2024 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2024-042	Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Medicare & Medicare Services (CMS); Yale CORE	Hospital Inpatient Quality Reporting Program; Hospital Value-Based Purchasing Program; Hospital-Acquired Condition Reduction Program

Measure Overview
Developer-provided 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 procedures. 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. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk adjust for patient conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix and, therefore, promote hospital quality improvement and better inform consumers about care quality.
CMS-provided program rationale: CMS is considering including this quality measure in its quality reporting programs because the measure supports CMS's long-standing effort to link Medicare payments to health care quality in the inpatient hospital setting. This re-specified hospital-level risk-standardized complication rate quality measure is currently used successfully within a quality reporting program. It is going through the Measures Under Consideration (MUC) process for inclusion of Medicare Advantage (MA) beneficiaries to help ensure that within CMS quality reporting programs, quality measurement is tracked across all Medicare beneficiaries and not just the fee-for-service (FFS) population. Complications related to care is a priority area for outcomes measure development. It is an outcome that is likely attributable to care processes and is an important outcome for patients. The continued inclusion of this quality measure in a quality reporting program will help the agency move one step closer to achieving its strategic quality initiatives of improving quality and health

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Measure Overview
outcomes across the care journey and enabling a responsive and resilient health care system to improve quality.
Description: The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and/or TKA procedure. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to up to 90 days post-date of the index admission (the admission included in the measure cohort). 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.'.
Measure background: Measure currently used in a Medicare program, but the measure is undergoing substantive change
Numerator: The outcome for this measure is any complication occurring during the index admission [not coded present on admission (POA)] to 90 days post-date of 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": - 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. Exception: Subsequent inpatient admissions with a principal diagnosis code of COVID-19 (U07.1) or with a secondary diagnosis code of COVID-19 coded as POA on the claim within

Measure Overview

the seven/30-day time frames are not eligible for use by the measure (and are excluded) in determining whether the following complications occurred:

- AMI
- pneumonia or other acute respiratory complication
- sepsis/septicemia/shock
- pulmonary embolism.

The code list used to define the "Mechanical Complication" outcome includes 26 codes that reflect fractures of the pelvis, femur, tibia or fibula, or other bone following insertion of an orthopedic implant as well as periprosthetic fractures around the internal prosthetic left/right hip/knee joint or other/unspecified internal prosthetic joint.

Exclusions: None

Denominator: The cohort includes admissions for patients that meet all of the following inclusion criteria:

1. 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;
2. Aged 65 or older;
3. 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.);
   - 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.

Patients are eligible for inclusion in the denominator if they had an elective primary THA and/or a TKA AND had continuous enrollment in Medicare FFS and/or MA 12 months prior to the date of index admission.

Exclusions: The THA/TKA complication measure excludes index admissions for patients:

1. Without at least 90 days post-discharge enrollment in Medicare FFS and/or MA;
2. Discharged against medical advice (AMA); or
3. Who had more than two THA/TKA procedure codes during the index hospitalization; or
4. 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.

Measure Overview	
Exceptions: None	
Measure type: Outcome	**Measure has multiple scores:** No **Measure is a composite:** No **Measure is digital and/or an eCQM:** No **Measure is a paired or group measure:** No
Level of analysis: Facility	**Data source(s):** Digital-Administrative systems: Administrative Data (non-claims); Digital-Administrative systems: Claims Data
Care setting(s): Hospital inpatient acute care facility	**Risk adjustment or stratification:** Risk adjustment
CBE endorsement status: Endorsed; CBE ID 1550	**CBE endorsement history:** Endorsed, 2012; last maintenance review, 2021
Is measure currently used in CMS programs? Yes	**Measure addresses statutorily required area?** No

Meaningfulness

Importance	
Type of evidence:	Peer-Reviewed Original Research; Empirical data; Grey Literature [Source: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form, Evidence Attachment].
Importance: The submission reports performance scores as a rate across 3,007 hospitals: min., 1.56; 10th percentile, 2.91; median, 3.38; mean, 3.46; 90th percentile, 4.11; max., 7.59; standard deviation, 0.53. Developer also cites standardized complication rates between 1.6% and 6.2% for Medicare fee-for-service patients undergoing THA/TKA procedures April 2019-March 2022, demonstrating a gap in performance. THA and TKA are common procedures on Medicare beneficiaries, and the annual number of procedures is expected to continue to trend upward. Though infrequent, complications increase costs of these procedures; such complications include infection, pulmonary embolism, septicemia, bleeding, and death. Complication rates vary across hospitals, suggesting room for improvement [Source: Evidence Attachment]. Developer reports that two out of two patient representatives on the technical expert panel (TEP) agreed that the measure is meaningful and produces information that is valuable in making care decisions. During CBE maintenance endorsement in 2021, the committee found the importance of this measure sufficient. Committee members should consider whether recent measure changes (see Numerator, Denominator & Endorsement History section of this PA) affect their interpretation of this criterion.	
Rating: Met, Prior CBE Endorsement	

Measure Performance

The importance data provided (3,007 hospitals) corresponds to Table 4.2.5 in the Supplemental Methodology Report, which includes hospitals with at least 25 admissions. Because reliability has been calculated on hospitals with at least 25 admissions, Battelle used the mean and standard deviation from Table 4.2.6 ("with ICD-10-based risk variables" columns) to estimate the importance deciles (i.e., the data sorted and broken into 10 equal parts) in Table 1 below (for simplicity, a normal distribution was assumed).

Interpretation: The mean score for the 1,270 entities described in the testing submission for this measure was 3.4. For this ratio measure, a lower score indicates better quality of care.

Table 1. MUC2024-042 Performance Score Deciles

	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Score (SD)	3.4 (0.5)	1.2	2.2	2.7	2.9	3.1	3.3	3.5	3.7	3.9	4.1	4.6	5.6
Number of Entities	1,270	1	127	127	127	127	127	127	127	127	127	127	1

Conformance
Measure alignment with conceptual intent: This measure's specification is appropriate and aligned with the measure focus (complication rate associated with elective primary THA and/or TKA procedure) among Enrolled in Medicare fee-for-service (FFS) and/or MA patients age 65 or older with a qualifying elective primary THA/TKA procedure. Numerator and denominator populations are appropriate and exclusions align with clinical evidence.
Rating: Met, Prior CBE Endorsement

Feasibility	
eCQM Feasibility testing conducted:	No [Source: MERIT Submission Form]
Feasibility: All data elements exist in defined fields in electronic sources, but the developer did not assess United States Core Data for Interoperability (USCDI)/USCDI+ quality alignment. Aligning with USCDI standards for data elements can promote interoperability and improve feasibility. No modifications to provider workflow are necessary. The submission's discussion and MERIT submission form responses indicate feasibility in data elements and workflows. During the prior CBE endorsement process in 2021, the committee found the feasibility of this measure sufficient. Committee members should consider whether recent measure changes (see Numerator, Denominator & Endorsement History section of this PA) affect their interpretation of this criterion.	
Rating: Met, Prior CBE Endorsement	

Validity	
Validity testing:	Empiric Validity; Face Validity [source: MERIT Submission Form, Methodology Attachments]
Testing level(s):	Facility
Validity: The developer tested empiric validity in a sample of 1,132 facilities with at least 25 admissions between January 1, 2022, and December 30, 2022, by evaluating the measure's correlation with three quality metrics: 1) Star Rating Standardized Safety Group Scores (excluding THA/TKA complications), result –0.001 (p=0.975); 2) Star Rating Standardized Summary Scores (excluding THA/TKA complications), result –0.07 (p=0.019); 3) Star Rating Standardized Summary Scores (excluding safety measure group), result –0.08 (p=0.009). The first correlation was non-significant, and while the second and third correlation tests are in the hypothesized direction (higher complications should lead to lower Star Ratings) and significant, the correlations are very weak. The developer evaluated face validity by soliciting responses to the statement "the measure as specified can be used to distinguish between better and worse quality hospitals," using a Likert scale. Overall, 11 of 12 TEP members agreed with this statement, with four strongly agreeing, six moderately agreeing, and one somewhat agreeing. During the prior CBE endorsement process in 2022, the committee found the validity of this measure sufficient. Committee members should consider whether recent measure changes (see Numerator, Denominator & Endorsement History section of this PA) affect their interpretation of this criterion.	
Threats to validity: During the most recent maintenance endorsement, the developer revised measure to recalculate the risk model using a redefined set of risk factors. The developer reports they utilized individual ICD-10 codes instead of hierarchical condition categories [Source: Supplemental Methodology Report]. A key focus for the TEP meetings held in 2020-2022 was to help select risk factors and evaluate face validity for the revised risk model [Source: TEP Summary Report]. C-statistic shows acceptable calibration consistent over time; model performance comparable to currently implemented method, sufficient statistical testing performed to support model.	
Rating: Met, Prior CBE Endorsement	

Reliability	
Reliability testing method(s):	Signal-to-Noise [Source: MERIT Submission Form, Methodology Attachments]
Testing level:	Facility
Reliability discussion: The numerator and denominator for this measure are well defined. The developer calculated signal-to-noise reliability based on the between entity variance from the risk adjustment. The reliability provided in the measure submission materials was calculated for the hospital intercepts from the risk-adjusted model and not the final measure (as could be accomplished through alternative methods such as random split-half). This calculation method's constraints include potentially limited ability to account for real-world variation across entities. The reliability results provided (which represent the reliability of the predicted value only) were calculated from 1 year of data consisting of 1,787 hospitals with at least 25 admissions. The developer projected the reliability for 2-year data and provided estimated minimum, maximum, median, and 25th and 75th percentiles. Battelle interpolated these estimates to estimate deciles of reliability (Table 2). For the 2-year projections, about 90% of the entities would have a reliability >0.6, indicating that only 10% of entities had reliability below the acceptable threshold. For the predicted reliability values, the result indicates that this measure is capable of differentiating entities by quality of performance. During the prior CBE endorsement process in 2022, the committee found the reliability of this measure sufficient.	
Additional reliability analyses: Table 2 includes the minimum, maximum, and 25th and 75th percentiles provided. Deciles have been filled in with simple interpolation.	
Rating: Met, Prior CBE Endorsement	

Reliability Table

Table 2 shows deciles by reliability based on the information provided for the performance score (Table 4.2.6 in the Supplemental Methodology Report) and calculated reliability for the 1,787 entities described in the testing submission. Battelle created this table to provide reviewers with a standardized format to assess reliability.

Interpretation: For the 2-year projections, about 90% of the entities would have a reliability >0.6, indicating that only 10% of entities had reliability below the acceptable threshold and may not be able to differentiate between high and poor quality of care.

Table 2. MUC2024-042 Mean Reliability (by Reliability Decile)

Mean	SD	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max	IQR
0.80	0.15	0.56	0.58	0.63	0.68	0.71	0.75	0.82	0.86	0.89	0.91	0.95	0.997	0.21

Usability	
Usability considered in application:	Yes
Usability discussion: Developer did not indicate whether input was collected from accountable entities in the submission, and the TEP summary report attachment does not appear to address the question of usability. This measure is currently in use in the HVBP and HIQR programs, and the developer reports that no unintended consequences have been identified. During the prior CBE endorsement process in 2022, the committee found the usability of this measure sufficient. Committee members should consider whether recent measure changes (see Numerator, Denominator & Endorsement History section of this PA) affect their interpretation of this criterion.	
Rating: Met, Prior CBE Endorsement	

External Validity	
Was this measure tested in the same target population as the CMS program?	Yes
External validity discussion: The target population for this measure is Medicare fee-for-service and Medicare Advantage patients, and the developer tested it in hospital inpatient acute care facilities providing orthopedic surgical services. The measure is currently in use in two of the proposed Medicare programs (HVBP and HIQR). During the prior CBE endorsement process in 2022, the committee found the external validity of this measure sufficient. Committee members should consider whether recent measure changes (see Numerator, Denominator & Endorsement History section of this PA) affect their interpretation of this criterion.	
Rating: Met, Prior CBE Endorsement	

Appropriateness of Scale

Similar or related measures in program(s):	• CBE ID 1551: Hospital-Level 30-day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)
Measure appropriateness, equity, and value across target populations/measured entities: CBE ID #1551, a related measure, addresses a different measure focus: 30-day readmission rates associated with complications for THA/TKA. The developer did not identify any competing measures. Regarding equity of this measure's performance and benefit across populations, the developer's literature review and analysis do not provide sufficient information to assess the potential for differential benefit or harm to specific subgroups of participating hospitals or their patient populations. The committee should consider the distribution of benefit and risks/burdens of the measure within the proposed program population.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	Measure impacts cited include: improved health status, improved health care management and support, and reduced cost and risk of complications and death.
Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure on patient populations, there may be a need for further examination of near- and long-term impacts of this measure after implementation across provider and patient populations. Questions for the committee to consider: • What are the potential near- and long-term impacts of this measure on measured entities, the proposed programs (HVBP; HIQR; HACRP), and patient populations? • How will this measure mature through revisions in the future if added to the programs' measure sets?	