Summary of the Technical Expert Panel (TEP) Meetings

Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting Measure

July 2022

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

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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 performance. Under this contract, CORE is re-specifying the existing Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA), referred to as the "Hospital-level THA/TKA Measure" in the remainder of this report, for a new measure, Hospital-level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting,[1] referred to as "IP/OP 90-Day THA/TKA Complication measure" in this report. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 3. 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 second meeting, which focused on reviewing measure status, specifications, and testing results; soliciting feedback on 1) the addition of an inpatient/outpatient setting indicator to the risk model, 2) accounting for social determinants of health in the measure, and 3) face validity of the measure.

Measure Development Team

Dr. Lori Wallace, PhD, MPH leads the Measure Development Team. Dr. Wallace is an Associate Research Scientist at the Yale School of Medicine and Yale CORE who specializes in health behavior and health disparities. The remainder of the CORE 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 of the CORE development team.

[1] The measure was previously referred to as "90-Day Risk-Standardized Complication Rates Following Elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Potential Combined Inpatient and Outpatient Episode Payment Model (EPM) measure."

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 of the IP/OP 90-Day THA/TKA Complication Measure. CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team, stakeholder groups, as well as email blasts sent to CMS physician and hospital email listservs, and a posting on the CMS 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 March 2022 to March 2023.

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 and methodological 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
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 DuPré Brodie	Senior Director, Measurement & Accountability, Purchaser Business Group on Health (PBGH)	San Francisco, CA
Cheryl Fahlman, PhD, MBA, BSP	President, CAF Consulting Solutions	Washington, DC

Name	Title, Organization	Location
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
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
Nan Rothrock, PhD	Professor of Medical Social Sciences, Feinberg School of Medicine at Northwestern University	Chicago, IL
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 Surgery, American Association of Hip and Knee Surgeons, Associate Professor, University of Pittsburgh	Pittsburgh, PA
Prior TEP Members		
David C. Ayers, MD *Dates of TEP service: 2020-2021*	Professor of Orthopaedics, UMass Medical School	Worcester, MA
William G. Hamilton, MD	Clinical Instructor and Chair of the Quality Measures Committee, Anderson Orthopaedic Clinic and	Alexandria, VA

Name	Title, Organization	Location
Dates of TEP service: 2020-2021	American Association of Hip and Knee Surgeons	Alexandria, VA
Benita Lattimore *Dates of TEP service: 2020-2021*	Patient Expert	Chicago, IL
Patricia Walker *Dates of TEP service: 2020-2021*	Patient Expert	South Holland, IL
Jonathan L. Schaffer, MD, MBA *Dates of TEP service: 2020-2021*	Managing Director, eCleveland Clinic Information Technology Division, The Cleveland Clinic Foundation	Cleveland, OH
Adam Schwartz, MD, MBA *Dates of TEP service: 2020-2021*	Consultant of the Department of Orthopedic Surgery, Associate Professor of Orthopaedic Surgery, Mayo Clinic; American Academy of Orthopaedic Surgeons	Phoenix, AZ
Robert Sterling, MD *Dates of TEP service: 2020-2021*	Orthopaedic Surgeon, Associate Professor of Orthopaedic Surgery, Association of Hip and Knee Surgeons, Johns Hopkins University	Baltimore, MD

TEP Meetings

CORE held its first TEP meeting in August 2020, a meeting at which both the IP/OP 90-Day THA/TKA Complication Measure and the Clinician-level THA/TKA PRO-PM were presented. The IP/OP 90-Day THA/TKA Complication Measure team held its second TEP meeting on June 21, 2022 (see Appendix B for the TEP meeting schedule). This summary report contains a summary of the two TEP meetings.

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. This is 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 for the IP/OP 90-Day THA/TKA Complication Measure and Clinician-level

THA/TKA PRO-PM. One TEP member provided input via email prior to the meeting. For further details, please see Appendix C.

During the first TEP meeting, CORE educated the TEP on the background and approach to developing the IP/OP 90-Day THA/TKA Complication Measure and the Clinician-level THA/TKA PRO-PM Measure. Information on how the IP/OP 90-Day 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 who were unable to join the in-person TEP teleconference were given the recordings and detailed meeting minutes.

The following bullets represent a **high-level summary** of what was presented and discussed relevant to the IP/OP 90-Day THA/TKA Complication Measure during the first TEP meeting. For further details, please see Appendix D.

IP/OP 90-Day THA/TKA Complication Measure

Overview

- CORE presented the IP/OP 90-Day THA/TKA Complication Measure overview and emphasized that the measure aligns with the Hospital-level THA/TKA Complication Measure. The measure outcome is a yes/no assessment of whether a complication occurred during an index encounter for the elective procedure or during a readmission within the specified timeframe for a given complication.
- CORE highlighted that the IP/OP 90-Day THA/TKA Complication Measure will expand the measure cohort beyond patients who have procedures performed in the hospital to also include patients who have procedures performed in hospital outpatient departments (HOPDs) and expand the outcome to consider complications that occur during emergency department visits and observation stays.
- CORE presented the IP/OP 90-Day THA/TKA Complication Measure timeline, noting that measure testing is anticipated to begin in winter 2020, continued stakeholder engagement is expected in the fall of 2020, and finalization of the measure and public comment feedback is expected by winter 2022.

TEP Feedback

- Two TEP members noted concern that the measure does not include claims from ambulatory surgical centers (ASCs) and that procedures that occur in this setting should be measured equally alongside inpatient and other outpatient THA/TKA procedures.
- One TEP member questioned why Present on Admission (POA) codes were not used in the outpatient setting.
    - Another TEP member inquired via email about POA in the outpatient setting.

The materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

- One TEP member noted that hospitals' and clinicians' definitions of the complications vary.
- One TEP member inquired about the volume of the inpatient versus the outpatient cohort.
- One TEP member asked clarifying questions about the expectations for measuring these outcomes in the outpatient versus the inpatient setting. The TEP member further noted the possibility of either finding that measurement can transcend the outpatient vs. inpatient setting, or that the two settings are completely different and the modeling will have to be reworked.
- One TEP member stressed the importance of harmonization across ASCs, HOPDs, and inpatient settings so that there are similar measures across each setting.
- One TEP member commented on inconsistencies in billing practices, noting that outpatient billing codes are sometimes used even though the patient may have been admitted for a one-night observation stay.
    - Another TEP member agreed, adding that the way a claim is coded does not always represent the full patient encounter. Something being coded as an outpatient case does not necessarily mean the patient was, in fact, treated as an outpatient.
- Several TEP members discussed the IP/OP 90-Day THA/TKA Complication Measure outcome, noting concern that complications such as urinary tract infection (UTI) or constipation were not included in the measure outcome.
    - One TEP member added that although UTI and constipation lead to a poor patient experience, functional deficits such as stroke, acute kidney injury, or renal failure are significant and should be considered in the complications list.
- One TEP member suggested review of the complications list and proposed using the Delphi method of engagement to assess the importance of new complications, noting that other complications may be equally or more impactful for patients.
- Two TEP members suggested complications such as cardiopulmonary complications and blood transfusion to consider for the measure outcome.

Summary

- Most TEP members supported the measure cohort and outcome expansion to include hospital outpatient department claims. In addition, TEP members proposed consideration of measuring outcomes in ASCs. Several TEP members proposed additional complications and measure enhancements for developers to consider during re-specification.

Further comments from a TEP member about concerns with inclusion of complications in the emergency department and during observations stays, laterality validity for outpatient complications, and socioeconomic status risk factors are contained in a detailed summary of the pre-TEP meeting email provided in Appendix C.

Second TEP Meeting Overview

Prior to the second TEP meeting, TEP members attended information sessions to review measure background and updates since the first TEP meeting in August 2020.

During the second TEP meeting, CORE reviewed updates to the IP/OP 90-Day THA/TKA Complication Measure, solicited feedback about addition of an IP/OP setting indicator in the risk model and accounting for social determinants of health (SDOH) in the measure, and requested feedback on the face validity of the measure.

Following the meeting, TEP members were able to comment on detailed meeting minutes.

The following bullets represent a **high-level summary** of what was presented and discussed relevant to the IP/OP 90-Day THA/TKA Complication Measure during the second TEP meeting. For further details, please see Appendix E.

IP/OP 90-Day THA/TKA Complication Measure

Overview

- CORE presented the IP/OP 90-Day THA/TKA Complication Measure overview and noted the rationale for the combined setting measure is a response to the increased volume in THA/TKA procedures in OP setting due to the removal of THA/TKA procedures from the IP-only list and inclusion on the Ambulatory Surgical Center (ASC) Covered Procedures List in the calendar year 2018, 2020, and 2021 Final Rules.
- CORE reviewed a comparison of the unadjusted (observed) complication outcomes across the IP and OP settings, noting the complication rates for THA and TKA procedures are lower in the OP setting, likely due to patients receiving care in the OP setting being healthier (fewer coded comorbidities), younger, and less frail than those receiving care in the IP setting.
- CORE acknowledged that the decision to perform a THA/TKA procedure in the inpatient versus outpatient setting is a complex decision representing access, clinical triage (including frailty and functional status), patient and surgeon preference, hospital policy, and other factors. CORE noted that model performance was improved by including a setting indicator in the risk model (compared to modeling inpatient and outpatient settings separately), although hospital-level results were similar with or without a setting indicator.
- CORE reviewed the NQF SDOH Conceptual Model for the measure, noting it is a useful framework to think about how SDOH might impact quality of care and complication outcomes, particularly factors that might influence a hospital's impact on patient outcomes. There are a multitude of factors that may or may not be able to be addressed by either the hospital or clinicians; some factors are accounted for in the risk model (such as increased comorbidity and some aspects of frailty) while others (social and economic factors, physical environment, clinical care/access to care, health behaviors, and functional status) are not. CORE also discussed the two potential methods for

accounting for SDOH in the risk model: risk adjustment and stratification. Both methods can be applied either to the measure itself and/or to payment assignment. As this measure is intended for a yet to be determined cross setting model, CMS/CMMI will make the final implementation decisions regarding social drivers of health.
- CORE asked TEP members to complete a survey regarding measure face validity via email after the meeting.

TEP Feedback

- Two TEP members expressed disagreement with the conclusion that OP patients are younger and less frail than IP patients, stating that the lower rates are due to better, more coordinated care provided in the outpatient versus inpatient setting.
- One TEP member commented that the IP and OP setting is based on coding at the hospital level and asked if claims review data has demonstrated accuracy in how patients are categorized.
- One TEP member asked whether the measure would be stratified by setting or if the setting is a risk adjustment variable for the measure.
- One TEP member asked how long after the procedure risk factors are considered.
- One TEP member asked whether the measure considers comorbidities in addition to age.
- One TEP member noted concerns about there being minor differences in age and comorbidities and that there is not enough difference to explain the difference in the outcomes by setting.
- Two TEP members commented that OP procedures often include overnight stays.
- One TEP member commented that the setting indicator is appropriate based on the statistics.
- One TEP member expressed concern for the potential of erasing quality and disparity issues if the risk model adjusted for social drivers of health instead of stratified by social drivers of health.
- Two TEP members suggested that CMS consider using socioeconomic status in the measure risk adjustment and stratification.
- Several TEP members indicated support for accounting for SDOH, either through adjusting or stratifying the measure and/or adjusting or stratifying the payment.

Summary

- TEP members expressed mixed support for including a setting specific indicator, some of which reflected doubts regarding its validity as defined by claims data.
- TEP members noted a preference for accounting for SDOH through stratification of measure results and/or at the payment assignment level to minimize the risk of masking quality differences.

Next Steps

Ongoing Measure Development

CORE will continue to encourage further feedback and questions from TEP members via email. Additionally, CORE will continue to engage stakeholders in a Clinical Working Group and will hold a public comment to solicit feedback on measure specifications.

Conclusion

TEP feedback on CORE's approach to measure development helped inform the development of measure specifications and ongoing reevaluation items. CORE will continue to engage with the TEP as the measure moves through measure endorsement and implementation planning.

Appendix A. CORE Measure Development Team

Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Role
Lori Wallace, PhD	Project Lead
Kathleen Balestracci, PhD, MSW	Division Lead
Andrea Barbo Barthel, MS	Lead Analyst
Jasie Mathew, MBA	Project Coordinator
Elena Hughes, MSc	Research Support
Matthew Saenz, BS	Research Support
Zhen Tan, MS	Supporting Analyst
Zhenqiu Lin, PhD	Analytic Director
Jacqueline Grady, MS	Analyst Oversight
Shefali Grant, MPH	Project Manager
Lisa Suter, MD	Contract Director, Quality Measurement Program

Appendix B. TEP Call Schedule

TEP Meeting #1

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

TEP Meeting #2

Tuesday, June 21, 2022 – 4:30-6:30PM EST (Location: Zoom Teleconference)

Appendix C. Detailed Summary of Feedback from Pre-TEP Communication

TEP members received detailed meeting materials prior to the first TEP meeting. Provided below is a summary of the email communication received, as well as the responses provided by CORE, prior to the first TEP meeting on August 26, 2020.

Pre-TEP Questions:

1. The previous denominator was DRG (diagnosis-related group) 469/470, which requires multiple ICD-10 codes are needed to be captured to cover all scenarios. It is more readily captured by the CPT. Has this been tested against the current methodology? Do the ICD-10/PCS codes map out to those DRGs?

   The measure denominator is not defined by DRGs – DRGs are used to identify THA/TKA patients in the CJR model, but all of CMS' claims-based THA/TKA quality measures only use ICD-10 (ICD-9 prior to 2015) codes to define the denominator population. The ICD-10 codes map roughly to DRGs but offer more granularity for measurement than DRGs. Complications that occur during the index hospitalization and reflect hospital quality impact DRGs and therefore CMS decided not to use DRGs for these quality measures.

2. Why do ASC's get a free pass? They have been approved for OP TKA.

   CMS quality measures are implemented within payment programs and models. ASCs have their own payment program, but we will clarify with CMMI whether any model for which the combined inpatient/outpatient THA/TKA complication measure might include ASCs and update the measure accordingly.

3. Why are POA conditions not captured for HOPD OP cases? Are they not captured over the 12-month pre-operative period?

   CPT codes do not include POA modifiers – it is a limitation of these types of codes. As the use of POA modifiers in the inpatient setting is relatively recent (and originally incentivized by payment programs such as not paying for decubitus ulcers and pressure sores that develop during a hospital stay), the original measures used validated algorithms to identify and remove codes representing potential complications of care from the risk models. While not ideal, we believe a similar approach should be feasible to address the lack of CPT POA modifiers.

4. ED/Observation visits create infection codes based on normal wounds due to inexperience/misdiagnosis. Total knees will frequently have low grade erythema and will be warmer than the opposite knee for a year. It is not uncommon that ED visits create infection codes that are inappropriate. An infection should be limited to those patients that need operative intervention for both the IP/OP 90-Day THA/TKA Complication measure and the surgeon specific measure.

We agree – the original measure did not include urinary tract infections (UTIs) and deep venous thromboses (DVTs) for this same reason. Administrative codes represent a spectrum of complications, from minor to major, and the clinical experts who advised the original measure development did not feel hospitals should be penalized for their rates of these events. Our Work Group (Drs. Jay Lieberman, James Huddleston, Mary O'Connor, Kathryn Schabel, and Kevin Bozic) felt similarly and recommended certain potential complications of care that occur only in the emergency department (such as myocardial infarction and pneumonia within seven days of elective THA/TKA) should not be considered complications in the measure. These types of decision (what outpatient complication events constitute valid and clinically significant enough events to be included in the measure) will be a focus of future TEP meetings. The TEP's input on these measure decisions is critical to ensuring the measure integrity and validity.

5. Laterality validity is critical to know if outpatient "complications" are attributable within 90 days of the index procedure and not some previous procedure. TJA patients often have had more than one joint replaced. Is there any check on that validity?

   We agree that laterality is a feature of ICD-10 codes that will improve measure specificity. We do not want hospitals that do not code laterality to get a 'pass' for complications simply by not coding laterality. We will think with our Work Group and the TEP how best to incorporate laterality into this and all of the orthopedic measures CORE develops and maintains.

6. Trauma/falls should be excluded. This is a more fragile population with risk for syncope and/or balance disorders. It is not the hospital or the surgeon's failure if the patient falls and suffers a periprosthetic event.

   Fractures leading to THA are excluded from the measure. In addition, the existing measure risk adjusts for markers of frailty to account for patient case mix differences. However, the hospital can improve patient outcomes by optimizing management of medical comorbidities, rehabilitation and discharge planning to reduce these events. Guidance on how to best capture frailty using administrative claims data is evolving and we look forward to working with the TEP to ensure these measures best account for this important predictor of clinical outcomes.

7. Data continues to demonstrate that socioeconomic (SES) risk factors are important. There is a potential for SES driven discrepancies as to which patients undergo outpatient versus inpatient care. 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 dual eligible Medicare and Medicaid 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.

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 DuPré 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 Barthel, Kathleen Balestracci, Susannah Bernheim, Jacqueline 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 IP/OP 90-Day 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.
- IP/OP 90-Day 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 IP/OP 90-Day 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.

The materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

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 IP/OP 90-Day 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.

- 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 IP/OP 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: IP/OP 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 IP/OP 90-day THA/TKA Complication Measure. She noted 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 Complication 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 resulted in 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 admission or outpatient encounters. 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 readmission within 90 days from the start of the index admission.
- The IP/OP 90-Day THA/TKA measure is also considering observation and emergency department visits as potential settings.

The materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

- 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 materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

- 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 IP/OP 90-Day THA/TKA 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 IP/OP 90-

Day THA/TKA 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 IP/OP 90-Day THA/TKA 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 IP/OP 90-Day THA/TKA 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.

Appendix E. Detailed Summary of TEP Meeting #2

Orthopedic Technical Expert Panel Meeting #2 Minutes

Tuesday, June 21, 2022, 4:30 – 6:30 PM EST

Participants

- **Technical Expert Panel (TEP):** Thomas C. Barber, Phyllis Bass, Vinod Dasa, Rachel DuPré Brodie, Cheryl Fahlman, Cynthia S. Jacelon, Craig Miller, Michael H. Perskin, Nan Rothrock, Margaret A. VanAmringe, Christine Von Raesfeld, Kevin Woodward, Adolph J. Yates
- **Yale New Haven Health Services Corporation—Centers for Outcomes Research and Evaluation (CORE):** Kathleen M.B. Balestracci, Andrea Barbo Barthel, Jacqueline Grady, Shefali Grant, Elena Hughes, Jasie Mathew, Matthew Saenz, Lisa G. Suter, Zhen Tan, Lori Wallace
- **Expert Clinical Consultant:** Kevin Bozic

Executive Summary

- The purpose of the second TEP meeting was to review updates to the Hospital-level 90-day RSCR following Elective Primary THA/TKA for a Combined IP/OP Setting measure, to solicit feedback about addition of an IP/OP setting indicator in the risk model and accounting for SDOH in the measure, and to request feedback on the face validity of the measure.
- The TEP shared several considerations related to the combined IP/OP measure.
    - Regarding inclusion of the IP/OP setting indicator in the risk model, TEP members noted concern about defining IP and OP procedures based solely on hospital coding practices, which can vary among hospitals and may not be adequately audited; OP procedures may include multiple night stays and differences between OP and IP populations, such as frailty, must not be oversimplified since treatment protocols for patients expected to be OP vary with those expected to be IP. TEP members supported inclusion of the IP/OP setting indicator in the risk model.
    - Regarding accounting for SDOH within the measure, TEP members noted a preference for accounting for SDOH at the measurement level to minimize the risk of masking quality differences. The TEP noted concerns about potential misinterpretation of disparity results due to underrepresentation of non-White and dual eligible patients, both overall and in the OP setting, and about the structure of the measure inadvertently impacting access to care due to hospital and/or physician risk avoidance and cherry picking.

TEP Action Items:

- TEP members were invited to email cmsorthopedicmeasures@yale.edu with feedback on the reliability results, additional questions about, and/or feedback on the measure.
- TEP members were asked to vote on measure face validity via the post-webinar survey, and to include detailed comments with the rationale for their selections by Friday, June 24th.

CORE Action Items:

- Immediate next steps: CORE will distribute the face validity survey to TEP participants.
- CORE will add additional comments submitted by email after the call as an addendum to the minutes and will include them within the summary report.
- CORE will provide the minutes and the TEP Summary Report for review in advance of public posting.
- CORE will seek Public Comment (anticipated in Fall 2022) and will notify the TEP when the comment period has opened so the TEP can comment if they wish to do so.
- CORE will continue to work with CMS/CMMI to better define the measure implementation, including timing of implementation.

Detailed Discussion Summary

Introduction and Meeting Goals

- Ms. Jasie Mathew welcomed the group on behalf of CORE and conducted a roll call of TEP and CORE meeting participants. She noted the meeting is being recorded and will be shared with participants unable to attend the meeting.
- Ms. Mathew noted the purpose of the meeting is to review updates to the Hospital-level 90-day Risk-standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting measure.
- Ms. Mathew noted information provided during the recent information sessions is included in the appendix to the meeting slide deck. She requested participants submit additional questions in the meeting chat or send them by email after the call.
- Ms. Mathew facilitated the review and approval of the TEP charter and reminded the TEP the content of the discussion must remain confidential until made public by the Centers for Medicare & Medicaid Services (CMS), and that all personal health stories must be kept confidential.
- Ms. Mathew noted the meeting discussion is intended to solicit feedback about:
    - Addition of an IP/OP setting indicator to the risk model; and
    - Accounting for social determinants of health (SDOH) in the measure.
        - Ms. Mathew requested questions not relevant to these topics be asked in the meeting chat or by email following the meeting to ensure time to address the agenda items.

The materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

- Ms. Mathew stated that CORE is interested in TEP feedback on the reliability results, but that they would not have time to review them during the meeting; these results are included in slides 60-63 of the appendix to the meeting slide deck. Ms. Mathew asked for feedback on the reliability results to be provided by email after the meeting.
- Ms. Mathew noted TEP participants will vote on measure face validity via a post-webinar survey following the meeting and requested every TEP member complete the survey.

Measure Background

- Dr. Lori Wallace, the project lead, reviewed the measure background, noting the rationale for the combined setting measure is a response to the increased volume in THA/TKA procedures in OP setting due to the removal of THA/TKA procedures from the IP-only list and inclusion on the Ambulatory Surgical Center (ASC) Covered Procedures List in the calendar year 2018, 2020, and 2021 final rules.
- Dr. Wallace noted CMS tasked CORE with respecifying the existing (inpatient only) hospital-level risk-standardized complication measure to be setting neutral, by expanding the measure cohort to include procedures performed in both hospital inpatient and Hospital Outpatient Department (HOPD) settings, for potential use in a Center for Medicare and Medicaid Innovation (CMMI) payment model.
- Dr. Wallace noted the outcome was expanded to consider complications occurring during the index admission, emergency department (ED) visits, observation stays, and ASC encounters.
- Dr. Wallace stated the overall goal of respecification is to align quality improvement across settings, decrease costs, and reduce complications associated with THA/TKA procedures.
- Dr. Wallace noted since the last August 2020 TEP meeting, CORE met five times with Clinical Working Group, which represents four orthopedic professional societies, to discuss the measure respecification; the validity of counting complications identified during ED visits and observation stays; and to obtain feedback on the complication categories.
- Dr. Wallace noted CORE briefly paused the work to allow for the collection of additional outpatient THA data, to improve generalizability during measure development and testing, and to better align the measurement periods.

Current Measure Status and Outcome Definition

- Dr. Wallace noted CORE is currently completing measure testing and obtaining stakeholder input, with the intention of submitting the measure to the National Quality Forum (NQF) for initial endorsement this fall. CORE will continue to have discussions with CMMI regarding the future implementation of the measure.
- Dr. Wallace noted claims from April 2018 through March 2021 were used for development (respecification) and testing.

- Dr. Wallace reviewed a table with the outcome definition across settings, noting the period in which a complication may be counted and the setting in which it may be identified is specified for each of the complication categories. She shared an example of pneumonia, which counts as a complication if it occurs within 7 days of the index procedure during the IP or HOPD Index Encounter or an IP readmission and does not count if it occurred during an observation stay, ED visit, or ASC encounter.
- Dr. Wallace noted the rationale for limiting identification of complications based on setting is that there is a threshold for counting complications; complications that present in the ED rather than during an IP admission reflect a difference in severity.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member asked (via the meeting chat) whether cellulitis needing admission and treated with intravenous antibiotics (no surgery) counts as a complication.
        - Dr. Lisa Suter clarified that cellulitis with antibiotics without surgery is not considered a complication in this measure.
    - A TEP member asked (via the meeting chat) whether a patient that has an acute myocardial infarction (AMI) before leaving a planned outpatient THA/TKA and is admitted as an IP would be billed as an AMI complication; they expressed concern the complication may not be included in the measure in these cases.
        - Dr. Suter recognized that claims are an imperfect way to capture complications, but this scenario would be captured. With guidance from clinical experts, CORE, as the original measure developer, intentionally set a high bar for the measurement of complications to avoid misattributing complications to hospitals.

Comparing Inpatient & Outpatient THA/TKA Procedures

- Dr. Wallace reviewed a comparison of the unadjusted (observed) complication outcomes across the IP and OP settings, noting the complication rates for THA and TKA procedures are lower in the OP setting, likely due to patients receiving care in the OP setting being healthier, younger, and less frail than those receiving care in the IP setting.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member commented (via the meeting chat) that they disagreed with the conclusion that OP patients are younger and less frail.
        - Dr. Suter noted the measure includes only Fee-For-Service (FFS) patients and the findings only reflect FFS (Medicare Advantage [MA] patients are not included); CMS is investigating future inclusion of MA claims. The national FFS data show OP patients to be slightly younger with slightly fewer comorbidities and there is an expectation they are slightly less frail than IP patients.

    - A TEP member commented (via the meeting chat) they share concerns about the assumption that OP patients are younger and less frail and suggested this assumption does not reconcile with the patient communities they serve in.
    - A TEP member qualified that their observation is based on their work with MA data, and agreed with Dr. Suter the FFS population might have different demographics and outcomes; they remained concerned about making assumptions about frailty upfront and suggested it as an area for more examination.
    - A TEP member commented (via the meeting chat) that the IP and OP setting is based on coding at the hospital level. They asked if review of claims data has demonstrated accuracy in how patients are categorized.
        - Dr. Suter responded (via the meeting chat) that CORE could look into the feasibility of performing an analysis to better understand the accuracy of hospital coding.
- Dr. Wallace noted for THA, patients having OP procedures had a mean age of 73 years, compared with 74 years for those with IP procedures; OP patients were more likely to be male, to have unilateral procedures, and had fewer comorbidities.
- Dr. Wallace noted the Clinical Working Group suggested CORE explore subdividing the OP procedures into categories with and without overnight stays, and CORE has started exploring that possibility.

Risk Model Development & Measure Testing

- Dr. Suter noted with the addition of the OP procedures, the first thing CORE wanted to understand is the differences in the demographics and observed complication rates; this is a Medicare FFS population that is 65 and older, so it is a slightly different cohort than the MA population and is an older population than the entire population of patients receiving THA/TKA procedures.
- Dr. Suter noted CORE evaluated the existing inpatient-only measure risk model to determine how the existing risk factors performed when applied in the OP cohort using three different model performance scenarios:
    - The first scenario was to combine IP and OP into a single group and run the existing risk model for the existing Hospital Value-Based Payment Program (HVBP) inpatient measure.
    - The second scenario was to separate IP and OP procedures and calculate the models separately for those populations using the same risk variables.
    - The third scenario was to use a combined IP/OP model with the addition of a setting indicator in the model.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member requested clarification about the setting indicator.
        - Dr. Suter clarified the setting indicator is a binary variable that answers the question of whether the procedure occurred in the IP or OP setting.

    - A TEP member submitted a question (via the meeting chat) asking whether the measure would be stratified by setting or if the setting is a risk adjustment variable for the measure.
        - Dr. Suter clarified (via the meeting chat) the measure is risk adjusted by setting.
    - A TEP member submitted a question (via the meeting chat) asking how long after the procedure risk factors are considered.
        - Dr. Suter replied (via the meeting chat) that risk factors for 12 months before and including the index encounter are considered; for risk factors coded during the hospital stay, CORE excludes those that might represent a complication (with the possible exception of setting if included the IP/OP setting indicator in the risk model).
    - A TEP member asked (via the meeting chat) whether the measure considers comorbidities in addition to age.
        - Ms. Jaqueline Grady responded (via the meeting chat) that comorbidities coded as Present on Admission (POA) are included in addition to those billed during the prior 12 months.
- Dr. Suter reviewed a graphic displaying the odds ratio (OR) estimates with 95 percent confidence intervals for the variables in the risk model; the model includes historical claims for the 12 months prior to the procedures so even if a risk factor was not coded for the index procedure, it would be captured based on other Medicare claims data. The risk variables represent groups of codes rather than individual codes and can either increase or decrease the odds of a complication. Wider confidence intervals tend to be associated with rarer risk factors, such as patients on dialysis who are less likely to have an elective THA/TKA.
- Dr. Suter noted the age risk variable in the model appears to have a small effect due to it being age by year. For each year of age, you have about a ten percent increase in complication risk; however, the cumulative effect of age has a large effect on the overall risk of complications.
- Dr. Suter observed that the risk factors that increase the risk of complications in the IP setting also tend to increase the risk of complications in the OP setting, and there are very few factors where you see the risk of complications going in opposite directions; Dr. Suter noted the smaller population of patients in the OP setting may explain the few differences seen across the risk factors. These results suggested the risk variables perform similarly across the IP and OP populations.
- Dr. Suter reviewed the C-Statistic (area under the curve) and predictive ability for the three risk model scenarios, noting the combined model with setting indicator had the highest C-statistic (0.664) and the best predictive ability with wider spread; based on these results CORE is proposing including a setting indicator in the risk model.
- Dr. Suter reviewed the pros and cons of including the setting indicator in the model. Pros include setting being a nuanced variable that captures aspects of both quality and patient-level clinical severity. For example, immediate surgical complications tend to extend length of stay (LOS), but such complications also tend to be nausea, respiratory

distress and the like, which are either minor (nausea) or may represent frailty rather than poor quality of care. The model with the setting indicator had greater statistical validity, and reselection of risk variables is unlikely to gain significant model discrimination. Cons include the potential that the setting indicator may represent different information in different hospitals and settings; adding the setting variable reduces variation and may obscure aspects of quality; and social determinants of health (SDOH) are anticipated to have a complex relationship with setting and need further investigation.

    - A TEP member submitted a question (via the meeting chat) requesting clarification about how adding the setting indicator could obscure quality.
        - Dr. Suter clarified that patients who experience complications are in the hospital longer and there is a complex relationship between whether or not they are categorized as inpatient. If you have a complication, even if you were intended to have an OP surgery you may end up categorized as IP. In risk adjusting for a piece of information that was coded after the surgery, you may capture an aspect of quality.

- Ms. Mathew facilitated a round robin discussion to address the question, "Do you have any questions or concerns about the proposed risk model and/or including a setting indicator?" She indicated that TEP members can pass if they do not have questions or comments.
    - A TEP member noted concerns about not seeing large enough differences in age and comorbidities in their data to explain the difference in the outcome measures CORE is seeing. They observed from their work with OP joint replacements that the transition in practice setting has resulted in newer guidelines for how to treat these patients and better protocols for treatment, such as earlier ambulation, which can result in better outcomes. Providers in the OP arena do things differently than in the IP setting, and so it is not just having a healthier patient population. They noted SDOH are a very big factor because most providers will not perform an OP procedure for someone that does not have good support systems at home, which can be related to SDOH. They noted concern about the setting indicator and suggested if CORE is doing comparisons, they would rather have an indicator of SDOH instead of a setting indicator. They noted a bias toward more care in the OP environment because of the changes that improve patient care in that setting.
    - A TEP member asked for clarification about whether this was a univariate or multivariate analysis and if there is a list of everything that was put in to control between the settings.
        - Dr. Suter noted the list of variables on slide 19 included all the risk model variables.
        - The TEP member asked whether race and ethnicity variables were included in the risk model.
        - Dr. Suter confirmed race and ethnicity were not included in the model. Some readmission measures are stratified by dual eligibility, which is

included on claims data, and this information is shared confidentially with hospitals. CMS recognizes the importance of SDOH. She encouraged participants to put questions about SDOH in the chat since that is a later topic on the agenda.

- A TEP member asked about complications that are dependent on setting, such as Deep Vein Thrombosis (DVT), which research suggests may be a function of length of stay which is only coded for the IP setting; they asked how CORE is accounting for complications like DVT that are a function of the setting.
    - Dr. Suter noted some hospitals may not do as well as others and their patients experience more complications resulting in those patients being categorized as IP, and CORE may be under-weighting those complications, so there is a trade-off. CORE does not want to underweight hospitals that have consistently lower quality. The question is how often it has enough impact to make a difference.
- A TEP member noted seeing research from a major health system in Los Angeles that showed their LOS hovering around three days came along with higher complication rates.
- A TEP member commented about the continuous age variable having small impact in the model and asked if age was tested in the model as a categorical variable.
    - Dr. Suter clarified that age is cumulative for any given patient; at age 70 there is a large impact and at age 85 it is a huge impact.
    - The TEP member expressed support for including the setting indicator and thinks the indicator is potentially masking other SDOH, but was not sure how those could be teased out.
- A TEP member requested clarification that the measure includes only hospital-based procedures and ASC procedures are excluded. They noted not having LOS with OP procedures is problematic because billing practices can vary across hospitals; there are situations where a patient may end up staying for three or four nights but the procedure is still billed as OP. They suggested hospitals fear billing these as IP procedures resulting in a Recovery Audit Contractor (RAC) audit, which is a countervailing force. They supported use of the setting indicator in the model, and noted the differences shared during the informational meetings suggested some significant differences in the incidence of serious comorbidities, such as cardiovascular disease, between IP and OP, which may not even be real. These patients may believe they are healthy but might have optimistic attitudes about their health and significant health issues, and they may not seek enough physician care. The TEP member would like to see groupings of comorbidities that may synergistically show a hazard as a group, for example metabolic syndrome with morbid obesity, or heart disease with renal disease and indications of organ damage from diabetes. These factors represent a higher risk when they occur together than as individual agents.

- A TEP member wondered if the differences in the C-statistics represent meaningful differences and what the model would show for a facility that performs only OP or only IP procedures. They noted if there were two facilities publicly reported as having average complication rates, as a patient they might still lean toward the facility that does more OP procedures.
- A TEP member agreed with the previous comment regarding OP procedures often including overnight stays, noting it is an important point. Regarding the lower C-statistic and predictive ability of the OP-only model, they suggested it may be due to having less data for OP procedures, especially for THA.
    - Dr. Suter agreed and noted THA procedures have only recently been paid for in the OP setting; it is possible over time as CORE accumulates more data, there may not be quite as much difference as the current data now suggests.
- A TEP member submitted a question (via the meeting chat) about the differentiation among hospitals, accounting for size comparison, procedure volume, rurality or urbanicity, accessibility of services, and teaching hospital status.
    - Dr. Suter replied (via the meeting chat) that rural hospitals have less access to resources like rehabs/SNFs and urban and teaching hospitals often have higher populations of patients with SDOH. The measure does not account for hospital characteristics.
- A TEP member commented (via the meeting chat) that the setting indicator is appropriate based upon the statistics. When they worked in acute care, OP patients were prepped differently and in a more robust manner when the pre-screen indicated good candidate for OP. They noted including the setting indicator may help to encourage these best practices.
- A TEP member commented (via the meeting chat) they did not see the predictive ability of the setting indicator, similar to the other risk adjustment variables. They were interested in the statistical significance of setting.
    - Dr. Suter responded (via the meeting chat) with the results for the setting indicator in the full model; the OR is 1.46 (1.41, 1.5).

Accounting for Social Determinants of Health

- Dr. Wallace reviewed the NQF SDOH Conceptual Model for the measure, noting it is a useful framework to think about how SDOH might impact quality of care and complication outcomes, particularly factors that might influence a hospital's impact on patient outcomes. Some factors are hospital level and can be controlled (hospital resources, procedure volume, discharge protocols, care coordination, and access to procedures) while others may or may not influence the hospital's impact and the hospital may or may not be able to mitigate (clinical risk factors, patient demographics, social and economic factors, insurance status, physical environment, access to housing and transit, functional status, access to care, patient health behaviors). Some of these factors are accounted for in the risk model while others are not.

- Dr. Wallace noted factors that are not currently included in the model include social and economic factors, physical environment, clinical care/access to care, health behaviors, and functional status. One of the challenges with examining these factors is CMS does not have data for all SDOH; many of these factors are measurable but the data is not consistently collected across hospitals.
- Dr. Wallace noted the different methods for accounting for SDOH are risk adjustment and stratification and these methods do different things. Risk adjustment includes the variable in the risk model and it either increases or decreases model's expectation that the patient experiences the outcomes as a result of including it in the risk model; this strategy defines the expected complication rate for patients, which may obscure disparities and quality differences. Stratification is calculating the complication rate separately for different groups or comparing complication rates among similar hospitals. For example, comparing hospital rates for Black patients only or comparing only hospitals with a large proportion of Black patients. Stratification maximizes the ability to identify or make disparities more transparent.
- Dr. Wallace explained that both methods (risk adjustment and stratification) can be applied to the measure or to payment based on measure results. CMS currently has mandatory hospital payment programs that focus on either the IP or OP setting and are site-specific. This measure is intended for a yet to be determined CMMI cross-setting model.
- Dr. Wallace noted CMS/CMMI will make the final implementation and SDOH decisions; CORE's goal is to share the TEP's input with CMS/CMMI.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member asked (via the meeting chat) how risk factors can reinforce disparities.
        - Dr. Suter clarified if Black patients have higher complication rates than White patients, risk adjustment anticipates the complication rate based on the risk variable. The model gets re-run annually based on the data and a coefficient for a risk factor is calculated (for example, diabetes) for Black vs. White patients. If Black patients have a higher complication rate and that expectation is built into the model, when a hospital's Black patients have more complications than White patients, the model treats this as an expected outcome. This may remove the incentive to improve disparities.
    - A TEP member commented (via the meeting chat) they agree with the potential for erasing quality or reinforcing disparities is of concern when the model adjusts for SDOH rather than stratifies by SDOH.
- Dr. Suter summarized the measure results related to SDOH, noting that fewer non-White patients are receiving procedures at all, and of those that do, they are less likely to have an OP procedure. Black patients have slightly lower complication rates in the OP setting, as compared to those who received IP procedures. In addition, Black patients having OP procedures experienced a slightly lower complication rate than White patients having OP procedures. CORE believes this is due to a complex filtering

process affecting who is offered the procedure; they would like to see fewer disparities and rates of procedures that better reflect national population demographics.

- Dr. Suter noted it is complicated to include race in the risk model because it behaves differently for the IP and OP settings. Further, including race in the risk model makes very little difference in the model fit.
- These results suggest, regardless of the proportion of patients with SDOH, the RSCRs look very similar (Spearman's Rho for all comparisons >0.999 with a p-value < 0.001) with or without SDOH in the model. It is hard to determine what this means because there are so many things that might impact whether non-White patients receive a procedure; over 90% of procedures are for White patients.
- Dr. Suter reviewed the table of observed complication rates and histograms comparing the RSCRs for facilities with the highest and lowest proportions of Black patients. She discussed differences in the outcome stratified by race, dual eligibility, and the Agency for Healthcare Quality and Research (AHRQ) Socioeconomic Status (SES) Index (ASI), which uses community level variables to describe the patient's residential neighborhood; ASI is a robust measure of income, unemployment, and other factors and a low ASI suggests a community with fewer resources.
- Dr. Suter noted dual eligibility and low-ASI are both significantly associated with increased complications after accounting for comorbidities, while exposure to racism does not have a significant association.
    - A TEP member requested clarification (via the meeting chat) about whether what is labeled as ASI is the same as the Area Deprivation Index (ADI) developed by Amy Kind at Wisconsin and used by Health Resources and Services Administration (HRSA).
    - Dr. Suter confirmed (via the meeting chat) the ASI is different than HRSA's ADI; CORE looked at the ASI and not the ADI. The ASI is correlated, but not perfectly correlated, with ADI.
- Dr. Suter asked (via the meeting chat) if anyone had thoughts about accounting for SDOH in measure calculation vs. payment calculation.
- TEP members had the following questions and comments regarding the measure:
    - A TEP member asked if dual eligibility and low-ASI are captured as patient-level variables.
        - Ms. Andrea Barthel clarified AHRQ SES data is based on the patient's zip code.
        - The TEP member noted concern about the community effect. They suggested CMS consider using SES in the risk adjustment and stratification, similar to what they use for the readmission measures; there is a perception among surgeons that people who are dual eligible have higher complication risk, which impacts whether procedures are offered. Including SES in the risk adjustment may result in increased access to the procedures.
    - A TEP member expressed support for accounting for SDOH, and noted there is literature supporting accounting for dual eligibility. They suggested SES should

be accounted for at the patient level, rather than community level. They added stratification may be the best approach to compare organizations and noted concerns about putting too much in the risk model and veiling quality disparities.

- A TEP member agreed that SES should be accounted for at the patient level, recognizing it may be challenging if CMS does not have accurate zip code data.
- A TEP member noted this measure does not do anything to help with increasing access to the procedure for underserved patients. He supports stratification for SDOH.
- A TEP member noted as a physical therapist who has worked in a variety of geographical locations, they believe it is important to include SDOH. The differences they have observed in patient attendance, and how well a patient can prepare before and attend follow up appointments after the procedure impacts outcomes.
- A TEP member stated at a minimum they support reporting the measure with stratification for quality improvement purposes. Their preference is to see it applied to the measure calculation rather than payment, as it would be beneficial to provide the information so hospitals can improve on disparities.
- A TEP member asked about the comparison of Black and White patients, and whether there were differences in age and comorbidities.
    - Dr. Suter noted they are similar except for there being a lower proportion of Black patients. In general, they may be younger than the White population. It may be interesting to look at the demographics and whether non-White patients are from higher SES, and whether the filtration process is causing the lower complication rates due to filtering out patients.
    - Dr. Suter noted adding SDOH to the risk model does not substantively change the C-statistic, predictive ability, or the facility-level RSCRs. Hospitals with higher proportion of Black patients have a slightly higher RSCR, but there is not a skewed distribution suggesting hospitals cannot do well on the measure.
- A TEP member asked if the low numbers of procedures for Black patients should cause us to distrust the data.
    - Dr. Suter noted this is the result of the pre-procedure filters; approximately one in seven people are Black and Black people have higher rates of hip and knee arthritis, yet they are not receiving THA/TKA procedures which suggests an access issue. The data show what is happening. If everyone who might receive a procedure did receive a procedure, the data would look different.
    - A TEP member noted if there are top notch Black candidates who get surgery while a more diverse population of White patients get surgery, it may explain the lack of disparity in the outcome. These data likely

underestimate the disparities. It appears race is unimportant while poverty is important, but that result is misleading.
        - Another TEP member agreed, noting the histograms show steep curves and the graphs represent clustering around a very low complication rate with narrow standard deviations. Hospitals and surgeons know only two or three complications can change their ranking and result in payment penalties; they are over-compensating for risks, and they assume other hospitals and surgeons are doing the same.
    - A TEP member noted applying stratification to the measure calculation is safer.
    - A TEP member noted (via the meeting chat) preference for stratification at the measure calculation level. They would like to see how application at the payment level might look. Given the disparity in the procedure volumes between dual and non-dual eligible and the low vs. high ASI, they are concerned that applying the stratification at the payment level might become a disincentive and further affect access.
    - A TEP member commented (via the meeting chat) that the best social measure for total joint is marital status, which is not available for all Medicare patients. The next best is dual eligibility, and it is critical. Risk adjustment is necessary. They suggested moving away from DRGs which have complication differentiation and instead get to DRGs paid differently based on risk. They prefer SDOH be addressed with risk adjustment and also payment adjustment to prevent rewarding higher complication rates, cherry picking, and risk avoidance.
    - A TEP member asked about tobacco use and the comorbidity list, and why CORE is using different risk variables across the measures.
        - Dr. Suter noted it is not a complication for this measure, but it is collected in CMMI's Comprehensive Care for Joint Replacement model, for the patient-reported outcomes measure. This is a claims-based measure while the patient-reported outcomes measure uses a different data source. Risk factors like tobacco use are not consistently captured within claims. As CMS moves toward digital quality measurement, it may create a better environment for including additional risk factors. It also depends on how the risk factor impacts the risk model for each measure. The legacy measure for this measure is in the process of risk model re-specification. Major psychiatric disorders are already included in the risk model.
    - A TEP member asked how to consider the face validity, given SDOH are not yet accounted for.
        - Dr. Suter suggested voting on the measure as it is and including more feedback in the comments about why you are rating it as you are and how changes could affect your rating.
    - A TEP member asked if there is a way to capture whether a patient is seeing their primary care physician, especially if they have SDOH. They wondered if

there is a way to capture when patients have or have not accessed services (supporting conservative therapy before procedures).
        - Dr. Suter noted this measure does not address appropriateness of care, but it is an interesting question. She noted access to PT services is not equal everywhere which would also impact whether services are accessed. It may make sense to look at this within payment models, comprehensive approaches to measurement, and/or bundled payment models like a MIPS Value Pathways (MVPs), which could be informed by patient-reported data. It is probably not as relevant for this measure but may be useful feedback for CMS.
    - A TEP member commented he is struggling with whether Black patients in the measure are representative of the overall Black population. His internal data shows Black patients start with lower functional status but one year after surgery they catch up, so the procedure appears to be an equalizer. About 45 percent of his case load is non-White.
- Dr. Kevin Bozic commented (via the meeting chat), thanking everyone on the TEP for their feedback.

Survey of TEP for Face Validity of Measure

- Ms. Mathew noted participants will receive an email following the meeting containing the face validity survey with two questions:
    - **Question #1:** IP/OP THA/TKA Complication measure as specified will provide a valid assessment of complications following elective THA/TKA.
    - **Question #2:** IP/OP THA/TKA Complication measure as specified can be used to distinguish between better and worse quality care among hospitals performing THAs/TKAs.
        - The six response options for both questions are:
            - 1=Strongly Agree
            - 2=Moderately Agree
            - 3=Somewhat Agree
            - 4=Somewhat Disagree
            - 5=Moderately Disagree
            - 6=Strongly Disagree
        - A comment box will be included for each question to allow for detailed feedback on caveats, concerns, and comments to be captured.
        - Votes are requested by end-of-day Friday, June 24th.

Next Steps

- On behalf of CORE, Ms. Mathew thanked the group for their participation, input, and feedback.
- Dr. Suter noted CORE will add additional comments submitted by email after the call as an addendum to the minutes and they will be included within the summary report.

The materials within this document do not represent final measure specifications for the IP/OP 90-Day THA/TKA Complication Measure.

- Ms. Mathew reviewed additional next steps:
    - CORE will provide minutes and the TEP Summary Report for review in advance of public posting.
    - Public Comment is anticipated in Fall 2022, and CORE will notify the TEP when the comment period has opened.
        - At the conclusion of the comment period, CORE will provide an update to the TEP on the input received.
    - CORE will potentially submit the measure for initial endorsement to NQF for the 2022 Fall cycle.
    - Measure implementation timing is yet to be determined.