Template

Peer Reviewed Journal Article Requirement

Section 101(c)(1) of the MACRA requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in MIPS. These measures will be submitted by CMS, to a journal(s) before including any new measure in the final list of annual clinical quality measures (CQM) under MIPS. The measure owner shall provide the required information for article submission under the MACRA per CMS “Call for Measures” submission process.

Measure owners submitting measures into JIRA must complete the required information by the Call for Measures deadline. Some of the information requested below may be listed in specific fields in the JIRA tool; however, to ensure that CMS has all of the necessary information and to avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document in JIRA. The information in JIRA must be consistent with the information below. This includes, but is not limited to:

Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians and Eligible Clinician Groups ***(MIPS THA/TKA complication measure)***

**Measure Owner:** *Centers for Medicare & Medicaid Services*

**Measure Developer:** *Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation*

**Description:** This measure is under development and it is a re-specified version of the measure, “hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)” (NQF 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinicians and/or clinician groups (“provider”) and assesses each provider’s complication rate, defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort).

1. **Statement**

* *Background (Why is this measure important?)*
* *Environmental Scan (Are there existing measures in this area?)*

THAs and TKAs are commonly performed procedures that improve quality of life. Between 2005 and 2011, 855,899 THAs and 2,040,667 TKAs were performed [1-2]. In 2014 alone, knee arthroplasty was the most common procedure performed on patients aged 65-84, and total and partial hip replacements in the age group were the second most frequently performed procedures [3]. Although these procedures dramatically improve quality of life, they are costly [4]. In 2014, THA and TKA aggregate costs for hospitalizations when knee arthroplasties and total/partial hip replacements were first listed on the record were $11.8 billion and $8.3 billion, respectively [3]. Medicare is the single largest payer for these procedures, covering approximately two-thirds of all THAs and TKAs performed in the US [5]. Combined, THA and TKA procedures account for the largest procedural expenditure in the Medicare budget [6].

Future utilization of THA and TKA is projected to increase significantly. By 2030, the demand for THAs is estimated to increase by 174% while the demand for TKAs is estimated to increase by 673% [7]. Complications increase costs associated with THA and TKA and affect the quality, and potentially quantity, of life for patients. Because these are commonly performed and costly procedures, it is imperative to address quality of care, especially with their projected growth.

Although complications following elective THA and TKA are not common, they are measurable and vary in prevalence across providers. Rates for periprosthetic joint infection following THA and TKA range across hospitals from 1.6% to 2.3%, depending upon the population [8-9]. Reported 90-day death rates following THA range from 0.7% to 2.7%. Rates for pulmonary embolism following TKA range from 0.5% to 0.9% [10-14]. Rates for wound infection in Medicare population-based studies vary between 0.3% and 1.0% [11-12, 14]. Rates for septicemia range from 0.1%, during the index admission to 0.3%, 90 days following discharge for primary TKA [11, 15]. Rates for bleeding and hematoma following TKA range from 0.9% to 1.7% [15-16].

The variation in complication rates across hospitals indicates there is room for quality improvement. A quality measure to address complications following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. In the case of THA/TKA, individual clinicians, in particular surgeons, are the key implementers of quality improvement strategies used by hospitals to reduce complication risk, as they play the primary role in the procedure.

Lastly, public and private payers have supported the implementation of orthopedic outcome measures. In 2013, CMS began to publicly report on the RSCRs for THA/TKA for the nation’s non-federal short-term acute care hospitals (including Indian Health Services hospitals) and Critical Access Hospitals as part of the Inpatient Quality Reporting (IQR) program and thereafter finalized the measure for the clinical care domain of the Hospital Value-based Purchasing (HVBP) program starting FY 2019 and the Comprehensive Care for Joint Replacement (CJR) model [17-18]. Even more recently, through its implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) and development of its Measure Development Plan (MDP), CMS identified orthopedic surgery as a priority area for specialty-focused clinician measurement when measuring quality of clinician care. A subsequent environmental scan identified clinician quality measure gap areas and specifically identified complications from orthopedic procedures as a specific subtopic that currently has no measures [19]. The MDP Technical Expert Panel (TEP) reviewed and agreed with the importance of measuring outcomes of orthopedic surgery as an important measure development area in the Quality Payment Program and clinician measurement under the MIPS [20]. Additionally, beyond current hospital payment and reporting programs, the Core Quality Measures Collaborative, a stakeholder group convened by America’s Health Insurance Plans, that included purchaser, consumer, CMS, the National Quality Forum, and physician organization representatives, identified orthopedic quality measurement as one of seven core measure sets to support quality improvement [21].

References

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2. Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. JAMA. 2012;308(12):1227-1236.

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12. Mahomed NN, Barrett JA, Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. 2003;85-A(1):27-32.

13. Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. 2008;79(6):812-819.

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20. Centers for Medicare and Medicaid Services, Health Services Advisory Group. CMS Quality Measure Development Plan: Supporting the Transition to The Quality Payment Program 2017 Annual Report. 2017; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2017-CMS-MDP-Annual-Report.pdf. Accessed January 10, 2018.

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1. **Gap Analysis**

* *Provide Evidence for the Measure (What are the gaps and opportunities to improve care?)*
* *Expected Outcome (Patient care/patient health improvements, cost savings)*
* *Recommendation for the Measure (Is it based on a study, consensus opinion, USPSTF recommendation etc.?)*

In preliminary analyses, we identified for each patient in the measure the clinician who billed for the procedure, as well as their group as defined by the tax ID number (TIN) under which they billed. Assigning the outcome to this billing clinician we constructed risk standardized complication rates (RSCRs) for TINs. We found that RSCRs ranged from 1.2% to 7.2% across these groups, a substantial increase. This is comparable to the variation in hospital RSCRs and indicates a meaningful gap in performance.

The median odds ratios (MORs) suggest meaningful increases in the risk of a complication if a procedure is performed by a higher risk eligible clinician or eligible clinician group compared to a lower risk eligible clinician or eligible clinician group. At the clinician level, the MOR value of 1.50 indicates that a patient has a 50% increase in the odds of a complication if the same procedure was performed by a higher risk eligible clinician compared to a lower risk eligible clinician; this indicates that the impact of quality on the outcome rate is substantial. At the clinician group level, the MOR value of 1.37 indicates that a patient has a 37% increase in the odds of a complication if the same procedure was performed by higher risk eligible clinician group compared to a lower risk eligible clinician group indicating that the impact of quality on the outcome rate is almost as substantial as for eligible clinicians.

The median RSCR is 2.7% at the clinician level and 2.8% at the clinician group level which indicates that 50% of clinicians have a complication rate of 2.7% or more (and for some it is quite higher), even after adjusting for patient age and comorbidities. When patients are asked about their expectations for complications after a planned surgery, many assume or desire a rate of zero. While these rates are low, they indicate variation across clinicians and clinician groups. The 10th and 90th percentile RSCRs (2.2 and 3.7, respectively, for clinicians; 2.2 and 3.5, respectively, for clinician groups) represent meaningful deviations from the median: a clinician performing at the 10th percentile is performing 18.5% better than an average performer (21.4% for clinician group), while a clinician performing at the 90th percentile is performing nearly 37.0% worse than an average performer (25% for clinician groups). Furthermore, the best performing clinicians (1.2%) are performing 55.6% better than an average performer, while the worst performing clinicians (7.2%) are performing 166.7% worse than an average performer. The best performing clinician groups (1.4%) are performing 50% better than an average performer, while the worst performing clinicians (5.7%) are performing 103.6% worse than an average performer. This variation supports an important quality gap, as some clinicians and clinician groups can achieve substantially lower rates than the average performer, while other clinicians and clinician groups are performing worse than an average performer. It is important to note that here an ‘average performer’ refers to a clinician or clinician group performing with the same quality as the national average but with the same case and procedure mix as the comparison clinician or group.

Overall, these results support meaningful variation in rates across clinician and clinician groups that are deserving of measurement.

1. **Reliability/Validity**
2. *What testing has been performed at the clinician level? Please provide testing results including the N value, Bonnie test case results, correlation coefficient and any other pertinent information or values to be considered.*

* Reliability Testing Results:

The provider-level reliability for both clinicians and clinician groups was estimated using “unit” reliability, that is, the reliability with which individual units (here, clinicians or clinician groups) are measured. The reliability of any one entity’s measure score will vary depending on the number of index admissions attributed as well as the variation of the outcome across patients assigned to the entity. Entities with higher volume will tend to have more reliable scores, while those with lower volume will tend to have less reliable scores. Specifically, we use the formula presented by Adams et al, to calculate provider-level signal-to-noise reliability [1]. For each measured entity (eligible clinician or eligible clinician group) the ratio of between entity variance (signal) to total variance (noise) was calculated.

Using the approach used by Adams et. al. [1], we obtained median reliability scores of 0.793 for ECs and 0.790 for EC groups. These values are considered “substantial” [2].

References

1. Adams JL, Mehrotra A, Thomas JW, McGlynn EA. Physician Cost Profiling — Reliability and Risk of Misclassification. New England Journal of Medicine. 2010;362(11):1014-1021.
2. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.*1977;33(1):159-174

* Validity Testing Results, clinician sites:

Face Validity

The majority of the TEP members, 13/16 or 81%, agreed that the measure scores were valid and useful, and 12/16 or 75% agreed that the measure would provide information that could be used to improve the quality of care.

Empirical Validity

There is substantial evidence that surgical complication rates for providers (surgeons and hospitals) decline with increasing volume; this includes complications for THA [1]. Thus, we assessed validity of the measure by examining the relationship between volume and the measure score for clinicians and clinician groups; for each provider type we calculated the correlation between volume and measure score and summarized the measure score for each decile of volume. To establish validity, we expect scores to be correlated with case volume at the clinician and clinician group level. The following table shows the results of assessing the relationship between provider volume and measure score.

|  |  |  |
| --- | --- | --- |
|  | Clinicians (N=7,928) | Clinician groups (N=3,572) |
| Correlation coefficient between admission volumes and RSCRs | -0.2379 P <0.0001 | -0.19026  P <.0001 |
| Deciles of volume | **Mean(RSCR)** | **Mean(RSCR)** |
| 0%~10% | 2.87 | 2.86 |
| 10%~20% | 2.86 | 2.86 |
| 20%~30% | 2.88 | 2.86 |
| 30%~40% | 2.89 | 2.82 |
| 40%~50% | 2.84 | 2.85 |
| 50%~60% | 2.87 | 2.85 |
| 60%~70% | 2.83 | 2.80 |
| 70%~80% | 2.76 | 2.78 |
| 80%~90% | 2.66 | 2.66 |
| 90%~100% | 2.42 | 2.49 |

There is a moderate but meaningful inverse relationship between volume and measure outcome (RSCR) for both clinicians and clinician groups.

References

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Topped-Out Analysis

Summary of “Topped-Out” Status for MIPS HKC measure (2013-2016 period)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Provider**  **EC=Eligible Clinician**  **ECG=Eligible Clinician Group** | **Volume Cutoff** | **N** | **P75th** | **P90th** | **Standard Error** | **75th and 90th percentiles within 2 standard errors of each other (or 10th and 25th percentiles, for inverse measures)** | **Truncated Mean** | **Truncated SD** | **Truncated Coefficient of Variation (TCV)** | **Truncated Coefficient of Variation less than 0.10** | **Topped Out** | **Signal to Noise Reliability** |
| EC | 25 | 7928 | 3.16 | 3.68 | 0.01 | No | 2.79 | 0.47 | 0.17 | No | No | Median (IQR) 0.793  (0.695-0.878) |
| EC | 50 | 5183 | 3.15 | 3.70 | 0.01 | No | 2.75 | 0.51 | 0.18 | No | No | - |
| EC | 100 | 2747 | 3.07 | 3.64 | 0.01 | No | 2.66 | 0.53 | 0.20 | No | No | - |
| EC | 200 | 1056 | 2.93 | 3.46 | 0.02 | No | 2.49 | 0.53 | 0.21 | No | No | - |
| ECG | 25 | 3572 | 3.09 | 3.47 | 0.01 | No | 2.79 | 0.37 | 0.13 | No | No | Median (IQR) 0.790  (0.647-0.907) |
| ECG | 50 | 2744 | 3.10 | 3.51 | 0.01 | No | 2.77 | 0.41 | 0.15 | No | No | - |
| ECG | 100 | 1900 | 3.09 | 3.55 | 0.01 | No | 2.73 | 0.45 | 0.16 | No | No | - |
| ECG | 200 | 1187 | 3.06 | 3.51 | 0.02 | No | 2.67 | 0.46 | 0.17 | No | No | - |

* *Exclusion frequency:*

1. *What were the minimum sample sizes used for reliability results?* Other Information

* *Is it risk adjusted? If so, how?*

Risk Adjustment

The goal of risk adjustment is to account for patient age, whether the patient had one or two procedures, and comorbid conditions that are clinically relevant and have strong relationships with the outcome, while illuminating important quality differences between hospitals. The measure adjusts for case-mix differences based on the clinical status of the patient at the time of admission. Conditions that may represent adverse outcomes due to care received during the index admission are not considered for inclusion in the risk adjustment. Although they may increase the risk of mortality and complications, including them as covariates in risk adjustment could attenuate the measure’s ability to characterize the quality of care delivered by hospitals. For each patient, risk-adjustment variables are obtained from inpatient, outpatient, and physician Medicare administrative claims data extending 12 months prior to the index admission and all claims data for the index admission itself.

In keeping with our key principle regarding alignment with the hospital-level measure, and because the hospital risk model was developed and validated at the patient-level using the same cohort adopted for this MIPS THA/TKA complication measure, we used the same risk factors as used by CMS’s hospital-level THA/TKA complication measure.

Comorbidities for inclusion in risk adjustment are identified in administrative claims during the 12 months prior to and including the index admission. To assemble the more than 16,000 ICD-9 codes and 70,000 ICD-10 codes into clinically coherent variables for risk adjustment, the measure employs the publicly available CMS hierarchical condition categories (CCs) to group codes into CCs and selects comorbidities for inclusion in risk adjustment on the basis of clinical relevance and statistical significance [1-4].

The following model variables below lists the conditions not adjusted for if they only appear in the index admission and not in the 12 months prior to admission. The CCs outlined below are used to identify risk variables in claims for discharges on or after October 1, 2015 as well as discharges prior to October 1, 2015. The ICD-10 code lists referenced in the tables that are used to identify certain risk variables (e.g., Post traumatic osteoarthritis) in discharges on or after October 1, 2015 are posted on [*QualityNet*](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772782693%20%20). For a list of ICD-9 codes used to identify these variables for discharges prior to October 1, 2015, please refer to the 2016 procedure-specific complication measure updates and specifications report posted on [*QualityNet*](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228774719413).

Model Variables

* Age minus 65 (years above 65, continuous)
* Male
* Index admissions with an elective THA procedure
* Number of procedures (two vs. one)
* Other congenital deformity of hip (joint)
* Post traumatic osteoarthritis
* Metastatic cancer and acute leukemia (CC 8)
* Other major cancers (CC 9-12)
* Respiratory/heart/digestive/urinary/other neoplasms (CC 13-15)
* Diabetes mellitus (DM) or DM complications (CC 17-19, 122-123)
* Protein-calorie malnutrition (CC 21)
* Morbid obesity (CC 22)
* Bone/joint/muscle infections/necrosis (CC 39)
* Rheumatoid arthritis and inflammatory connective tissue disease (CC 40)
* Osteoarthritis of hip or knee (CC 42)
* Osteoporosis and other bone/cartilage disorders (CC 43)
* Dementia or other specified brain disorders (CC 51-53)
* Major psychiatric disorders (CC 57-59)
* Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)
* Cardio-respiratory failure and shock
* Coronary atherosclerosis or angina (CC 88-89)
* Stroke (CC 99-100)
* Vascular or circulatory disease (CC 106-109)
* Chronic obstructive pulmonary disease (COPD) (CC 111)
* Pneumonia (CC 114-116)
* Pleural effusion/pneumothorax (CC 117)
* Dialysis status (CC 134)
* Renal failure (CC 135-140)
* Decubitus ulcer or chronic skin ulcer (CC 157-161)
* Trauma (CC 166-168, 170-173)
* Vertebral fractures without spinal cord injury (CC 169)
* Other injuries (CC 174)
* Major complications of medical care and trauma (CC 176-177)

Additionally, the measure does not adjust for the patients’ admission source or their discharge disposition (e.g., skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients’ clinical risk factors. Regional differences in resource availability and practice patterns may exert an undue influence on model results. Moreover, the accuracy of these admission and discharge disposition codes is not known. The measure also does not adjust for socioeconomic status (SES), race, or ethnicity. Variation in quality associated with these characteristics may be indicative of disparities in the quality of the care provided to vulnerable populations and adjusting for these factors would obscure these disparities. The measure does not adjust for provider characteristics either, since this would hold different types of providers to different quality standards, and because such characteristics may exist on a causal pathway to the outcome, rather than act as confounders. This approach is consistent with CMS’s hospital-level THA/TKA complication measure. The intent is for the measure to adjust for age and clinical characteristics while illuminating important quality differences. CMS’s hospital-level THA/TKA complication measure was endorsed by the NQF without adjustment for patient-level SES factors. For more information about this decision, please refer to the [*NQF website*](https://www.qualityforum.org/).

References

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* *What benchmarking information is available?*

We have not established any benchmarks for this measure. For MIPS quality measures, CMS establishes benchmarks using historical data and displays them in terms of deciles [1].

For more information on CMS quality measure benchmarking, please see the QPP 2019 Quality measure Benchmarks Overview [2].

References

1. Centers for Medicaid and Medicare Services. MIPS Quality Measure Benchmarks Overview. 2019; <https://mdinteractive.com/2019-mips-quality-benchmarks>
2. Centers for Medicaid and Medicare Services. Quality Measure Benchmarks Overview. 2019; <https://qpp-cm-prod-content.s3.amazonaws.com>
3. **Endorsement**

* *Provide NQF endorsement status (and ID) and/or other endorsing body (If measure is only endorsed for paper records, please note endorsement for only the data source being submitted)*

The MIPS THA/TKA complication measure for MIPS eligible clinicians has completed development. This measure has been submitted to NQF and is currently undergoing initial endorsement.

1. **Summary**

* *Alignment with CMS Quality Strategy or MACRA (If applicable)*

The proposed measure is intended to align with the Medicare Access & CHIP Reauthorization Act (MACRA) domains of patient safety.

* *Importance to MIPS or other CMS programs*

By incentivizing improved coordination of care for patients having elective THA and/or TKA procedures, this measure is expected to reduce the number of hospitalizations and days hospitalized for patients, reduce rates of complications, and produce cost savings resulting from fewer hospitalizations.

* *Rationale: Use of measure for inclusion in program (specialty society, regional collaborative, other)*

This measure is an adaptation of an existing, publicly reported measure for hospitals. The hospital measure is currently used in CMS programs for hospitals: it has been used by the Hospital Inpatient Quality Reporting Program (FY 2015 – FY 2019) and the Hospital Value-Based Purchasing Program (FY 2019). Although this measure has not yet been implemented, CMS developed the MIPS THA/TKA complications measure for use in the MIPS program.

* *Public reporting (if applicable)*

N/A; this measure has not yet been implemented.

* *Preferable relevant Peer-Review Journal for publication*

We recommend submitting this measure to Medicare Care, Health Affairs, Health Services Research or JAMA Network Open.