Summary of Technical Expert Panel (TEP) Meeting
August 26, 2020
Clinician-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM)

November 11, 2020

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

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The materials within this document do not represent final measure specifications for the Clinician-level THA/TKA PRO-PM.

Background

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 quality measures of hospital and clinician performance. Under this contract, CORE is developing a Clinician-level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM). The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 1. The contract number is HHSM-75FCMC18D0042, Task Order Number HHSM-75FCMC19F0001.

CORE is obtaining expert and stakeholder input on the proposed measure. The CORE Measure Development Team is comprised of experts in quality outcomes measurement and measure development. As is standard with all measure development processes, CORE has convened a technical expert panel (TEP) of clinicians, patient advocates, and other stakeholders. Collectively, the TEP members brought expertise in performance measurement, quality improvement, and orthopedics, specifically THA and TKA procedures.

This report summarizes the feedback and recommendations received from the TEP during the first meeting, which focused on the measure concept, the proposed measure development approach, and preliminary measure specifications.

Measure Development Team

Rachelle Zribi, BA leads the Measure Development Team. Ms. Zribi is a Research Project Coordinator II for the Quality Measurement Team at CORE and has supported several novel Measure Development teams including PRO-PMs. The remainder of the Measure Development Team provide a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See Appendix A for the full list of members for the CORE Measure Development Team.

The TEP

In alignment with the CMS Measures Management System (MMS), CORE held a 30-day public call for nominations and convened a TEP for the development and reevaluation of orthopedic measures, including the development of the Clinician-level THA/TKA PRO-PM. 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 TEP is composed of 20 members, listed in Table 1.

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions. The appointment term for the TEP is from January 2020 to March 2021.

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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
- Attend and actively participate in TEP conference calls
- Provide input on key clinical, methodological, and other decisions
- Provide feedback on key policy or other non-technical issues
- Review the TEP summary report prior to public release
- Be available to discuss recommendations and perspectives following TEP meetings and public release of the TEP Summary Report to CMS

Table 1. TEP Member Name, Affiliation, and Location

Name	Title, Organization	Location
David C. Ayers, MD	Professor of Orthopaedics, UMass Medical School	Worcester, MA
Thomas C. Barber, MD	Associate Deputy Physician in Chief, Memorial Sloan Kettering Hospital	New York, NY
Phyllis Bass	Patient Expert	Cypress, TX
Vinod Dasa, MD	Associate Professor, Louisiana State University Health Science Center	New Orleans, LA
Rachel DuPre Brodie	Senior Director, Measurement & Accountability, Pacific Business Group on Health (PBGH)	San Francisco, CA
Cheryl Fahlman, PhD, MBA, BSP	President, CAF Consulting Solutions	Washington, DC
William G. Hamilton, MD	Clinical Instructor and Chair of the Quality Measures Committee, Anderson Orthopaedic Clinic and American Association of Hip and Knee Surgeons	Alexandria, VA
Cynthia S. Jacelon, PhD, RN-BC, CRRN, FAAN	Professor, UMass Amherst School of Nursing; Association of Rehabilitation Nurses	Greenfield, MA
Craig T. Miller, PT	Director of Home Care Therapy and Senior PT, Rivetus Rehabilitation	Macomb, MI

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Name	Title, Organization	Location
Michael H. Perskin, MD	Associate Chair of Clinical Affairs and Assistant Professor in the Department of Medicine, American Geriatrics Society and New York University School of Medicine	New York, NY
Benita Lattimore	Patient Expert	Chicago, IL
Patricia Walker	Patient Expert	South Holland, IL
Nan Rothrock, PhD	Associate Professor of Medical Social Sciences, Feinberg School of Medicine at Northwestern University	Chicago, IL
Jonathan L. Schaffer, MD, MBA	Managing Director, eCleveland Clinic Information Technology Division, The Cleveland Clinic Foundation	Cleveland, OH
Adam Schwartz, MD, MBA	Consultant of the Department of Orthopedic Surgery, Associate Professor of Orthopaedic Surgery, Mayo Clinic; American Academy of Orthopaedic Surgeons	Phoenix, AZ
Robert Sterling, MD	Orthopaedic Surgeon, Associate Professor of Orthopaedic Surgery, Association of Hip and Knee Surgeons, Johns Hopkins University	Baltimore, MD
Margaret A. VanAmringe, MHS	Vice President, Public Policy and Government Relations, The Joint Commission	Washington, DC
Christine Von Raesfeld	Patient Expert	Santa Clara, CA
Kevin Woodward, PA-C, MMS	Physician Assistant of Orthopaedic Surgery, American Academy of Physician Assistants, John Hopkins University	Baltimore, MD
Adolph J. Yates, MD	Chief of Orthopaedics, Vice Chairman of the Quality Department of Orthopedic	Pittsburgh, PA

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Name	Title, Organization	Location
	Surgery, American Association of Hip and Knee Surgeons, Associate Professor, University of Pittsburgh	

TEP Meetings

CORE held its first TEP meeting in August 2020, a meeting at which both the Clinician-level THA/TKA PRO-PM and EPM THA/TKA Complication Measure were presented. The Clinician-level THA/TKA PRO-PM team anticipates holding one to two additional TEP meetings between September 2020 and March 2021 (see Appendix B for the TEP meeting schedule). This summary report contains a summary of the August 2020 TEP meeting.

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.

First TEP Meeting Overview

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the measure background and proposed approach to measure re-specification for the Clinician-level THA/TKA PRO-PM and the EPM THA/TKA Complication Measure. One TEP member shared several measure specification questions and provided input prior to the meeting. For further details, please see Appendix C.

During the first TEP meeting, CORE solicited feedback from the TEP on the measure concept and proposed approach to measure re-specification. CORE educated the TEP on the background and approach to developing the EPM THA/TKA Complication Measure and the Clinician-level THA/TKA PRO-PM Measure. Information on how the EPM THA/TKA Complication Measure and the Clinician-level THA/TKA PRO-PM align with the existing Hospital-level THA/TKA Complication Measure and the Hospital-level THA/TKA PRO-PM, respectively, was also provided. The TEP was invited to provide input on the measure concepts and approaches to each re-specification.

Following the meeting, TEP members unable to join the TEP teleconference were given recordings and detailed meeting minutes.

The following bullets represent a **high-level summary** of what was presented and discussed relevant for the Clinician-level THA/TKA PRO-PM during the first TEP meeting. For further details, please see Appendix D. (Please note that the high-level summary of the presentation and discussion of the EPM THA/TKA Complication Measure is presented in a separate TEP Summary Report.)

Measure Background and Approach to Re-specification

- CORE Presentation of a Measure Overview to the TEP
    - CMS contracted CORE to re-specify the existing hospital-level THA/TKA PRO-PM as a clinician or clinician group measure for the Quality Payment Program (QPP).
    - Ms. Zribi reviewed the project background, the existing hospital-level THA/TKA PRO-PM specifications, the approach to measure re-specification, and future topics the team will raise with the TEP.
    - For measure re-specification, CORE will use data from the development of the hospital-level THA/TKA PRO-PM (submitted through CMMI's Comprehensive Care for Joint Replacement [CJR] voluntary data collection), and will solicit input from the TEP, the Orthopedic Clinical Working Group, the Patient Working Group, and via a public comment period.
- TEP Feedback:
    - Several TEP members noted challenges to implementation and response rates. One TEP member noted the challenge of implementing the Clinician-level and Hospital-level THA/TKA PRO-PMs without national data collection and submission pathways. Several TEP members noted challenges of obtaining high response rates at follow up. One member specifically identified that small or rural hospitals with resource limitations may be specifically challenged.
    - Two TEP members advocated for incentivizing providers. One TEP member suggested that CMS should provide larger financial incentives to support the capacity to build the data infrastructure and develop clinical workflows for PROM data collection.
        - CORE agreed that patient-level data collection, such as PROs, are dependent on hospital and clinician resources. CORE noted that the TEP can help CMS learn from the institutions capturing PROM data as well.
    - Two TEP members noted the importance of considering measuring PROMs in other care settings, such as ambulatory surgical centers (ASCs) and hospital outpatient departments (HOPDs), as procedures are commonly performed outside of the inpatient setting. One TEP member noted the need to measure differences in outcomes based on inpatient and outpatient status. One TEP member noted a need for the orthopedic outcome measures, including the PRO-PM, to ensure harmonization of the measure cohorts across measurement of ASC, HOPD, and inpatient settings.
        - CORE acknowledged the performance of procedures in multiple settings and noted that considerations of including multiple settings will require measurement considerations, specifically differences in patient severity per setting. More understanding must be gained before a decision is made.
    - TEP members commented on post-operative follow-up. One TEP member questioned whether response rates would be higher if the timeframe for post-operative data collection was 6-9 months after the procedure instead of 9-12 months. Another TEP member suggested expanding the timeframe two months

before and after the 12-month post-operative data collection deadline for patients who cannot come in exactly at one year for follow-up.
        - CORE noted that the 9- to 12-month post-operative timeframe was chosen because clinicians wanted to allow enough time for adequate recovery. CORE has heard from some physicians requesting that this data collection window expand beyond 12 months to broaden data capture.
- Summary
    - TEP members generally supported the measure developers' approach to re-specification while providing critical points for developers to consider regarding implementation and response rates, expansion of the post-operative PROM data collection timeframe, and measuring outcomes in outpatient settings. Several TEP members raised concern about the burden of measure implementation and challenges in achieving high response rates.

Further comments from a TEP member about concerns with socioeconomic risk factor analysis, measure implementation, and additional measure specifications are contained in a detailed summary of the pre-TEP meeting email provided in Appendix C.

Next Steps

Ongoing Measure Development

CORE will continue to encourage further feedback and questions from TEP members via email until the next TEP meeting. Additionally, CORE will continue to engage stakeholders in a Clinical Working Group and a Patient Working Group to solicit feedback on measure specifications.

Conclusion

TEP feedback of CORE's approach to measure development will inform the development of measure specifications. CORE will continue to engage and seek input from the TEP as the measure is developed.

Appendix A. CORE Measure Development Team

Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Role
Rachelle Zribi, BA	Project Lead
Kerry McDowell, MS, MPhil	Project Manager
Fior Rodriguez, BS	Project Coordinator
Sheng Zhou, MD, ScM	Lead Analyst
Kyaw (Joe) Sint, PhD, MPH	Supporting Analyst
Miriam Katz, MPH	Research Support
Shani Legore, BA	Person and Family Engagement Communication Specialist
Darinka Djordjevic, PhD	Oversight Manager
Kathleen Balestracci, PhD, MSW	Oversight Director
Zhenqiu Lin, PhD	Director, Data Management and Analytics
Lisa Suter, MD, PhD	Contract Director, Quality Measurement Program

Appendix B. TEP Call Schedule

TEP Meeting #1

Wednesday, August 26, 2020 – 5:00-7:00PM EST (Zoom Teleconference)

TEP Meeting #2

TBD

Appendix C. Summary of Questions received Prior to TEP Meeting #1

TEP members received detailed meeting materials prior to the first TEP meeting. Provided below are questions submitted via email from a TEP member, as well as the responses provided by CORE, prior to the first TEP meeting on August 26, 2020.

1. Data continues to demonstrate that socioeconomic status (SES) risk factors are important. There is a potential for SES driven discrepancies as to which patients undergo procedures in outpatient versus inpatient status. Has this been analyzed?

   Social risk is a very important issue for quality measures, especially for measures that evaluate patients undergoing elective procedures such as THA and TKA. There are many potential approaches for addressing social risk in value-based payment programs, including risk adjustment of the quality metrics and stratification of either the quality metrics and/or payments. The Assistant Secretary for Planning and Evaluation (ASPE) has recently released guidance on this topic and CMS has prioritized reducing disparities in its measurement programs. For example, the Hospital Readmission Reduction Program (HRRP) now applies payment incentives within groups of hospitals categorized by their proportion of dually Medicare and Medicaid eligible patients. Dual eligibility is a potent marker of social risk and this approach ensures that hospitals with more complicated patients, such as dual eligible patients, are not financially penalized because their patients are more socially and economically disadvantaged. We will investigate the impact of social risk in detail when we talk about risk adjustment and look forward to the TEP's input on how best to ensure the quality measures do not result in negative consequences such as reduced access to care or worsening disparities. While CORE does not make decisions on how CMS implements these quality measures, all of the TEP's input is shared with CMS and will inform CMS' future implementation planning.
2. The PROM-PM data was collected at a hospital level with incentivization through the CJR. Is the data as reported by the hospital to be used for the surgeons?

   The development and testing data for the surgeon-level PRO-PM will use the data collected through CJR. These data were readily available for testing and no national surgeon-level dataset containing PRO data is currently available. Future implementation plans have not been finalized by CMS.
3. Will this be a voluntary Merit-based Incentive Payment System (MIPS) measure? If it is not voluntary, what are the minimum collection rates? How does the measure protect against selective reporting?

   These are all very important questions. CMS is funding the surgeon-level PRO-PM work through money allocated for the QPP, suggesting their intention is to eventually implement it in QPP. However, no specific implementation plans have been shared with CORE for either the hospital-level or surgeon-level PRO-PMs. The TEP's input on this will be critical to CMS' planning. Other measures that involved novel data collection, such as the hybrid hospital-wide readmission

measure that combines clinical vital sign and laboratory data with administrative claims data, are being implemented gradually, starting with voluntary submission and measurement.

4. Why is the PROM-PM not being applied to the hospitals (or is it)? The data captured to provide the testing of this measure was through hospital incentivization, not surgeon.

   As noted above, there are no specific plans for either measure yet – and no plans to hold hospitals in CJR accountable for their measure results. The proposed CJR model extension has extended the PRO data collection but has not added any plans to implement the PRO-PM in the model.

5. When was the final version of the PROM-PM presented to the TEP before undergoing National Quality Forum (NQF) endorsement? Is it to be applied at the hospital level? Has that rule proposal been submitted?

   As noted above, there are no specific plans for either measure yet – the final measure specifications for the Hospital-level THA/TKA PRO-PM measure was shared with the TEP on January 29, 2020. That measure passed the Scientific Methods Panel and NQF Committee and is now in an NQF Public Comment period.

6. There is an economy of scale in terms of capturing the PROMs. The collection of these through incentivization to the hospitals through the CJR relies on the application of collection efforts that are beyond a single surgeon or group. The surgeons being required to capture these will face variable resources depending on the size of the group and or hospital employment. Any consideration to this factor?

   This input is important for CMS to hear as they consider implementation planning for PRO-PMs.

7. Will either of these measures be used for surgeon specific NPI's (National Provider Identification) versus group TINs (Taxpayer Identification Number)? The latter spread risk variably depending on size. If it is going to rely on TINs, how does the measure work in very large multispecialty groups numbering in the thousands?

   In general, the surgeon-level measures can be reported at the level of the individual clinician (a unique TIN-NPI combination) or at the level of the clinician group (a unique TIN). This means that very large multispecialty groups could have results reported for the THA/TKA complication measure if they perform enough THA/TKA procedures. In such cases, the group receives a measure result, even if it only represents the care provided by a subset of their clinicians.

Appendix D. Detailed Summary of TEP Meeting #1

Orthopedic Technical Expert Panel (TEP) Meeting #1 Minutes

Wednesday, August 26, 2020 5:00-7:00 PM ET

Participants

- Technical Expert Panel (TEP): Phyllis Bass, Vinod Dasa, Rachel Dupre Brodie, Cheryl Fahlman, William Hamilton, Cynthia S. Jacelon, Benita Lattimore, Craig Miller, Michael H. Perskin, Christine Von Raesfeld, Adam Schwartz, Robert Sterling, Margaret A. Vanamringe, Patricia Walker, Kevin Woodward, Adolph J. Yates
- Yale New Haven Health Services Corporation- Centers for Outcomes Research and Evaluation (CORE): Andrea Barbo, Kathleen Balestracci, Susannah Bernheim, Jacquelin Grady, Andreina Jimenez, Miriam Katz, Shani Legore, Yixin Li, Fior Rodriguez, Lisa Suter, Kyaw Sint, Lori Wallace, Sheng Zhou, Rachelle Zribi
- Expert Clinical Consultant: Kevin Bozic

Executive Summary

- The purpose of the first TEP meeting was to educate the TEP on the background and approach to developing the EPM THA/TKA Complication Measure and Clinician-level THA/TKA PRO-PM. The TEP was invited to provide input on the measure concepts and approaches to re-specifications.
- The TEP shared several considerations for both measures.
    - EPM THA/TKA Complication Measure:
        - TEP members noted concern that the measure does not include claims for procedures performed in ambulatory surgery centers (ASCs). TEP members discussed the EPM THA/TKA Complication Measure outcome and provided recommendations for complications that should be considered in the measure outcome.
    - Clinician-Level THA/TKA PRO-PM Measure:
        - Measure Implementation: TEP members noted the importance of a national data collection and submission mechanism for the measure to be successful. TEP members noted the importance of incentivizing adoption of collecting PROs and recommended a phased approach to allow practices of all sizes/locations, including small, rural, or low resources practices, to build the capacity to collect and submit PROMs.
        - Data Collection Timeframe: TEP members recommended consideration of allowing for a longer post-operative follow up timeframe.
        - Clinical Settings: TEP Members noted that the measure should consider procedures performed in ASCs and HOPDs.

TEP Action Items:

- TEP members were invited to email cmsorthopedicmeasures@yale.edu with any additional comments and suggestions. Members were asked to review and comment on the meeting summary.

CORE Action Items:

- Immediate next steps: The development team will continue measure development and testing activities, with consideration of specific issues raised by the TEP.
- The team will convene the next TEP meeting by webinar, mostly likely in the Fall or Winter of 2020.

Detailed Discussion Summary

Welcome

- Ms. Andreina Jimenez welcomed the group on behalf of CORE. She reminded the group that the purpose of bringing together the TEP is for the development and re-evaluation of two orthopedic measures. She noted that the minutes and summary report will be distributed following the meeting.
- Ms. Jimenez reviewed the meeting agenda and reminded the group that the content of TEP discussions must remain confidential until made public by the Center for Medicare & Medicaid Services (CMS) and that all personal opinions and experiences, including personal health information, shared during TEP meetings are to remain confidential. Ms. Jimenez stated that TEP members represent themselves and not the organizations with which they are affiliated. She noted that the work is funded by CMS and that CMS, the Center for Medicare & Medicaid Innovation (CMMI), or Quality Payment Program (QPP) members may sit in on these calls.
- Ms. Jimenez provided a brief description of CORE and its measure development work.

Introductions

- Ms. Jimenez introduced the EPM THA/TKA Complication Measure team members.
- Ms. Fior Rodriguez introduced the QPP THA/TKA PRO-PM team members.
- Dr. Lisa Suter provided an introduction and thanked members of the TEP for joining the call. The purpose of this meeting is to provide foundational information about the two measures what CORE will re-specify. CORE's goal is to create a partnership with the TEP over time with the aim of engaging this TEP with many different measures. Some questions TEP members have regarding these measures may be out of scope for today, for example social risk and implementation questions, but these could be pertinent in future conversations. There may not be full consensus on the topics discussed, but CORE is eager to ensure all voices are heard and all perspectives are respected. CMS reviews the summary report and posts it publicly following these meetings for maximum transparency.

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- TEP members briefly introduced themselves and described their key interests or experiences related to these measures. Members disclosed any potential conflict of interest (COI).
- Dr. Kevin Bozic, a member of the clinical workgroup and consultant working with CORE for 12 years in performance measure initiatives development, introduced himself.

Review and Approval of the TEP Charter

- Ms. Rodriguez facilitated the review and approval of the TEP charter. Members agreed there were no concerns and the charter was unanimously ratified and approved.

Measure Background: Current Orthopedic Measures

- Ms. Rodriguez presented the current orthopedic measures. She noted where the orthopedic measures fit into the reporting and payment programs.
- Ms. Rodriguez reiterated the focus of the discussion would be the Clinician-level Total Hip Arthroplasty/Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-based Performance Measure (PRO-PM) and the 90-Day Risk-Standardized Complication Measure Following Elective THA and/or TKA for a Potential Combined Inpatient and Outpatient EPM.
- Ms. Rodriguez noted the EPM 90-day THA/TKA Complication Measure is focused on hospital performance and tied to hospital payment. The measure specifications are based on the existing Hospital-level THA/TKA Complication Measure. The QPP THA/TKA PRO-PM is focused on clinician and clinician groups using patient-reported outcome data. The QPP program is tied to clinician payment and the measure specifications are based on the existing hospital-level THA/TKA PRO-PM.

Measure Overview: EPM 90-day THA/TKA Complication

- Dr. Lori Wallace, the project lead, welcomed the group and indicated she would be providing a high-level overview of the EPM 90-day THA/TKA Complication Measure. She noted that this will be referred to as the EPM measure, and that the presentation would review the existing measure, provide the timeline for measure development, and list potential topics and questions for future discussion.
- Dr. Wallace noted that the purpose of the measure is a re-specification of the existing inpatient hip/ knee replacement measure for a combined inpatient and outpatient CMMI Episode Payment Model (EPM). CMMI supports innovative payment models. The rationale for expanding the measure is an increase in TKA procedures in the outpatient setting, indicating that this setting should be assessed in order to accurately capture the quality of care. The existing Hospital-level THA/TKA Complications Measure will be referred to interchangeably as the inpatient or hospital measure.
- The purpose of the original measure was to identify the medical and surgical complications that could be attributable to the care provided during and after an elective total hip or total knee arthroplasty procedure. The outcome is a dichotomous yes or no assessment of whether a complication occurred during an index admission for

the elective procedure or if a complication occurred during a readmission within the specified time for that complication.

- Dr. Wallace described the components of the measures, focusing on those areas that require refinement. The cohort setting, the patients included in measure, is being expanded in the new measure to include patients with procedures performed in outpatient departments. The cohort definition, the patients eligible to be included in the measure, will remain the same in both measures. These patients are Medicare beneficiaries age 65 and older who have had a qualifying elective primary THA/TKA during index admissions. This excludes fracture, bony metastases or partial or revision THA/TKA procedures. Patients must be enrolled in Medicare fee-for-service (FFS) Part A during the index admission and enrolled in Parts A and B for 12 months prior to the admission date.
- Dr. Wallace described the expansion of the new measure to include complications that occur during the index procedures in the hospital or outpatient departments as well as complications that occur during emergency department visits and observation stays. The current codes to identify complications are ICD-10 CM, PCS and Present on Admission (POA) codes. The new measure will expand the type of procedure codes to include the CPT and HCPCS codes used in outpatient billing. POA is not used in outpatient claims.
- Dr. Wallace described the outcome definition for those conditions that are included in the complication outcome. These are the same for both the current and new measures. Clinically significant outcomes are those attributed to the THA or TKA procedure and identifiable using claims data. These complication outcomes were clinically vetted during the development and reevaluation of the original hospital measure, which has been in use by CMS since 2013. In order to identify if a complication occurred during the procedure, there are two overarching questions which are as follows:
    - Did the condition or event occur?
    - Did it occur within the specified timeframe?
- The algorithm for both measures indicates it is considered a complication if any of the following occur:
    - An acute myocardial infarction (AMI), pneumonia or other acute respiratory complication, sepsis or shock occur during the index admission or subsequent inpatient admission within 7 days from the start of the index admission;
    - A pulmonary embolism, surgical site bleeding or other surgical site complication, or death occurs during the index admission or subsequent inpatient admission within 30 days from the start of the index admission;
    - A mechanical complication, periprosthetic joint infection or wound infection occurs during the index admission or subsequent admission within 90 days from the start of the index admission.
- The EPM measure is also considering observation and emergency department visits as potential settings.
- Dr. Wallace walked through the timeline for this measure and noted that many activities will happen concurrently. The schedule begins with this first TEP meeting. In the fall,

winter, and into the spring of 2021, measure testing will be conducted, which involves running statistical analyses to test measure validity. CORE will continue with stakeholder engagement in the fall of 2020. CORE will hold meetings with the TEP and the Clinical Working Group at various points throughout measure development, which would extend through the winter of 2021. CORE aims to finalize this measure and obtain public comment feedback by the spring or winter of 2022.

- Dr. Wallace presented future topics and anticipated questions for the group. CORE will seek to confirm that outpatient THA/TKA procedures were adequately captured. CORE will request TEP members to review and provide feedback on complications captured during emergency room visits and observation stays. A consideration for the group is how to accurately identify complications in the outpatient setting in the absence of POA coding. CORE asks that the TEP members help define the measure outcome algorithm for both the inpatient and outpatient setting.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member asked why the measure did not include cases from freestanding ambulatory surgical centers (ASCs). With many surgeries now being performed in that setting, a fair number of cases would be missed.
        - Dr. Wallace noted that the CMS quality measures are aligned with payment programs and models. ASCs have their own payment programs. CORE can ask CMMI if they have plans to include ASCs in future models.
    - A TEP member asked why POA codes were removed in the outpatient setting.
        - Dr. Wallace indicated she was unsure of the history of POA codes being included in the outpatient realm or captured in outpatient claims.
        - Dr. Suter noted that CPT codes do not contain modifiers that allow providers to indicate present issues the same way inpatient codes do. This is likely due to the extended period of an inpatient encounter where any onset issue is more critical. She recommended reviewing the document circulated earlier by email in response to questions by a TEP member. When the first complication measure for hospitals was developed, POA codes existed but were not being used. CORE worked with clinicians to create an algorithm to identify potential complications of care. For example, when a pneumonia code is present during the index admission where the procedure was performed with no history of pneumonia in the previous 12 months, this was attributed to complication of care as opposed to a risk-adjustment. For this measure, it is not a prolonged encounter and the procedure is performed on relatively healthy people. Coding for issues such as a heart attack, diabetes or pneumonia in an outpatient setting for an outpatient elective procedure reflects the health history of a patient. TEP members should keep this approach in mind to accurately capture the patient's clinical history. Although it is frustrating not to have granularity in the codes, it is something to work around.

- A TEP member inquired about the existence of a master document to see the granularity of the definitions of the complications, noting these definitions vary even amongst hospitals.
    - Dr. Wallace responded that CORE can share the original methodology reports and specification and update reports, which provide some information.
    - Dr. Suter added that CORE can provide more detail. CORE has well-documented ICD 10 codes for complications in the inpatient setting. She noted that the role of the TEP is to ensure that the translation of this measure to the outpatient setting is valid. The goal is to create measures that ultimately incentivize improvement. CORE does not want to create a measure that incentivizes poor behavior or negatively affects clinical practice. There will be areas of tradeoff. These are high stakes measures that are likely to be implemented in a future payment model. The team will discuss the tradeoffs and CORE will gather member feedback for what feels most appropriate to minimize harm.
- A TEP member asked about the volume of inpatient versus outpatient procedures and if the intent for reporting on measures is to separate those that occur in these two settings.
    - Dr. Wallace replied that the group will address this in more detail in future meetings and offline. The discussion may circle back to this later in the call if time permits.
- A TEP member asked whether surgical site infections count as complications under this outcome definition.
    - Dr. Wallace confirmed that these are included under the periprosthetic joint infection and wound infection definition and would require both a diagnosis and prognosis code.

Measure Overview: QPP THA/TKA PRO-PM

- Ms. Rachelle Zribi, the project lead for this measure, presented the overview of this measure.
- CMS contracted CORE to re-specify the existing Hospital-level THA/TKA PRO-PM as a clinician or clinician group measure for the Quality Payment Program (QPP). CORE will adapt the current hospital-level measure to be applicable to clinician and clinician groups. This is CORE's third re-specification project aimed at re-adapting hospital-level measures to be applicable to clinicians and clinician groups.
- The QPP was created in 2015 and transformed the Medicare clinician payment system from fee-for-service (FFS) to Pay for Performance. Participants receive an overall score that includes quality measures such as process measures, outcome measures, and experience measures.
- Ms. Zribi reviewed terminology related to this work. Patient Reported Outcomes (PROs) describe patient-reported concepts such as pain or function. Patient Reported Outcome Measures (PROMs) are the instruments that capture PROs. A Patient Reported

Outcome-based Performance Measure (PRO-PM) is the performance measure that uses PRO data to define the measure outcome.

- Ms. Zribi described the history of the existing hospital-level THA/TKA PRO-PM. The Hospital-level THA/TKA PRO-PM began measure development in 2013. The measure was specified and tested with input from patients, providers, and clinical experts. It passed endorsement by the National Quality Forum (NQF) in 2020 and is currently undergoing public comment.
- Ms. Zribi described the existing Hospital-level THA/TKA PRO-PM specifications and noted that they will be discussed in greater detail in the future. The current Hospital-level THA/TKA PRO-PM uses two PROMs. For hip patients, the PROM is the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR), which is a survey that consists of 6 questions on pain and function. For knee patients, there is the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR), a survey with 7 questions on pain and function. These surveys are psychometrically valid and were selected with length and overall burden in mind.
- The data sources for the PRO-PM are the PROM data, administrative claims data, and additional risk variable data. The cohort is Medicare FFS beneficiaries ages 65 and older who undergo elective, non-urgent surgeries. Pre-operative PRO data is collected 90 to 0 days before the procedure and post-operative PRO data is collected 270 to 365 days after the procedure. Both the pre-operative and post-operative PROM collection windows allow some flexibility in data collection. The post-operative timeframe aligns with existing follow up appointments and allows enough time for patient recovery.
- Ms. Zribi described the risk-adjustment process, which accounts for varying patient case mix across entities such as hospitals. The hospital-level measure team developed a clinically-derived risk model with 19 variables including health literacy, back pain, pain in non-operative lower extremity joint, and the baseline PROMIS Global Mental Health subscale score. PRO-PMs rely on novel data collection, so PRO-PMs need to consider response bias. The hospital measure conducted analyses to address potential non-response bias.
- The patient-level outcomes were defined using both patient input and empirical evidence. The outcome definition for THA is whether the patient meets or exceeds the substantial clinical benefit (SCB) threshold, defined as an increase of 22 points on the HOOS, JR, from their pre-operative to post-operative PROM assessment. Similarly, the outcome definition for TKA is whether the patient meets or exceeds an SCB threshold of 20 points on the KOOS, JR from their pre-operative to post-operative PROM assessment. The hospital-level outcome is the risk-standardized proportion of patients undergoing elective primary THA/TKA who meet or exceed the SCB thresholds.
- The goal of the clinician-level PRO-PM is to capture the full spectrum of care and incentivize quality. Patients have expressed a desire to have measure results that reflect physician level performance. CORE will develop and test the measure using data from the hospital-level PRO-PM development, specifically the CMMI Comprehensive Care for Joint Replacement (CJR) voluntary data collection. CORE will solicit input from the TEP,

Clinical Working Group, and Patient Working Group. In the future, there will be a public comment period.

- Ms. Zribi noted potential future discussion topics. For the clinician and clinical group attribution methodology, CORE proposes using the approach that was developed for the QPP THA/TKA Complication Measure. For risk adjustment, CORE proposes using the clinically-derived risk model that was developed for the Hospital-level THA/TKA PRO-PM. CORE will analyze non-response and incomplete PRO data using the approach developed by the Hospital-level THA/TKA PRO-PM. CORE will investigate future inclusion of the outpatient procedures in the measure cohort when data are available.
- Ms. Zribi presented the measure development timeline for this measure, which is similar to the timeline for the EPM measure. This first TEP meeting occurred in August and CORE will continue measure development and testing through the winter of 2020. CORE aims to meet with stakeholder groups throughout the development process, which will continue through the summer of 2021.
- TEP members had the following questions and comments in response:
    - A TEP member asked how the PROM data required for this measure would be collected at the national scale, particularly the follow-up PROM data one year later when many patients may not return to their physician. The member noted that without a mechanism to capture this information, many clinicians may not collect the data.
        - Ms. Zribi thanked the TEP member for their question and responded that there is no current implementation plan for this measure. CORE is interested in gathering the TEP feedback on how best to incentivize clinicians to capture PROM data and what an ideal mechanism would be to allow for high response rates and have a low burden.
    - The TEP member noted that capturing PROMs is aspirational and even with dedicated efforts, they have seen poor response rates. The TEP member noted that electronic methods have increased their research institute's patient responses for the HOOS, JR and KOOS, JR, and highlighted that rural and small hospitals may not have any resources to implement this. The TEP member noted that national implementation using a database, such as the American Joint Replacement Registry (AJRR), may be an option. The TEP member reiterated that implementation is an important consideration before designing the measure.
        - Another TEP member agreed with the importance of considering measure implementation and shared that joint surgeons are motivated to collect data on their patients, but it is challenging to achieve high responses. The TEP member noted that it would be equally important to incentivize patient response.
        - Dr. Suter shared that CMS has embarked on a mission to move to digital quality measures, with the goal of 100% digital quality measurement by 2030. Historically, electronic health records (EHRs) were developed first for billing, then for clinical care, and quality measurement was a lower priority. There is parallel work within CMS to innovate digital

measurement; though it is not specifically geared towards PROs or orthopedic measures, it will inform this measure. CMS aims to collect information from a range of sources and integrate this at the point of care for integration with clinical decision making and benchmarking. The hospital measure was developed at the beginning of working towards EHR measures. In addition, the CJR model did not restrict the mode of data collection nor how clinicians communicated the PROM scores to patients and integrated data collection efforts into clinical workflow. This group can help CMS learn from the institutions capturing PROM data well and encourage institutions to use these best practices.

- Dr. Suter agreed that patient-level data collection, such as PROs, are dependent on hospital and clinician resources. However, it is difficult for CMS to incentivize this work until there are quality measures. Although technology allows PRO data collection to be done, not everyone in the country can invest resources in those technologies. The TEP can highlight these issues and share ways that CMS can implement a measure to move the field forward. For example, CMS has implemented hybrid measures for a voluntary reporting period combining claims data and electronic clinical data for a single quality measure. Therefore, there is a precedent for implementing novel measures and learning from them without penalty.
- Dr. Suter further noted that non-response is an issue for all PRO-PMs and there will never be an expectation for 100% response rates. We believe there are reasonable targets to reach. HCAHPS currently has 10-15% response rates and their response rates have declined over time for many reasons. This measure will assess the impact of non-response on the measure and follow the current Hospital-level measure approach to accounting for non-response. In the future, some of these challenges may be addressed by removal of clinicians from public reporting if they do not meet a certain response rate threshold or stratification by peer groups serving the same patient groups. Dr. Suter noted that it is possible that this measure may not move forward until it is electronically specified and CMS establishes all electronic standards in the future, and TEP feedback can help CMS progress towards that.
    - A TEP member acknowledged from the perspective of a CJR-participating hospital that although it is challenging to capture PROs, they have been participating in the voluntary data collection effort for 5 years and, along with other CJR participant hospitals, have successfully captured hundreds of thousands of outcomes that allowed for development of the hospital-level PRO-PM. The TEP member noted that their hospital utilized the mandatory bundle to incentivize the data collection. The TEP member noted that an economy of scale must exist for that type of data collection at the hospital or hospital system level for the measure to succeed. There is the expectation of CMS to move to more universal alternative payment models and it is possible that CJR would expand to a national scale. At

that point, hospitals would need to capture PROs, so there will be dual-incentivization for surgeons to capture information electronically. However, if not all hospitals are participating in an alternative payment model with that built in incentivization, it will be difficult for PROs to be captured nationally. The TEP member also noted that, regarding a surgeon-specific measure, many surgeons are performing THA/TKAs in ASCs. Therefore, even with alternative payment models imposed on hospitals, the ASCs are a different environment in terms of economies of scale and the setting where ultimately these measures will need to be captured.

        - A TEP member shared that it would be beneficial if CMS provided larger financial incentives to support capacity building, data infrastructure, and workflows to report on these measures. The member noted that many CJR-eligible hospitals decided to not invest in the voluntary data submission because the incentive was not large enough. The TEP member noted that their organization promoted a phased approach to submit PROs over 3 to 4 years to first incentivize the baseline measurement and then, as hospitals became experienced, funding was incentivized for the follow up PRO measurement. The TEP member suggested CMS support IT infrastructure to allow for the capture of these data or the AJRR existing infrastructure, especially for smaller hospitals or those without a high level of experience. The TEP member also commented that clinician buy-in would increase if the measures are useful in the clinical setting. The TEP member also noted that CMS incentivization of practice transformation and measurement-based care may help providers collect PROMs.
    - A TEP member raised consideration about the SCB thresholds and the post-operative PROM collection window. The TEP member asked if the research indicates clinically significant thresholds could be applied at an earlier timeframe; for example, if a 15-point increase between 6-9 months could be acceptable.
        - Dr. Suter clarified if the question was that shorter post-op timeframe would garner higher response rates.
        - The TEP member agreed and questioned if low follow up response rates were due to the fact that some patients are not seen during the 9- to 12-month timeframe. The TEP member questioned if the measure had a shorter follow up timeframe, whether the response rate would increase and still be a valid measure. The TEP member questioned if evidence existed to show an increase in scores from 6-9 months equates to what would have been seen for the 9- to 12-month scores.
        - Dr. Suter commented that these questions are important for aligning quality measures with clinical practice due to the lack of uniform clinical practice around the country. The 9- to 12-month post-operative PROM

data collection timeframe was chosen because clinicians wanted the post-operative data collection window to extend far enough out from the procedure to reflect adequate recovery. Dr. Suter explained that during the development of the hospital-level measure, there were discussions that hip replacement patients recover faster than knee replacement patients, so a longer timeframe might be required for TKAs. CORE has heard feedback from some physicians requesting an extension on the data collection beyond 12 months to broaden the post-operative PROM data capture. Dr. Suter noted that extending the timeframe allows more flexibility for that one-year follow-up, but some patients have high social risk factors, or may change physical location, making the extension difficult.

- A TEP member inquired, based on recollection from a previous TEP meeting, whether 365 days was used as a cut-off because of the inability of CMS logistics to capture data beyond that time.
    - Dr. Suter replied that the timeframe was selected based on preference rather than a logistical barrier. Dr. Suter noted that is an innovative measure and experience from CJR demonstrated that more flexibility in the post-operative PRO data collection window may be needed.
    - Dr. Bozic noted that previous evidence was presented to the TEP indicating there was a difference between when scores peaked and leveled off for hip and knee replacement patients. The evidence showed that the scores leveled off between 6-9 months but the TEP decided to use the timeframe of 12 months to capture all potential change. Dr. Bozic noted that because patients do not come back for follow ups at exactly one year, he suggested centering the window around a year but allow flexibility on both ends of the window.
    - Another TEP member agreed and recommended expanding the timeframe to allow for two months on either side.

- A TEP member asked about CORE's expectation, given that HOPD is now a focus, if the outcomes for outpatient and inpatient would be measured similarly. For example, if a patient is sent home at 27 hours versus 18 hours, is there a clinical difference?
    - Dr. Suter noted that CMS did not reimburse for procedures that were not full inpatient stays. The clinical practice evolution and improvements in clinical care and perioperative protocols have made it reasonable to perform procedures in the outpatient setting. The change in CMS reimbursement is based on these changes in the level of clinical work. Quality programs are more restrictive so there are no measures that cross the different settings in those payment programs. CMMI aims to be more comprehensive and flexible by creating a payment model that

crosses these settings. Similar to CJR, it is possible there may be forgiveness or exclusion from other payment models. Many clinical events or procedures do occur in multiple settings. This is one of the first elective procedures that considers cross setting measurement and will offer insight for CMS to develop a multiple setting payment program. That point relates back to the earlier question as to whether CMS would separate inpatient and outpatient measurement. This is an open question. Fundamentally, QPP is the one area with some flexibility because it assigns who is held responsible for the measure result, such as the clinician or clinician group, rather than detail the setting of the event or encounter. Hospital measurement programs are very clear in what is considered inpatient versus outpatient and they do not have measures that cross those settings. The TEP's responsibility is to flag the unintended consequences and areas of concern when moving across settings. For elective hip and knee procedures, is this going to reduce access? Will healthy patients be seen outpatient and very sick patients be admitted for an inpatient stay? If that is the case, the TEP may need to separate the measurements because it would be inappropriate to combine these different populations. More understanding must be gained before that decision is made.

- TEP members indicated that this point was helpful. The TEP could find that the inpatient measurement is no different than the outpatient measurement and the measure can transcend location, or these two measurements are different and the group will need to rework the modeling for the measures.

- A TEP member pointed out that if CMMI proceeds with the current rule proposal for Performance Year 6 for CJR, the data will combine the HOPD and inpatient THA and TKA. There will be data coming in with PROs that include outpatient and inpatient procedures up to 20-25% of cases through outpatient HCPCS billing. The denominator definition must be modified in order to find those HCPCS codes, which have historically been Diagnosis-related Group (DRG) 469 or 470. If implemented, there is a need to consider the cost and develop a quality measure. The complications measure would follow, then ideally the PRO, and finally the harmonization across ASC, HOPD, and inpatient so there are similar measures in these settings. This mix of outpatient and inpatient ensures that all Medicare patients getting hip and knee replacements are captured.
- A TEP member inquired for those in the bundle whether there was any major shift seen in ratio of DRG 469 and 470 in inpatient cases and if there were lower amounts of complex patients performed in the bundled setting.
    - A TEP member noted based on their experience, it depends on how aggressively a hospital is using DRG 469. Hospital coding blogging site experts advise hospitals should run around 9% for DRG 469, but the actual CMS experience is around 6%. Their institution is conservative

regarding what is considered DRG 469 and are at around 3%. Many of those 3% are actually hip fractures within CJR and thus sit in a separate category. Overall, no matter how aggressively a hospital uses DRG 469, it is a small percentage. It is relevant to look for any significant change in comorbidities or risk of mortality. DRG 469 seems arbitrary upon admission and is generated for an inpatient complication during the stay but does not necessarily have a risk appearance for a patient going into operation.

- Dr. Wallace revisited the question regarding the volume of cases for TKAs. She provided the volume for inpatient hip and knee procedures was 296,314 and TKA outpatient procedures was 96,006, which includes observation stays. These numbers do not account for cohort exclusions.
    - A TEP member speculated that with trend data it would show movement to the outpatient setting.
    - Dr. Wallace agrees that we can anticipate that the outpatient numbers will increase.
    - A TEP member noted something billed as an outpatient case could actually have been admitted under observation for a one-night stay. Hospitals have been risk averse to QIO and rack audits for patients going home, so these are not truly outpatient. This is about 25% of those cases. Parts of the country using CJR drop to about 15%. People respond in an economically appropriate fashion by keeping healthy patients in the CJR and not going outside for the procedure, which would generate a DRG.
- Dr. Suter noted that COVID-19 may accelerate hip and knee procedures being performed in the outpatient setting. Even though the COVID-19 infection rate is low in Connecticut, it is still understandably difficult to get patients to come to the hospital setting for care at this time.
- A TEP member noted that the way a claim is coded does not always represent how a patient was treated. The TEP must consider separating the claims as it affects the appearance of the results. Outpatient numbers may appear better, but that may not be the case if there is a coding issue on the claim.

- A TEP member noted the inclusion of complications such as acute myocardial infarction (AMI), pneumonia, sepsis, and mechanical complications for the EPM measure. Their patients experience other complications in addition to these. The member challenged why these other medical complications including urinary tract infection (UTI), urinary retention, chest pain, and nausea, which are more common, are not included.
    - Dr. Suter noted it was important for this group to consider how to re-specify the current Hospital-level EPM measure. It is currently limited to the complications listed. The measure does not include UTI, constipation or others based on the historical perspective of ensuring claims data are

capturing a complication that hits a severity threshold. This does not diminish other aspects of a patient's post-operative experience as unimportant or potentially life threatening, but due to challenges of the data source, they have been chosen not to be included. Any changes the TEP makes to the list of complications would have implications for all other versions of this measure. This EPM complication measure already exists at the hospital level and at the surgeon and surgical team level. It is possible to move away from the current complications if the group finds that necessary, but the group must consider the data set and the implications across CMS's measures. It was suggested that it may be best to pause making any changes to that list and come back to this in the next iteration of the measure.

- A TEP member noted that because this is the patient-reported outcome measure other functional deficits such as stroke, acute kidney injury or renal failure that lead to prolonged disability are significant. The counter argument is if the loss of function is picked up in another measure. While the other complications such as UTI and constipation lead to a poor patient experience and maybe some disability, these are more difficult.
- A TEP member indicated from previous TEP panel discussions that the current complications were chosen because of their incidence and significance. The member suggested going forward that there may be other things equally important to capture. It was suggested to ask a patient group to rate the importance of these complications as another way to gain patient input.
- A TEP member agreed that incontinence is an important quality of life issue.
- A TEP member commented that complications such as sepsis or AMI may have been more impactful previously when patients stayed longer in the inpatient setting. We may see that things are not as important as practice evolves.
- Another TEP member noted that the data shows more cardiopulmonary complications in outpatient than inpatient settings.
- A TEP member recommended that blood transfusion should also be considered as an addition to the list of complications.

Next Steps

- The CORE team will circulate the meeting minutes and summary report. It is requested that TEP members review these items before they are posted for public comment.
- CORE anticipates holding one or two more of these TEP meetings between September 2020 and March 2021. Those meetings will be measure specific, with one for EPM and one for QPP. Surveys or emails may also be forthcoming in between meetings to request TEP member input.

- On behalf of CORE, Ms. Jimenez thanked the group for their feedback and asked that any additional questions to be emailed to the team.