

**Patient-Reported Outcomes Following Elective Primary Total
Hip and/or Total Knee Arthroplasty:
Hospital-Level Performance Measure(s)**

DRAFT Measure Methodology Report

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Hospital-Level THA/TKA PRO-PM DRAFT Methodology Report

Patient

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Executive Summary

Background

This report presents the Centers for Medicare & Medicaid Services' (CMS's) progress to date in developing a hospital quality measure(s) for total hip and/or total knee arthroplasty (THA and/or TKA) patients based upon patient-reported outcome surveys (PROMs). PROMs capture patients' self-assessments of their health and provide a mechanism for evaluating the effectiveness of patient-centered care. Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) is developing the hospital-level measure under contract to CMS. CORE is designing the measure to evaluate hospital quality. The measure will potentially employ multiple platforms for data collection, including electronic health records (EHRs), as well as other mechanisms.

CORE is holding this interim public comment period to solicit public comment on the measure decisions to date. This report provides an interim summary of our work and sets forth next steps to inform public comment on measure development.

We are currently in Phase 2 of a multiphase measure development process. During Phase 1 of measure development, we specified the measure cohort, timing of data collection, and the list of viable and preferred PROMs to measure the outcome. In Phase 2, we will finalize the outcome definition, specify the risk-adjustment model, and continue to explore optimal approaches to PROM data collection.

Concurrent with our work on the THA/TKA hospital PROM-based measure, the Office of the National Coordinator for Health Information Technology (ONC) contracted with Booz Allen Hamilton to develop two PROM-based electronic clinical quality measures to assess improvement following THA/TKA. These measures are designed to evaluate the care provided by individual clinicians, or “eligible professionals”, (eligible professionals under CMS's EHR Incentive Program are physicians and select other care providers [e.g., nurse practitioners, dentists] who are not hospital based) and are intended purely as eMeasures, without capability for reporting in non-EHR environments. We have therefore harmonized CMS's measure development process with ONC's. Specifically, we convened a joint technical expert panel (TEP) with the aim of consistently specifying components of the EHR and hospital-based measures (i.e., the patient cohort, PROMs to be used, and timing of data collection) to minimize data collection burden across programs.

In this report we present preliminary, partial measure specifications. We used a wide variety of methods to develop specifications. Therefore this report includes detailed findings assembled through:

- Reviewing the literature on PROM use to identify and define the technical decisions that need to be made in building a measure and to assemble the evidence for alternative choices;
- Interviewing experts involved in implementing PROMs for quality assessment, including international experts experienced in national public reporting and United States (US) experts launching PROMs as part of THA/TKA registries; and
- Convening a national TEP jointly with ONC to provide input on components of measure design.

Preliminary Partial Measure Specifications

To date, we have preliminarily specified the measure cohort, timing of data collection, and the list of viable and preferred PROMs to define the outcome. We have also developed a list of candidate risk-adjustment variables. We list the measure decisions to date below; a more detailed description and rationale for each decision is provided in the body of the report.

Cohort Definition: The measure cohort includes primary elective THA/TKA procedures and excludes patients with fractures and revisions.

Measure Outcome Definition: The outcome definition has three major components: the PROM instruments used, the approach to calculating patients' improvement scores from the pre- and postoperative PROM results, and the timeframe set for surveying patients pre- and postoperatively to evaluate the change in their health status. The measure will use one or more of the following PROM instruments: the Patient Reported Outcomes Measurement Information Systems (PROMIS)- Global or the Veterans Rand 12 Item Health Survey (VR- 12), and/or the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments, with the final outcome to be defined at a later date. The approach to calculating the improvement represented by the pre- and postoperative PROM results has not been finalized. The preoperative data collection timeframe will be 90 to 0 days before surgery, and the postoperative data collection timeframe will be 180 to 270 days following surgery; these timeframes are consistent with current data collection windows used by national registries.

Risk Adjustment: We identified a specific set of candidate clinical risk-adjustment factors listed in this report. The final measure's risk model has yet to be developed. Final risk variable selection for the risk model will involve empiric testing of the candidate risk variables in THA/TKA PROM data as well as consideration of the feasibility and reliability of each variable.

Summary

In summary, we present initial partial measure specifications for a PROM-based hospital-level performance measure(s) for primary elective THA/TKA patients. This proposed hospital-level measure(s) will inform patients in their choice of provider, inform healthcare providers about opportunities to improve patient-centered care, and strengthen incentives for quality improvement.

Introduction

Terminology

There exist many acronyms related to patient-reported outcomes. Throughout this report, we use the terminology advanced by the National Quality Forum (NQF): A “**PRO**” refers to the concept of a patient-reported outcome; a “**PROM**” refers to a survey instrument that captures patient-reported outcomes; a “**PRO-PM**” is a performance measure that uses PRO data to define the measure outcome.¹

Why Use PROs for Performance Measurement?

PROMs are standardized instruments that capture patients’ self-assessments of their health. They provide a direct way to capture patients’ experience of care and its results. PROMs can assess multiple health domains, including physical health, emotional well-being, and social functioning, through measuring outcomes relevant to each domain, such as symptoms, functional status, and mental status. As a result, they provide rich information on how care affects multiple dimensions of patients’ well-being. Currently, only PROMs assessing patients’ experience with the healthcare system are widely used as performance measures, not PROMs that ask patients how the care affected their health.² Patient-reported outcomes are a critical type of outcome needed for healthcare quality assessment.

This focus aligns with the strong interest in PROMs for performance measurement outlined in the National Quality Strategy (NQS) and the quality domains identified by the Institute of Medicine (IOM).^{3,4} Patient-centeredness is one of the ten principles of the NQS and one of the IOM’s quality domains.

Many scientifically sound and well-tested PROMs exist. They fall into two broad categories:

- Condition-specific instruments are developed for use in specific groups of patients with particular conditions or undergoing specific interventions. These instruments may focus on multiple domains of health or be more narrowly focused on a single domain, such as functional status. In either case, these instruments address outcomes that are more specific to the condition or procedures, such as considering only lower extremity pain and function following hip or knee surgery.
- Generic tools assess general health-related quality of life. These instruments can be used to assess the health status of healthy people or of patients with particular or multiple health conditions, but they are more general in nature and assess overall quality of life. They typically cover multiple outcome domains.

PROMs can provide timely information on patient health status, function, and symptoms over time that can be used to improve patient-centered care and inform clinical decision-making.⁵ Nevertheless, the use of PROMs in clinical practice is still limited. Hence, the use of PROMs for national performance measurement will require new data collection, rather than simply the aggregation of routinely collected data.

Why Measure THA/TKA PROs?

We decided to measure PROs following THA/TKA because THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (e.g., pain, mobility, and quality of life) can be measured in a scientifically sound way⁶ and influenced by a range of improvements in care.⁷⁻¹² Thus, PRO-PMs for THA/TKA can meet NQF's measure criteria of importance, scientific acceptability, feasibility, and usability.

Importance

Elective THA/TKAs are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 27 million Americans.¹³ Osteoarthritis accounts for more than half of all arthritis-related hospitalizations, and in 1997 there were more than 400,000 hospitalizations with osteoarthritis listed as the principal diagnosis.¹⁴ Knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,¹⁵ and roughly 80% of patients with osteoarthritis have some limitation in mobility.¹⁶ THA and TKA offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without conferring a high risk of complications and/or death.¹⁷⁻²⁰ As the goal of the procedures is to improve quality of life, they are therefore ideal candidates for assessing PROs.

Due to their frequency and cost, THA and TKA are also priority areas for outcome measure development. More than one-third of the US population 65 years and older suffers from osteoarthritis.²¹ Between 2009 and 2012, there were 337,419 THA procedures and 750,569 TKA procedures for Medicare fee-for-service patients 65 years and older.²² Estimates place the annual insurer cost of osteoarthritis in the US at \$149 billion, with Medicare direct payments to hospitals performing THA/TKA exceeding \$15 billion annually.²³

Administrative claims-based elective primary THA/TKA risk-standardized complication and readmission measures will be publicly reported starting in 2013, assessing outcomes important to patients and clinicians. However, neither of these measures captures the reasons for which patients undergo elective THA and TKA: Will I have less pain and more mobility after surgery? In short, will my quality of life be improved after undergoing the procedure? Therefore, a quality measure based upon PRO data provides both patients and providers a unique and critical perspective on care quality.

THA/TKA procedures provide a particularly rich test bed for developing quality measures based upon patient-reported experiences and piloting performance measures based upon PROMs. These procedures are commonly performed in older patients who have marked pain and functional limitation preoperatively, and who often experience significant improvements postoperatively. However, not all patients experience benefit;²⁴ many note that their preoperative expectations for functional improvement have not been met;²⁵⁻²⁸ and the degree and extent of variation in these outcomes across US hospitals is unknown. However, clinical practice variation has been well documented in the US;²⁹⁻³¹ readmission and complication rates vary across hospitals;^{22,32} and international experience documents hospital-level variation in PROMs following THA/TKA.

Feasible and Measurable

In addition, there are multiple generic and condition-specific tools to evaluate patient-reported symptoms, pain, and functional status that have been used and validated in THA/TKA patients. There are international models for using these PROMs for performance measurement following THA/TKA.^{24,33} Although hospital-level variation in PROs has not been formally reported in the US, several things support that both performance and measurement gaps exist within the US: United Kingdom (UK) data demonstrates greater than 15% differences in the proportion of patients improved after surgery across hospitals;^{34,35} there is established variation in both readmission and complication rates in the US;^{22,32} and surgical practices vary broadly.^{30,31} Together, these support examining PROs following THA/TKA.

THA/TKA procedures also provide an opportunity for initiating public reporting of PRO-PMs because there are already multiple initiatives expanding their use within the US. There are several efforts led by orthopedic surgeons and their professional societies to create regional and national patient registries. In addition, ONC is including THA/TKA PROM reporting in Meaningful Use, and is currently refining their process measures promoting THA/TKA PROM data collection for the EHR Incentive program. These initiatives are driven both by an interest in improving clinical care and by the need to evaluate long-term device safety, further prompted by recent publicized orthopedic device failures.³⁶

In addition to the fact that orthopedics is advanced in its development and use of validated measurements of PROs for research (if not yet for clinical care), an elective procedure such as THA/TKA provides a clear time zero (a reference time) for measurement: the date of the surgery. This allows use of a standardized measurement time frame across hospitals, which reduces measurement bias. In contrast, a PRO-PM for heart failure could use a hospitalization to define the time zero. However, the precise relationship of the care during that hospitalization to any subsequent changes in PROMs is less clear for a chronic disease than for an elective procedure aimed at improving function and reducing pain, such as THA/TKA.

Influenced by Clinical Practice and Care Coordination

Finally, it is important to acknowledge that optimal clinical outcomes depend not just on the surgeon performing the procedure, but on the entirety of many individuals' efforts involved in the care of that patient, as well as on care coordination across provider groups and specialties, and the patient's engagement in their recovery. Even the very best surgeon will not get outstanding results if there are gaps in the quality of care provided by others caring for the patient before, during, and after surgery. The goal of hospital-level outcome measurement is to capture the full spectrum of care in order to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. THA/TKA provides a suitable environment for optimizing care, as there are many studies indicating how providers can improve outcomes of the patients by addressing aspects of pre-, peri-, and postoperative care.⁷⁻¹²

Methodology

Measure Development Process

CORE is leading the development of the measure under the guidance of CMS. The CORE team consists of a multidisciplinary panel of clinicians, health service researchers, and analysts with expertise in outcome measures development. CORE has enlisted for our working group a national clinical leader in the field of orthopedics as a consultant to provide clinical input. CORE also has convened through a public process a national TEP consisting of expert clinicians, methodologists, researchers, patient representatives, and providers. CORE is holding this interim public comment period to solicit stakeholder input on the current measure methodology.

Measure Design Decisions to Date

The measure is currently under development, but we have reached closure on some aspects of the measure specifications, including the cohort of patients included in the measure, aspects of the outcome definition, and the list of candidate risk variables. We employed discussions with our working group and other clinical experts, ONC's contracted measure developer, and our TEP to produce the recommendations on the cohort, outcome decisions, and candidate risk variables below. For each section, we present the proposed measure specification, followed by a detailed rationale. Other aspects of the outcome definition and risk model are still under consideration.

Measure Cohort (Admissions Included in Measure)

- *Include only elective primary THA/TKA procedures in the hospital performance measure; exclude patients with fractures and revisions*
- *Develop separate measures for THA and TKA patients; consider a composite measure for reporting*

Rationale for Focusing on Elective Primary THA/TKA Procedures

Patients who present urgently for non-elective THA or TKA procedures, such as those with hip fractures, tend to be frailer and carry a greater comorbidity burden than their peers undergoing elective THA/TKA procedures and thus represent a distinct clinical population not appropriate for inclusion in a performance measure of elective THA/TKA. Furthermore, these patients cannot complete preoperative PROMs, a critical piece of information to gauge response to surgery. Similarly, patients undergoing non-primary procedures, such as revision THA/TKA, have experienced complications from their primary procedure and are receiving a salvage procedure. As such, these patients may not provide accurate quality information about the hospital where they receive their current (revision) procedure. In addition, a PRO-PM will likely be most useful for patients who are undergoing an elective initial THA/TKA and who consequently have the greatest freedom to choose the hospital at which to have the surgery.

Therefore, similar to the measure cohorts for CMS's THA/TKA complication and readmission measures, we recommend excluding all patients presenting with a relevant anatomic lower extremity or pelvic fracture, those undergoing revision procedures, or those requiring removal of hardware or related to a complication of a prior mechanical complication. This cohort will best reflect the care provided by the hospital performing the elective THA/TKA procedure as well as ensure appropriate risk adjustment across a more homogeneous group of patients.

The final data sources for this measure(s) are still under consideration; however, administrative claims will likely be used to define the measure cohort. Detailed specifications of the measure cohort definitions for the existing readmission and complication measures are publicly available in the respective measure methodology reports (<http://www.qualitynet.org>).^{37,38} The PROM-based measures will likely require minor modifications of these measure cohort definitions and/or additional exclusions to account for elements relevant to a PRO-PM, such as the impact of incomplete PRO survey data.

Rationale for Measuring THA and TKA PROMs Separately

An additional consideration for the THA/TKA PROM-based functional status measure cohort is whether to combine THA and TKA procedures into one composite measure or to report them separately. During measure development of the claims-based THA/TKA measures, we found that hospital readmission and complication rates were similar for the two procedures, and at many hospitals, the staff involved in the care of these two patient groups were the same. For these reasons, and to ensure adequate case volume to allow calculation and reporting of reliable hospital-level performance, we combined THA and TKA procedures in the readmission and complication measures.

However, PROMs can capture both pain and functional status following THA/TKA, and are therefore affected by the recovery trajectories anticipated for these two procedures. Specifically, our clinical experts advised us that the recovery arc differs for patients undergoing THA compared with TKA. Rehabilitation following TKA is more complicated and lengthier than recovery following THA.³⁹⁻⁴²

After examining data from the United Kingdom's National Joint Registry, we determined that preoperative PROM scores are lower on average for THA versus TKA procedures, regardless of whether a generic or condition-specific instrument is used, while postoperative scores are higher regardless of PROM used. PROM outcome results differ between THA and TKA procedures, even at six to nine months postoperatively. Finally, there is wider variation in hospital performance assessments when calculated using risk-adjusted THA versus TKA outcomes, with wider qualitative variation with TKA as compared to THA PROM data. Together, these data indicate that hospital-level PROM outcome scores collected up to nine months postoperatively differ between THA and TKA, and that this difference could affect hospital performance measurement. Therefore, we recommend that hospital performance for the care of THA and TKA patients be assessed using separate measures, and, if needed for sample size requirements, these measures can potentially be combined into a composite score that preserves the distinctions in clinical outcomes between these patient groups.

Measure Outcome: Timing of PROM Data Collection to Define Measure Outcome

There is no consensus as to the optimal time to collect PROM data either before or after THA/TKA procedures. Structured interviews with US surgeons and hospitals systematically collecting PROM data from their THA/TKA patients by NCQA and the Dartmouth Institute as part of ONC's measure development demonstrated a wide range of data collection timeframes. To inform the timing of data collection for use in performance measurement, we reviewed the literature, consulted with experts, and asked our TEP to advise us.

- *Preoperative PROM Data Collection: The proposed preoperative data collection timeframe for this measure will consist of the window between 90 and 0 days before surgery.*
- *Postoperative PROM Data Collection: The proposed postoperative data collection timeframe for this measure will consist of the window between six and nine months (180 to 270 days) following surgery.*

Rationale for 90 to 0 Day Preoperative PROM Data Collection

Clinical experts agree that preoperative PROM data provides not only a baseline assessment of the patient's preoperative health status but also can provide critical risk variables for predicting how that patient will respond to surgery. Many US registry-based efforts to collect PROM data do not specify that preoperative PROM data be collected within a defined window. Clinical experts noted that PROM data collected too far in advance of THA/TKA may not accurately reflect patients' baseline status before surgery, although there is limited data to inform the selection of an appropriate preoperative data collection window. PROMs collected prior to elective THA/TKAs – which are most often performed for osteoarthritis, which is a chronic, slowly progressive, degenerative joint process – are unlikely to vary much in the immediate preoperative time period.⁴³

In collaboration with our TEP, we therefore evaluated two potential timeframes for collecting preoperative data for this measure: within 90 days before surgery and within 30 days before surgery. We selected these specific options as there is precedent for a 90-day data collection timeframe and we proposed the 30-day timeframe based upon clinical experience that demonstrated higher response rates and greater physician agreement with a shorter preoperative PROM data collection timeframe.⁴⁴ Clinical experts also note that a 30-day window corresponds to the Joint Commission requirement for a history and physical examination within 30 days of surgery.⁴⁵

The TEP recommended a 90-day preoperative window for data collection. All surgeons on the TEP believed that elective primary THA and TKA candidates were unlikely to have significant changes in preoperative PROM scores within 90 days of surgery. In addition, they indicated that the additional time to collect data would increase response rates, particularly as the precise data collection mechanism has yet to be specified and is likely to vary across hospitals and surgical practices.

Rationale for 180 to 270 Day Postoperative PROM Data Collection

Postoperative PROM collection ranges from as early as three months after surgery, to up to several years after surgery.⁴⁶⁻⁴⁸ Regional and national registries most commonly collect PROM data within six to 12 months following THA/TKA, and clinical experts and published literature indicate that full clinical rehabilitation is often not reached until one year after surgery.^{49,50}

To address the question of when to collect postoperative PROM data after THA/TKA, we performed a systematic literature review to examine the differences in PROM results at different time points after surgery. In total, we identified seven articles that collected PROM data at both three and six months postoperatively.⁴⁹⁻⁵⁵ Of these seven, only one found both statistically and clinically meaningful differences between preoperative and three-month postoperative PROM assessments and no difference between three and six month postoperative assessments.⁵¹ Naylor et al. assessed pain via visual analog scale (VAS) and 36-Item Short Form Health Survey (SF-36) scores at baseline (preoperatively) and three months postoperatively; study authors found a statistically significant increase at three months postoperatively, but no differences between three- and six-month postoperative assessments. The remaining studies demonstrated continued clinical improvements between three and six months after surgery.

We identified five articles that collected PROM data at six and 12 months after THA/TKA.^{49-51,55,56} Johansson et al. found that Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at six months after THA were no different than those at 12 and 24 months after THA. Three studies of TKA recipients demonstrated continued improvement at three, six, and 12 months after surgery,^{49,50,55} thus supporting that six month PROM postoperative assessments may be more informative than three-month postoperative data, but also suggesting 12-month postoperative data may be more informative than six-month postoperative data for TKA.

PROM data from the New Zealand Joint Registry demonstrates that six-month PROM results are highly correlated with revision rates within two years following THA/TKA.⁴⁶ A person with a six-month Oxford Hip Score of >42 has a 0.42% risk of revision within two years, compared with a 6.46% risk with a score of <27. Similarly, a person with an Oxford Knee Score of >42 has a 0.50% risk of revision within two years, compared to a 6.11% risk with a score of <27. These data support that PROM results collected as early as six months following THA/TKA may be adequate for the purposes of quality measurement, even if the patients have not reached their final functional status.

The TEP recommended CMS collect data between six and 12 months after THA/TKA procedures in order to both allow maximum flexibility in when the data are collected and fully capture the clinical improvement. However, discussions with the TEP, our working group, and the ONC contractors have made it clear that consensus among the orthopedic community regarding the optimal timing of data collection and postoperative clinical assessment is lacking.

There was consensus among the surgeons on the TEP that THA patients improved more quickly postoperatively than TKA patients, although a TEP member noted that total joint replacement data support that a majority of both THA and TKA patients show clinically significant improvement at six

months. Some surgeons advocate early PROM assessment after surgery in order to inform clinical decision-making and the need for further surgical intervention. Others advocate assessments at six and/or 12 months after surgery in order to assess clinical improvement.

Finally, both published literature⁵⁵ and anecdotal experience of THA/TKA surgeons collecting PROM data indicate that response rates decline over time and the losses to follow-up three to six months after THA/TKA are not negligible. In addition, these losses may be greater among under-resourced patient populations. This finding differs from the UK experience, where response rates are higher among patients living in lower socioeconomic areas, but is consistent with experience in clinical areas outside orthopedics collecting PROMs.⁵⁷⁻⁶⁰

Therefore, to balance capturing clinical improvement with maximizing response rates, we propose defining the data collection period for postoperative PROM data between 180 days and 270 days following THA/TKA for use in this measure. As with preoperative data collection, the impact of a broad window for postoperative data collection on hospital performance estimates will be closely examined during the remaining measure development process.

Measure Outcome: Selection of PROM Instruments for Defining the Measure Outcome

The measure developer will define the measure outcome using THA/TKA PROM data collected with:

- *The Patient-Reported Outcomes Measurement Information System (PROMIS)-Global;*
- *The Veterans RAND 12 Item Health Survey (VR-12); and/or*
- *The Hip dysfunction and Osteoarthritis Outcome Score (HOOS) or Knee injury and Osteoarthritis Outcome Score (KOOS) PROM instruments.*

Rationale for Selected PROM Instruments

The PROMIS-Global is a 10 question survey that addresses physical, mental, social and global health domains.⁶¹ The VR-12 is a 12 question survey that assesses similar domains and summarizes the score using a Physical Health Summary Measure and Mental Health Summary Measure scores.⁶² These surveys are considered “generic” PROMs in that they assess general aspects of health and well-being and are not specific to THA/TKA patients. In contrast, the HOOS and KOOS surveys each ask 40 questions regarding hip- or knee-related symptoms and pain, physical function, and quality of life that are specific to the experience of patients with hip or knee pain, respectively.⁶³ All four PROMs are non-proprietary instruments.

In order to select PROMs suitable for use in a hospital-level performance measure, we performed an environmental scan and literature review to identify existing PROMs⁶ and assess their performance characteristics in THA/TKA patients based upon published criteria.^{5,64,65} We also consulted a range of clinical and orthopedic quality measurement experts regarding their experience collecting PROM data in THA/TKA patients.

Clinical experts consulted – as well as a recent Food and Drug Administration (FDA) public meeting of representatives from industry, academia, clinical orthopedics, and rehabilitation – recommended that both generic and condition-specific PROMs be used to capture the full spectrum of relevant risk variables (e.g., mental well-being) and outcomes (e.g., functional status). Our TEP also supported this recommendation. Of note, the two patients on our TEP noted that the generic PROMs captured the information that was most meaningful to them.

In addition to confirming the need for collection of both generic and condition-specific PROMs during the pre-and postoperative timeframes, the TEP highlighted that the ideal combination of instruments should capture emotional health; assess pain and mobility separately in order to assist surgeons in care planning; and consider the needs of individuals with lower levels of education, English language skills, literacy, and numeracy.⁶⁶ The PROMs selected by the TEP represent validated, non-proprietary PROMs that have either been tested in patients undergoing THA/TKA or, in the case of the PROMIS-Global, had undergone rigorous testing during development with plans to test in patients undergoing THA/TKA. In addition, these specific PROMs offered information most valuable to the TEP members, including the ability to distinguish different clinical outcomes such as pain and function, which are combined in other PROMs not selected.

Risk Adjustment

The risk-adjustment model is under development. CORE, in consultation with the working group and the TEP, identified candidate risk-adjustment variables of interest that were both clinically relevant and had an evidence-based relationship with the outcome. Risk variables were drawn from the published literature through a systematic literature review and environmental scan, as well as from orthopedists surveyed about what risk variables they consider important in predicting THA/TKA outcomes. We listed in [Table 1](#) and [Table 2](#) the 27 candidate risk variables for which we are requesting public comment.

Table 1 and Table 2 list variables that one or more TEP members ranked as “high priority” for inclusion in risk adjustment. We separated these high priority variables into two tables based on whether risk-adjustment data are available for the variable. Table 1 presents variables for which data are available in existing data sources. Table 2 lists risk variables for which one or more members of the TEP ranked the variable as “high priority”, but which are not available in current data sources, would require additional data collection beyond the PROM instrument(s) and, for many of the variables, there is no consensus definition at this time.

All diagnostic codes during the 12 months prior to the THA/TKA procedure, as well as those codes indicating conditions present on admission for the qualifying THA/TKA hospitalization, will be evaluated for possible inclusion in the risk model. We will specifically investigate codes identified by our clinical experts and TEP as potentially important risk predictors for THA/TKA outcomes, such as ICD-9-CM 716 Traumatic arthropathy and ICD-9-CM 711 Arthropathy associated with infections. Specific individual comorbidities are only listed below for anatomic and surgical comorbidities highlighted by clinical experts and the TEP.

In addition, the burden of novel data collection for PRO-based performance measures adds complexity to risk adjustment for these measures. The fact that poorly or incompletely collected data may be asymmetrically distributed across lower socioeconomic or disadvantaged populations has the potential to directly affect measure scores. Although other outcome measures are also potentially affected by sociodemographic factors, PROM-based measures are particularly vulnerable to biased data collection. We have included several sociodemographic risk variables in the list below. Also, while not included as candidate risk variables, we will also be examining the impact of factors such as response rate and data quality on measure results during measure development.

Table 1. Candidate Risk Variables under Consideration for Inclusion in the Risk-Adjustment Model for Which Data Are Currently Available

Risk Variable	Proposed Definition	Category
Age	Date of birth	Sociodemographic
Gender	Male/Female	Sociodemographic
Race	Black vs. White	Sociodemographic
Social Functioning	VR-12 social functioning question	Sociodemographic
Preoperative PRO Score	Defined by PROM score and/or subscale score	Functional Assessment
Body Mass Index (BMI)	Kg/m ² : Underweight (BMI<18.5); Healthy weight (BMI 18.5-24.9); Overweight (BMI 25.0-29.9); Obese (BMI ≥30) and/or administrative claims codes	Medical Comorbidity
Medical Comorbidities	All diagnostic and procedural inpatient and outpatient claims submitted within 12 months prior to and including the index admission for the THA/TKA surgery	Medical Comorbidity
Pain/Pain with Activity	Subscales from collected PROMs that address pain	Medical Comorbidity
Smoking Status	Available administrative claims codes and/or standard field from Electronic Health Record	Medical Comorbidity
Presence of Anxiety or Depression	Subscales from collected PROMs that address mental health	Mental Health
Angular Deformity	Administrative claims codes (e.g., ICD-9-CM 736.3 Acquired deformity of hip)	Surgical & Anatomic Comorbidity
Congenital Deformity	Administrative claims codes e.g., (ICD-9-CM 755.63 Other congenital deformity of hip (joint))	Surgical & Anatomic Comorbidity
Flexion Contracture	Administrative claims codes (e.g., ICD-9-CM 718.46 Contracture of joint, lower leg)	Surgical & Anatomic Comorbidity
Previous Infection	Administrative claims codes (e.g., ICD-9-CM 711 Arthropathy associated with infections)	Surgical & Anatomic Comorbidity

Table 2. Candidate Risk Variables under Consideration for Inclusion in the Risk-Adjustment Model That Are Not Available in Existing Data Sources (i.e., Require Additional Data Collection and/or Consensus to Define the Variable)

Risk Variable	Proposed Definition	Category
Living Circumstances	A consensus definition would need to be developed	Sociodemographic
Motivation Score	A consensus definition would need to be developed	Sociodemographic
Social Support	A consensus definition would need to be developed	Sociodemographic
Education	A consensus definition would need to be developed	Sociodemographic
Workman's Compensation	A consensus definition would need to be developed; program definition/requirements vary across states	Sociodemographic
Employment	A consensus definition would need to be developed	Sociodemographic
Socioeconomic status /Income	A consensus definition would need to be developed	Sociodemographic
American Society of Anesthesiologists (ASA) Physical Status Classification	ASA grade 1, 2, 3 or 4	Medical Comorbidity
Helplessness	A consensus definition would need to be developed; potentially captured by other available risk variables	Mental Health
Abduction Deficiency	A consensus definition would need to be developed	Surgical & Anatomic Comorbidity
Extensor Mechanism Deficiency	A consensus definition would need to be developed	Surgical & Anatomic Comorbidity
Radiographic Severity	Kellgren-Lawrence grade 0-3, 4, 5	Surgical & Anatomic Comorbidity
Range of Motion	A consensus definition would need to be developed	Surgical & Anatomic Comorbidity

Final risk variable selection for the risk model will involve empiric testing of the candidate risk variables in THA/TKA PROM data as well as consideration of the feasibility and reliability of each variable. The principles underlying the assessment of individual risk variables in the context of risk model development are summarized below:

- The goal of risk adjustment is to “level the playing field” and account for patient characteristics that are beyond the control of the hospital. Therefore, risk variables must represent clinically important risk predictors; that is, they must be predictive of the outcome (in this case, the change in PROs after THA/TKA) and be beyond the control of the hospital.
 - ✓ The goal is not perfect risk prediction – this would imply that the hospital has NO impact on clinical outcomes (all variation is entirely explained by patient characteristics and all healthcare providers offer identical care). We know this is not true – providers can improve care and outcomes by active quality improvement efforts (e.g., patient education, adjustments to patient care before or after surgery, etc.).

- Risk variables must be feasible to collect and report. If a variable creates a data collection burden to patients, surgeons, hospitals, or the healthcare system, the value of including the variable in the risk model should outweigh the burden.
 - ✓ The definition of burden is subjective. These measures can only be implemented by requiring that hospitals, surgeons, and patients collect the PROM data both before and after the THA/TKA. The TEP recommended that we collect both a generic PROM (the PROMIS Global or VR-12) plus a hip- or knee-specific PROM (the HOOS or KOOS). It is our goal to minimize any *additional* data collection requirements beyond the PROM surveys if possible.
- Risk variables must be reliably and consistently defined so that the risk variables carry the same information across all hospitals.
- Finally, we will only include risk variables that have been tested empirically in the preliminary risk model. If risk factors are important but unavailable, we can either test available surrogate risk factors (for a preliminary risk model) and/or pursue additional data collection (for future iterations of the risk model).

Summary

In summary, we are pursuing a multiphase approach to the development of a hospital-level PRO-PM for elective primary THA/TKA patients. The preliminary, partial measure specifications call for:

- 1) Excluding patients with fractures and/or revision procedures from the measure cohort;
- 2) The use of a generic PROM (PROMIS-Global or VR-12) and/or condition-specific PROM (HOOS/KOOS instruments) to collect PROs before and following elective primary THA/TKA procedures;
- 3) Data collection within 90 days before surgery and between 180 and 270 days following surgery; and
- 4) A set of candidate risk-adjustment variables to be considered for the final risk model.

We reached these preliminary specifications through input from the combined CMS/ONC TEP, our CORE working group, the ONC staff and contractor, and many experts familiar with and experienced collecting THA/TKA PROMs. We encourage public comment on ALL aspects of measure development, including the partial specifications summarized above, as well as input regarding anticipated barriers to implementation and data collection, or aspects of measure development that have yet to be finalized. We look forward to the continued engagement of multiple stakeholders in the final phases of this work.

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