the uniformity of medical management is beyond the scope of this measure. Nevertheless, CMS believes that hospital variation in a variety of areas, such as choice of discharge medications, timing of follow-up appointments, and utilization of cardiac rehabilitation may contribute to meaningful differences in risk-standardized improvement rates across PCI hospitals. As such, CMS anticipates that the PCI PRO-PM will lead to improved and more consistent care for patients

undergoing these procedures. With regards to the 28-60 day time frame for follow up, this time period was selected to provide clinicians and hospitals with a reasonable amount of flexibility to minimize the impact of PROM collection on clinical practice. There are data to support that this time frame is appropriate and will not impact hospital performance on the measure.

Summary of specific comments – Hospital Burden

- One commenter felt it is important to avoid duplication of efforts in data collection and burden related to reaching the minimum response rates needed to ensure the measure is reliable and valid at the hospital level.

Response:
Thank you for your comment. CMS will work to ensure that the collection of PROM results will have a minimal burden on clinicians. In addition, CMS will continue to test the minimum sample sizes required for the scientific acceptability of the measure during pilot testing.

Summary of specific comments – Unintended Consequences

- One commenter pointed out that a potential unintended consequence of the measure could be that hospitals avoid attempting high-risk PCI procedures where success is less likely.

Response:
Thank you for your comments. CMS appreciates the concern raised by the commenter and will monitor for evidence of case avoidance as part of measure reevaluation and surveillance.

- One commenter described potential sources of bias that might impact measure results, including hospitals making judgments on whether patients will likely self-report, or hospitals failing to administer the follow up PROM specifically among patients whose symptom status had worsened. Additionally, the commenter noted that the severity of pre-procedure symptoms could influence the degree of change achieved between baseline and follow up.

Response:
Thank you for your comments. CMS appreciates the concern about potential sources of bias. In regards to the potential for incomplete follow up, CMS will monitor the proportion of patients with missing information by hospitals and any impact it has on measure performance.

Overall Analysis of the Comments and Recommendations

We appreciate the thoughtfulness of the comments provided. The majority of general comments about the measure were supportive of PRO-PMs in general, and the focus of the proposed measure on the non-emergent PCI population. The majority of concerns were focused on the measure specifications including expanding the exclusion criteria, reevaluating the MID definitions, and reassessing the risk model. There was also strong support for conducting a pilot study to further

test the measure and refine the specifications prior to implementation. CMS and the measure developer are actively investigating options for conducting additional testing prior to implementation to address many of the concerns raised in this public comment period.

Table 1. Summary of Verbatim Public Comments for PCI PRO-PM

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization Commenters	Email Address	Type of Organization	Recommendations/ Actions Taken
8/17/16	PCI PRO-PM	The Federation of American Hospitals (FAH) appreciates the opportunity to submit comments on the draft CMS Hospital-level Patient-reported Outcome-based Performance Measure for Patients Undergoing Non-Emergency Percutaneous Coronary Intervention (PCI). FAH supports the need to assess the impact of hospital care on patient outcomes but questions the need for a hospital-level patient-reported outcome (PRO) measure for this procedure. The FAH is concerned that the materials available for review provided little to no evidence to demonstrate that the care provided by a hospital following PCI directly impacted a patient's functional status and quality of life. Rather, most of the literature cited discussed the appropriateness of the procedure and the skill of the surgeon, which are indirect correlations to the hospital's quality of care and a patient's PRO. Focusing on those measures for which there is clear, demonstrated link between the care provided by a hospital and the PRO would ensure that hospital resources and quality improvement efforts are targeted to those patients and procedures that are within the hospital's control. The FAH does not believe this link was made for this measure focus. Regarding the measure specifications, further work is needed to ensure that the minimally important	Jayne Chambers, Senior Vice President of Quality, Federation of American Hospitals	jchambers@fah.org	Hospital Association	See pages 2-8

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization Commenters	Email Address	Type of Organization	Recommendations/ Actions Taken
		difference (MID) is based on strong science and not expert consensus as it is currently specified. Until this MID is examined further and there is strong evidence to support the definitions proposed, the measure should not be used for accountability purposes. The FAH also notes that additional feasibility, reliability and validity assessments must be completed on the measure as a whole and more specifically on the risk adjustment model. Additional sociodemographic variables must be tested beyond the preliminary ones used in the PRISM project. The initial analyses also show that left ventricular ejection fraction (LVEF) values were significantly identified with patient improvements; yet, this data element continues to remain challenging to collect. The feasibility of collecting this variable must be further examined and solutions proposed prior to widespread implementation of this measure. The FAH strongly supports the recommendation that a large pilot study be implemented as the next step to determine feasibility of data collection and implementation. This pilot study should be representative of the hospitals that would be considered eligible for the measure. Additional emphasis should be placed on the ability to collect the data without requiring duplication of effort by the surgeon and the minimum response rates needed to ensure that the measure is reliable and valid at the				

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization Commenters	Email Address	Type of Organization	Recommendations/ Actions Taken
		hospital level.				
8/17/16	PCI PRO-PM	Thank you for the opportunity to provide comments on the Patient-Reported Outcome Performance Measure for Patients Undergoing Non-Emergent Percutaneous Coronary Intervention (PCI). The Pacific Business Group on Health (PBGH) is a non-profit organization that leverages the strength of its 65 members—who collectively spend $40 billion a year purchasing health care services for more than 10 million Americans—to drive improvements in quality and affordability across the U.S. health system. Patient-reported outcomes (PROs) can be used to determine if patients benefit from treatment in ways that matter to them, to providers and to society: improved functioning, reduced pain, and improved quality of life. When regularly used to assess quality, PRO performance measures advance new opportunities for patient engagement and performance improvement. We commend CMS and Yale for advancing development of these important outcome measures. The prevalence and cost of PCI and variation in results clearly establishes this as an important area for quality assessment. Notably, a primary purpose of the procedure is to reduce symptoms that impact quality of life and functional status (e.g., angina frequency and exercise capacity), which makes it ripe for PRO-	David Lansky, PhD President and CEO Pacific Business Group on Health	sglier@pbgh.org	Non-profit hospital member group	See pages 2-8

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization Commenters	Email Address	Type of Organization	Recommendations/ Actions Taken
		based measurement in particular. In general, we are supportive of the measure currently under development. For example, we support using the SAQ-7, a newer, shorter version of the SAQ which has been in use for over a decade. Patients often prefer more concise instruments and the subsequent greater response rate can better inform quality improvement and accountability functions. We also support pairing a generic health status survey with a disease-specific survey. Both day-to-day functioning and overall health status are important to patients. However, we caution against being too conservative in the selection of the minimally important difference. As noted in the TEP report, there is variation in the outcomes of PCI and this variation should be reflected in the PROM results. In addition to the measure as currently proposed, we strongly urge the development of a physician-level measure as well. Physicians play a central role in the quality of care for PCI patients and clinician-level performance information can support feedback for quality improvement as well as value-based purchasing and public reporting functions. PBGH has been a strong advocate for meaningful and actionable measures of patient-reported outcomes. This measure addresses an important gap area and appropriately uses patient-generated information to assess the outcomes of care that matter most to patients. Thank you again for the opportunity to				

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		provide feedback to the TEP on this important issue. We look forward to continuing to engage public and private purchasers in the CORE's activities. Please contact me should you require any additional information or clarification.				
8/17/16	PCI PRO-PM	Thank you for the opportunity to comment. These comments are my own, but based on conversations with measures and quality experts in cardiology, as I chair the Science and Quality Committee of the American College of Cardiology, giving me opportunity to interact with leaders in this field. The following comments are in reference to: Hospital-Level Patient-Reported Outcome-Based Performance Measure for Patients Undergoing non-Emergent Percutaneous Coronary Intervention The draft measure is very well thought-out and designed, and represents a valuable effort to advance the use of PRO-PM's. After careful review of the measure, the following suggestions for the measure developers are intended to provide additional insights as the measure is finalized: • It may be prudent to first pilot the measure before general use, especially in programs that involve major financial incentives to hospitals and clinicians. The developers may want to initially consider	Richard J. Kovacs M.D. FACC	rikovacs@iu.edu	Individual	See pages 2-8

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization Commenters	Email Address	Type of Organization	Recommendations/ Actions Taken
		measuring the proportion of patients with CAD undergoing elective PCI who completed pre- and post-procedure SAQs. Once compliance has increased, the measure can be modified to then include examining the improvement score as well as accounting for missing data. The developers should also account for the possibility that health systems that waited for patients to have severe angina before referring to PCI would have a much better PCI response than health systems that allowed moderate angina patients to have PCI. • In all, it would be much better to use PROs for patient populations by diagnosis (e.g. fraction of post MI patients with significant angina), than to focus on procedures. However, the proposed measure is a good starting point. • In terms of risk adjustment, additional variables should be considered including patient sex, vascular status, LV function, diabetes, and history of prior stroke. Efforts should be made to define socioeconomic and disadvantaged populations. • Scoring: The two methods may not yield useable information and it may be important to have retrospective examination data for patients that were "poor" self-reporters. • Potential Biases:				

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		○ Selection: Hospitals will be making a judgement about whether patients will likely self-report. ○ Ascertainment Bias: Patients whose angina worsened may not complete the second SAQ measurement, for example. This is a threat to validity. ○ The severity of pre-procedure patient reported symptoms may influence the degree of patient reported outcome. • In terms of the 28-60-day PROM collection timing, assurances should be made to ensure uniformity of medical management across physicians and institutions, as well as standardization of the chosen instrument(s) at the prescribed times. Related is that some may receive cardiac rehab, while others may not. • While table D-5 provides the most common scenarios where there are confounding clinical problems, it should not be viewed as definitive and all-inclusive, and language to that effect might be reassuring. For example, while TAVR might be the most important other intervention that may currently be encountered, advances in mitral interventions might warrant adding mitral to the list in a few years. • An unintended consequence of the measure may be to withhold treatment from people without a good understanding of their heart				

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		disease and with other confusing symptoms (e.g., other causes of dyspnea or chest pain - i.e., might report no change in chest pain out of confusion as to which of symptoms reflected ischemia). This may also reduce the likelihood of tackling complex lesions for which positive outcome is less predictable even if pain is refractory and surgery not an option (unless the developers intended for this). Thank you for the opportunity to provide feedback into the development of this performance measure.				