# Summary of Technical Expert Panel (TEP) Evaluation of Measure: Patient-Reported Outcome Performance Measure for Patients Undergoing Non-Emergent Percutaneous Coronary Intervention

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**Prepared by:**
Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

This material was prepared by CORE under contracts to the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.

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## Background

The Centers for Medicare & Medicaid Services (CMS) contracted Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) to develop quality measures that use patient outcomes to assess the quality of patient care. Specifically, CORE is developing a patient-reported outcome performance measure (PRO-PM) for patients undergoing non-emergent percutaneous coronary intervention (PCI).

CORE is obtaining expert and stakeholder input on the proposed measure. The CORE measure development team meets regularly and is comprised of experts in interventional cardiology, quality outcomes measurement, and measure development. Additionally, CORE has convened a technical expert panel (TEP) of clinicians, patient advocates, experts in patient-reported outcome measures (PROMs) and quality improvement, and a purchaser representative to provide input on key methodological decisions.

This report summarizes the feedback and recommendations provided by the TEP at the first meeting regarding the proposed measure. Preliminary technical specifications of the measure will be finalized by the end of September 2015. Measure development will continue past September 2015.

## Measure Development Team

Dr. Jeptha Curtis is leading the CORE measure development team. Dr. Curtis is a practicing interventional cardiologist, Director of the American College of Cardiology Analytic Center at CORE, and an Associate Professor in the Section of Cardiovascular Medicine at the Yale University School of Medicine with experience in outcomes research and measure development. The remainder of the CORE internal measure development team provide a range of expertise in outcome measure development, PROMs, health services research, clinical medicine, statistics and measurement methodology. See Appendix A for the full list of members of the CORE development team.

## Cardiology and Patient-Reported Outcome Measure Consultants

CORE has convened individuals with expertise relevant to interventional cardiology, PROMs, and quality measurement to serve as members of the measure work group. See Appendix A for the list of CORE's cardiovascular and PROM consultants. These individuals provide feedback on the proposed approach to measure development and guide key decisions.

## The TEP

In alignment with the CMS Measures Management System (MMS), CORE under the guidance of CMS held a 30-day public call for nominations and convened a TEP for the development of the PRO-PM for patients undergoing non-emergent PCI. CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team and

stakeholder groups, email blasts sent to CMS physician and hospital email listservs, and through a posting on CMS's website.

The role of the TEP is to provide feedback on key methodological and clinical decisions made in consultation with CORE. The TEP is comprised of individuals with diverse perspectives and backgrounds and includes clinicians, patient advocates, experts in quality improvement, and a purchaser representative. The appointment term for the TEP is from May 2015 through September 2015, with the potential to extend beyond September 2015.

## Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP Nomination Form, statement of interest, and curriculum vitae
- Review background materials provided by CORE prior to each TEP meeting
- Participate in TEP conference calls
- Provide input on key clinical and methodological decisions
- Provide feedback to CORE on key policy or other non-technical issues
- Review the TEP summary report prior to public release
- Be available to discuss recommendations following submission of the measures to CMS

# TEP Members

| Name | Organization (Title) | Location |
|---|---|---|
| Meenu Arora, BHMS, MBA | Sequoia Hospital (Quality Improvement Leader) | Redwood City, CA |
| Susan Campbell, MPH | WomenHeart: The National Coalition for Women with Heart Disease (Vice President of Public Policy) | Washington, DC |
| David Cella, PhD | Northwestern University Feinberg School of Medicine (Professor and Chair, Department of Medical Social Sciences) | Chicago, IL |
| Gregory Dehmer, MD | Baylor Scott & White Health (Medical Director, Cardiovascular Services; Director, Division of Cardiology) | Temple, TX |
| Rachel Grob, MA, PhD | Center for Patient Partnerships, University of Wisconsin-Madison (Director of National Initiatives) | Madison, WI |
| Jennifer Eames Huff, MPH | Pacific Business Group on Health (Director of Consumer-Purchaser Alliance) | San Francisco, CA |
| Hani Jneid, MD | Baylor College of Medicine (Assistant Professor of Medicine; Director of Interventional Cardiology Research); Michael E. DeBakey VA Medical Center (Director of Interventional Cardiology) | Houston, TX |
| Richard Josephson, MS, MD | Case Western Reserve University School of Medicine (Professor of Medicine); University Hospitals Case Medical Center (Director of Cardiac Intensive Care Unit; Director of Cardiovascular and Pulmonary Rehabilitation) | Cleveland, OH |
| Frederick Masoudi, MD, MSPH | University of Colorado Denver Anschutz Medical Campus (Professor of Medicine, Cardiology) | Aurora, CO |
| Debra McQuillen, RN, MAS | Scripps Health (Assistant Vice President, Cardiovascular Care Line) | San Diego, CA |
| Collette Pitzen, RN, BSN, CPHQ | Minnesota Community Measurement (MNCM) (Clinical Measure Developer) | Minneapolis, MN |

# TEP Meetings

CORE held one TEP meeting in May 2015 and anticipates holding one to two additional meetings between June and September 2015 (see Appendix B for TEP meeting schedule). This summary report contains a summary of the May 2015 meeting only.

TEP meetings follow a structured format consisting of the presentation of key issues identified during measure development as well as CORE's proposed approaches to addressing the issues, followed by an open discussion of these issues by the TEP members.

During the first TEP meeting, CORE solicited feedback from the TEP about the measure concept, proposed measure cohort, and selection of which PRO instrument(s) would be most appropriate for use in a hospital-level performance measure. TEP members provided considerable input on the preliminary cohort definition and feedback on PRO instrument selection and raised various measure development considerations. Specifically, the TEP made the following recommendations:

- Feedback on PCI PRO-PM Measure Concept:
    - TEP members generally supported the proposed measure concept: a PRO-PM for patients undergoing non-emergent PCI.
    - Two TEP members recommended that CORE consider the impact of patient characteristics, such as gender, race, and literacy, on PROM results
    - One TEP member recommended that CORE consider developing a PCI PRO-PM that could be applied to not only hospitals but also clinicians.
- Feedback on PCI PRO-PM Measure Cohort:
    - TEP members generally supported the preliminary measure cohort to focus on patients with stable coronary artery disease and exclude patients with ST-segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI), and unstable angina.
    - TEP members generally supported the recommendation to consider expanding the cohort to include additional patient populations in future iterations of the measure.
    - One TEP member recommended to either exclude or otherwise account for PCI procedures performed in conjunction with other major cardiovascular procedures, such as hybrid revascularization, percutaneous valve implantation, or organ transplantation.
- Feedback on PRO Instrument Selection:
    - One TEP member recommended the CORE team investigate the relationship between mental health and perception of quality life and its impact on the changes in health status following PCI.
    - One TEP member recommended that endorsing a generic instrument applicable to a variety of disease conditions and procedures that would allow comparisons across different conditions/procedures.
    - A TEP member shared challenges experienced while working with the European Quality of Life 5-Dimensional Classification EQ-5D instrument.

## Public Comment

The measure will undergo a public comment period after September 2015. After the close of the public comment period CORE will gain TEP member input on the comments and CORE's responses.

## Conclusion

TEP feedback was instrumental in refining CORE's approach to measure development. Table 1 describes the key issues discussed during the TEP meetings and the TEP responses. The TEP continues to provide clinical and methodological expertise as CORE continues to develop the measure.

# Key Issues and Feedback Discussed During First TEP Meeting

**Table 1: Overview of Key Issues and Feedback**

| Topic | Key Issues Discussed | TEP Feedback/Discussion |
|---|---|---|
| Project Overview | CORE reviewed the proposed measure concept and its importance. CORE is developing a PRO-PM for patients undergoing non-emergent PCI that can be used to assess hospital-level performance measurement. The overarching purpose of the project is to develop a measure that can be used to enhance the quality of care provided to patients. CORE presented its decision to focus on a change in PROM score pre- and post-PCI. | TEP members supported the proposed measure concept.<br><br>One TEP member inquired whether the measure could meaningfully differentiate between changes in PROs related and unrelated to the PCI procedure without a control group of patients who did not undergo PCI. CORE responded that a reasonable long-term goal is to incorporate PRO measurement into efforts to assess population health including patients with stable coronary artery disease treated with medical therapy, PCI, or coronary artery bypass grafting. This measure is a reasonable first step that will capture important information about outcomes following PCI and promote the inclusion of PROs into routine care.<br><br>A TEP member inquired whether the proposed measure would adjust for the confounding influence of other procedures, such as transcatheter aortic valve replacement (TAVR) or other therapies, such as medical therapy or cardiac rehabilitation. CORE replied that inclusion and exclusion criteria for measure will be designed to identify and remove patients for whom PCI is incidental to, rather than the main effector of, their outcomes (e.g. TAVR, organ transplantation). However, the goal of the measure is to assess the overall quality of care provided to patients undergoing PCI, including the intensity of medical therapy and referral to cardiac rehabilitation.<br><br>Two TEP members recommended that CORE consider the impact of patient characteristics, such as gender and literacy, on PROM results. CORE agreed and noted that these issues can |

| Topic | Key Issues Discussed | TEP Feedback/Discussion |
|---|---|---|
| | | be assessed once pilot data is available and testing occurs.<br><br>A TEP member recommended that CORE consider clinician-level PRO measurement, which might facilitate quality improvement. Another TEP member shared their experience reporting a PRO-PM measure at the practice-level to avoid technical challenges posed by small sample sizes per clinician. CORE agreed that there would likely be challenges to measuring at the clinical level because of small sample size. Nevertheless, CORE explained that although many of the measures CORE has developed for CMS in the past are specified at the hospital level, these measures have been adopted and modified by other organizations to allow for reporting at the clinician level.<br><br>**Summary: TEP members were supportive of the project goal. TEP members raised important considerations for future analysis of PRO-PM results.** |
| Preliminary Measure Cohort | CORE reviewed the preliminary measure cohort and its rationale. CORE explained the advantages to narrowly focusing the cohort on elective PCI patients with stable coronary artery disease (CAD). CORE reviewed the preliminary recommendation to exclude emergency, non-elective procedures performed on patients with ST-segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI), and unstable angina patients. | TEP members supported the preliminary measure cohort as described.<br><br>TEP members agreed to exclude STEMI patients since the systematic collection of pre-procedural PROMs would not be feasible given that these procedures are frequently performed on an emergent basis.<br><br>TEP members agreed to exclude NSTEMI patients since the benefits of PCI in this population extend beyond symptom relief. Additionally, CORE explained that since some NSTEMI patients undergo PCIs on an emergent basis, this population would have challenges associated with the routine collection of pre-procedural PROMs.<br><br>The majority of TEP members recommended excluding unstable angina patients from the measure cohort. However TEP members |

| Topic | Key Issues Discussed | TEP Feedback/Discussion |
|---|---|---|
| | | expressed support for future efforts to either expand the cohort to include unstable angina or develop a complementary measure including patients with unstable angina.<br><br>**Summary: TEP members generally agreed with the preliminary measure cohort definition. The majority of TEP members recommended including PCI patients with stable CAD in the measure cohort. TEP members recommended excluding STEMI, NSTEMI, and unstable angina patients from the cohort. TEP members agreed that the measure cohort could be expanded to include additional patient populations (e.g. unstable angina) in future iterations.** |
| PRO Instrument Selection | CORE presented a summary of evidence for candidate PRO instruments that included both generic and disease-specific instruments (Appendix C). The summary included information on psychometric properties, burden, and the proprietary nature of the instruments.<br><br>CORE sought feedback from the TEP on whether to endorse a generic, disease-specific, or combination of generic and disease-specific instruments for a PRO-PM.<br><br>CORE will share with the TEP information regarding the impact of the use of proprietary instruments for a PRO-PM in subsequent meetings. | A TEP member recommended CORE investigate the relationship between mental health and perception of quality of life in PCI patients and its potential impact on the measure's outcome. CORE noted the recommendation and stated that they will explore this further when pilot data becomes available.<br><br>A TEP member asked if rough estimates are available for the costs of instruments per patient or for a site license. CORE noted that they are attempting to gather this information, but that the pathway to obtain permission to use proprietary instruments has yet to be finalized. In general, CORE stated that a goal of measure development is to minimize patient and provider burden.<br><br>A TEP member asked if data on the responsiveness of candidate instruments in other cardiovascular conditions or treatments will be a consideration. CORE responded that this would be reasonable, but that the primary consideration should be whether an instrument would be appropriate for the measure currently under development. |

| Topic | Key Issues Discussed | TEP Feedback/Discussion |
|---|---|---|
| | | A TEP member recommended that a single instrument applicable to a variety of disease conditions or procedures allow for future measure PRO-PM development of other conditions and future comparisons across different conditions/procedures.<br><br>A TEP member clarified that the PROMIS-Global instrument can be administered as a computer-adaptive test (CAT), but suggested that it be used as a static instrument for this effort.<br><br>A TEP member shared some of the challenges they had experienced working with the EQ-5D tool.<br><br>**Summary: TEP members did not come to consensus on PRO instrument selection, but raised important considerations. CORE will distribute a survey to TEP members to obtain additional feedback on candidate PRO instruments and assist in PROM selection. The survey results and decisions regarding PROM selection will be reviewed during the next TEP call.** |

# Appendix A. CORE Measure Development Team

**CORE Members**

| Name | Title/Affiliation | Contact Information |
|---|---|---|
| Harlan Krumholz, MD, SM | Director, CORE | harlan.krumholz@yale.edu |
| Susannah Bernheim, MD, MHS | Director of Quality Measurement Programs; Clinical Investigator, CORE | susannah.bernheim@yale.edu |
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| Stefanie Rohde, BA | Research Assistant, CORE | stefanie.rohde@yale.edu |
| Rana Searfoss, BA | Project Coordinator, CORE | rana.searfoss@yale.edu |
| Lisa Gale Suter, MD | Associate Director of Quality Measurement Program; Management Lead, CORE | lisa.suter@yale.edu |
| Yongfei Wang, MS, MS | Supporting Analyst, CORE | yongfei.wang@yale.edu |
| Rachelle Zribi, BA | Research Assistant, CORE | rachelle.zribi@yale.edu |

**Cardiovascular and PROM Consultants**

| Name | Title/Affiliation |
|---|---|
| Steven Bradley, MD, MPH | Staff Cardiologist, VA Eastern Colorado Health Care System; Assistant Professor, Department of Medicine (Cardiology), University of Colorado School of Medicine |
| Ralph Brindis, MD, MPH, MACC | Clinical Professor of Medicine, University of California, San Francisco; Senior Medical Officer, External Affairs, ACC National Cardiovascular Data Registry |
| John Dinkler, MD, MPH | Doctoral Candidate, University of California, Los Angeles Fielding School of Public Health |

# Appendix B. TEP Call Schedule

**TEP Meeting #1**
Monday, May 4, 2015 – 5:00-6:30pm ET (Location: Webinar)

**TEP Meeting #2**
TBA, Anticipated July 2015

**TEP Meeting #3**
TBA, Anticipated August 2015

# Appendix C. Candidate PRO Instruments

**PRO Instruments Under Consideration**

| Instrument Type | Instrument Name |
|---|---|
| Generic | European Quality of Life 5-Dimensional Classification (EQ-5D) |
| | Patient-Reported Outcomes Measurement Information System- Global (PROMIS-Global) |
| | Short Form Health Survey with 12 items (SF-12)/ Veterans RAND 12-Item Health Survey (VR-12) |
| Disease-Specific | Coronary Revascularization Outcome Questionnaire (CROQ) |
| | HeartQol Questionnaire (HeartQoL) |
| | MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew) |
| | Rose Dyspnea Scale (RDS) |
| | Seattle Angina Questionnaire (SAQ) |
| | Seattle Angina Questionnaire-7 (SAQ-7) |