

CBE ID

1550

Title

Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

Project

Cost and Efficiency

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

After the endorsement meeting, the developer of CBE #1550 submitted an appeal due to the following rationales:

- 1. Procedural error in the endorsement process; excessive focus on outpatient setting exclusion, which is outside of the scope of the specified inpatient measure.*
- 2. Misapplication of measure evaluation criteria, particularly risk adjustment.*

The appellant posited the:

- 1. Recommendation Group focused on outpatient setting procedures, which is outside the scope of endorsement.*
- 2. Risk model accounts for clinical risk; additional variables unnecessary. Shift to outpatient procedures creates a uniform risk population. Measure specifications align with care delivery.*
- 3. Minimum case volume for public reporting ensures accurate representation. Hierarchical regression modeling used to estimate performance.*

The Appeals Committee voted to uphold the appeal based on both rationales above. Therefore, the measures' s endorsement decision was overturned to Endorsed with Conditions. When the measure returns for maintenance (5 years), the measure developer should have:

- Explored the proportion of procedures done in the ASC/HOPD* setting and evaluate the need for adjustment (e.g., risk, stratification) based on impact to case mix.*
- Explored additional approaches to the reliability assessment to account for low-volume facilities (e.g., borrowing strength).*

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2024

Initial Endorsement

Tue, 01/31/2012 - 12:02

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and/or TKA procedures for Medicare patients (Fee-for-Service [FFS] and Medicare Advantage [MA]) aged 65 and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to up to 90 days after the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome; if a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes."

1.7 Composite Measure

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Critical Access, Hospital: Inpatient

1.10 Measure Rationale

The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policymakers with information about hospital-level, risk-standardized complication

rates following primary elective THA and/or TKA. This re-specified hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure (hereafter “THA/TKA Complications”) captures complications following a primary elective (inpatient only) THA/TKA procedure in hospitals. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. The re-specified measure now includes both Medicare Advantage (MA) and Fee-for-Service (FFS) beneficiaries. Expanding the measure’s cohort to include both MA beneficiaries in the Centers for Medicare & Medicaid Services (CMS) hospital outcome measures helps ensure that hospital quality is measured across all Medicare beneficiaries and not just the FFS population.

According to CMS, Medicare/Medicaid Part B National Summary, in 2019 the annual volume of primary TKA was 480,958 and that of primary THA was 262,369 with forecasts suggesting an increase in demand for procedures due to gains in post-surgery care, aging population, and increasing osteoarthritis (Singh et al., 2019). Complications following a THA/TKA can vary in frequency and drive the overall cost leading to a substantial burden on both the patient and the healthcare system (Schwarzkopf et al., 2019). Improving complex and critical aspects of care, such as communication between providers, rapid response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to better patient outcomes.

The THA/TKA Complications measure addresses a priority area for outcomes measurement. It is an outcome that is likely attributable to care processes and is an important outcome for patients. Measuring and reporting complication rates inform healthcare providers about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. This measure also provides patients with information that could guide their choices. Furthermore, the measure increases transparency for consumers and has the potential to lower healthcare costs associated with complications following this common elective procedure.

References

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- Singh, J. A., Yu, S., Chen, L., & Cleveland, J. D. (2019). Rates of total joint replacement in the United States: future projections to 2020-2040 using the national inpatient sample. *The Journal of rheumatology*, 46(9), 1134-1140.

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.13a Attach Data Dictionary

[2024_THA_TKA_DataDictionary.xlsx](#)

1.14 Numerator

The outcome for this measure is any one of the specified complications occurring during the index admission to 90 days after the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes." The specific complications captured by this measure are: Acute myocardial infarction (AMI) during the index admission or a subsequent inpatient admission that occurs within seven days from the start of the index admission; Pneumonia or other acute respiratory complication during the index admission or a subsequent inpatient admission that occurs within seven days from the start of the index admission; sepsis/septicemia/shock during the index admission or a subsequent inpatient admission that occurs within seven days from the start of the index admission; surgical site bleeding or other surgical site complication during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission; pulmonary embolism during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission; death during the index admission or within 30 days from the start of the index admission; mechanical complication during the index admission or a subsequent inpatient admission that occurs within 90 days from the start of the index admission; or periprosthetic joint infection/wound infection or other wound complication during the index admission or a subsequent inpatient admission that occurs within 90 days from the start of the index admission.

1.14a Numerator Details

The outcome for the THA/TKA Complications measure is dichotomous (yes for any complication(s); no for no complications). Therefore, if a patient experiences one or more of the complications outlined in Section 1.14, the outcome variable will get coded as a "yes". Complications are counted in the measure only if they occur during the index hospital admission (and are not present on admission) or during a readmission.

The complications captured in the numerator (see Section 1.14) are identified during the index admission OR associated with a readmission up to 90 days post-date of index admission, depending on the complication.

The follow-up period for complications from the date of the index admission is as follows:

- The follow-up period for **acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock** is **seven days** from the date of index admission because these conditions are more likely to be attributable to the procedure if they occur within the first week after the procedure. Additionally, analyses indicated a sharp decrease in the rate of these complications after seven days.
- **Death, surgical site bleeding, and pulmonary embolism** are followed for **30 days** following admission because clinical experts agree these complications are still likely attributable to the hospital performing the procedure during this period and rates for these complications remained elevated until roughly 30 days post admission.
- The measure follow-up period is **90 days** after admission for **mechanical complications and periprosthetic joint infection/wound infection**. Experts agree that mechanical complications and periprosthetic joint infection/wound infections due to the index THA/TKA

occur up to 90 days following the index admission.

- The measure counts **all complications occurring during the index admission regardless of when they occur**. For example, if a patient experiences an AMI on day 10 of the index admission, the measure will count the AMI as a complication, although the specified follow-up period for AMI is seven days. Clinical experts agree with this approach, as such complications likely represent the quality of care provided during the index admission.

The measure does not count complications in the complications outcome that are coded as present on admission (POA) during the index admission; this prevents identifying a condition as a complication of care if it was present on admission for the THA/TKA procedure.

For a full list of codes defining complications, see the Data Dictionary attached in Section 1.13. The 2024 THA/TKA Measure Dictionary tab “HKComp Outcome Inclusion” provides the specific codes used to identify complications.

1.15 Denominator

The cohort includes admissions for patients that meet all of the following inclusion criteria: 1. Enrolled in Medicare (Fee-for-Service [FFS] or Medicare Advantage[MA]) for the 12 months prior to the date of admission and during the index admission; 2. Aged 65 or older; 3. Having a qualifying elective primary THA/TKA procedure. A qualifying elective primary THA/TKA procedure is defined as a procedure without any of the following: Fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim (Note: Periprosthetic fractures must be additionally coded as present on admission [POA] in order to disqualify a THA/TKA from cohort inclusion, unless exempt from POA reporting.); A concurrent partial hip or knee arthroplasty procedure; A concurrent revision, resurfacing, or implanted device/prosthesis removal procedure; Mechanical complication coded in the principal discharge diagnosis field on the index admission claim; Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim; or, Transfer from another acute care facility for the THA/TKA.

1.15a Denominator Details

The cohort includes admissions for patients who meet all of the following inclusion criteria below.

- **Enrolled in Medicare fee-for-service (FFS) and/or MA for the 12 months prior to the date of admission; and enrolled in FFS or MA during the index admission;**
 - *Rationale:* The 12-month prior enrollment criterion ensures that the comorbidity data used in risk adjustment can be captured from inpatient, outpatient, and physician claims data for up to 12 months prior to the index admission, to augment the index admission claim itself.
- **Aged 65 or older;**
 - *Rationale:* Medicare beneficiaries younger than 65 are not included in the measure because they are considered to be too clinically distinct from Medicare beneficiaries who are 65 or older.
- **Having a qualifying elective primary THA/TKA procedure. Elective primary**

THA/TKA procedures are defined as those procedures without any of the following:

- **Fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim** (Note: Periprosthetic fractures must be additionally coded as present on admission (POA) in order to disqualify a THA/TKA from cohort inclusion, unless exempt from POA reporting.);
 - *Rationale:* Patients with fractures have higher mortality, complication, and readmission rates, and the procedures are typically not elective.
- **A concurrent partial hip or knee arthroplasty procedure;**
 - *Rationale:* Partial arthroplasty procedures are primarily done to treat fractures and are typically performed on older patients who are frailer and have more comorbid conditions
- **A concurrent revision, resurfacing, or implanted device/prosthesis removal procedure;**
 - *Rationale:* Revision procedures may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication, and readmission rates. Resurfacing procedures are a different type of procedure involving only the joint's articular surface and are typically performed on younger, healthier patients. Elective procedures performed on patients undergoing removal of implanted device/prosthesis procedures may be more complicated.
- **Mechanical complication coded in the principal discharge diagnosis field on the index admission claim;**
 - *Rationale:* A complication coded as the principal discharge diagnosis suggests the procedure was more likely the result of a previous procedure and indicates the complication was POA. These patients may require more technically complex arthroplasty procedures and may be at increased risk for complications, particularly mechanical complications
- **Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim;**
 - *Rationale:* Patients with these malignant neoplasms are at increased risk for complications, and the procedure may not be elective.
- **Transfer from another acute care facility for the THA/TKA.**
 - *Rationale:* The THA/TKA Complications measure does not include admissions for patients transferred to the index hospital, as they likely do not represent elective THA/TKA procedures (see additional information below).

The measure uses International Classification of Diseases, Tenth Revision, Clinical Modification/Procedure Coding System (ICD-10-CM and ICD-10-PCS) codes on claims to define a THA/TKA procedure and to identify a THA/TKA procedure as non-elective or non-primary (and disqualify the admission from cohort inclusion). Codes that define the cohort can be found in the "HKComp Cohort Inclusions" tab in the Data Dictionary.

1.15b Denominator Exclusions

This measure excludes index admissions for patients:

- Without at least 90 days post-discharge enrollment in Medicare Fee-for-Service (FFS) or Medicare Advantage (MA);
- Discharged against medical advice (AMA);
- With more than two THA/TKA procedure codes during the index hospitalization;
- With a principal diagnosis code of COVID-19 (ICD-10-CM code U07.1) or with a secondary diagnosis code of COVID-19 coded as present on admission (POA) on the index admission claim.

1.15c Denominator Exclusions Details

This measure excludes index admissions for patients:

- **Without at least 90 days post-discharge enrollment in Medicare Fee-for-Service (FFS)and/or Medicare Advantage (MA);**
 - *Rationale:* The 90-day complication outcome cannot be assessed in this group since claims data are used to determine whether a complication of care occurred.
- **Discharged against medical advice (AMA);**
 - *Rationale:* Providers did not have the opportunity to deliver full care and prepare the patient for discharge.
- **With more than two THA/TKA procedure codes during the index hospitalization;**
 - *Rationale:* Although clinically possible, it is highly unlikely that patients would receive more than two elective THA/TKA procedures in one hospitalization. Coding in such cases may reflect a coding error.
- **With a principal diagnosis code of COVID-19 (ICD-10-CM code U07.1) or with a secondary diagnosis code of COVID-19 coded as POA on the index admission claim.**
 - *Rationale:* COVID-19 patients are removed from the THA/TKA cohort in response to the COVID-19 PHE, and to maintain alignment with the THA/TKA Complications measure included in the FY 2025 Hospital VBP Program.

After the above exclusions are applied, the measure randomly selects one index admission per patient per time period for inclusion in the cohort so that each episode of care is mutually independent with the same probability of the outcome. Additional admissions within that time period are excluded.

1.15d Age Group

Older Adults (65 years and older)

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The measure estimates hospital-level risk-standardized complication rate (RSCRs) following

elective primary THA/TKA using a hierarchical logistic regression model. In brief, the approach simultaneously models data at the patient and hospital levels to account for variance in patient outcomes within and between hospitals (Normand and Shahian, 2007). At the patient level, it models the log odds of a complication occurring within 90 days of the index admission using age, sex, selected clinical covariates, and a hospital-specific intercept. At the hospital level, it models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of a complication at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSCR is calculated as the ratio of the number of “predicted” to the number of “expected” admissions with a complication at a given hospital, multiplied by the national observed complication rate. For each hospital, the numerator of the ratio is the number of complications within 90 days predicted on the basis of the hospital’s performance with its observed case mix, and the denominator is the number of complications expected based on the nation’s performance with that hospital’s case mix. This approach is analogous to a ratio of “observed” to “expected” used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital’s performance given its case mix to an average hospital’s performance with the same case mix. Thus, a ratio of less than one indicates lower-than-expected complication rates or better quality, and a ratio of greater than one indicates greater-than-expected complication rates or worse quality.

The “predicted” number of admissions with a complication (the numerator) is calculated by using the coefficients estimated by regressing the risk factors and the hospital-specific intercept on the risk of having an admission with a complication. The estimated hospital-specific intercept is added to the sum of the estimated regression coefficients multiplied by the patient characteristics. The results are log-transformed and summed over all patients attributed to a hospital to get a predicted value. The “expected” number of admissions with a complication (the denominator) is obtained in the same manner, but a common intercept using all hospitals in our sample is added in place of the hospital-specific effect. The results are log-transformed and summed over all patients in the hospital to get an expected value. The predicted over-expected ratio is then multiplied by the national observed rate to calculate the risk-standardized complication rate. To assess hospital performance for each performance period, we re-estimate the model coefficients using the years of data in that period.

This calculation transforms the ratio of predicted over expected into a rate that is compared to the national observed complication rate. The hierarchical logistic regression models are described fully in the original methodology report posted on *QualityNet*:

<https://www.qualitynet.org/inpatient/measures/complication/methodology>.

References

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1.18a Attach measure score calculation diagram

[Measure Calculation_THATKAComplications.pdf](#)

1.19 Measure Stratification Details

This measure is not stratified.

1.20 Types of Data Sources

Administrative Data, Claims Data

1.25 Data Source Details

Medicare fee-for-service (FFS) claims and Medicare Advantage (MA) encounters, in addition to Medicare administrative data, are used to derive all components of the measure.

1.26 Minimum Sample Size

The measure does not have a minimum sample size.

2.1 Attach Logic Model

[All Figures and Tables THA TKA Complications.pdf](#)

2.2 Evidence of Measure Importance

THA and TKA are among the most commonly performed orthopedic surgeries worldwide aimed at relieving pain and restoring function in patients with severe arthritis and joint damage. According to the American Academy of Orthopedic Surgeons (AAOS), between 2012 and 2022 more than 1.6 million total knee arthroplasties and over 1 million total hip arthroplasties were performed in the United States (AAOS Report, 2023). Based on 2000-to-2014 data, one study predicted that annual THA volumes are projected to grow to 635,000 procedures a year by 2030 and TKA volumes to 1.26 million procedures a year by 2030 (Sloan et al., 2018).

Complications following a THA/TKA can vary in frequency. Periprosthetic joint infections can range from 0.2% to 2% in THA and TKA including for the Medicare population. (Bourget-Murray et al., 2023; Bozic et al., 2014; Kurtz et al., 2018). Venous thromboembolism (VTE), including deep vein thrombosis and pulmonary embolism, is reported to occur in about 0.6% to 3.0% of patients (Simon et al., 2023). Reported 90-day death rates after THA or TKA were 0.65% (95% confidence interval (CI) 0.50 to 0.81) and 0.39% (95% CI 0.32 to 0.49), respectively (Berstock et al., 2014; Berstock et al., 2018). Rates for septicemia range from 0.1%, during the index admission to 0.3%, 90 days following discharge for primary TKA (Bozic et al., 2014). In the data submitted for this THA/TKA Complications measure (representing 272,164 procedures performed between January 1, 2022, and December 31, 2023), hospital-level, risk-standardized complication rates ranged from 1.5% to 8.7%.

Since THAs and TKAs are commonly performed and costly procedures, it is imperative to address quality of care to improve complication rates. There is evidence that complications following a

THA/TKA procedure can be impacted by improvements in critical aspects of care, such as communication between providers, prevention of response to complications, patient safety, and coordinated transitions to the outpatient environment (Bozic et al., 2014; Kurtz et al., 2018). Several studies indicate that by implementing quality improvement efforts including multidisciplinary care teams, pre- and post-counseling and education around THA/TKA procedures, and shared decision-making, hospitals can reduce complications and overall associated costs (Kulshestra et al., 2022; Wong et al., 2022; Sorensen et al., 2019). Since THAs and TKAs are commonly performed and costly procedures, it is imperative to address quality of care.

Addressing complications can also mitigate the economic challenges associated with these common orthopedic procedures. Medicare expenditures for THA and TKA are expected to increase by almost 50% by 2030, driven by the growing number of procedures and rising costs (Singh et al., 2019). This projection underscores the importance of implementing strategies to manage and reduce costs, such as improving surgical outcomes and postoperative care for both individual patients and the healthcare system (Pagano et al., 2018; Liu and Young, 2020). The variation in complication rates across hospitals indicates there is room for quality improvement and targeted efforts to reduce these complications could result in better patient care and potential cost savings (Navathe et al., 2017; Cyriac et al., 2016; Borza et al., 2019). Measurement of patient outcomes allows for a comprehensive view of quality of care that reflects complex aspects of care such as communication between providers and coordinated transitions to the outpatient environment. These aspects are critical to patient outcomes and are broader than what can be captured by individual process of care measures. Please see Section 6.2.1 for additional evidence for hospital-level interventions that impact THA/TKA Complication rates.

References

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2.4 Performance Gap

Table 1, Table 2, and Figure 2 (in the attachment) show that there is meaningful variation in the distribution of measure scores (risk-standardized complication visit rates or RSCRs) using the most recent testing data (January 1, 2022 - December 31, 2023). As shown in Table 1, RSCRs range from 1.47% to 8.79%; the median is 3.50%; the 10th percentile is 2.91% and the 90th percentile is 4.42%. The best performer (1.47%) has a risk-standardized complication rate that is 72.40% better than the median (3.50%); the worst performer (8.79%) has a risk-standardized complication rate that is 2.5 times or 151% worse than the median (3.50%).

We provide further evidence of variation by calculating and interpreting the median odds ratio (Merlo, et al., 2006). The median odds ratio, in this context, calculates the odds of the outcome (complications) if the same patient were treated at a higher-risk hospital compared with a lower-risk hospital. The mean odds ratio for the THA/TKA Complications measure is 2.21, indicating that a patient has 2.2 times the odds (or 121% greater risk) of a complication if they were initially admitted to a hospital for THA/TKA procedure at a high-risk facility compared to a lower-risk facility indicating meaningful variation in performance.

References

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Table 1. Performance Scores by Decile

	Performance Gap												
	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean													
Performance Score	3.60	1.47	2.57	3.06	3.26	3.39	3.47	3.53	3.68	3.89	4.19	4.96	8.79
N of Entities	3,124	1	312	312	313	312	313	312	313	312	313	312	1
N of Persons													
/ Encounters	272,164	1,072	106,482	30,500	17,776	13,147	8,589	9,316	24,331	18,378	18,134	25,511	112
/ Episodes													

2.6 Meaningfulness to Target Population

Measuring and reporting complication rates to inform patients, providers, and hospitals can help improve care, strengthen incentives for quality improvement, and improve the quality of care received by Medicare patients. As many providers may not be monitoring their patients' complications after surgery, they may underestimate adverse events, suggesting the need for better measurement to drive quality improvement. In addition, for THA and TKA, most patients have sufficient time to consider their options and understand the quality differences between hospitals. Therefore, both patients and providers benefit from this outcome measure – a broad, patient-centered outcome that reflects procedure-specific complications among patients undergoing THA/TKA.

Complications following surgery have been shown to impact broader patient outcomes such as

quality of life. For example, a 2019 study found that patients who experience postoperative complications were more likely to report lower quality of life in comparison to patients who did not experience complications, and the magnitude of the impact was similar to other variables such as increased age and the presence of comorbidities (Woodfield et al., 2019). The relationship between post-surgical complications and reduced quality of life has been confirmed in multiple more recent studies (Downey et al., 2023; Kauppila et al., 2020). Importantly, individuals typically undergo elective THA/TKA procedures to improve their quality of life, however for patients with complications after TKA, complications have been shown to be significantly associated with lower quality of life (Askari, et al., 2024).

There are currently no other national, publicly reported measures of THA/TKA complications, which underscores the measurement gap that would exist without this measure. In addition, this measure complements the existing, nationally-reported (all-cause, unplanned) THA/TKA Readmission measure, but provides more granular information about rates of specific complications. Thus, this measure addresses an important quality measurement area and enhances the information available to patients choosing among hospitals. Furthermore, providing outcome rates to hospitals makes visible meaningful quality differences and incentivizes improvement.

References

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3.1 Contributions Towards Closing Care Gaps

Please see the "All Tables and Figures THA TKA Complications" attachment for all tables and figures that are referred to within this submission, unless otherwise specified.

Social Risk Factor Summary

Overall, and consistent with the literature, we found that there is a low proportion of patients with social risk factors undergoing THA/TKA procedures. While patients with social risk factors (Dual Eligibility (DE)/high Area Deprivation Index (ADI)) who do undergo THA/TKA have higher unadjusted outcomes, however, there is almost no impact on measure scores when adding each variable to the risk adjustment model. This suggests that the clinical risk variables in the model already account for most of the risk associated with these two social risk factors. We also found that the model performs well for patients with DE and high ADI separately. CMS has, therefore, decided not to adjust this quality measure for social risk factors. However, with respect to its use in a payment program (THA/TKA Complications measure is being proposed for the Hospital Value-Based Program [HVBP]), CMS has finalized a new payment adjustment methodology to account for health equity; starting in 2026, HVBP will allow hospitals to earn up to 10 bonus points to their Total Payment Score, accounting for the hospital's proportion of patients with dual eligibility (CMS, 2023).

Social Risk Factor Testing

To understand the impact of social risk factors on the THA/TKA Complications measure, we assessed the following: prevalence of each social risk factor (DE, high ADI) among hospitals, association with the unadjusted outcome, model calibration for patients with each social risk factor, and impact on measure scores. Each analysis is described in more detail below. All analyses used the CY2022 dataset (one year of Medicare Advantage (MA)+Fee-for-Service (FFS) data, January 1, 2022-December 31, 2022).

For the THA/TKA Complications measure, the median hospital proportion of patients (among hospitals with at least 25 admissions, n= 1,270 hospitals) was 5.13% for the DE variable and 6.78% for the high ADI variable (see Table 10 in the attachment).

As shown in Table 11 (see attachment), unadjusted complication rates for patients with DE or high ADI were higher than for patients without either social risk factor (mean unadjusted rates for DE vs non-DE, 4.0% vs 3.4%; high ADI vs. low ADI, 4.0% vs 3.3%).

We also examined the model calibration for each social risk factor to determine if the risk model (without including either social risk factor) performs well for patients with each social risk factor (see Figure 4A and 4B and Figure 5A and 5B in the attachment). The results show that the model is well-calibrated for both sets of patients.

To understand the impact of each variable on the THA/TKA Complications measure score, we calculated measure scores with and without each social risk factor and then calculated the differences in measure scores and the correlation between measure scores (Table 12 in the attachment). Results show that measure scores calculated with and without social risk factors are highly correlated (correlation coefficient 1.000 and 0.989 for DE and high ADI, respectively), and differences between measure scores are very small.

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4.1 Feasibility Assessment

The THA/TKA Complications measure is a claims-based measure, and the measure score is calculated automatically from claims data which are routinely generated during the delivery of care. This measure does not require additional data collection by facilities, which eliminates the reporting burden for hospitals. Since data are collected through standard claims submissions and processed by CMS, this measure does not introduce implementation challenges.

CMS monitors feedback from the public and measured entities through CMS's Q&A portal on *QualityNet*; there have been no concerns about feasibility or burden related to this measure. There are no concerns about patient confidentiality because the measure is based on claims data submitted by facilities to CMS, and CMS then uses that data for both payment and calculation of the measure score.

We did not perform an analysis of missing data for the measure because it is based on a 100% sample of paid, final action claims submitted by facilities for payment. To ensure complete claims, we allow at least 3 months of time between accessing the data and the end of the performance period.

4.3 Feasibility Informed Final Measure

Because this is a claims-based measure there is no burden on the facility and no feasibility concerns; rates are automatically calculated by CMS based on claims data submitted by facilities for payment.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

For most of the testing in this submission, we used two years of Medicare (Fee-for-Service (FFS) and Medicare Advantage (MA)) data (January 1, 2022-December 31, 2023). Descriptions of the data used for testing are outlined in Table 3 ("All Figures and Tables THA TKA Complications" attachment, pages 3-5).

5.1.2 Differences in Data

Please see Section 4.1.4 for details. Differences in data used for testing are outlined in Table 3 ("All Figures and Tables THA TKA Complications" attachment, pages 3-5).

5.1.3 Characteristics of Measured Entities

Characteristics of measured entities differ depending on the dataset. Please see Table 3 ("All Figures and Tables THA TKA Complications" attachment, pages 3-5).

5.1.4 Characteristics of Units of the Eligible Population

The datasets, dates, number of measured hospitals, and number of admissions used in each type of testing are in Table 3 (see "All Figures and Tables THA TKA Complications" attachment, pages 3-5).

For most measure testing, we used Medicare data from January 1, 2022-December 30, 2023. These datasets also include data on each patient for the 12 months prior to the index admission and contain facility inpatient and Medicare Enrollment Database (EDB) data.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

We tested facility-level measure score reliability using the signal-to-noise method, using the formula presented by Adams and colleagues (Adams et al., 2010; Yu et al., 2013). Specifically, for each facility, we calculate reliability using the hospital intercept estimated through the random intercept of the hierarchical logistic regression model, which is the quality signal, as follows:

$$\text{Reliability} = (\sigma_{\text{facility-to-facility}}^2) / (\sigma_{\text{facility-to-facility}}^2 + (\sigma_{\text{facility error variance}}^2) / n)$$

Where facility-to-facility variance is estimated from the hierarchical logistic regression model, n is equal to each facility's observed case size, and the facility error variance is estimated using the variance of the logistic distribution ($\pi^2/3$). This calculation provides a valid reliability score because the hospital intercept (random effects) of the hierarchical logistic regression model is highly correlated with the standardized readmission ratio (SRR), which is used to calculate the measure score (the SRR is multiplied by a constant [the national unadjusted readmission rate] to derive the risk-standardized readmission rate or RSRR). The correlation between the hospital intercept and the SRR for this measure is 0.999 ($p < .0001$). As stated in Section 1.18, the hospital intercept represents the underlying risk of a readmission at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals. Please see the formula provided in the attachment in Section 1.18a for additional details.

References

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5.2.3 Reliability Testing Results

Please see the "All Tables and Figures THA TKA Complications" attachment for all tables and figures that are referred to within this submission, unless otherwise specified.

We calculated signal-to-noise reliability for all hospitals in the testing sample (n= 3,124) and hospitals with at least 25 cases (n= 1,777), the volume threshold for public reporting of measure scores on *Care Compare* (Table 4 in the attachment). We used two years of data for the analysis (CY2022/2023). For hospitals with at least 25 cases, the median reliability score was 0.784, ranging from 0.545 to 0.997. The 25th and 75th percentiles were 0.623 and 0.784, respectively. Table 5 (in the attachment) provides the Battelle-required table of measure scores within deciles of reliability.

5.2.4 Interpretation of Reliability Results

Using two years of performance data, signal-to-noise reliability ranged from 0.545- 0.997 with a median of 0.784 for facilities with at least 25 procedures. Most hospitals with at least 25 procedures fall above the minimum signal-to-noise reliability threshold of ≥ 0.6 .

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results													
 	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.776	0.545	0.567	0.625	0.674	0.720	0.766	0.808	0.844	0.882	0.918	0.961	0.997
Mean													
Performance	3.59	3.57	3.65	3.75	3.72	3.75	3.78	3.71	3.68	3.57	3.38	2.87	2.16
Score													
N of Entities	1,777	33	180	182	170	176	181	181	175	178	178	176	1
N of Persons													
/ Encounters	259,441	825	4,946	6,363	7,350	9,522	12,416	15,988	19,840	27,949	42,677	112,390	6,172
/ Episodes													

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

Please see the "All Tables and Figures THA TKA Complications" attachment for all tables

and figures that are referred to within this submission, unless otherwise specified.

For this submission, we provide evidence of validity through face validity conducted during measure development, and empiric validity through examining associations of THA/TKA Complications measure scores with volume. Below we describe the methodology; the results are provided in the subsequent section.

Face Validity Using Technical Expert Panel

During measure re-specification (which included an expansion of the cohort to include Medicare Advantage patients and reselection of risk variables) we re-assessed the THA/TKA Complications measure's face validity with a technical expert panel (TEP) of national experts and stakeholder organizations. We systematically assessed the face validity of the measure score as an indicator of quality by soliciting TEP members' agreement with the following statement (via an online survey): "The risk-standardized complication rate obtained from the measures as specified can be used to distinguish between better and worse quality hospitals."

The TEP is comprised of clinicians, health services researchers, statisticians, patients, patient advocates/caregivers, health insurance representatives, and hospital administrators (see Table 6 in the attachment for additional details on panel members).

The survey offered participants six response options ranging from "strongly disagree" to "strongly agree" on a six-point scale:

- 1=Strongly disagree
- 2=Moderately disagree
- 3=Somewhat disagree
- 4=Somewhat agree
- 5=Moderately agree
- 6=Strongly agree

Empiric Validity

To demonstrate empirical validity for the THA/TKA Complications measure, we assessed the measure score's correlation with the quality construct of volume.

Volume may be considered a quality construct in that it is a proxy for underlying quality-related factors. Hospitals with higher operative volume for THA/TKA procedures may have surgeons and staff with greater experience and repeated performance of evidence-based processes, allowing for the development and implementation of standardized care delivery, which in turn can reduce errors and delays in care and improve outcomes. Higher volume hospitals may also invest in more specialized support systems and training (Jha, 2015) and may also have more resources to invest in quality improvement and participation in formal quality improvement registries, such as the American Joint Replacement Registry (Hedge et al., 2023).

There is evidence that surgical complication rates for providers (both surgeons and hospitals) decline with increasing THA and TKA volume (Sibley et al., 2017; Murphy et al., 2019; Courtney et

al., 2018). Thus, we assessed the validity of the measure by examining the relationship between volume and the measure score for hospitals. To establish validity, we expect THA/TKA measure scores to be correlated with case volume at the hospital level. We hypothesized that there would be a weak to moderate, negative relationship between hospital admission volume and THA/TKA Complications measure scores, with higher volumes associated with better (lower) THA/TKA Complications measure scores.

These concepts are discussed in Section 2.2 and Section 6.2.1 and are shown in the logic model (Figure 1 in the attachment).

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5.3.4 Validity Testing Results

Please see the "All Tables and Figures THA TKA Complications" attachment for all tables and figures that are referred to within this submission, unless otherwise specified.

Face Validity

A total of 12 TEP members responded to the face validity survey. 11 of 12 TEP members (91.7%) agreed (strongly, moderately, somewhat) with the face validity statement; 1 of 12 TEP members (8.3%) moderately disagreed.

The specific counts for each voting category are shown below:

- Strongly agree: 4 (33.3%)
- Moderately agree: 6 (50%)
- Somewhat agree: 1 (8.3%)
- Somewhat disagree: 0 (0.0%)
- Moderately disagree: 1 (8.3%)

- Strongly disagree: 0 (0.0%)

Empiric Validity

Table 7 (see attachment) shows THA/TKA risk-standardized complications rates (RSCRs) within deciles of hospital admission volume (cohort volume). RSCRs decline with increasing admission volume, starting with the 7th decile. RSCRs are the lowest in the highest-volume decile (within hospitals with the highest admission volume). The overall Pearson's correlation coefficient between RSCRs and hospital volume is -0.25 ($p < .0001$). The correlation coefficient between THA/TKA RSCRs and hospital volume for hospitals with at least 200 procedures is -0.138 ($p < .0001$), and for hospitals with less than 200 procedures is -0.099 ($p < .51$).

5.3.5 Interpretation of Validity Results

The validity of this measure is supported by three sources of evidence: (1) empiric validity testing supporting a volume/outcome relationship, (2) strong face validity, and (3) evidence of improvement (in the currently reported measure).

Our empiric validity testing examined the quality construct of volume, based on literature supporting a volume/outcome relationship between THA/TKA volume and complications. We found a significant association in the expected strength and direction between THA/TKA hospital volume and the THA/TKA Complications measure: higher THA/TKA hospital volume was significantly associated with lower THA/TKA Complications measure scores (better performance). We also saw that this relationship significant at higher hospital volume (≥ 200 procedures), but not lower volumes (< 200) which is also consistent with the literature.

The validity of this respecified THA/TKA Complications measure is further supported by updated, strong face validity results during measure re-specification (91.7% agreement of face validity from the Technical Panel Experts (TEP)).

Finally, analyses based on the current publicly reported Fee-for-Service (FFS)-only THA/TKA Complications measure show that there has been improvement in measure scores over time (see Section 6.2.4) in a setting of quality improvement efforts (see Section 6.2.1).

Taken together, these results support the validity of the THA/TKA Complications measure.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis), Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

The goal of risk adjustment is to adjust for case-mix differences across the hospitals. Risk

adjustment supports fair and accurate comparison of outcomes across measured entities by including an adjustment for factors such as age, comorbid diseases, and indicators of patient frailty, which are clinically relevant and have relationships with the outcome.

In pursuing an approach that best leverages the data and analytical advancements since initial measure development, we developed and evaluated a framework to use individual ICD-10 codes for risk adjustment. The main advantage of leveraging ICD-10 codes in place of the prior method (that used an ICD-10 grouper, CMS's Condition Categories, or CCs) is the ability to address the clinical heterogeneity found in the broadly defined CCs. Our previous research indicates that the model performance of the mortality measures is significantly improved by using individual codes instead of CCs (Krumholz et al., 2019).

Selection of Clinical Risk Variables

For candidate risk variables, we included all secondary ICD-10 codes documented as present-on-admission (POA) during the index admission (except for the palliative care code of Z51.5, which, effective October 1, 2021, was considered POA-exempt), and both principal and secondary ICD-10 codes in the 12 months prior to admission from any inpatient, outpatient, and professional provider claims. We also considered the principal discharge diagnosis code for the index admission. In addition, we considered age, frailty, sex, an indicator for whether the admission was Medicare Advantage (MA) vs. Fee-for-Service (FFS), and other non-individual-ICD variables in the existing publicly reported THA/TKA Complications measure. The variable selection of individual ICD codes mainly relied on data-driven methodologies involving three key steps: 1) pre-processing, 2) evaluating association with outcome, and 3) consideration of associations between other non-individual-code variables, including frailty, with the outcome.

In pre-processing, we screened and included index and history (pre-index) codes if their prevalence exceeded 0.5% and 2.5%, respectively. Further, co-occurring index and pre-index codes with Pearson correlation coefficients greater than 0.8 were combined into one risk variable. Finally, pairs of identical index and pre-index ICD-10 codes with similar odds ratios that acted in the same direction (where the difference in association with the outcome, measured by odds ratio (OR), was less than 0.2) were merged.

In the second step, we included the remaining candidate variables including age in a multivariable logistic regression model that underwent variable selection through 1,000 iterations of bootstrapping. We selected variables that were statistically significantly associated with outcomes ($p < 0.05$) in at least 70% of the bootstrapped samples. Additional variables were added if there was a resulting increase in c-statistic of at least 0.0005 for each additional variable or an increase of at least 0.005 for including additional variables within the next 5% of bootstrapped samples (e.g. moving from 70% to 65%). Lastly, we included other non-individual-ICD variables from the current FFS-only THA/TKA Complications measure if the regression coefficients were statistically significant when added to the models.

Lastly, based on evidence from the literature, expert input, guidance from the consensus-based entity for measure endorsement, the Assistant Secretary for Planning and Evaluation (ASPE, 2020), input from other stakeholders, as well as prior testing results, we included a claims-based indicator of frailty that was developed for CMS's Multiple Chronic Conditions measure (Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation

(YNHHSC/CORE), 2019) in the final model for all measures. We did not include sex as a variable since sex can be considered a socio-demographic variable. After variable selection, we also added into the model the history of coronavirus disease 2019 (COVID-19) variable to be consistent with current CMS policy.

For the combined MA and FFS cohort, the risk adjustment model was updated to include an MA indicator (versus FFS) as a main effect. This was to adjust for the generally higher prevalence of comorbidities in the MA cohort, especially among the pre-index variables that were derived from services in the outpatient setting (e.g. physician visits).

Social Risk Factors

Although some recent literature evaluates the relationship between patient social risk factors and the complication outcome, few studies directly address causal pathways or examine the role of the hospital in these pathways (Trivedi et al., 2014; Buntin et al., 2017; Borza et al., 2019). Moreover, the current literature examines a wide range of conditions and risk variables with no clear consensus on which risk factors demonstrate the strongest relationship with complication.

The social risk factors that have been examined in the literature can be categorized into three domains: (1) patient-level variables, (2) neighborhood/community-level variables, and (3) hospital-level variables.

Patient-level variables describe the characteristics of individual patients and include the patient's race and ethnicity, income, or education level. For example, Black and Hispanic patients have been shown to experience higher rates of postoperative complications, longer lengths of stay, and more frequent non-home discharges (Rudisill et al., 2023; Usiskin and Misra, 2022; Brown, Paisner, and Sassoon, 2022)). These disparities are often influenced by socioeconomic factors such as lower income or education levels, which can limit access to healthcare services, preventive care, or rehabilitation (Alvarez et al., 2022). Additionally, barriers such as language proficiency or health literacy may further exacerbate these challenges and contribute to poorer outcomes and higher rates of complications for patients with social risk factors (Suleiman et al., 2021).

Neighborhood/community-level variables use information from sources such as the American Community Survey as either a proxy for individual patient-level data or to measure environmental factors. Studies using these variables use one-dimensional measures such as median household income or composite measures such as the AHRQ-validated SES index score (Blum et al., 2014; Courtney et al., 2016; Martsolf et al., 2016; White et al., 2018). Some of these variables may include the local availability of clinical providers (Herrin et al., 2015; Herrin et al., 2016).

Hospital-level variables measure attributes of the hospital which may be related to patient risk. Examples of hospital-level variables used in studies are ZIP code characteristics aggregated to the hospital level or the proportion of Medicaid patients served in the hospital (Gilman et al., 2014; Joynt et al., 2013; Jha et al., 2013; Xu et al., 2018).

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of complication following an acute illness or major surgery, like the factors themselves, are varied and complex. There are at least four potential pathways that are

important to consider:

- **Patients with social risk factors may have worse health at the time of hospital admission.** Patients who have lower income/education/literacy or unstable housing may have a worse general health status and may present for their hospitalization or procedure with a greater severity of underlying illness. These social risk factors, which are characterized by patient-level or neighborhood/community-level (as proxy for patient-level) variables, may contribute to worse health status at admission due to competing priorities (for example, restrictions based on job), lack of access to care (e.g., geographic, cultural, or financial), or lack of health insurance. Given that these risk factors all lead to worse general health status, this causal pathway should be largely accounted for by current clinical risk adjustment.
- **Patients with social risk factors may receive care at lower-quality hospitals.** Patients of lower income, lower education, or unstable housing have inequitable access to high-quality facilities, in part because such facilities may be less likely to be found in geographic areas with large populations of poor patients. Thus, patients with low income may be more likely to be seen in lower-quality hospitals, which can explain the increased risk of complications following hospitalization.
- **Patients with social risk factors may receive differential care within a hospital.** The third major pathway by which social risk factors may contribute to complications risk is that patients may not receive equivalent care within a facility. For example, patients with social risk factors such as lower education may require differentiated care (e.g. provision of lower literacy information – that they do not receive).
- **Patients with social risk factors may experience worse health outcomes beyond the control of the healthcare system.** Some social risk factors, such as income or wealth, may affect the likelihood of complications without directly affecting health status at admission or the quality of care received during the hospital stay. For instance, while a hospital may make appropriate care decisions and provide tailored care and education, a lower-income patient may have a worse outcome post-discharge due to competing financial priorities that don't allow for adequate recuperation or access to needed treatments, or a lack of access to care outside of the hospital.

We developed and used the conceptual framework described below to identify potential social risk factors. We analyzed two well-studied social risk factors that could best be operationalized in data, outlined below. We note that this measure already adjusts for age and note that the risk model already accounts for patient comorbidities which may differ among patients with social risk factors.

Dual-Eligible (DE) Status

Dual eligibility for Medicare and Medicaid is available at the patient level in the Medicare Master Beneficiary Summary File. The eligibility threshold for Medicare beneficiaries aged 65 or older considers both income and assets. For the dual-eligible (DE) indicator, there is a body of literature demonstrating differential health care and health outcomes among beneficiaries (ASPE, 2020).

Area Deprivation Index (ADI)

While we previously used the AHRQ SES variable in these types of analyses, we now use the

validated ADI (Forefront Group, 2023). We made this change to align with other CMS work on social risk factors that now use the ADI. We describe the ADI variable below.

The ADI, initially developed by the Health Resources & Services Administration, is based on 17 measures across four domains: income, education, employment, and housing quality (Kind et al., 2018; Singh, 2003).

The 17 components are listed below:

- Population aged ≥ 25 y with < 9 y of education, %
- Population aged ≥ 25 y with at least a high school diploma, %
- Employed persons aged ≥ 16 y in white-collar occupations, %
- Median family income, \$
- Income disparity
- Median home value, \$
- Median gross rent, \$
- Median monthly mortgage, \$
- Owner-occupied housing units, % (homeownership rate)
- Civilian labor force population aged ≥ 16 y unemployed, % (unemployment rate)
- Families below the poverty level, %
- Population below 150% of the poverty threshold, %
- Single-parent households with children aged < 18 y, %
- Households without a motor vehicle, %
- Households without a telephone, %
- Occupied housing units without complete plumbing, % (log)
- Households with more than 1 person per room, % (crowding)

ADI scores were derived using the beneficiary's 9-digit ZIP Code of residence, which is obtained from the Master Beneficiary Summary File and is linked to 2017-2021 US Census/American Community Survey (ACS) data. In accordance with the ADI developers' methodology, an ADI score is calculated for the census block group corresponding to the beneficiary's 9-digit ZIP Code using 17 weighted Census indicators. Raw ADI scores were then transformed into a national percentile ranking ranging from 1 to 100, with lower scores indicating lower levels of disadvantage and higher scores indicating higher levels of disadvantage. Percentile thresholds established by the ADI developers were then applied to the ADI percentile to dichotomize neighborhoods into more disadvantaged (high ADI areas=ranking equal to or greater than 85) or less disadvantaged areas (Low ADI areas= ranking of less than 85).

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5.4.2a Attach Conceptual Model

[4.4.2 Conceptual Model Rationale_THA TKA Complications.pdf](#)

5.4.3 Variable Distribution Across Measured Entities

Table 8 (see "All Figures and Tables THA TKA Complications" attachment) shows the risk variable frequencies and odds ratios for the final risk variables selected by the process described in Section 4.4.2. Risk variables are also provided within the attached data dictionary. Results related to social risk factors can be found in Section 5 (Equity).

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

Table 8 (see "All Figures and Tables THA TKA Complications" attachment) shows the risk variable frequencies and odds ratios for the final risk variables selected by the process described in Section 4.4.2.

5.4.5 Calibration and Discrimination

Model Performance Testing Methods

To assess model performance, we assessed model discrimination, calibration, and overfitting. To assess discrimination, we computed two discrimination statistics, the c-statistic and predictive ability (Table 9 in the attachment). These analyses used the CY2022 dataset (derivation and validation). For calibration, we provide calibration (risk-decile) plots (see Figure 4A and 4B in the attachment) for CY2022 and CY2023 data.

The **c-statistic** is the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model can distinguish between a patient with and without an outcome.

Predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects; therefore, for a model with good predictive ability, we would expect to see a wide range in observed outcomes between the lowest and highest deciles of predicted outcomes. To calculate the predictive ability, we calculated the range of mean observed THA/TKA Complications between the lowest and highest predicted deciles of THA/TKA Complications probabilities.

For **model calibration**, we assessed calibration plots, with mean predicted and mean observed outcomes plotted against deciles of predicted outcomes. The closer the predicted outcomes are to the observed outcomes, the better calibrated the model is. We provide results for CY2022 (derivation sample) and CY2023 (validation sample).

In addition, we assess model calibration through risk-decile plots, one year for CY2022 data and CY2023 data. In addition, we provide an analysis of **overfitting**. Overfitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients. Estimated calibration values of γ_0 close to 0 and estimated values of γ_1 close 1 provide evidence of good calibration of the model

Model Performance Testing Results

Please see Table 9 and Figures 3A and 3B in the attachment "All Figures and Tables THA/TKA Complications " (pages 9-10) for the model testing results. The results are also described below.

The c-statistic was 0.671 in the derivation sample, and 0.663 in the validation sample (Table 9).

Predictive ability ranged from 1.18%-8.65% in the derivation sample, and 1.34%-8.36% in the validation sample. Risk decile plots show that higher deciles of the predicted outcomes are associated with higher observed outcomes in both CY2022 and CY2023 data (Figures 3A and 3B). Overfitting results are shown in Table 9.

5.4.6 Interpretation of Risk/Case-mix Factor Findings

Discrimination

The c-statistic of 0.671 in the development sample, and 0.663 in the validation sample indicate excellent model discrimination. The model indicated a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects.

Calibration

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show a good calibration of the model. The predictive ability of the model shows a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects. Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show good calibration of the model. As seen in the calibration plots for CY2022 and CY2023, higher deciles of predicted outcomes are associated with higher observed outcomes. This indicates good calibration of the model in data from two time periods.

Over-fitting (γ_0 , γ_1)

If γ_0 is substantially far from zero and γ_1 is far from one, there is potential evidence of over-fitting. Our testing results show that while γ_1 is almost one, γ_0 is further from zero than expected. However, overfitting in the context of risk-standardization does not reflect the actual use of the measure because, with each update of data for any performance period, the model variable coefficients are recalculated, therefore, we are never calculating results with “new” data using the coefficients from the prior year.

Overall Interpretation

Interpreted together, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix).

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.1 Current Status

Not in use

6.1.3 Current Use(s)

Public Reporting, Payment Program, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Other

6.1.3 Program Details

Name of the program and sponsor

Hospital Inpatient Quality Reporting (HIQR) (CMS)

URL of the program

<https://qualitynet.cms.gov/inpatient/iqr>

Purpose of the program

The purpose of the Hospital Inpatient Quality Reporting (HIQR) program is to encourage hospitals to report quality data to improve healthcare outcomes and ensure they receive full Medicare payment updates.

Geographic area and percentage of accountable entities and patients included

Nation-wide (excepting Maryland); includes >4,000 hospitals, including hospitals paid through IPPS and voluntarily, CAHs.

Applicable level of analysis and care setting

The level of analysis is facility level. The care setting is short-term acute care hospitals.

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Name of the program and sponsor

Hospital Value-Based Purchasing (HVBP) programs, Centers for Medicare and Medicaid Services (CMS)

URL of the program

<https://qualitynet.cms.gov/inpatient/hvbp>

Purpose of the program

The purpose of the Hospital Value-Based Purchasing (HVBP) program is to incentivize hospitals to improve the quality of care by linking Medicare payments to performance on quality measures, enhancing patient outcomes.

Geographic area and percentage of accountable entities and patients included

All subsection d hospitals across the nation, excluding Maryland (about 3,000 hospitals).

Applicable level of analysis and care setting

The level of analysis is facility level. The care setting is short-term acute care hospitals.

6.1.3a Other Current Use

This version of the measure is planned for implementation in the Hospital Inpatient Quality Reporting (HIQR) and Hospital Readmission Reduction Program (HRRP) programs, to replace the FFS-only measure.

6.2.1 Actions of Measured Entities to Improve Performance

Improving complication rates following Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) involves a multifaceted approach focusing on preoperative, intraoperative, and postoperative strategies. Preoperatively, optimizing patient health through rigorous preoperative screening and comorbidity management can significantly reduce complications (Liu et al., 2020). Intraoperatively, employing advanced surgical techniques and technologies, such as computer-assisted navigation and minimally invasive approaches, has been shown to decrease complication rates (Biau et al., 2019). Postoperatively, enhancing recovery protocols, including early

mobilization and comprehensive rehabilitation, helps prevent complications such as deep vein thrombosis and joint stiffness (Pagnano et al., 2018). Additionally, adherence to infection prevention measures, such as antibiotic prophylaxis and sterile techniques, is crucial for minimizing the risk of periprosthetic infections (Kurtz et al., 2021). Collectively, these strategies contribute to better outcomes and reduced complication rates for THA and TKA patients.

A patient-centered approach that includes preoperative education, optimization of health, and adherence to rehabilitation protocols is crucial. Educating patients about their roles in minimizing risks is crucial; studies show that preoperative education can significantly enhance patient outcomes by ensuring better understanding and adherence to postoperative care (Kurtz et al., 2018).

A timely health evaluation and efficient preoperative care for patients might facilitate the early identification of potential risk factors, such as untreated comorbidities. Research shows that timely and efficient action to manage conditions such as diabetes and obesity can significantly lower infection rates and enhance overall health outcomes for THA/TKA patients (Antonelli & Chen, 2019; Giorgino et al., 2021; Ahmad et al., 2022). Another aspect of providing high-quality care is using evidence-based recommendations in perioperative care, such as implementing standardized care protocols for pain management and mobility improvement. For instance, enhanced recovery after surgery (ERAS) protocols, which place a strong emphasis on early mobilization and multimodal analgesia, have been associated with shorter hospital stays and reduced complication rates for THA/TKA patients (Kaye et al., 2019; Li et al., 2019; Choi et al., 2022).

Additionally, recent efforts such as the Comprehensive Care for Joint Replacement (CJR) Model are designed to improve care for Medicare patients undergoing hip and knee replacements. With the goal of improving the quality and efficiency of care for Medicare patients undergoing hip and knee replacements, the CJR model offers incentives to hospitals to encourage preoperative optimization and coordinated care throughout the surgical episode. The model emphasizes timely care of comorbid diseases and promotes the implementation of evidence-based procedures to lower complications, hospital readmissions, and overall costs by linking financial incentives to patient outcomes (CMS, 2023). In addition, to encouraging provider collaboration, this integrated approach ensures patients receive comprehensive care from the time of pre-surgery through recovery.

Another component of the care continuum that affects complication rates after THA/TKA procedures is clear and effective patient communication to ensure that patients are adequately prepared for discharge (You et al., 2024). Teaching patients how to take care of their wounds, manage their medications, and identify early warning signs of complications like infection or thromboembolic events are all part of comprehensive discharge planning. Research evidence suggests that the adoption of structured discharge protocols can significantly lower readmission rates and enhance patient outcomes (Gonçalves-Bradley et al., 2016; Becker et al., 2021).

Improving communication between healthcare professionals involved in care transitions is also significant in lowering postoperative complications [Patel & Bechmann, 2023]. Communication breakdowns that occur during the transition from surgical teams to inpatient care and rehabilitation might result in information being lost, including changes to drug schedules or unresolved postoperative issues. Research shows that using electronic health records (EHR) with

clear, standardized documentation of the patient's condition and treatment plan enhances the continuity of care between the nursing, surgical, and rehabilitation teams (Stoicea et al., 2018). Bardram and Houben (2018) show that EHRs contain collaborative affordances that enable collaborative action and workflow among different actors. The authors identify four collaborative affordances: portability (to navigate health records between locations), co-located access (to support simultaneous access), shared overview (to collectively build a shared information overview), and mutual awareness (to maintain mutual awareness of the work's progress), all of which improve provider-to-provider communication and care transitions. Multidisciplinary team meetings also ensure that all medical professionals agree with the patient's status and plans for discharge, which enhances the patient's recovery and lowers the risk of complications (Nag et al., 2024).

Finally, hospitals can use resources provided by CMS to help improve the drivers of hospital visits. To support quality improvement, CMS shares reports with measured entities that include measure results benchmarked against the state and nation (hospital-specific reports [HSRs]). These reports include, among other details, the principal diagnosis code associated with the hospitalization, which allows hospitals to tie their quality improvement efforts to the specific reasons for rehospitalization that are occurring. CMS gives hospitals 30 days to preview their results and submit questions before public reporting on the data catalog on Data.cms.gov (also known as the Provider Data Catalog) and Medicare.gov (also known as Care Compare) websites in July.

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6.2.2 Feedback on Measure Performance

Stakeholders can submit questions and issues to CMS through an online tool (Q&A tool) available to the public on *QualityNet*. CMS responds to each question submitted by stakeholders. Through the Q&A tool, stakeholders have asked for assistance with their questions including interpreting their facility's patient-level data, understanding measure specifications (inclusion, exclusion, risk adjustment), and interpretation/clarification of results.

6.2.3 Consideration of Measure Feedback

Each year, we review and consider issues raised through the Q&A or in the literature related to this measure, and those issues are considered by measure and clinical experts. Any issues that warrant additional analytic work due to potential changes in the measure specifications are addressed as a part of annual measure reevaluation. If small changes are indicated after additional analytic work is complete, those changes are usually incorporated into the measure in the next measurement period. If the changes are substantial CMS may propose the changes through rulemaking and adopt the changes only after CMS receives public comment on the changes and finalizes those changes in rulemaking.

Each year we also review and consider changes to HCPCS and ICD-10 codes that are then incorporated into the measure. Those code set files are made available to the public on *QualityNet*.

As noted, the Medicare Advantage (MA) population was an update to this measure's cohort. MA beneficiary enrollment has been rapidly expanding as a share of Medicare beneficiaries. In 2023, nearly 51% of the eligible Medicare beneficiaries — or 30.8 million people — were covered by MA plans (Ochieng et al., 2023). The Congressional Budget Office projects that by 2030, 62% of beneficiaries will be covered by MA plans (Congressional Budget Office, 2022).

The inclusion of MA beneficiaries has several important benefits for the reliability and validity of the hospital outcome measures. The addition of MA beneficiaries to FFS significantly increases the size of the measure's cohort, which enhances the reliability of the measure scores, leads to more hospitals receiving results, and increases the chance of identifying meaningful differences in quality for some low-volume hospitals (Kyanko et al., 2024). This update is currently undergoing the MUC 2024 submission process.

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6.2.4 Progress on Improvement

The THA/TKA Complications measure described in this CBE submission has been extensively updated, with cohort expansion (adding in Medicare Advantage (MA) patients), and risk variable re-selection. In addition, the performance period has been changed from three years to two years. Because of those changes, we are unable to compare the performance of this updated THA/TKA Complications measure with the performance of the previous measure.

We provide, however, a comparison of the distribution of risk-standardized complication rates (RSCRs) from the Fee-for-Service (FFS)-only measure, across different time periods. Table 13 (in the attachment) shows when comparing the distribution of risk-standardized scores across four time periods of the version of the FFS-only measure, hospital-level THA/TKA Complications risk-standardized complications rates (RSCRs) generally decrease across performance periods. This improvement in both RSCRs can also be seen from a density plot of performance over time (see Figure 6 in the "All Figures and Tables THA TKA Complications" attachment).

6.2.5 Unexpected Findings

There have been no unexpected findings, negative or positive, during the implementation of this measure, including unintended impacts on patients.

7.1 Supplemental Attachment

[THA-TKAComplications_SupplementaryFiles.zip](#)

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