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

Draft Measure Methodology Report

Submitted by

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Disclaimer: The views, thoughts, and opinions expressed in this report belong solely to the authors, and not necessarily to any contributors or consultants, including the Clinical Working Group and TEP members and their affiliated organizations. Acknowledgement of input does not imply endorsement of the methodology and policy decisions.

Executive Summary

Measure Background

Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (collectively, Total Joint Arthroplasty (TJA) in this report) are commonly performed surgical procedures that can dramatically improve a person's quality of life through pain reduction and improved function. Over the last decade, there has been a steady increase in the number of TJAs performed on Medicare fee-for-service (FFS) patients aged 65 and older.[1] Researchers project the number of TJAs performed to reach over two million annually by 2030, which would result in a significant increase in Medicare expenditures.[2] Additionally, the number of TJAs being performed across outpatient surgical locations is continuing to rise, as they represent a safe, cost-effective alternative for select patient populations.[3-10] The shift in procedure setting coincides with the increase in demand for TJA procedures, necessitating the creation of quality measures that consider outcomes across more diverse settings.

The Centers for Medicare & Medicaid Services (CMS) contracted with Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (CORE) to develop a re-specified version of an existing, administrative, claims-based measure, the Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), NQF 1550 ("existing Hospital-level THA/TKA Complication measure" in this report). The new measure, Hospital-level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting ("IP/OP 90-Day THA/TKA Complication measure" in this report), expands the cohort definition of the existing Hospital-level THA/TKA Complication measure by including patients who undergo elective primary TJA procedures in hospital outpatient departments (HOPDs). The new measure also expands the outcome of the existing measure to include certain complications that occur during emergency department (ED) visits, observation stays, and Ambulatory Surgical Center (ASC) encounters, and better aligns quality measurement of TJA procedures and TJA-associated complications of care across inpatient and outpatient settings.

Measure Development

This report describes our approach to the development of the IP/OP 90-Day THA/TKA Complication measure. We leveraged the work and clinical expertise of those involved in the initial development and annual reevaluation of the existing Hospital-level THA/TKA Complication measure, which has received and maintained NQF endorsement since 2012. We also engaged a diverse set of stakeholders throughout the development of the IP/OP 90-Day THA/TKA Complication measure to elicit feedback on the measure concept, expansion of the cohort and outcome definitions to the outpatient setting, as well as risk model development and measure testing. These engagements included meetings with a Clinical Working Group (CWG) and a nationally convened Technical Expert Panel (TEP) consisting of patients, providers, and other stakeholders.

Measure Specifications

Data Sources

We used Medicare administrative claims data and enrollment information for patients who had qualifying elective THA and/or TKA procedures between April 1, 2018, and March 31, 2021, for measure re-specification and testing. Specifically, this measure uses Medicare inpatient, outpatient, and physician/professional claims for Medicare FFS inpatient and outpatient services for the 12 months prior to an index encounter and for the three months after. The IP/OP 90-Day THA/TKA Complication measure also uses the Medicare Enrollment Database (EDB) to obtain Medicare beneficiary demographic, benefit/coverage, and vital status information, and to obtain information on several inclusion/exclusion indicators, such as Medicare status upon admission and vital status upon discharge.

Measure Cohort (Denominator)

The measure cohort includes Medicare FFS beneficiaries 65 years of age and older undergoing a qualifying elective primary THA and/or TKA procedure in the inpatient or outpatient setting of an acute care hospital. To be eligible, patients must be enrolled in Medicare FFS Part A and Part B for the 12 months prior to and including the date of the encounter. Patients must also meet specific inclusion and exclusion criteria based on and aligned with the existing Hospital-level THA/TKA Complication measure and updates made to account for the outpatient context. Specific information on the cohort inclusion and exclusion criteria can be found here.

Measure Outcome (Numerator)

The IP/OP 90-Day THA/TKA Complication measure will be used to estimate a hospital-level RSCR associated with elective primary TJA procedures performed on Medicare FFS beneficiaries 65 years of age or older in hospital inpatient and outpatient settings. The complication outcome is a dichotomous outcome coded as a "yes" if a patient experiences one or more complications specified by the measure within up to 90 days of the index encounter, or as a "no" if no complication occurs. Complications are counted in the measure only if they occur during an index encounter, during an inpatient readmission, or are captured in claims associated with an observation stay, an ED visit, or an ASC encounter within the applicable timeframe and setting associated with each complication type. Specific information on the measure outcome definition can be found here.

Risk Adjustment

The IP/OP 90-Day THA/TKA Complication measure adjusts for case-mix differences using a broad set of risk factors aligned with the existing Hospital-level THA/TKA Complication measure. We conducted exploratory analyses to compare the risk factors and basic demographic characteristics (e.g., age, gender, race) of patients in the inpatient and outpatient cohorts of the IP/OP 90-Day THA/TKA Complication measure. We examined the similarities and differences in the prevalence of risk adjustment variables representing patients' comorbid conditions identified in both inpatient and outpatient claims for 12 months prior to the index encounter, as well as conditions that are 'Present on Admission (POA)' for patients who are in the inpatient cohort.[11] Since POA indicators are not available in outpatient claims, the latter provision does not apply to the outpatient cohort. Conditions that may represent adverse outcomes due to care received during the index encounter are not included in risk adjustment.

Measure Calculation

The IP/OP 90-Day THA/TKA Complication measure will use a similar approach to the existing Hospital-level THA/TKA Complication measure to calculate hospital-specific RSCRs, using hierarchical logistic regression models to account for patient clustering within hospitals. The RSCR is calculated as the ratio of the number of "predicted" to the number of "expected" encounters 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 patients with complications within the specified time-period (up to 90 days) predicted based on the hospital's performance with its observed case mix, and the denominator is the number of patients with 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. Conceptually, this 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 lower ratio indicates lower-than-expected complication rates or better quality, and a higher ratio indicates higher-than-expected complication rates or worse quality.

Measure Testing

Measure testing was conducted following a carefully considered multi-step approach using Medicare FFS claims data from THA and TKA procedures performed between April 1, 2018, and March 31, 2021. These data included: 36 months of inpatient THA/TKA procedures (Apr 2018-Mar 2021); 36 months of outpatient TKA procedures (Apr 2018-Mar 2021); and 15 months of outpatient THA procedures (Jan 2020-Mar 2021). Patient-level logistic regression was used to evaluate the performance of the existing inpatient-only hospital measure risk model variables in the IP/OP 90-Day THA/TKA Complication measure. Procedures performed in the inpatient and outpatient setting were examined in separate and combined models using the same risk model variables from the existing measure, and the performance of each respective model was evaluated and compared using the C-statistic, predictive ability, and internal calibration plots.

Signal-to-noise measure score reliability testing was conducted and showed that the median signal-to-noise ratio was sufficiently high across all hospitals with at least one case of eligible THA/TKA procedures (0.78), and across hospitals with at least 25 cases (0.85). Assessment of face validity by TEP members indicated strong support of the measure as a valid assessment of complications following elective primary THA/TKA and for use of the measure to distinguish between better and worse hospital quality of care. Stakeholders supported accounting for race and/or social drivers of health (SDOH) through measure score or payment stratification in implementation planning; future implementation plans are under consideration by CMS and the Center for Medicare and Medicaid Innovation (CMMI).

In summary, this report provides a detailed description of the overall approach, empiric analyses, and stakeholder input that support the importance, scientific acceptability, and meaningfulness of this re-specified, cross-setting IP/OP 90-Day THA/TKA Complication measure for use in a to-be-determined CMMI episode payment model.

1. Measure Introduction

1.1 Measure Overview

The Centers for Medicare & Medicaid Services (CMS) contracted with Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (CORE) to develop the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting measure ("IP/OP 90-Day THA/TKA Complication measure" in this report).

The IP/OP 90-Day THA/TKA Complication measure is a re-specified version of an existing measure: Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), NQF #1550, ("existing Hospital-level THA/TKA Complication measure" in this report). The re-specified measure described in this report is designed to be setting-neutral; the original measure cohort — Medicare fee-for-service (FFS) patients aged 65 years and older who have undergone an elective primary THA or TKA procedure (collectively "Total Joint Arthroplasty" or "TJA" in this report) in a hospital inpatient setting — will be expanded to include beneficiaries who have TJA procedures performed in hospital outpatient departments (HOPDs). The measure outcome will also be expanded to include certain TJA complications that occur in outpatient settings, including during emergency department (ED) visits, observation stays, and Ambulatory Surgical Center (ASC) encounters.

A series of changes announced in the Calendar Year (CY) 2018, CY 2020, and CY 2021 Outpatient Prospective Payment System (OPPS) Final Rules provide the rationale for the IP/OP 90-Day THA/TKA Complication measure.[12-14] These changes include: the removal of TKA procedures from the Inpatient Only (IPO) List,[14] the removal of THA procedures from the IPO List, and the addition of TKA procedures and, most recently, THA procedures, to the ASC Covered Procedures List (CPL).[12, 13] Each rule change lends additional support for measure development. After the OPPS Final Rules removed TKA and THA procedures from the IPO list, there was a sizable increase in the number of these procedures performed in the outpatient setting.[15, 16] As TJA procedures are increasingly performed in more diverse surgical locations, measures are needed to monitor outcomes and quality of care across these settings.

The goal of this measure is to improve TJA outcomes by measuring and reporting RSCRs for TJA procedures performed in both hospital inpatient and hospital outpatient settings. Measuring and reporting complication rates for procedures performed across these settings will help inform healthcare providers about opportunities to improve care and strengthen incentives for advancements in the quality of care delivered to Medicare FFS beneficiaries. This, in turn, has the potential to lower healthcare costs by reducing complications associated with TJA procedures. Complications that occur across multiple settings are more likely to be influenced by care coordination, a focus of episode payment programs.[6] Accordingly, the IP/OP 90-Day THA/TKA Complication measure can serve as a critical surveillance tool to ensure that cost reduction does not adversely impact quality of care.

This methodology report includes comprehensive information on the importance, development approach, and specifications of the IP/OP 90-Day THA/TKA Complication measure. It provides detailed information on the measure cohort, outcome, risk model development, the processes for measure score calculation, and results of measure testing.

1.2 Key Terminology

Throughout this report, we use the terminology advanced by CMS, the Center for Medicare and Medicaid Innovation (CMMI), and the National Quality Forum (NQF). CMMI allows the Medicare and Medicaid programs to test payment models that improve care, lower costs, and better align payment systems to support patient-centered practices. CMMI carefully evaluates innovative reform efforts widely used in the private sector. It is unique in its ability to develop provider-proposed approaches and quickly adjust models in response to feedback from clinicians and patients. NQF is a not-for-profit, nonpartisan, membership-based organization created in 1999 to promote and ensure patient protections and healthcare quality through measurement and public reporting. NQF measures and standards provide an important foundation for initiatives to improve healthcare value, patient safety, and achieve better outcomes. Relevant terminology can be found in Appendix B.

1.3 THA/TKA as a Measure of Quality

1.3.1 Importance

TJAs are common surgical procedures that can significantly improve a patient's quality of life through pain reduction and improved function. From 2016 to 2019, approximately 1,012,190 TJA procedures were performed on Medicare FFS patients aged 65 years and older.[1] The number of TJAs performed has steadily increased over the last decade and is projected to reach over two million annually by 2030.[2, 16, 17] This increase in procedure volume is expected to be accompanied by an annual increase in the cost of TJAs, which reached $11 billion for hospitals and $5 billion for Medicare in 2004 and 2006, respectively.[18] Based on projections of the annual demand for TJA procedures, Medicare expenditures on TJA could reach $50 billion by 2030.[18] Medicare is the single largest payer for TJA procedures, serving as the primary payer for over 60 percent of TJA procedures.[2, 19] Combined, these procedures account for the largest procedural cost in the Medicare budget.[20, 21]

A series of changes announced in the CY 2018 and CY 2020-2021 OPPS Final Rules sequentially removed TKA and THA procedures from the IPO List, allowing both procedures to be performed in the outpatient setting.[12-14] Subsequently, TKA procedures and, most recently, THA procedures, were added to the ASC CPL, making both procedures billable in the ASC setting.[12, 13] These changes resulted in a sizable increase in the number of TJAs performed in the outpatient setting, providing a rationale for development of the IP/OP 90-Day THA/TKA Complication measure through re-specification and expansion of the existing Hospital-level THA/TKA Complication measure cohort and outcome. Internal CORE analyses also reflect this growth in the demand for TJA procedures, showing that approximately 82,400 outpatient TKA procedures were performed on Medicare FFS beneficiaries between January 2018 and March 2019, only 14 months after these procedures were approved for Medicare reimbursement in the outpatient setting.[15] Similarly, approximately 72,800 THA procedures were performed in the outpatient setting between January 2020 and March 2021, just 15 months after these procedures were removed from the IPO List. This shift from the inpatient to the outpatient setting is expected to continue, with some projections estimating that 51% of TKA procedures will be performed in the outpatient setting by 2026.[22]

Because TJAs are common procedures performed in diverse settings, it is important to consider the cost associated with the setting in which the procedure is performed. Studies suggest there is a significant cost differential for TKAs performed in the outpatient versus the inpatient setting with cost savings of up to 30 percent.[23] Lovald et al. compared differences in cost, complications, and mortality in Medicare TKA patients with a standard three- to four-night inpatient stay to the same in outpatient TKA patients and found a cost reduction of $8,527 in the outpatient group compared to the standard inpatient length-of-stay group.[24] Studies conducted by Husni et al. and Kimball et al. support this trend, showing cost reductions of $4,091 and $6,824, respectively, with decreasing length of stay.[25, 26]

Complication rates are also important to consider when examining TJAs performed in the inpatient and outpatient setting. Complications following elective TJA procedures are rare, but the results can be devastating, especially as these elective surgeries are intended to reduce pain and improve function, not to prolong life. Evidence shows periprosthetic joint infection rates following TJAs range from 0.7% to 1.6%, depending on the population.[27, 28] Reported 30- and 90-day death rates following THA range from 0.4% to 0.7%.[28, 29] Reported 30-day death rates following TKA in a Medicare population range from 0.1% to 0.3%.[30] Rates for pulmonary embolism following THA and TKA range from 0.5% to 1.2%,[5] and from 0.5% to 1.1%,[28, 31] respectively. Rates for wound infection in Medicare population-based studies vary between 0.21% and 1.0%.[28, 29, 32] Rates for sepsis/septicemia range from 0.09% during the index admission to 0.3% 90 days following discharge for primary TKA.[28, 32] Rates for bleeding and hematoma following TKA range from 0.94% to 1.7%.[33] Rates for pneumonia following TKA range from 0.3% to 0.5%.[30]

Initial studies comparing TJA complication rates in the inpatient versus outpatient setting have arrived at differing conclusions. Some studies found lower complication rates after outpatient procedures compared to inpatient procedures, suggesting that the outpatient setting may represent a cost-effective alternative for select patient populations.[25, 34, 35] Other early studies reported finding comparable complication rates across inpatient and outpatient settings,[3-10] and others have reported differential outcomes and costs depending upon the type of procedure (TKA versus THA) and specific outpatient setting (HOPD versus ASC).[36]

Using data from a cohort of non-Medicare patients matched on age, sex, American Society of Anesthesiologists (ASA) class, race, BMI, and other risk factors, Lan et al. found outpatient TKA procedures were associated with a lower likelihood of experiencing an adverse event compared to inpatient TKA procedures, and found no significant difference in the rate of 30-day readmissions when compared to risk-matched inpatient procedures.[35] They also found similar results for outpatient THA procedures, which were associated with a lower likelihood of any minor adverse event, but no significant difference in the 30-day readmissions rate compared to risk-matched THA procedures performed in the inpatient setting.[35] Importantly, the authors also noted that patients undergoing outpatient procedures tended to be younger, have a lower ASA class, and fewer comorbid conditions.[35]

Multiple studies have reported comparable complication outcomes for procedures performed in outpatient and inpatient settings.[3-10] For example, Aynardi et al. conducted a small, observational, case-controlled study in a single hospital facility to compare the outcomes of patients undergoing inpatient and outpatient THA procedures and found no differences in complications between these groups.[4] Carey et al. provided a more nuanced profile, finding evidence of variation in complication outcomes across the inpatient and outpatient settings. TKA complication rates did not differ substantially in the comparisons between the inpatient versus the ASC (6.29% vs. 5.48%, P =.387) and HOPD versus the ASC (5.33% vs. 4.67%, P = .646) settings. Significant differences in THA complication rates were observed, however, in the comparisons between the inpatient and ASC (5.83% vs. 1.93%, P < .001) and HOPD and ASC (5.17% vs. 1.11%, P = .011) settings.[36]

Information on the variability in THA complication rates is currently lacking for procedures performed on Medicare FFS beneficiaries aged 65+ in hospital outpatient settings due to limitations on available data, but DeMik et al. found that following removal of TKAs from the IPO List in 2018, rates of total 30-day complications were significantly lower in 2018 compared to the 2015-2017 three-year period (3.7% vs. 4.5%, P = .04). Rates of any reoperation were also significantly lower (1.2% from 2015-2017 vs. 0.6% in 2018, P = .03), with no significant changes in rates of readmission or wound complications. This data suggest the increased number of TKAs performed in the outpatient setting did not lead to greater complication rates in the Medicare population.[37]

Not every study has supported the move to performing outpatient procedures. A recent meta-analysis conducted by Bordoni et al. found that outpatient procedures are associated with a greater number of complications compared to inpatient procedures. They stressed, however, that additional high-level studies are needed to confirm their findings due to concerns about a moderate risk of bias in the included studies.[38] The latter concern is also echoed in meta-analyses conducted by Bemelmans et al.[39] and Migliorini et al.,[9] who recommend viewing the findings across studies with caution due to methodological and other issues. These issues include heterogeneity in the patient populations and follow-up times across studies, unaccounted differences in surgical practice patterns, and potential selection bias from retrospective study designs. Differences in the definition of "outpatient" status have also been noted.[40]

The lack of consensus on complication rates in outpatient versus inpatient settings, as well as the concerns noted above, suggests the need for further analyses. Indeed, studies that described complication rates across settings support the need for future analyses to confirm past results, providing further support for this measure and need for surveillance of TJA complications across diverse care settings.[2, 3, 39]

Targeted efforts to reduce TJA complications could result in better patient care and potential cost savings.[41] Re-specifying the existing Hospital-level THA/TKA Complication measure for use in a potential combined inpatient and outpatient episode payment model has many benefits, including:

- Providing a critical metric for monitoring patient outcomes in the setting of cost containment or reduction;
- Improving transparency about hospital quality if the measure is publicly reported;
- Incentivizing coordination of care across care settings and clinicians, especially for longer-term outcomes after elective procedures;
- Incentivizing quality improvement among providers; and
- Improving health for patients served by inpatient and outpatient facilities.

Importantly, the re-specified measure will help ensure quality is not compromised by this shift to performing TJA procedures in the outpatient setting.

1.3.2 Performance and Preventability

Results from the existing Hospital-level THA/TKA Complication measure show variation in complication rates based on inpatient procedures and provide evidence of an opportunity for improvement. Analyses conducted using data from April 1, 2016, to March 31, 2019, Medicare administrative claims data (N=962,744 admissions from 3,418 hospitals) demonstrated a mean RSCR of 2.5%, median RSCR of 2.4%, and an RSCR range from 1.2% to 10.6% in the measure cohort.[1] Data from the re-specified IP/OP 90-Day THA/TKA Complication measure demonstrate a mean RSCR of 2.91%, with a range from 5.86% to 1.53%.

Findings from several studies suggest complications after THA/TKA procedures are preventable. Husni et al. examined the influence of critical pathways (care plans meant to achieve optimal procedure efficiency by delineating the sequence of actions) on the postoperative outcomes after TKA procedures. The authors found that patients operated upon in hospitals that used critical pathways had a lower risk of postoperative complications, including death, compared to patients operated on in hospitals without critical pathways.[26] Researchers also found that patients on critical pathways had significantly lower odds of experiencing any adverse event (adjusted odds ratio (OR) = 0.68, 95% CI 0.50, 0.92) compared to patients without a critical pathway, and had an average length of stay that was 0.5 days shorter after controlling for patient- and hospital-level factors.[26] Similarly, in their literature review, Bert et al. summarize methods for establishing a successful outpatient TJA program within the framework of bundled payment reimbursement.[6] They outlined a number of patient- and provider-level strategies for minimizing postsurgical complications and improving patient recovery including patient risk assessment, care coordination, staff training, and the use of proper sterilization and pain management techniques. Li et al. also stressed proper patient selection, proper patient/family education, opioid-sparing analgesia, and prompt care coordination and post-discharge.[42] This would suggest that prevention of postsurgical complications is possible and that many prevention methods are within hospitals' control.[6]

1.3.3 Measurement Gap

There is a defined need to develop quality measures that consider the increasing number of TJA procedures performed each year, and the increasingly diverse settings in which these procedures are performed. CMS currently has two publicly reported quality measures that provide information on facility-level outcomes (30-day readmissions, 90-day complications) occurring after elective primary THA/TKA procedures; both measures focus on procedures performed only in the hospital inpatient setting, however. Similarly, CMS has two publicly reported measures that provide information on outcomes (unplanned inpatient admission, observation stay, ED visit) following orthopedic or surgical procedures, including THAs and TKAs, performed in the ASC or HOPD setting, respectively. Both outpatient measures report on a variety of other procedures, however, and are thus less useful as a quality signal for THA and TKA complication outcomes. Furthermore, the measure results are not directly comparable, making it harder for patients and providers to weigh the risk and benefits of a procedure performed in a particular setting. The IP/OP 90-Day THA/TKA Complication measure fills an important gap by expanding the existing Hospital-level THA/TKA Complication measure to provide information on the quality of care associated with THA and TKA procedures performed in the hospital inpatient and outpatient settings. It will also capture certain complications that occur across all settings (index inpatient/outpatient encounter, inpatient readmission, observation stay, ED, and ASC encounters).

To the extent feasible, we harmonized with existing related measures, specifically with CMS's existing Hospital-level THA/TKA Complication and Readmission measure. Importantly, while this measure represents the same outcome and a similar patient population (patients undergoing elective primary THA/TKA procedures) to the existing Hospital-level THA/TKA Complication measure, the goal of the IP/OP 90-Day THA/TKA Complication measure is to provide a more accurate quality assessment tool for payment models that cross care settings. Therefore, this measure will never directly compete with the existing Hospital-level THA/TKA Complication measure in a CMS program because it is intended for use only in applications that capture data from both the inpatient and HOPD settings. Learning from this re-specification work will also inform updates and expansions to harmonized measures that cross settings, such as NQF #3493 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 in CMS's Quality Payment Program.

1.3.4 Feasibility and Usability

This measure uses administrative claims and enrollment data that is generated during the provision of care and as such, allows for quality assessment without imposing an additional data collection or measure reporting burden to hospitals or providers. The existing Hospital-level THA/TKA Complication measure has been endorsed by NQF and is used by CMS to publicly report on hospital quality. During development of the IP/OP 90-Day THA/TKA Complication measure, we drew on the methodology used in the publicly reported, existing Hospital-level THA/TKA Complication measure. Therefore, we anticipate the former measure will demonstrate similar feasibility. Further, there are no fees associated with the use of this measure. Administrative data are routinely collected as part of the billing process and require no extra resources by hospitals to comply.

The usability and value of this measure was assessed during the measure development process by soliciting critical input from our Clinical Working Group (CWG), Technical Expert Panel (TEP), and, through this public comment, the public. Meetings were held with the CWG and TEP to request input and feedback on key methodological and clinical decisions to ensure the measure is meaningful and useful to stakeholders, patients, and consumers.

1.4 Measure Use

The goal of IP/OP 90-Day THA/TKA Complication measure development was to re-specify the existing Hospital-level THA/TKA Complication measure to include procedures performed in both inpatient and outpatient hospital settings for potential use in a future episode payment model (EPM). EPMs are designed to incentivize participating providers to look at a patient's treatment needs across settings – to improve coordination, reduce expenditures, and maintain or improve quality of care – with the goal of identifying opportunities to optimize treatment processes and deliver care more efficiently. Learning from this re-specification work will also inform future updates and expansions to harmonize measures in cross-setting programs such as CMS's Quality Payment Program.

1.5 Approach to Measure Development

CMS contracted with CORE to develop a re-specified version of the existing Hospital-level THA/TKA Complication measure. The CORE Project Team consists of a multidisciplinary group of individuals with expertise in measure development, health services research, clinical medicine, statistics, and measurement methodology.

We developed this measure in consultation with national guidelines for publicly reported outcome measures, including the CMS Measure Management System Guidance,[43] those published by NQF,[44, 45] and as articulated in the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes."[46] Following these standards has ensured a transparent and comprehensive process with expert input throughout development (see Acknowledgements). Below we review our approach to measure development.

1.5.1 Information Gathering

Since this is a re-specification of an existing measure, the information gathering step focused primarily on empiric analyses and stakeholder input regarding the inclusion of TJA procedures performed in HOPDs in the measure cohort and the addition of certain complications occurring in outpatient settings (ED visits, observation stays and ASCs) to the measure outcome definition. These are detailed below and in Sections 2. Methods and 3. Results.

1.5.2 Expert and Stakeholder Input

Throughout measure development, we engaged with several stakeholder groups to elicit feedback on the measure concept, outcome, and cohort. Currently, we have obtained stakeholder input through three mechanisms. First, we consulted with our Expert Clinical Consultant, Dr. Kevin Bozic, who provided guidance on key clinical and methodological decisions. Second, we consulted with an advisory CWG of four clinicians, each representing the four national THA and/or TKA professional societies: The Knee Society, The Hip Society, The American Academy of Orthopaedic Surgeons, and The American Association of Hip and Knee Surgeons. CWG members provided input on the expansion of the cohort to the outpatient setting and the clinical appropriateness of extending the outcome definition to certain observation stays, ED visits, and ASCs. The CWG expressed consensus regarding the validity of each complication in each respective clinical context or contexts. The CWG also provided feedback on the risk model, measure testing results, the use of a setting indicator (e.g., inpatient vs. outpatient setting for the index procedure), and analyses evaluating the impact of social drivers of health on this measure. Third, we held a national call for nominations and convened a TEP that included methodological experts from several relevant disciplines, as well as four patient experts. Convening a national TEP ensures transparency and helps method developers obtain balanced input from multiple stakeholders. We reviewed the measure concept, approach to re-specification, and results of measure testing and analyses regarding social drivers of health with the TEP. All meeting minutes and a summary document of all meetings were publicly posted following each meeting.

2. Methods

2.1 Overview

The IP/OP 90-Day THA/TKA Complication measure uses ICD-10-CM (The International Classification of Diseases, 10th Revision, Clinical Modification) diagnosis codes, ICD-10 procedure codes (ICD-10 Procedure Coding System [PCS]), and Current Procedural Terminology (CPT®) codes to define the cohort, outcome, and risk adjustment variables. Measure specifications are built upon specifications from the existing Hospital-level THA/TKA Complication measure, including the IP cohort and IP outcome definitions and risk adjustment variables. We updated the existing measure specifications as needed to be in alignment with the coding practices used in the outpatient environment. We solicited input from members of a CWG and a national TEP on the changes to the measure specifications and to evaluate the feasibility, reliability, and validity of the outcome definition and measure logic. Details on the methods used for measure re-specification and testing are outlined below.

2.2 Data Sources

We use Medicare administrative claims data and enrollment information for patients with qualifying procedures between April 1, 2018, and March 31, 2021. Specifically, we used the following data sources:

1. Medicare inpatient, outpatient, and physician/professional claims: these include data for Medicare FFS inpatient and outpatient services such as Medicare inpatient hospital care, HOPD services, and physician claims for the 12 months prior to an index encounter and for the three months after.
2. Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This data source is used to obtain information on several inclusion/exclusion indicators such as Medicare status on admission, vital status at discharge, and death information post-discharge. These data have previously been shown to accurately reflect patient vital status.[47]

2.2.1 Limitations

Differences in coding practices used on inpatient and outpatient claims (e.g., Present on Admission (POA) coding) made exact alignment with the existing Hospital-level THA/TKA Complication measure challenging. For example, if a complication associated with an IP index procedure is coded as a secondary diagnosis, it would only count as a complication in the measure if it were not coded as POA. Since POA coding is not used on outpatient HOPD claims, if a complication associated with an OP index procedure is coded as a secondary diagnosis, we assumed it is not POA and counted it as a complication in the measure.

In addition, IP/OP 90-Day THA/TKA Complication measure development occurred during the SARS-CoV-2 (COVID-19) pandemic. Examination of trends in inpatient and outpatient THA/TKA procedure volume from April 2018 to March 2021 indicated a marked reduction in THA/TKA volumes to nearly zero in April 2020, followed by a slowly increasing trend upwards. While outpatient volumes have risen more rapidly than inpatient volumes, the total number of eligible THA/TKA procedures has not reached pre-COVID-19 levels within our re-specification and testing dataset. The prevalence of COVID-19 in the measure cohort is exceptionally rare, as expected for an elective procedure. The impact of COVID-19 on the IP/OP 90-Day THA/TKA Complication measure re-specification, particularly in terms of disparities in access to these procedures, is unclear. CMS continues to monitor the impact of COVID-19 on its measures and programs.

2.2.2 Generalizability

The IP/OP 90-Day THA/TKA Complication measure cohort includes Medicare FFS patients aged 65 and older exclusively at this time. Potential impediments to generalizability may arise if the initial population of Medicare beneficiaries undergoing outpatient THA/TKA procedures are not representative of patients who undergo outpatient THA or TKA procedures in the future. CMS is exploring the inclusion of Medicare Advantage patients in its claims-based hospital-level measures but is currently limited by the availability of pre-index procedure data for risk adjustment.

2.3 Measure Cohort (Denominator)

The target population for the measure includes Medicare FFS beneficiaries 65 years of age and older undergoing elective primary THA and/or TKA procedures in the inpatient and outpatient setting of non-federal, short-term, acute care hospitals.

2.3.1 Inclusion Criteria

To be included in the measure cohort, patients must meet the following inclusion criteria:

1. Enrolled in Medicare FFS Part A and Part B for the 12 months prior to and including the date of the encounter.
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 as POA in the principal or secondary discharge diagnosis fields on the index encounter;
     - This criterion is not applicable to periprosthetic fractures for procedures performed in the outpatient setting.
   - A concurrent partial hip or knee arthroplasty procedure in discharges on or after October 1, 2015;
   - A concurrent revision, resurfacing, or implanted device/prosthesis removal procedure;
   - Mechanical complication coded in the principal discharge diagnosis field on the index encounter;
   - 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 encounter; or
   - Transfer from another acute care facility for the THA/TKA.
   - For outpatient procedures only: Healthcare Common Procedure Coding System (HCPCS) modifiers indicating discontinued procedures.

To harmonize with the existing Hospital-level THA/TKA Complication measure and ensure sufficient case volumes for reporting, this measure is intended to use a 36-month measurement period. Alternate measurement periods may be considered by CMS/CMMI as supported by measure reliability testing results and as indicated by the measure application and payment model.

After the above exclusions are applied, the measure randomly selects one index admission per patient per 12-month 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 period are excluded.

If a randomly selected admission within the second 12-months of the measurement period (e.g., April 1, 2019 – March 31, 2020) falls within 90 days of a randomly selected index admission for the first 12-months of the measurement period (e.g., April 1, 2018 – March 31, 2019), the measure includes both admissions; however, a complication that falls within the defined time frame for both admissions would only be captured in the complication outcome for the admission in the second time period. For example, if a patient has a randomly selected admission on March 1, 2019, and then again on April 2, 2019, and then has a readmission for pulmonary embolism on May 3, 2019, the pulmonary embolism is attributed to the April 2, 2019, admission.

2.3.2 Exclusion Criteria

The measure excludes index encounters for patients:

1. Without at least 90 days post-discharge enrollment in Medicare FFS.

   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.

2. Who were discharged against medical advice (AMA).

   Rationale: Providers did not have the opportunity to deliver full care and prepare the patient for discharge.

3. Who had more than two THA/TKA procedure codes during the index encounter.

   Rationale: Although clinically possible, it is highly unlikely patients would receive more than two elective THA/TKA procedures in one hospitalization, which may reflect a coding error.

All exclusions were determined by careful clinical review and have been made based on clinically relevant decisions to ensure accurate calculation of the measure. To ascertain impact of exclusions on the cohort, we will examine overall frequencies and proportions of the total cohort excluded for each exclusion criterion. These exclusions are consistent with similar NQF-endorsed measures.

2.4 Measure Outcome (Numerator)

This measure will report the hospital-level RSCR within 90 days of the index encounter. The composite complication is a dichotomous outcome ("yes" for any complication[s]; "no" for no complications). Therefore, if a patient experiences one or more of the following complications within 90 days of the index encounter, the outcome variable will get coded as a "yes." Complications are counted in the measure only if they occur during the index encounter or are captured in claims that are associated with an observation stay, ED visit, or ASC encounter, as indicated in Table 1 below:

Table 1: Specific Complications and Settings include in the Measure Outcome (Numerator)

Follow-up Period in Days	Complication	Count as complication if observed within the post-index follow-up period? Inpatient Admission	Count as complication if observed within the post-index follow-up period? Observation Stay	Count as complication if observed within the post-index follow-up period? ED visit	Count as complication if observed within the post-index follow-up period? ASC
During index encounter or within 7 days from the start of the index encounter	Acute myocardial infarction (AMI)	Yes	No	No	No
During index encounter or within 7 days from the start of the index encounter	Pneumonia	Yes	No	No	No
During index encounter or within 7 days from the start of the index encounter	Sepsis/septicemia/shock	Yes	No	No	No
During index encounter or within 30 days from the start of the index encounter	Surgical site bleeding or other surgical site complication	Yes	Yes	No	Yes

Follow-up Period in Days	Complication	Count as complication if observed within the post-index follow-up period? Inpatient Admission	Count as complication if observed within the post-index follow-up period? Observation Stay	Count as complication if observed within the post-index follow-up period? ED visit	Count as complication if observed within the post-index follow-up period? ASC
During index encounter or within 30 days from the start of the index encounter	Pulmonary embolism	Yes	Yes	No	No
During index encounter or within 30 days from the start of the index encounter	Death	Yes	Yes	Yes	Yes
During index encounter or within 90 days from the start of the index encounter	Mechanical complication	Yes	Yes	Yes	Yes
During index encounter or within 90 days from the start of the index encounter	Periprosthetic joint infection/wound infection or other wound complication	Yes	Yes	No	Yes

Note that the index encounter is defined as either an index inpatient admission or index outpatient procedure to be considered for inclusion in the outcome. The start of the index encounter is the admission date for inpatient procedures and the procedure date for outpatient procedures. For further details, please see Appendix C, Table 1.

The complications represent substantive negative clinical outcomes that the existing Hospital-level THA/TKA Complication measure development team, TEP, and published literature support found can be meaningfully influenced by hospital and peri-operative care. Some require both diagnostic and procedure codes to enhance face validity. For further information regarding the existing Hospital-level THA/TKA Complication measure or the most recent specifications, including detailed definitions of the included complications, please refer to CMS's Complication Measure Methodology webpage at:
https://qualitynet.cms.gov/inpatient/measures/complication/methodology

The CWG and TEP for the IP/OP 90-Day THA/TKA Complication measure agreed with the updated complication definition. They agreed certain outpatient outcomes events occurring in certain settings may lack face validity and thus should be excluded from the definition. For example, a patient with a principal diagnosis of sepsis seen only in the ED but without an associated observation stay or inpatient admission likely does not represent a truly septic patient and thus was not considered part of the measure outcome.

2.5 Attribution

For this measure, hospitals are the measured entities. All non-federal, acute, inpatient United States (US) hospitals (including territories) with Medicare FFS beneficiaries aged 65 years and older are included.

2.6 Risk Adjustment

The goal of risk adjustment is to account for patient characteristics, such as age and comorbid conditions, at the time of admission that are clinically relevant, have strong relationships with the outcome, and are outside of the control of the reporting entity without obscuring important quality differences. Since the IP/OP 90-Day THA/TKA Complication measure is a re-specification of the existing Hospital-level THA/TKA Complication measure, we conducted exploratory analyses to examine the similarities and differences between the inpatient and outpatient cohorts with respect to risk factors used in the existing Hospital-level THA/TKA Complication measure, as well as basic patient demographic characteristics (e.g., age, gender, race). The existing measure risk model includes several factors that are strong predictors of patient frailty and functional status, including malnutrition, osteoporosis and vertebral fractures, dementia, paralysis, and decubitus ulcers.

We examined risk-adjustment variables for patients' comorbid conditions identified in both inpatient and outpatient claims for the 12 months prior to the index encounter, as well as those coded as POA for patients in the inpatient cohort.[11] Since POA indicators are not available in outpatient claims, for the outpatient cohort, conditions that may represent adverse outcomes due to care received during the index encounter are not adjusted for in the model.

2.6.1 Clinical Setting

This measure includes patients undergoing procedures in both the inpatient and outpatient settings. Initial empiric analyses indicated that observed complication rates were lower after outpatient procedures compared to inpatient procedures despite relatively modest differences in clinical risk factor frequency across setting (Table 3 and Table 4, below). Through discussions with internal clinical and health policy experts, the CWG, and the TEP, we concluded there are multiple factors influencing the decision to perform elective THA/TKA procedures in the inpatient versus outpatient setting. These factors include clinical risk assessment by the surgical team (including underlying patient frailty), hospital policies and resources, patient preference, and SDOH such as transportation, access to care, housing situation, home support, health literacy, and income. We defined clinical setting as inpatient versus outpatient (observation stay or day surgery) using administrative encounter information. We then assessed the validity of this clinical setting definition by examining the correlation between setting and length of stay in days.

To explore the influence of clinical setting on the risk model, we then assessed model performance using three approaches: 1) using a single risk model with regression coefficients estimated from the combined cohort of inpatient and outpatient procedures (single combined IP/OP model); 2) using two distinct models, one for each setting with identical risk factors but allowing regression coefficients to vary by setting; and 3) a single combined model (as in #1) but with an indicator variable added reflecting inpatient versus outpatient (HOPD) setting. As discussed below (Section 2.7), we assessed model performance through calibration plots and statistics, C-statistics, and predictive ability.

2.6.2 Social Drivers of Health

As a portion of risk due to social drivers of health is due to increased comorbidity, we examined model fit and predictive ability of clinical risk variables first, followed by assessment of social drivers of health. Even after accounting for clinical comorbidities and SDOH, however, research has shown that Black patients were still less likely to undergo TKA, suggesting there are additional factors underlying this disparity. Outcomes commonly assessed in the literature include specific complications (including pulmonary embolism, deep vein thrombosis, excessive bleeding, and prosthetic joint and other infections), mortality, readmission, and length of stay; below we focus on all outcomes except for length of stay which is not part of the outcome definition for the IP/OP 90-Day THA/TKA Complication measure.

Race and Ethnicity

Many studies have evaluated the relationship between race and ethnicity and outcomes and the evidence for an association is mixed. On the one hand, a recent (2022) systematic review found that most studies show higher rates of complications for Black and Hispanic patients compared with White patients.[48] For example, several recent studies have found that after controlling for comorbidities, Black and Hispanic patients were more likely to have higher rates of complications following THA/TKA procedures.[49, 50] A 2020 study in the Kaiser Permanente System found similar results, showing worse outcomes for Black patients compared with White patients.[51] Some of these disparities could be due to worse pre-operative function as well as higher odds of receiving care at low-quality, low-volume hospitals.[52-57]

On the other hand, a 2018 study that used a large, international clinical registry (ACS-NSQIP) found that outcomes (a composite of complications) between White and Black men and women were similar; women had a higher rate of complications due to a higher rate of transfusions.[58] In addition, a 2019 study in a US total joint replacement registry that examined insured patients found that while 90-day ED visit rates were higher for Black, Hispanic, and Asian patients, rates of infection, venous thromboembolism, readmission, and mortality were similar or lower compared with White patients.[59] In our own empiric results for this measure, we find that unadjusted complication rates are similar for Black and non-White patients, but somewhat higher for other (non-Black, non-White) patients (Table 9).

More recently, however, researchers found that when controlling for SDOH using the Area Deprivation Index (ADI), outcomes for Black and White patients were similar,[60] suggesting that SDOH variables may be the more dominant driver of outcomes.

Social Drivers of Health

A recent study from the Cleveland Clinic used the ADI to examine disparities in THA/TKA outcomes. Study authors found that patients with higher ADI scores (greater drivers of health) had higher readmission rates compared with patients with lower ADI scores, but that 90-day emergency department visits and reoperations did not differ significantly between the two groups.[61] As mentioned above, when White and Black patients are similar in terms of their ADI scores, outcomes are also similar, suggesting that SDOH, rather than race, may be driving differences in outcomes.[61]

In a study examining the association between dual eligibility and THA/TKA outcomes, after controlling for comorbidities, patients with dual eligibility (dual Medicare and Medicaid coverage) were more likely to visit the ED within 90 days compared with non-duals.[62]

Other Factors

In addition to race and social drivers of health, other factors such as frailty, age, gender, and provider density have been examined for their relationship to THA/TKA outcomes. As described above, variables differ in their association with the specific complications. For example, age is associated with a greater risk of cardiac complications.[63] Women are more likely to experience venous thromboembolism,[64] whereas men are at higher risk of death, AMI, pneumonia, and surgical site infections.[65] Frailty has been shown to be associated with a higher risk of reoperation and readmission.[66] Finally, no association has been seen between THA/TKA outcomes and primary care provider density.[67]

The intent of the measure is to adjust for patient demographic and clinical characteristics while illuminating important quality differences. Based on the literature showing a relationship between SDOH and complications, and in assessing the available risk variables that can be linked to claims data, we conducted analyses using the following SDOH available within our data sources: non-White race, dual eligibility, and low socioeconomic status (SES) using the Agency for Healthcare Research and Quality (AHRQ) SES index. The AHRQ SES Index (or ASI) is a proxy measure of SES that was developed by AHRQ specifically for use with Medicare data due to the lack of person-level SES data in Medicare files. The index is based on the ZIP code associated with a beneficiary's place of residence and includes the following census variables: percentage of persons in the labor force who are unemployed; percentage of persons living below poverty level; median household income; median value of owner-occupied dwellings; percentage of persons 25 years of age or older with less than a 12th grade education; the percentage of persons 25 years of age or older completing four or more years of college; and the percentage of households that average one or more persons per room. Higher ASI scores indicate higher SES.[68]

Many patient-level factors are accounted for in the existing Hospital-Level THA/TKA Complication measure risk model whereas other factors, namely social drivers of health, are not accounted for in the risk. We emphasize that other CMS payment programs, however, such as

CMS's Hospital Readmission Reduction Program, and payment models such as CMMI's Comprehensive Joint Replacement (CJR) model, have recently started to account for dual eligibility within the payment program rather than the quality measure(s). Implementation planning for this measure has not been finalized. As this measure assesses patients undergoing an elective procedure where known disparities exist, CMS will continue to assess the impact of SDOH for this measure over time.

2.7 Statistical Approach to Model Development

Using patient-level logistic regression, we examined model performance with the same set of risk factors as in the existing Hospital-level THA/TKA Complication measure on the following cohorts: inpatient only, outpatient only, and combined inpatient and outpatient. For the combined inpatient and outpatient cohort, we also examined the addition of a setting indicator (inpatient versus outpatient) in the risk model. We evaluated model performance by comparing the C-statistic, predictive ability, and internal calibration plots of each respective model. We considered model performance to be similar between the inpatient- and outpatient-cohort models using the following criteria: 1) the 95% confidence interval of the C-statistic for the two cohorts overlapped, and 2) the calibration plots were similar between the cohorts. We also examined the direction and magnitude of the odds ratios from the multivariable model, as well as potential interactions between the current risk factors and setting of procedure.

2.8 Calculation of Measure Score

The IP/OP 90-Day THA/TKA Complication measure followed a similar approach to that of the existing Hospital-level THA/TKA Complication measure to calculate the measure score:

The measure will be used to estimate RSCRs following elective primary THA/TKA in hospital-based inpatient and outpatient settings using hierarchical logistic regression models. This approach simultaneously models data at the patient and hospital levels to account for variation in patient outcomes within and between hospitals.[69] At the patient level, it models the log-odds of a complication occurring within the specified time period (up to 90 days) after the index encounter and a hospital-specific effect. At the hospital level, it models the hospital-specific effect as arising from a normal distribution. The hospital effect represents the underlying risk of a complication at the hospital after accounting for patient risk. The hospital-specific effects are given a distribution to account for the clustering (non-independence) of patients within the same hospital.[69] If there were no differences among hospitals, then after adjusting for patient risk, the hospital effects should be identical across all hospitals.

The RSCR is calculated as the ratio of the number of "predicted" to the number of "expected" encounters 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 patients with complications within the specified time period (up to 90 days) predicted based on the hospital's performance with its observed case mix, and the denominator is the number of patients with 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. Conceptually, this approach 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 lower ratio indicates lower-than-expected complication rates or better quality, and a higher ratio indicates higher-than-expected complication rates or worse quality.

The “predicted” number of encounters with a complication (the numerator) is calculated by using the coefficients estimated by regressing the risk factors and the hospital-specific effect on the risk of having an encounter with a complication. The estimated hospital-specific effect 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 encounters with a complication (the denominator) is obtained in the same manner, but a common effect 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.

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.[69, 70]

2.9 Measure Testing

2.9.1 Data Element Reliability

The data elements used in the IP/OP 90-Day THA/TKA Complication measure are the same as those used in the existing Hospital-level THA/TKA Complication measure. The data element reliability has been assessed in the existing complication measure.[70] To confirm data element reliability, the individual variables are regularly evaluated for missing values, out-of-range values, and other data quality issues. Variables known to be of poor quality due to unreliable coding were identified and excluded during development of the original measure. Specifically, fields known to be coded inconsistently across hospitals or providers were avoided. Instead, only audited fields and fields that are utilized for payment were considered for use in the measure.

As noted above, we also examined the distribution of length of stay in days by clinical setting to provide external validity for this additional risk variable.

2.9.2 Measure Score Reliability

The reliability of a measure is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is the hospital and reliability is the extent to which repeated measurements of the same hospital give similar results. The reliability of the measure score was assessed using a signal-to-noise approach.[71] The reliability of any one facility’s measure score will vary depending on the number of patients admitted for an elective THA/TKA procedure. Facilities with higher case volume (with more patients undergoing eligible THA/TKA procedures) will tend to have more reliable scores, while facilities with lower volume will tend to have less reliable scores. Therefore, we used the formula presented by Adams et al.[72] to conduct facility-level reliability testing and presented the distribution of reliability values across hospitals.

2.9.3 Data Element Validity

In constructing the measure, we utilized only those data elements from the claims that have both face validity and reliability. The data elements used in the IP/OP 90-Day THA/TKA Complication measure are the same as those used in the existing Hospital-level THA/TKA Complication measure. During original measure development, the administrative claims-based definition of THA/TKA complication (original model specification) was validated against medical record data.[70]

In addition, we avoided the use of fields that are thought to be coded inconsistently across providers. Specifically, we only used fields that are consequential for payment and that are audited. CMS has several hospital auditing programs in place to assess overall claims code accuracy, ensure appropriate billing, and to facilitate overpayment recoupment. CMS routinely conducts data analyses to identify potential problem areas, detect fraud, and audit important data fields used in our measures. This includes diagnosis and procedure codes and other elements that are consequential to payment.

2.9.4 Measure Score Empiric Validity

To assess validity of the measure score, we identified and assessed the correlation of the IP/OP 90-Day THA/TKA Complication measure with other measures that target the same domain of quality (e.g., complications, safety, or post-procedure utilization) for the same or similar patient populations. The goal is to identify whether the identification of better performance in this measure is related to the identification of better performance in other relevant structural or outcome measures. After a literature review and consultations with measures experts in the field, there were very few measures identified that assess the same domains of quality. Given that challenge, we selected the following to use for empiric validity testing:

1. Overall Hospital Star Rating: CMS's Overall Hospital Star Rating assesses hospitals' overall performance (expressed on Hospital Compare graphically as stars) based on a weighted average of "group scores" from different domains of quality (mortality, readmissions, safety, patient experience, imaging, effectiveness of care, timeliness of care). Each group has within it, measures that are reported on Hospital Compare, including the existing Hospital-level THA/TKA Complication measure. Group scores for each individual group are derived from latent-variable models that identify an underlying quality trait for each group. Group scores are combined into an overall hospital score using fixed weights; overall hospital scores are then clustered using k-means clustering into five groups and are assigned one to five stars (the hospital's Star Rating). For the validity testing presented in this testing form, we used hospital's Star Ratings (July 2021) from 2,747 Medicare FFS hospitals with at least one eligible THA/TKA procedure and 2,358 Medicare FFS hospitals with at least 25 eligible procedures. For this comparison, we removed hospital's results for the existing Hospital-level THA/TKA Complication measure to avoid falsely elevating the correlation due to the harmonized legacy measure. The full methodology for the Overall Hospital Star Rating can be found at: https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/resources

2. Hospital THA/TKA Surgical Volume: There is evidence that surgical complication rates for providers (both surgeons and hospitals) decline with increasing volume.[73-75] Thus, we assessed measure validity by examining the relationship between hospital-level THA/TKA volumes and RSCRs.

We examined the relationship of performance between the IP/OP 90-Day THA/TKA Complication measure scores (RSCRs) and each of these external measures of hospital quality. For the external measures, the comparison was against performance within quartiles of the Star Ratings overall category (1-5 Stars), as well as hospital THA/TKA surgical volume. We predicted the IP/OP 90-Day Complication measure scores would have a small association with the Overall Hospital Star Rating scores, with lower RSCRs associated with better Star Ratings. With THA/TKA surgical volume, we assume lower RSCRs will be moderately associated with higher volume hospitals.

2.9.5 Measure Score Face Validity

The IP/OP 90-Day THA/TKA Complication measure was developed in consultation with national guidelines for publicly reported outcome measures, with outside experts, and with the public. We assessed face validity by asking TEP members to rate the measure according to the following two statements using a six-point scale (1 = Strongly Agree, 2 = Moderately Agree, 3 = Somewhat Agree, 4 = Somewhat Disagree, 5 = Moderately Disagree, 6 = Strongly Disagree):

- Statement #1: The IP/OP 90-Day THA/TKA Complication measure as specified will provide a valid assessment of complications following elective THA/TKA.
- Statement #2: The IP/OP 90-Day THA/TKA Complication measure as specified can be used to distinguish between better and worse quality care among hospitals performing THAs/TKAs.

3. Results

3.1 Measure Cohort

The IP/OP 90-Day THA/TKA Complication measure exclusions by cohort are provided in Figure 1. There were 989,587 total THA/TKA procedures that met the measure inclusion/exclusion criteria. Of these, 67% (N=658,403) were performed in the inpatient setting and 33% (N=331,184) were performed in the outpatient setting.

Table 2 shows that Medicare patients undergoing THA/TKA procedures in the OP setting were more likely to be younger, male, and White, and less likely to be dually eligible for Medicare and Medicaid than those in the IP setting. Clinical risk variable frequency was similar among beneficiaries who had procedures performed in the IP and OP setting. The prevalence of some risk variables (particularly those associated with greater frailty and/or clinically significant comorbidity) are slightly higher in the IP versus OP setting (Table 3).

Figure 1: IP/OP 90-Day THA/TKA Complication Measure Cohort Exclusions

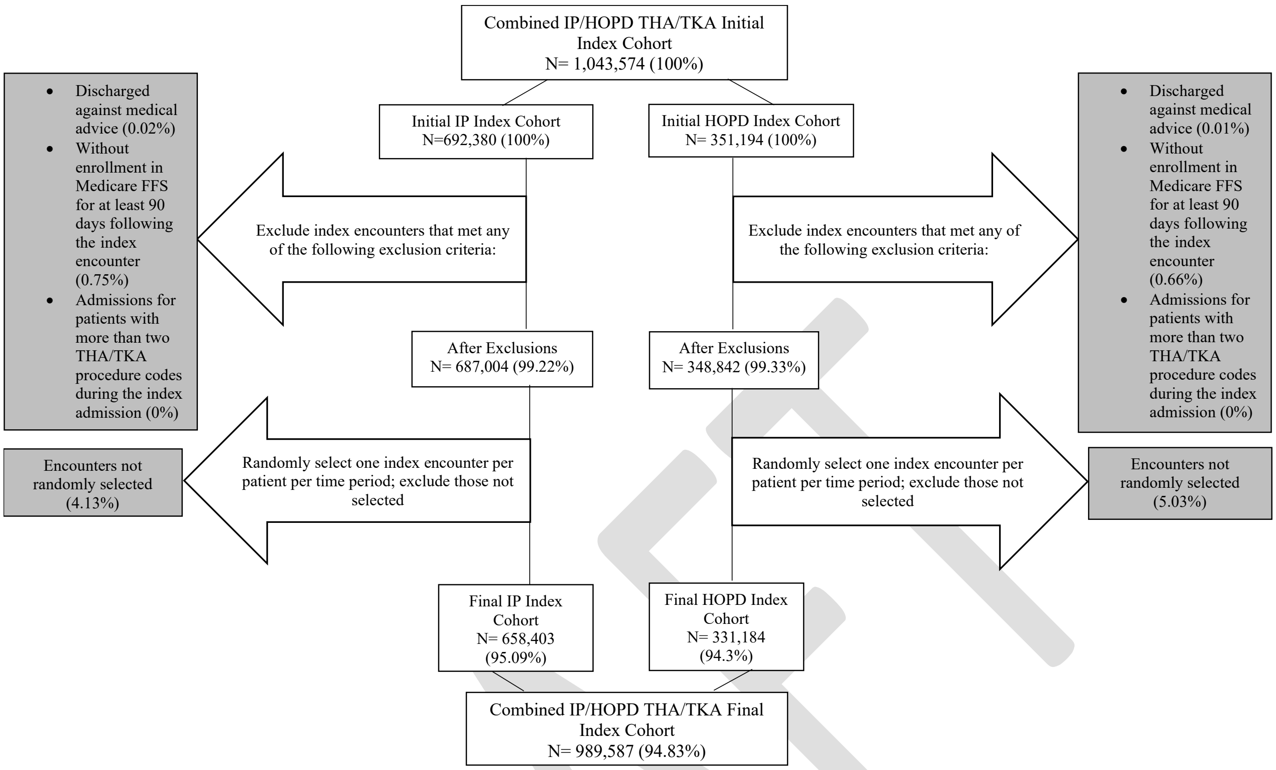

Table 2: IP/OP 90-Day THA/TKA Complication Measure Cohort Demographic Characteristics

*	Measurement Period April, 2018 to March 31, 2021	Measurement Period April, 2018 to March 31, 2021	Measurement Period April, 2018 to March 31, 2021
Demographics	**Inpatient THA/TKA N (%)**	**Outpatient THA/TKA N (%)**	**Both N (%)**
Total procedures**	658,403	331,184	989,587
Age distribution in years, Mean (Standard Deviation)	74 (6)	73 (5)	74 (6)
Male	242,997 (36.91)	135,807 (41.01)	378,804 (38.28)
Race and Ethnicity - White	596,281 (90.56)	301,525 (91.04)	897,806 (90.73)
Black	30,452 (4.63)	12,158 (3.67)	42,610 (4.31)
Other	6,213 (0.94)	3,203 (0.97)	9,416 (0.95)
Asian	4,570 (0.69)	2,289 (0.69)	6,859 (0.69)
Hispanic	4,478 (0.68)	2,252 (0.68)	6,730 (0.68)
North American Native	2,743 (0.42)	911 (0.28)	3,654 (0.37)
Dual status at discharge	25,150 (3.82)	7,837 (2.37)	32,987 (3.33)

*Cell intentionally left empty.

**The number of total procedures is smaller than reported elsewhere due to the random selection of one procedure per patient per year.

Table 3: Prevalence of Existing Hospital-level THA/TKA Complication Measure Risk Model Variables in IP/OP 90-Day THA/TKA Complication Measure Cohort by Setting

Patient Characteristics, N (%) unless otherwise specified	THA/TKA Setting Combined	THA/TKA Setting Inpatient	THA/TKA Setting Outpatient
Age in years, Mean (Standard Deviation)	74 (6)	74 (6)	73 (5)
Male	378,804 (38.28)	242,997 (36.91)	135,807 (41.01)
Index admissions with an elective THA procedure	347,216 (35.09)	275,382 (41.83)	71,834 (21.69)
Number of procedures (two vs. one)	12,624 (1.28)	11,543 (1.75)	1,081 (0.33)
Metastatic cancer and acute leukemia (CC 8)	6,890 (0.70)	4,930 (0.75)	1,960 (0.59)
Other major cancers (CC 9-12)	125,787 (12.71)	85,569 (13.00)	40,218 (12.14)
Respiratory/heart/digestive/urinary/other neoplasms (CC 13-15)	184,836 (18.68)	123,694 (18.79)	61,142 (18.46)
Diabetes mellitus (DM) or DM complications (CC 17-19, 122-123)	261,104 (26.39)	180,393 (27.40)	80,711 (24.37)
Protein-calorie malnutrition (CC 21)	6,415 (0.65)	5,157 (0.78)	1,258 (0.38)
Bone/joint/muscle infections/necrosis (CC 39)	28,829 (2.91)	23,311 (3.54)	5,518 (1.67)
Rheumatoid arthritis and inflammatory connective tissue disease (CC 40)	103,386 (10.45)	72,781 (11.05)	30,605 (9.24)
Osteoarthritis of hip or knee (CC 42)	963,020 (97.32)	641,648 (97.46)	321,372 (97.04)
Osteoporosis and other bone/cartilage disorders (CC 43)	242,374 (24.49)	166,584 (25.30)	75,790 (22.88)
Dementia or other specified brain disorders (CC 51-53)	38,668 (3.91)	29,289 (4.45)	9,379 (2.83)
Major psychiatric disorders (CC 57-59)	59,741 (6.04)	42,497 (6.45)	17,244 (5.21)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)	15,580 (1.57)	11,569 (1.76)	4,011 (1.21)
Cardio-respiratory failure and shock (CC 84), plus ICD-10-CM codes R09.01 and R09.02	27,563 (2.79)	21,625 (3.28)	5,938 (1.79)
Coronary atherosclerosis or angina (CC 88-89)	231,970 (23.44)	163,600 (24.85)	68,370 (20.64)
Stroke (CC 99-100)	18,294 (1.85)	13,370 (2.03)	4,924 (1.49)
Vascular or circulatory disease (CC 106-109)	220,476 (22.28)	160,895 (24.44)	59,581 (17.99)
Chronic obstructive pulmonary disease (COPD) (CC 111)	107,013 (10.81)	78,202 (11.88)	28,811 (8.70)
Pneumonia (CC 114-116)	35,438 (3.58)	26,114 (3.97)	9,324 (2.82)
Pleural effusion/pneumothorax (CC 117)	14,000 (1.41)	10,501 (1.59)	3,499 (1.06)
Dialysis status (CC 134)	1,962 (0.20)	1,623 (0.25)	339 (0.10)
Renal failure (CC 135-140)	150,937 (15.25)	109,491 (16.63)	41,446 (12.51)
Decubitus ulcer or chronic skin ulcer (CC 157-161)	19,670 (1.99)	14,986 (2.28)	4,684 (1.41)
Trauma (CC 166-168, 170-173)	45,092 (4.56)	32,723 (4.97)	12,369 (3.73)
Vertebral fractures without spinal cord injury (CC 169)	10,119 (1.02)	7,493 (1.14)	2,626 (0.79)

Patient Characteristics, N (%) unless otherwise specified	THA/TKA Setting Combined	THA/TKA Setting Inpatient	THA/TKA Setting Outpatient
Other injuries, modified (CC 174Y)	250,156 (25.28)	170,288 (25.86)	79,868 (24.12)
Major complications of medical care and trauma (CC 176-177)	45,321 (4.58)	32,391 (4.92)	12,930 (3.90)
Morbid obesity (CC 22)	94,620 (9.56)	67,243 (10.21)	27,377 (8.27)
Other congenital deformity of hip (joint)	87,699 (8.86)	59,131 (8.98)	28,568 (8.63)
Post traumatic osteoarthritis	13,644 (1.38)	8,393 (1.27)	5,251 (1.59)

Table 4 shows the univariate odds ratios for the risk variables, which are the same variables as those used in the existing Hospital-level THA/TKA Complication measure risk model. The unadjusted odds ratios for the risk variables are similar in magnitude and directionality across the inpatient and outpatient settings.

The unadjusted (observed) complication rate following inpatient and outpatient THA/TKA procedures is presented in Table 5. The overall unadjusted complication rate following THA/TKA procedures performed in the inpatient setting (3.39%) was lower than that of the outpatient setting (1.87%), as expected. Unadjusted complication rates associated with THA procedures were also higher in comparison to its TKA procedure counterpart in each setting included in the measure outcome, consistent with published literature and the existing Hospital-Level THA/TKA Complication measure.

Table 4: Unadjusted Odds Ratios of Existing Hospital-level THA/TKA Complication Measure Risk Model Variables in IP/OP 90-Day THA/TKA Complication Measure Cohort by Setting

Patient Characteristics	Unadjusted OR (95% CI) THA/TKA Setting Combined	Unadjusted OR (95% CI) THA/TKA Setting Inpatient	Unadjusted OR (95% CI) THA/TKA Setting Outpatient
Age in years	1.04 (1.03, 1.04)	1.03 (1.03, 1.03)	1.03 (1.03, 1.04)
Male	1.01 (0.98, 1.03)	1.01 (0.98, 1.04)	1.11 (1.05, 1.16)
Index admissions with an elective THA procedure	1.88 (1.83, 1.92)	1.70 (1.66, 1.75)	1.79 (1.70, 1.89)
Number of procedures (two vs. one)	1.15 (1.04, 1.27)	0.99 (0.90, 1.10)	1.35 (0.92, 1.98)
Metastatic cancer and acute leukemia (CC 8)	1.47 (1.30, 1.65)	1.42 (1.25, 1.62)	1.46 (1.11, 1.93)
Other major cancers (CC 9-12)	1.05 (1.01, 1.08)	1.03 (0.99, 1.07)	1.05 (0.97, 1.13)
Respiratory/heart/digestive/urinary/other neoplasms (CC 13-15)	0.98 (0.95, 1.01)	0.97 (0.93, 1.00)	1.00 (0.94, 1.07)
Diabetes mellitus (DM) or DM complications (CC 17-19, 122-123)	1.26 (1.22, 1.29)	1.25 (1.22, 1.29)	1.16 (1.10, 1.23)
Protein-calorie malnutrition (CC 21)	2.63 (2.39, 2.90)	2.51 (2.27, 2.78)	2.05 (1.53, 2.74)
Bone/joint/muscle infections/necrosis (CC 39)	2.14 (2.04, 2.25)	2.02 (1.91, 2.13)	1.79 (1.54, 2.09)
Rheumatoid arthritis and inflammatory connective tissue disease (CC 40)	1.42 (1.38, 1.47)	1.40 (1.35, 1.46)	1.35 (1.25, 1.46)
Osteoarthritis of hip or knee (CC 42)	0.96 (0.89, 1.03)	0.93 (0.85, 1.01)	0.98 (0.85, 1.13)
Osteoporosis and other bone/cartilage disorders (CC 43)	1.18 (1.15, 1.21)	1.18 (1.15, 1.22)	1.08 (1.02, 1.15)
Dementia or other specified brain disorders (CC 51-53)	1.77 (1.69, 1.86)	1.68 (1.60, 1.77)	1.70 (1.50, 1.91)
Major psychiatric disorders (CC 57-59)	1.58 (1.52, 1.65)	1.53 (1.47, 1.61)	1.59 (1.44, 1.74)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)	1.86 (1.74, 2.00)	1.81 (1.67, 1.95)	1.72 (1.44, 2.06)
Cardio-respiratory failure and shock (CC 84), plus ICD-10-CM codes R09.01 and R09.02	2.53 (2.41, 2.66)	2.40 (2.28, 2.53)	2.25 (1.97, 2.57)
Coronary atherosclerosis or angina (CC 88-89)	1.50 (1.47, 1.54)	1.47 (1.43, 1.52)	1.42 (1.34, 1.51)
Stroke (CC 99-100)	1.63 (1.52, 1.75)	1.57 (1.46, 1.70)	1.57 (1.33, 1.86)
Vascular or circulatory disease (CC 106-109)	1.59 (1.55, 1.63)	1.53 (1.49, 1.57)	1.48 (1.39, 1.57)
Chronic obstructive pulmonary disease (COPD) (CC 111)	1.90 (1.84, 1.96)	1.87 (1.80, 1.93)	1.67 (1.55, 1.80)
Pneumonia (CC 114-116)	1.94 (1.84, 2.03)	1.89 (1.79, 1.99)	1.73 (1.54, 1.95)
Pleural effusion/pneumothorax (CC 117)	2.08 (1.93, 2.23)	1.96 (1.81, 2.12)	2.13 (1.79, 2.54)
Dialysis status (CC 134)	3.28 (2.80, 3.83)	2.90 (2.45, 3.43)	4.01 (2.65, 6.08)
Renal failure (CC 135-140)	1.65 (1.61, 1.70)	1.63 (1.58, 1.68)	1.45 (1.36, 1.55)
Decubitus ulcer or chronic skin ulcer (CC 157-161)	2.34 (2.21, 2.48)	2.21 (2.07, 2.36)	2.34 (2.02, 2.70)
Trauma (CC 166-168, 170-173)	1.86 (1.78, 1.94)	1.81 (1.72, 1.90)	1.77 (1.59, 1.96)
Vertebral fractures without spinal cord injury (CC 169)	1.93 (1.77, 2.11)	1.81 (1.65, 2.00)	2.08 (1.70, 2.54)
Other injuries, modified (CC 174Y)	1.33 (1.30, 1.37)	1.33 (1.30, 1.37)	1.27 (1.20, 1.34)
Major complications of medical care and trauma (CC 176-177)	1.88 (1.80, 1.97)	1.81 (1.72, 1.90)	1.96 (1.78, 2.16)

Patient Characteristics	Unadjusted OR (95% CI) THA/TKA Setting Combined	Unadjusted OR (95% CI) THA/TKA Setting Inpatient	Unadjusted OR (95% CI) THA/TKA Setting Outpatient
Morbid obesity (CC 22)	1.56 (1.51, 1.61)	1.54 (1.49, 1.60)	1.41 (1.31, 1.53)
Other congenital deformity of hip (joint)	1.52 (1.47, 1.58)	1.46 (1.40, 1.52)	1.72 (1.60, 1.85)
Post traumatic osteoarthritis	1.10 (1.00, 1.21)	1.18 (1.06, 1.32)	0.99 (0.81, 1.21)

Table 5: Unadjusted THA/TKA Complication Rates by Setting*

**	THA/TKA Inpatient n (%)	THA /TKA Outpatient n (%)	THA Inpatient n (%)	THA Outpatient n (%)	TKA Inpatient n (%)	TKA Outpatient n (%)
No. of hospitals	3,363	2,912	3,176	2,365	3,308	2,858
No. of index procedures	658,403	331,184	275,382	71,834	383,068	259,357
Overall Unadjusted Complication Rate	22,306 (3.39)	6,187 (1.87)	12,178 (4.42)	2,035 (2.83)	10,131 (2.64)	4,152 (1.60)
Complications during **index** procedure (includes all)	6,511 (0.99)	827 (0.25)	3,190 (1.16)	229 (0.32)	3,323 (0.87)	598 (0.23)
Complications that resulted in **inpatient** admission (includes all)	13,065 (1.98)	4,205 (1.27)	7,332 (2.66)	1,372 (1.91)	5,734 (1.50)	2,833 (1.09)
Complications that resulted in an **observation** stay (includes SSB, PE, Death, MC, PJI)	1,483 (0.23)	582 (0.18)	761 0.28	177 (0.25)	722 (0.19)	405 (0.16)
Complications that resulted in an **ED** visit (includes Death, MC, PJI)	1,882 0.29	513 (0.16)	1,738 0.63	410 (0.57)	144 (0.04)	103 (0.04)
Complications that resulted in an **ASC** visit (includes SSB, Death, MC, PJI)	197 0.03	147 (0.04)	72 0.03	16 (0.02)	125 (0.03)	131 (0.05)
Death w/in 30 days	1,294 0.20	325 (0.10)	555 0.20	72 (0.10)	739 (0.19)	253 (0.10)

*Legend: AMI (Acute Myocardial Infarction), PN (Pneumonia), SEP (Sepsis) w/in 7 days
SSB (Surgical Site Bleeding), PE (Pulmonary Embolism), Death w/in 30 days
MC (Mechanical Complications), PJI (Periprosthetic Joint/Wound Infection) w/in 90 days
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3.2 Attribution

Table 6 presents the volume distribution of THA/TKA procedures performed in the inpatient and outpatient settings. The median number of THA/TKA procedures across 3,452 hospitals is 83 for the inpatient setting (IQR: 23-237) and 25 for the outpatient setting (IQR: 3-118). For THA procedures, the median number of inpatient procedures is 38 (IQR: 10-106) and 5 for the outpatient setting (IQR: 0-27). For TKA procedures, the median number of inpatient procedures is 47 (IQR: 14-133) and 20 for the outpatient setting (IQR: 2-94). The smaller volume of outpatient THAs is likely due to the staggered removal of these procedures from the IPO List.

Table 6: Volume Distribution of THA/TKA Performed in the Inpatient and Outpatient Settings

Measurement Period April 1, 2018, to March 31, 2021*	THA/TKA Inpatient	THA/TKA Outpatient	THA/TKA Both	THA/TKA % Procedures Performed in Outpatient Setting
No. of hospitals	3,452	3,452	3,452	N/A
No. of index procedures	658,403	331,184	989,587	N/A
Mean	191	96	287	30%
Standard Deviation (SD)	317	171	429	26%
Max	7,222	2,125	7,990	100%
P99	1,351	840	2,015	100%
P95	738	401	1,064	77%
P90	493	267	741	67%
Q3	237	118	373	49%
Median	**83**	**25**	**128**	**26%**
Q1	23	3	34	6%
P10	5	0	9	0%
P5	2	0	4	0%
P1	0	0	1	0%
Min	0	0	1	0%

*The data examined include 36-months of inpatient THA/TKA and outpatient TKA procedures (4/1/2018-3/31/2021) and 15-months of outpatient THA procedures (1/1/2020-3/31/2021).

3.3 Risk Model Development and Testing

We evaluated the performance of the existing (inpatient-only) Hospital-level THA/TKA Complication measure risk variables in the inpatient and outpatient cohorts separately and combined (Table 7). In the separate models for the inpatient and outpatient settings, we used the same risk variables that were used in the existing Hospital-level THA/TKA Complication measure; the risk variable beta coefficients were calculated for inpatient- or outpatient-only procedures, respectively. Model discrimination (measured by C-statistic) and predictive ability (assessed as the comparison of highest to lowest deciles to evaluate the ability of model to distinguish high-risk subjects from low-risk subjects) were better when the model was applied in the combined and inpatient-only settings compared to the outpatient-only setting.

We also examined the model performance of a single combined model that included the procedure setting as a risk variable in the model. As Table 7 shows, a single combined model (combining inpatient and outpatient settings) with a setting-specific risk variable produced the highest discrimination. The C-statistic was lower for the inpatient-only (0.651) and outpatient-only (0.638) subgroup models, respectively, compared to that of the single combined model with a setting indicator (0.664). Furthermore, the predictive ability of the single combined model improved when the setting-specific variable was included in the model [Predictive ability (lowest decile %, highest decile %): 1.268%, 7.096% vs. 1.034%, 7.191%]. Calibration plots (Appendix C, Figures 9-11) confirmed the finding of improved calibration for the inpatient and outpatient subgroups in the single combined model with the setting-specific risk variable. Results for the setting risk variable from the final hierarchical model showed that patients in the inpatient cohort had significantly greater odds of experiencing a complication than patients in the outpatient cohort (OR = 1.43, 95% CI 1.39-1.470). Table 8 presents the variable frequencies and adjusted odd ratios from the final risk adjustment model.

Table 7: Model Performance Across Setting-Specific and Combined Inpatient/Outpatient Cohorts

*	**Risk factors included are same as in Hospital-Level THA/TKA Complication Measure model** **Single model combining inpatient and outpatient**	**Risk factors included are same as in Hospital-Level THA/TKA Complication Measure model** **Separate model for inpatient**	**Risk factors included are same as in Hospital-Level THA/TKA Complication Measure model** **Separate model for outpatient**	**Risk factors included: same risk factors as in Hospital HK-C measure plus setting of procedure (inpatient vs outpatient)** **Single model combining inpatient and outpatient**
C-statistic (95% CI)	0.659 (0.656, 0.662)	0.651 (0.648, 0.655)	0.638 (0.631, 0.646)	0.664 (0.661, 0.667)
Predictive Ability**	1.180% - 7.10%	1.438% - 8.01%	0.880% - 4.28%	1.034% - 7.191%

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**Observed complication rate: First decile (%) – Last decile (%)

Table 8: Final Risk Adjustment Model Variable Frequencies and Adjusted Odds Ratios

Variable	Combined IP/OP THA/TKA N=989,587 N (%)	Combined IP/OP THA/TKA N=989,587 Adjusted OR (95% CI)
Intercept	*	0.01 (0.01, 0.01)
Claim setting (inpatient)	658,403 (66.53%)	1.46 (1.41, 1.5)
Years over 65 (continuous)	8.72 (5.72)	1.03 (1.02, 1.03)
Male	378,804 (38.3)	1.02 (0.99, 1.05)
Index admissions with an elective THA procedure	347,216 (35.1)	1.75 (1.71, 1.79)
Number of procedures (two vs. one)	12,624 (1.3)	1.5 (1.35, 1.65)
Metastatic cancer and acute leukemia (CC 8)	6,890 (0.7)	1.16 (1.03, 1.32)
Other major cancers (CC 9-12)	125,787 (12.7)	0.93 (0.89, 0.96)
Respiratory/heart/digestive/urinary/other neoplasms (CC 13-15)	184,836 (18.7)	0.93 (0.9, 0.96)
Diabetes mellitus (DM) or DM complications (CC 17-19, 122-123)	261,104 (26.4)	1.09 (1.07, 1.12)
Protein-calorie malnutrition (CC 21)	6,415 (0.6)	1.28 (1.16, 1.42)
Bone/joint/muscle infections/necrosis (CC 39)	28,829 (2.9)	1.24 (1.17, 1.31)
Rheumatoid arthritis and inflammatory connective tissue disease (CC 40)	103,386 (10.4)	1.2 (1.16, 1.24)
Osteoarthritis of hip or knee (CC 42)	963,020 (97.3)	0.94 (0.87, 1.01)
Osteoporosis and other bone/cartilage disorders (CC 43)	242,374 (24.5)	1.07 (1.04, 1.1)
Dementia or other specified brain disorders (CC 51-53)	38,668 (3.9)	1.2 (1.14, 1.26)
Major psychiatric disorders (CC 57-59)	59,741 (6)	1.34 (1.29, 1.4)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)	15,580 (1.6)	1.24 (1.15, 1.34)
Cardio-respiratory failure and shock (CC 84), plus ICD-10-CM codes R09.01 and R09.02	27,563 (2.8)	1.34 (1.26, 1.41)
Coronary atherosclerosis or angina (CC 88-89)	231,970 (23.4)	1.16 (1.13, 1.2)
Stroke (CC 99-100)	18,294 (1.8)	1.09 (1.01, 1.17)
Vascular or circulatory disease (CC 106-109)	220,476 (22.3)	1.17 (1.14, 1.21)
Chronic obstructive pulmonary disease (COPD) (CC 111)	107,013 (10.8)	1.37 (1.33, 1.42)
Pneumonia (CC 114-116)	35,438 (3.6)	1.15 (1.09, 1.22)
Pleural effusion/pneumothorax (CC 117)	14,000 (1.4)	1 (0.92, 1.08)
Dialysis status (CC 134)	1,962 (0.2)	1.4 (1.19, 1.65)
Renal failure (CC 135-140)	150,937 (15.3)	1.21 (1.17, 1.25)
Decubitus ulcer or chronic skin ulcer (CC 157-161)	19,670 (2)	1.36 (1.28, 1.45)
Trauma (CC 166-168, 170-173)	45,092 (4.6)	1.21 (1.15, 1.27)
Vertebral fractures without spinal cord injury (CC 169)	10,119 (1)	1.2 (1.09, 1.31)
Other injuries, modified (CC 174Y)	250,156 (25.3)	1.11 (1.08, 1.14)

Variable	Combined IP/OP THA/TKA N=989,587 N (%)	Combined IP/OP THA/TKA N=989,587 Adjusted OR (95% CI)
Major complications of medical care and trauma (CC 176-177)	45,321 (4.6)	1.29 (1.23, 1.35)
Morbid obesity (CC 22)	94,620 (9.6)	1.52 (1.47, 1.58)
Other congenital deformity of hip (joint)	87,699 (8.9)	1.1 (1.06, 1.15)
Post traumatic osteoarthritis	13,644 (1.4)	1.11 (1, 1.22)

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3.3.1 Social Drivers of Health Assessment

Table 9 presents observed complications rates across settings by race. Unadjusted complication rates for all racial groups are lower in outpatient versus inpatient settings. Notably, Black and other non-White beneficiaries have lower observed complication rates than Whites in both the Inpatient- and Outpatient-only cohorts. This may reflect significantly restricted offer and acceptance rates in these populations, as evidenced by the low numbers of non-White patients in the cohort.

Table 10 presents observed complications rates across settings by dual eligibility status. Medicare beneficiaries who were dually eligible for Medicare and Medicaid in the combined IP/OP cohort had higher unadjusted complication rates (4.33%) compared to their counterparts who did not have dual-eligibility status (2.83%). Likewise, the results of analyses on procedures performed in the IP-only and OP-only settings by dual eligibility status showed that dual eligibility status was associated with higher unadjusted THA/TKA complication rates in both inpatient and outpatient settings. The difference was largest for procedures performed in the inpatient setting, however (4.88% vs. 3.33%).

Table 11 presents observed complications rates across settings by ASI score, organized into "low SES" (Q1 of ascending-ordered ASI) and "higher SES" (Q2-Q4 ASI). The results for the combined IP/OP model show that Medicare beneficiaries who have a lower ASI score have a higher observed complication rate (3.20%) as compared to their counterparts who have a higher ASI score (2.84%). Similar findings were also observed in the analyses for the IP-only and OP-only settings; a lower ASI score was associated with a higher unadjusted complication rate in each respective setting.

Table 12 presents the odds ratios and corresponding 95% confidence intervals (CIs) for race, dual eligibility, and ASI score, based on estimates from univariate patient-level models and the multivariate hierarchical model. The results from both the univariate and hierarchical models show that the association between race and odds of a complication was not significantly different between Black versus White beneficiaries in the measure cohort. In contrast, the odds of a complication differed significantly in the comparison between other non-White versus White beneficiaries (OR = 0.901, 95% CI, 0.84-0.97), but only in the univariate model. This finding was attenuated and no longer significant after clustering and patient risk factors were accounted for in the multivariate hierarchical model.

Table 12 also presents the odds ratios for the dual versus non-dual eligibility and low versus high ASI scores from the univariate and hierarchical models. These results are in line with the unadjusted complication rate findings for both groups (Table 10 and Table 11, respectively). Specifically, the findings from the hierarchical model showed that the odds ratio for dual versus non-dual eligibility was 1.19 (95% CI, 1.12-1.26) and for low versus high ASI score was 1.06 (95% CI, 1.02-1.10).

Table 9: Comparison of Observed Complication Rates for Medicare Beneficiaries by Race

*	*	Inpatient (N=644,737)	Outpatient (N=322,338)	Both (N=966,625)
No. of procedures (%)	White	596,281 (92.5)	301525 (93.5)	897,806 (92.9)
No . of procedures (%)	Black	30,452 (4.7)	12158 (3.8)	42,610 (4.4)
No . of procedures (%)	Other non-White	18,004 (2.8)	8655 (2.7)	26,659 (2.7)
Unadjusted complication rate	White	3.42%	1.89%	2.91%
Unadjusted complication rate	Black	3.39%	1.76%	2.92%
Unadjusted complication rate	Other non-White	3.04%	1.76%	2.63%
Difference from White	White	REF	REF	REF
Difference from White	Black	-0.03%	-0.13%	0.01%
Difference from White	Other non-White	-0.38%	-0.13%	-0.28%

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Table 10: Comparison of Observed Complication Rates in Medicare Beneficiaries by Dual Eligibility Status

*	*	Dual Eligibility Inpatient (N=658,346)	Dual Eligibility Outpatient (N=331,157)	Dual Eligibility Both (N=989,503)
No. of procedures (%)	Dual	25,150 (3.8)	7,837 (2.4)	32,987 (3.3)
No. of procedures (%)	Non-Dual	633,196 (96.2)	323,320 (97.6)	956,516 (96.7)
Unadjusted complication rate	Dual	4.88%	2.54%	4.33%
Unadjusted complication rate	Non-dual	3.33%	1.85%	2.83%
Difference from Non-dual	Dual	1.55%	0.69%	1.50%
Difference from Non-dual	Non-dual	REF	REF	REF

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Table 11: Comparison of Observed Complication Rate of Medicare Beneficiaries by Low Versus Higher AHRQ SES Index (ASI) Score

*	*	**AHRQ SES Index (ASI) (Q1 vs Q2-Q4)** **Inpatient (N=655,786)**	**AHRQ SES Index (ASI) (Q1 vs Q2-Q4)** **Outpatient (N=330,136)**	**AHRQ SES Index (ASI) (Q1 vs Q2-Q4)** **Both (N=985,922)**
No. of procedures (%)	Low ASI	73,088 (11.1)	33,972 (10.3)	107,060 (10.9)
No. of procedures (%)	Higher ASI	582,698 (88.9)	296,164 (89.7)	878,862 (89.1)
Unadjusted complication rate	Low ASI	3.80%	1.91%	3.20%
Unadjusted complication rate	Higher ASI	3.34%	1.86%	2.84%
Difference from high ASI	Low ASI	0.46%	0.05%	0.36%
Difference from high ASI	Higher ASI	REF	REF	REF

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Table 12: Association between Social Drivers of Health and THA/TKA Complication Risk

*	**From univariate patient-level model**	**From multivariate hierarchical model (adjusted for age, sex, clinical risk factors and accounting for clusters within hospitals)**
Social Driver of Health	OR (95% CI)	OR (95% CI)
Exposure to racism (Black vs. White)	1.005 (0.949-1.065)	0.957 (0.901-1.016)
Exposure to racism (Other non-White vs. White)	0.901 (0.835-0.972)	0.981 (0.907-1.060)
Dual eligibility (dual vs. non-dual)	1.553 (1.471-1.640)	1.186 (1.120-1.256)
Low AHRQ SES Index (ASI) (Q1 vs. Q2-Q4)	1.133 (1.092-1.174)	1.055 (1.016-1.096)

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The distributions of the change in RSCRs when SDOH were included in the model were small and centered around zero (data not shown). The Spearman rho correlation coefficients between RSCRs calculated with and without adjusting for SDOH are all close to 1 (0.9996-0.9997), with P-values < .001.

In summary our results show that:

- Observed complication rates were lower or similar for patients of Black or other non-White race compared with White race, and higher for patients with dual eligibility or low ASI.
- The distribution of measure scores between the lowest (first) quartile versus the highest (fourth) quartile based on the hospital proportion of patients with SDOH overlapped for all social drivers of health.

- The odds ratios for the outcome in the presence of all risk-model variables were insignificant and <1.0 for Black race and significant and >1.0 for dual eligibility and low ASI.
- Measure scores for the facilities with the highest proportion of patients with SDOH (dual eligibility or low ASI) were not correlated with measure scores.
- Measure scores calculated with and without SDOH were highly correlated with small differences.
- Risk models showed good risk prediction for subsets of patients with SDOH (data not shown), apart from some deciles for the dual-eligibility risk variable.

CMS/CMMI are committed to implementing the measure to prevent unintended consequences of worsening access and/or outcome disparities among patients undergoing THA/TKA procedures. The decision to adjust for SDOH is a complex decision and influenced by the intended measure application. In addition, CMMI has indicated a desire to maintain alignment with the existing Hospital-level THA/TKA Complication measure. After examining the empiric analytic results and receiving feedback from the TEP, CMS/CMMI decided not to risk adjust the measure for SDOHs but will consider how to account for SDOH through stratification by race and/or SDOH at the time of implementation. This could include accounting for SDOH in any payment calculations through measure score adjustment, measure score stratification, payment adjustment, and/or payment stratification by dual eligibility, as CMS has done in other payment programs (such as the Hospital Readmission Reduction Program or HRRP) and CMMI has done in payment models (such as the Comprehensive Joint Replacement, or CJR model). We believe the absence of significant racial disparities in these data reflect the complex realities of how patients of non-White race or with SDOH access elective procedures such as THA/TKA.

3.4 Measure Results

Table 13 shows the distribution of THA/TKA procedure volume, unadjusted complication rates, and RSCRs for hospitals included in the measure. Figure 2 and Figure 3 display the distribution of observed complication rates for all hospitals and those with at least 25 cases, respectively. Figure 4 and Figure 5 display the distribution of RSCRs for all hospitals and those with at least 25 cases, respectively.

The mean and median number of procedures for all hospitals (N=3,452) is 286.7 (Standard Deviation (SD): 429.21) and 128 (IQR: 34, 373), respectively. For hospitals that have performed 25 or more index procedures (N=2,747), the mean number of procedures is 357.6 (SD: 454.80) with a median of 205 (IQR: 79, 462). Out of all 3,452 hospitals, the mean RSCR is 2.91%, and the median RSCR is 2.86% (Figure 3). The maximum and minimum are 5.86% and 1.53%, respectively, with an IQR of 2.65-3.12%. Out of the 2,747 hospitals that have at least 25 index procedures, the mean RSCR is still 2.91%, and the median RSCR is 2.85% (Figure 5). The maximum and minimum are the same as those in all hospitals, with an IQR of 2.59-3.18%.

Although the median RSCR is 2.86%, the IQR represents 16% of this value and the delta between the 10^{th} and 90^{th} percentiles is 38% of the median RSCR.

The median odds ratio suggests a meaningful increase in the risk of complications if a patient has a THA/TKA procedure at a higher risk hospital compared to a lower risk hospital. A median odds ratio value of 1.33 indicates that a patient has a 33% increase in the odds of a complication at a higher risk performance hospital compared to a lower risk hospital, indicating the impact of quality on the outcome rate.

The variation in rates suggests there are meaningful differences in the quality of care received across hospitals for THA/TKA procedures. This evidence supports measurement to reduce the variation.

Table 13: Distribution of Hospital THA/TKA Volumes, Unadjusted Complication Rates and RSCRs

*	Volume All hospitals No. of procedures	Volume All hospitals % OP	Volume Hospitals >/=25 No. of procedures	Volume Hospitals >/=25 % OP	Unadjusted complications rate (%) All hospitals	Unadjusted complications rate (%) Hospitals >/= 25	RSCR (%) All hospitals	RSCR (%) Hospitals >/= 25
No. of hospitals	3,452	3,452	2,747	2,747	3,452	2,747	3,452	2,747
No. of index procedures	989,587	331,184	982,384	329,338	989,587	982,384	989,587	982,384
Mean	286.67	30.29	357.62	31.28	3.62	3.34	2.91	2.91
SD	429.21	26.34	454.80	23.64	5.05	2.16	0.47	0.52
Max	7,990	100.00	7,990	100.00	100.00	20.00	5.86	5.86
99%	2,015	100.00	2,158	86.05	20.00	11.02	4.37	4.41
95%	1,064	76.83	1,180	72.37	10.00	7.41	3.76	3.83
90%	741	67.31	855	64.96	6.90	6.06	3.49	3.56
75%	373	48.83	462	49.32	4.29	4.17	3.12	3.18
Median	128	26.09	205	28.88	2.81	2.94	2.86	2.85
25%	34	5.64	79	9.93	1.54	2.06	2.65	2.59
10%	9	0.00	43	0.99	0.00	1.22	2.40	2.34
5%	4	0.00	32	0.00	0.00	0.00	2.22	2.16
1%	1	0.00	25	0.00	0.00	0.00	1.87	1.80
Min	1	0.00	25	0.00	0.00	0.00	1.53	1.53

*Cell intentionally left empty.

Figure 2: Unadjusted Complication Rates Across All Hospitals

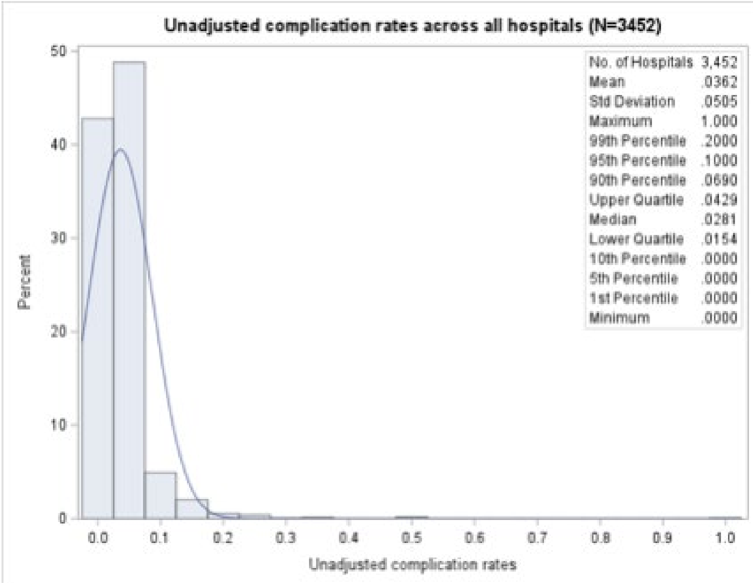


Figure 3: Unadjusted Complication Rates Across Hospitals with ≥ 25 cases

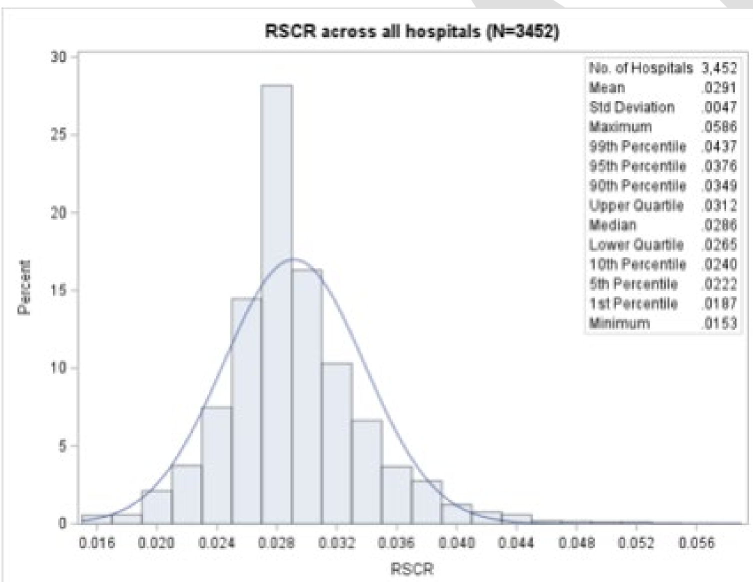


Figure 4: RSCRs Across All Hospitals

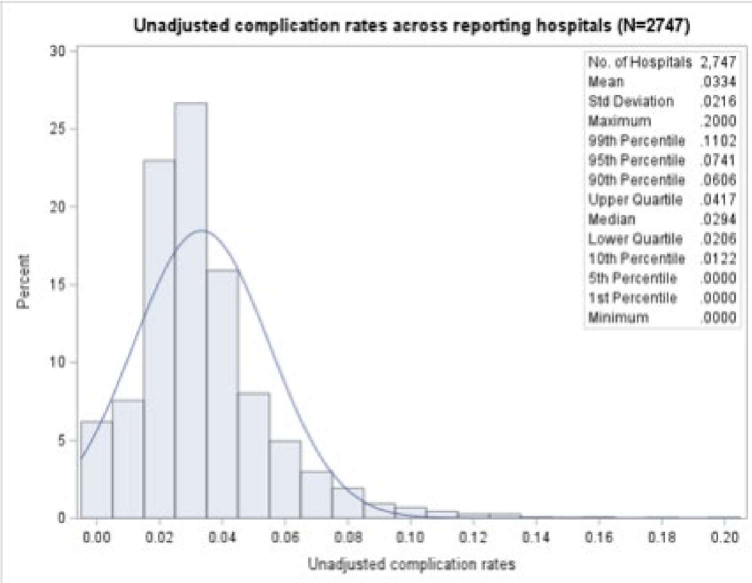
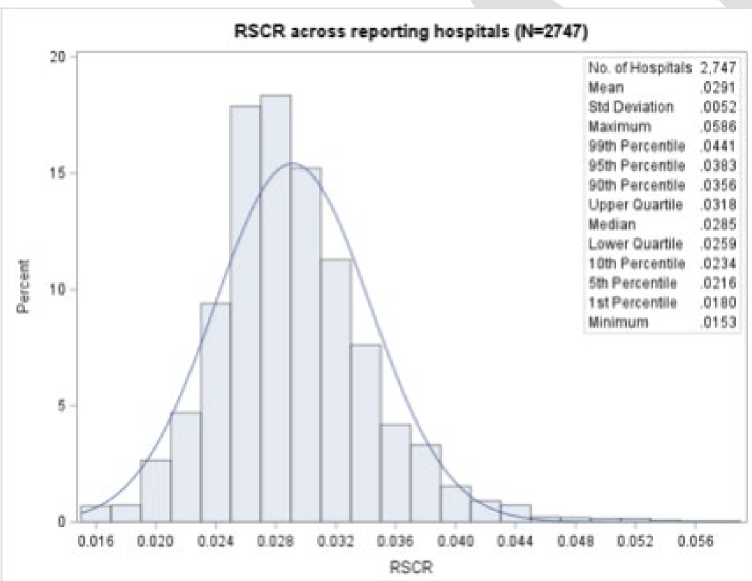


Figure 5: RSCRs Across Hospitals with ≥ 25 cases



3.4 Reliability Testing Results

3.4.1 Measure Score Reliability

We estimated the reliability of the measure score using signal to noise reliability (facility-level reliability), which is the reliability with which individual units (hospitals) are measured. It is meaningful to consider the separate notion of "unit" reliability—that is, the reliability with which individual units (here, hospitals) are measured. The reliability of any one facility's measure score will vary depending on the number of patients admitted for an elective THA/TKA procedure. Facilities with more volume (in other words, with more eligible procedures) will tend to have more reliable scores, while facilities with lower volume will tend to have less reliable scores. Signal to noise reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real difference in performance.

Table 14 shows the volume thresholds required to achieve various signal-to-noise reliability results based on the hierarchical model between-hospital variance estimates with the model including setting and other risk factors. A minimum volume of 25 procedures yields reliability of 0.4 or greater for all hospitals. This threshold captures approximately 80% of hospitals, but 99% of procedures and complications are accounted for within those 80% of hospitals. As the volume threshold (and therefore reliability) increases, the proportion of hospitals captured by the measure decreases, but a large majority of outcomes and complications are still accounted for.

Table 15 presents the median signal-to-noise reliability across all hospitals with at least one eligible THA/TKA procedure is 0.78 (IQR: 0.48 – 0.91). The median signal-to-noise reliability across hospitals with at least 25 cases, which corresponds to a minimum reliability of 0.4, is 0.85 (IQR: 0.69 – 0.93).

Table 14: Volume Thresholds Required for Specific Signal-to-Noise Reliability Targets

*	No. of hospitals	No. of THA/TKA procedures	No. of complications
Hospitals with >=1 THA/TKA procedure	3,452 (100.0%)	989,587 (100.0%)	28,493 (100.0%)
Hospitals with THA/TKA procedure volume >= 25 (minimum reliability >= 0.4)	2,747 (79.6%)	982,384 (99.3%)	28,153 (98.8%)
Hospitals with THA/TKA procedure volume >= 37 (minimum reliability >= 0.5)	2,549 (73.8%)	976,441 (98.7%)	27,904 (97.9%)
Hospitals with THA/TKA procedure volume >= 55 (minimum reliability >= 0.6)	2,314 (67.0%)	965,698 (97.6%)	27,529 (96.6%)
Hospitals with THA/TKA procedure volume >= 85 (minimum reliability >= 0.7)	2,016 (58.4%)	945,389 (95.5%)	26,732 (93.8%)

*Cell intentionally left empty.

Table 15: Distribution of Signal-to-Noise Reliabilities

Distribution of signal-to-noise reliabilities	All hospitals	Hospitals volume >= 25 (minimum reliability >= 0.4)	Hospitals volume >= 37 (minimum reliability >= 0.5)	Hospitals volume >= 55 (minimum reliability >= 0.6)	Hospitals volume >= 85 (minimum reliability >= 0.7)
No. of hospitals	3,452	2,747	2,549	2,314	2,016
Mean	0.674	0.795	0.822	0.849	0.879
Standard Deviation (SD)	0.283	0.159	0.131	0.105	0.076
Max	0.995	0.995	0.995	0.995	0.995
Q3	0.911	0.927	0.932	0.936	0.941
Median	0.779	0.849	0.864	0.879	0.897
Q1	0.480	0.685	0.732	0.775	0.825
Min	0.027	0.408	0.505	0.602	0.701

3.5 Validity Testing Results

3.5.1 Data Element

We assessed the validity of the claims-based setting indicator by examining the length of stay in days by setting. We found 99.6% of all eligible outpatient procedures had a length of stay less than or equal to 3 days, which is consistent with the CMS definition of observation status.

3.5.2 Measure Score Validity

We empirically assessed the validity of the measure score by calculating the measure's correlation with other measures that target the same domain of quality (e.g., complications, safety, or post-procedure utilization) for the same or similar populations and for which we anticipate there should be directional concordance in hospital performance. The goal was to identify whether better performance in this IP/OP 90-Day THA/TKA Complication measure was related to better performance on other relevant structural or outcomes measures. For the external measures, the comparison was against performance within quartiles of the Star Ratings overall category (1-5 Stars), as well as hospital THA/TKA surgical volume. We predicted the IP/OP 90-Day THA/TKA Complication measure scores would have a small association with the Overall Hospital Star Rating scores, with lower RSCRs associated with better (higher) Star ratings. With THA/TKA surgical volume, we hypothesized that lower (better) RSCRs would be moderately associated with higher volume hospitals.

Comparison to Star-Rating Summary Scores

Figure 6 and Figure 7 show box and whisker plots of the distribution of RSCRs within each quartile of Star Rating summary scores for all hospitals (Figure 6) and hospitals with 25 or more cases (Figure 7). The diamonds represent the mean RSCRs for each Star Rating summary score quartile. The correlation between THA/TKA complications and Star Rating summary score is -0.101 ($P < .0001$) for all hospitals and -0.121 ($P < 0.0001$) for hospitals with 25+cases, which suggests that hospitals with lower THA/TKA RSCRs are more likely to have higher Star Rating summary scores, especially at the extremes.

Figure 6: Comparison to Star Rating Summary Scores for All Hospitals

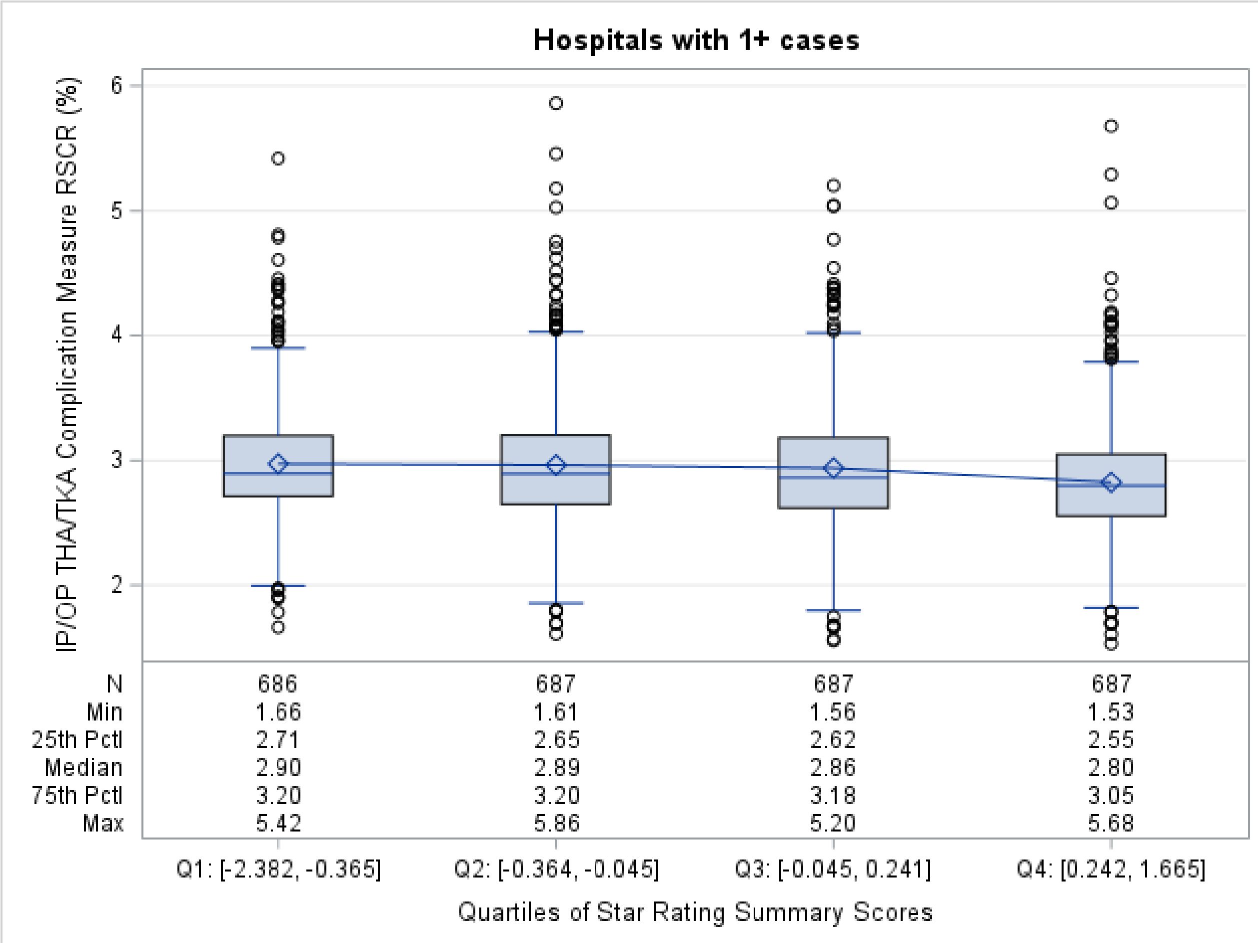
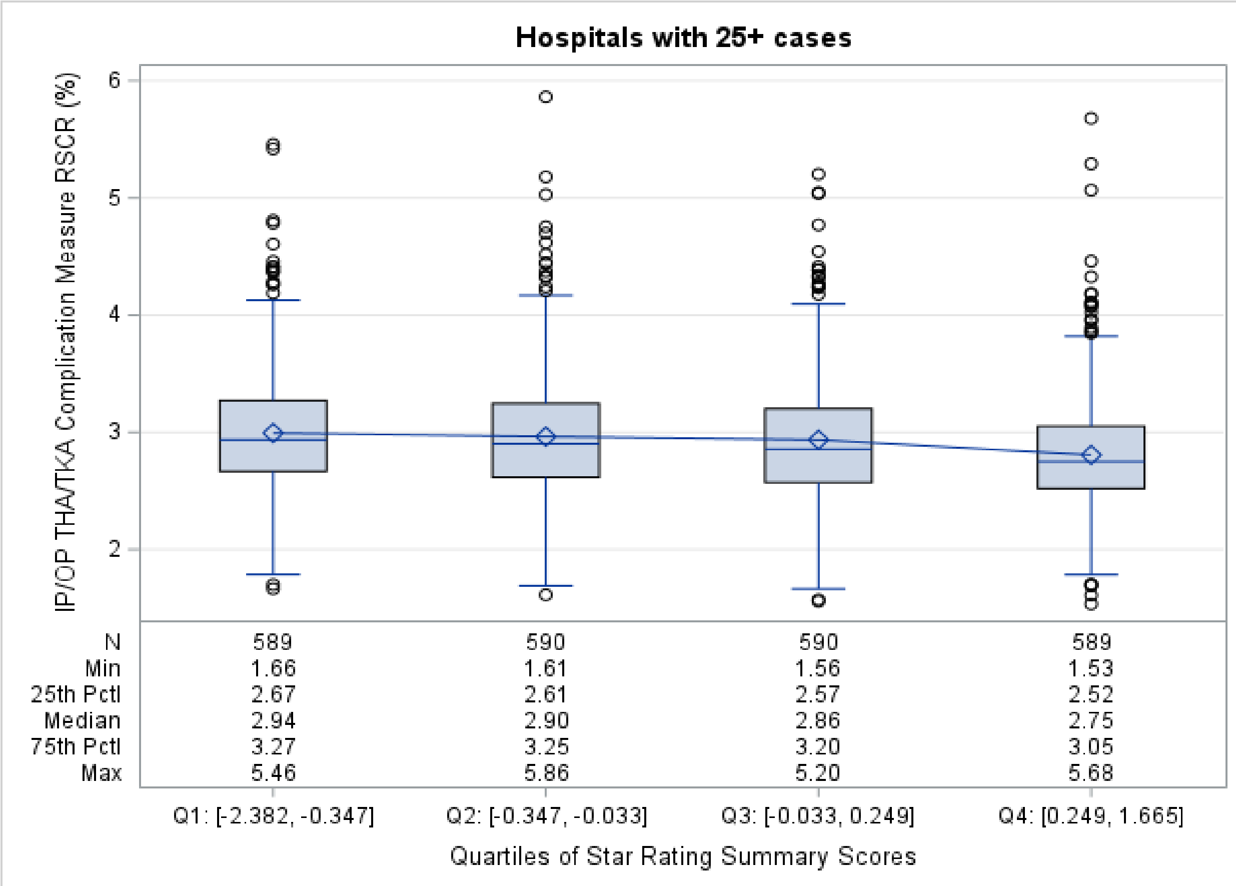


Figure 7: Comparison to Star Rating Summary Scores for Hospitals with 25+ Cases



Comparison to Hospital THA/TKA Surgical Admission Volume

Figure 8 and Figure 9 illustrate the relationship between quartiles of hospital-level THA/TKA case volume and RSCRs for all hospitals (Figure 8) and for hospitals with 25+ cases (Figure 9). There is a small correlation between higher volume hospitals (those in the upper quartiles) and lower (better) RSCRs. The correlation between hospital-level RSCRs and procedure volume was -0.24 (*P* < .0001) for all hospitals and -0.26 (*P* < .0001) for hospitals with 25+ cases, which supports the finding that hospitals with lower THA/TKA RSCRs are more likely to have higher THA/TKA volumes.

Figure 8: Comparison to Hospital THA/TKA Surgical Admission Volume for All Hospitals

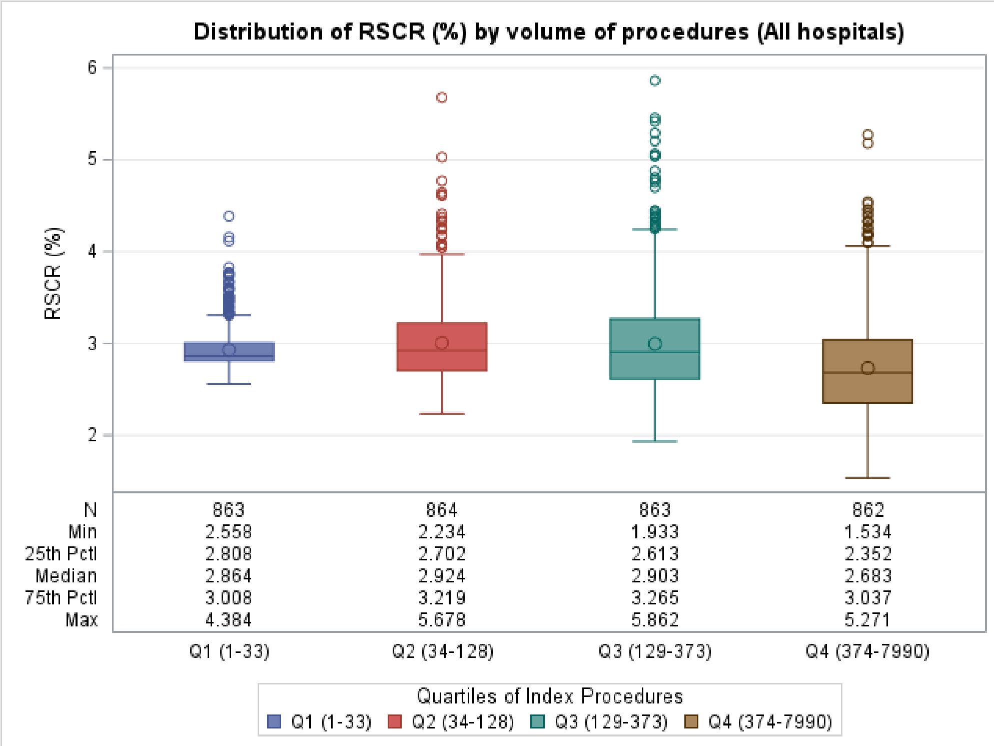
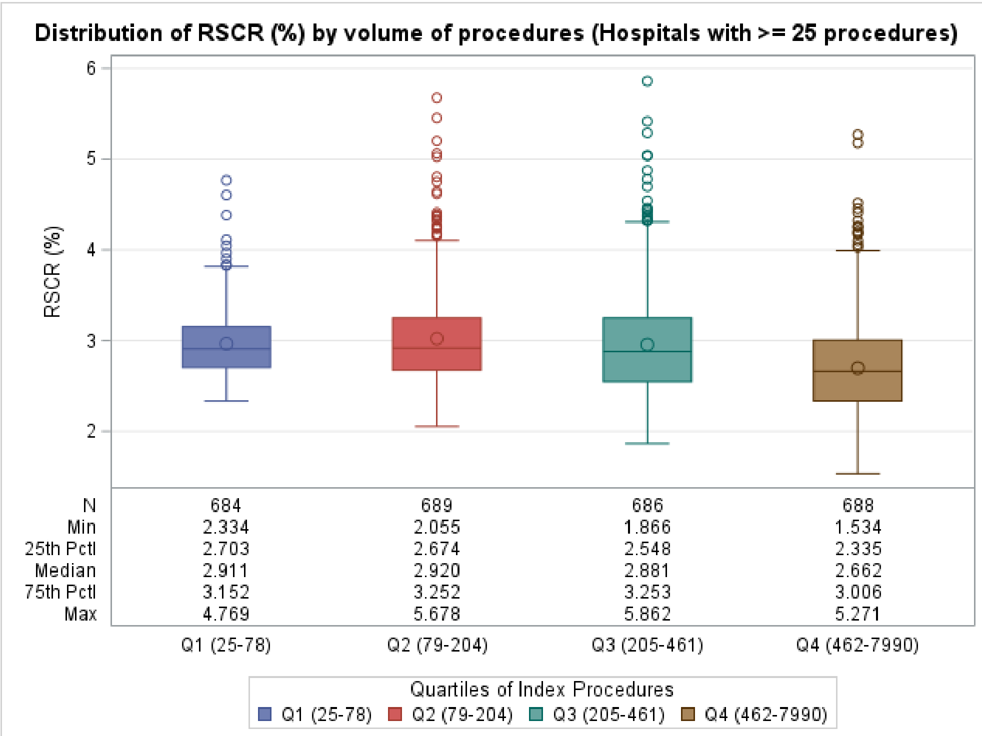


Figure 9: Comparison to Hospital THA/TKA Surgical Admission Volume for Hospitals 25+ Cases



3.5.3 Overall Measure Face Validity

We assessed face validity by asking TEP members to rate the measure according to the following two statements using a six-point scale (1 = Strongly Agree, 2 = Moderately Agree, 3 = Somewhat Agree, 4 = Somewhat Disagree, 5 = Moderately Disagree, 6 = Strongly Disagree):

- Statement #1: The IP/OP 90-Day THA/TKA Complication measure as specified will provide a valid assessment of complications following elective THA/TKA.
    - Among the 12 of 13 TEP Members who provided responses, 5 responded "Strongly Agree," 6 responded "Moderately Agree," and 1 responded "Somewhat Agree" to this question.
- Statement #2: The IP/OP 90-Day THA/TKA Complication measure as specified can be used to distinguish between better and worse quality care among hospitals performing THAs/TKAs.
    - Among the 12 of 13 TEP Members who provided responses, 3 responded "Strongly Agree," 6 responded "Moderately Agree," and 3 responded "Somewhat Agree" to this question.

No TEP member disagreed with either statement. Among the 5 of 12 respondents who provided additional comments, 3 commenters encouraged CMMI to account for patient social drivers of health, including adjusting for or stratifying by SDOH if this measure is implemented in a payment program. Two commenters encouraged CMS/CMMI to contain to monitor racial and other disparities in THA/TKA outcomes. One commenter recommended considering opiate use in future measure reevaluation.

In summary, the TEP supported the face validity of this measure as demonstrated by universal agreement in responses to the two face validity statements.

4. Report Conclusions

CMS contracted with CORE to respecify CMS's existing Hospital-level THA/TKA Complication measure to include outpatient (HOPD) procedures and expanded the outcome definition to capture complications occurring in the outpatient setting. The measure is intended for use in a future cross-setting CMMI payment model.

We engaged with diverse stakeholders throughout measure re-specification and testing. The measure displays meaningful variation in hospital performance. According to this measure, a patient has a 33% increase in the odds of a complication at a hospital with higher risk performance compared to a lower risk hospital. Reliability testing, empiric measure score validity results, and overall measure face validity responses by a diverse panel of clinicians and patients support the measure's strong scientific acceptability.

We included a setting indicator in the risk model to capture the complex factors influencing this decision but did not include race, ethnicity, or social drivers of health in the model as these did not impact hospital measure results. Due to known racial and SDOH disparities in access and outcomes following these procedures, however, the CWG and TEP felt strongly that race and ethnicity and SDOH should be accounted for during implementation, either through stratification of measure score and/or payment calculation by race and ethnicity and social drivers of health. CMS/CMMI have not proposed a plan for implementing for this measure and will take stakeholder input into account when finalizing implementation planning.

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Appendix A: Acknowledgement Details

Table 16: Appendix A, Table 1: CORE Expert Clinical Consultant

Name	Organization (Title)	Location
Kevin Bozic, MD, MBA	Dell Medical School at the University of Texas, Austin (Professor and Chair of the Department of Surgery and Perioperative Care); American Joint Replacement Steering Committee; American Academy of Orthopaedic Surgeons; American Association of Hip and Knee Surgeons	Austin, TX

Table 17: Appendix A, Table 2: Technical Expert Panel (TEP) Member Name, Affiliation, and Location

Name	Organization (Title)	Location
David C. Ayers, MD	University of Massachusetts (UMass) Medical School (Professor and Chair of Orthopedics and Physical Rehabilitation)	Worcester, MA
Thomas C. Barber, MD	Memorial Sloan Kettering Hospital (Deputy Physician in Chief)	New York, NY
Phyllis Bass	Patient Expert	Cypress, TX
Vinod Dasa, MD	Louisiana State University Health Sciences Center (Professor of Clinical Orthopedics, Director of Research)	New Orleans, LA
Rachel DuPré Brodie	Purchaser Business Group on Health (Senior Director of Measurement & Accountability)	San Francisco, CA
Cheryl Fahlman, PhD, MBA, BSP	CAF Consulting Solutions (President)	Gaithersburg, MD
William G. Hamilton, MD	Inova Mount Vernon Hospital and American Association of Hip and Knee Surgeons (Chair of Orthopedic Surgery; FOCAL Chair)	Alexandria, VA

Name	Organization (Title)	Location
Cynthia S. Jacelon, PhD, RN-BC, CRRN, FGSA, FAAN	University of Massachusetts Amherst School of Nursing (Professor and Executive Associate Dean)	Greenfield, MA
Benita Lattimore	Patient Expert	Chicago, IL
Craig T. Miller, PT	Rivetus Rehabilitation and American Physical Therapy Association (Director of Home Care Therapy and Senior PT)	Macomb, MI
Michael H. Perskin, MD	The American Geriatrics Society; New York University School of Medicine (Clinical Professor of Medicine)	New York, NY
Nan Rothrock, PhD	Feinberg School of Medicine of Northwestern University (Professor of Medical Social Sciences)	Chicago, IL
Jonathan L. Schaffer, MD, MBA, FACS, FHIMSS, FABOS	The Cleveland Clinic (Staff and Program Director)	Cleveland, OH
Adam Schwartz, MD, MBA	Consultant of the Department of Orthopedic Surgery, Associate Professor of Orthopaedic Surgery, Mayo Clinic, 2021	Phoenix, AZ
Robert Sterling, MD	Johns Hopkins University School of Medicine (Associate Professor of Orthopaedic Surgery and Vice Chair for Quality, Safety, and Service); American Association of Hip and Knee Surgeons	Baltimore, MD
Margaret A. VanAmringe, MHS	The Joint Commission (Vice President for Public Policy and Government Relations)	Washington, DC
Christine Von Raesfeld	Patient Expert	Santa Clara, CA
Patricia Walker	Patient Expert	South Holland, IL
Kevin Woodward, PA-C, MMS	American Academy of Physician Assistants, Maryland Academy of Physician Assistants, John Hopkins University (Physician Assistant of Orthopaedic Surgery)	Baltimore, MD
Adolph J. Yates, MD, FAAOS, FAOA	UPMC-Shadyside Hospital (Chief of Orthopedic Surgery), University of Pittsburgh School of Medicine (Professor and Vice Chair for	Pittsburgh, PA

Name	Organization (Title)	Location
Adolph J. Yates, MD, FAAOS, FAOA	Quality, Department of Orthopedic Surgery); American Association of Hip and Knee Surgeons	Pittsburgh, PA

Table 18: Appendix A, Table 3: Clinical Working Group Member Name, Affiliation, and Location

Name	Organization (Title)	Location
James I. Huddleston, III, MD	Stanford University Medical Center (Associate Professor and Chief of Arthritis Service, Department of Orthopaedic Surgery), American Association of Hip and Knee Surgeons (Chair of the Advocacy Council)	Stanford, CA
Jay R. Lieberman, MD, FAOOS	Keck School of Medicine of the University of Southern California (Professor and Chair, Department of Orthopaedic Surgery, Director of Institute of Orthopaedics), Viterbi School of Engineering of the University of Southern California (Professor of Biomedical Engineering), The Hip Society (Second Vice President)	Los Angeles, CA
Mary I. O'Connor, MD	Chief Medical Officer, Vori Health; The Knee Society	New Haven, CT
Kathryn (Kristy) Schabel, MD, FAAOS	Oregon Health and Science University (Associate Professor of Orthopaedic Surgery, Adult Reconstruction); American Academy of Orthopaedic Surgeons	Portland, OR

Table 19: Appendix A, Table 4: Code Review Experts Member Name, Affiliation, and Location

Name	Organization (Title)	Location
Frank Voss, MD	University of South Carolina (Clinical Associate Professor of Orthopedic Surgery)	Columbia, SC
John Heiner, MD	University of Wisconsin School of Medicine (Orthopedic Surgery Specialist)	Madison, WI

Appendix B: Glossary

Acute care hospital: A hospital that provides inpatient medical care for surgery and acute medical conditions or injuries. Short-term acute care hospitals provide care for short-term illnesses and conditions.

Center for Medicare and Medicaid Innovation (CMMI): The Innovation Center allows the Medicare and Medicaid programs to test models that improve care, lower costs, and better align payment systems to support patient-centered practices. The Innovation Center carefully evaluates innovative reform efforts widely used in the private sector and is unique in its ability to develop provider-proposed approaches and quickly adjust models in response to feedback from clinicians and patients.

Cohort: The index admissions used to calculate the measure after inclusion and exclusion criteria have been applied.

Episode Payment Model (EPM): A form of bundled payment**.** A bundling payment system created by the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) that aims to improve health for beneficiaries, while reducing healthcare spending. The model reimburses all healthcare providers at a given institution working on the same case.

Index admission: Any admission included in the measure calculation as the initial admission for a THA/TKA surgery and is evaluated for the outcome.

Index encounter: An index encounter is defined as either an index inpatient admission during which an elective primary total hip arthroplasty (THA) or total knee arthroplasty (TKA) is performed or an index outpatient procedure date on which the THA/TKA surgery is performed.

Medicare fee-for-service (FFS): Original Medicare plan in which providers receive a fee or payment for each individual service provided directly from Medicare. Only beneficiaries in Medicare FFS, not in managed care (Medicare Advantage), are included in the measures.

Outcome: The result of a broad set of healthcare events that affect patients' well-being.

Risk-adjustment variables: Patient demographics and comorbidities used to adjust for differences in case mix across hospitals.

Risk-standardized complication rate (RSCR): The risk-standardized complication rate is the standardized complication rate (SCR) multiplied by the national observed complication rate.

Re-specify: To update and/or revise measure specifications as needed for application to a different care setting or programmatic use. For this measure, we will be expanding the cohort to include THA/TKA surgeries performed in outpatient facilities in addition to inpatient procedures.

Appendix C: Additional Analytic Results and Figures

Appendix Table 1 lists the complications included in the measure outcome definition by setting and indicates whether Present on Admission (POA) codes are required. For example, Acute Myocardial Infarction (AMI) events are included in the measure outcome if they occur during the index encounter or within seven days of the admission date for inpatient procedures or procedure date for outpatient (HOPD) procedures. AMIs must be coded either during the index inpatient admission or must be coded during a readmission (without a POA code, indicating the AMI occurred after admission and presumably as a complication of the THA/TKA procedure). AMI codes that occur within the seven-day window but are associated with ONLY an ED visit, observation stay, or Ambulatory Surgical Center (ASC) encounter (no inpatient admission or readmission) are NOT included in the complication definition. This is because such events likely do not represent serious clinical complications and the clinicians advising on measure development and respecification felt such events did not meet the threshold of clinical severity to be included in the measure. This distinction is predominantly applicable to short-term medical complications, such as AMI, sepsis, and pneumonia. As with the existing Hospital-level THA/TKA Complication measure, this measure requires that bleeding and prosthetic joint infection complications must have both a diagnosis code for the complication and a procedure code indicating the bleeding event or infection required a procedural treatment to be included in the outcome.

Table 20: Appendix C, Table 1: Present on Admission Assumptions for Complications Observed in Outpatient Setting where POA Indicator is Not Used

Complication	Setting of Complication	THA/TKA was done inpatient Complication was coded as principal discharge diagnosis	THA/TKA was done inpatient Complication was coded as secondary diagnosis and POA	THA/TKA was done inpatient Complication was coded as secondary diagnosis and NOT POA	THA/TKA was done in HOPD Complication was coded as principal discharge diagnosis	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and POA	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and NOT POA
Acute Myocardial Infarction (During index admission or within 7 days of admission date)	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)
Acute Myocardial Infarction (During index admission or within 7 days of admission date)	Coded in a readmission	YES	YES	No	YES	YES	No
Acute Myocardial Infarction (During index admission or within 7 days of admission date)	Coded in an ED visit	No	No	No	No	No	No

Complication	Setting of Complication	THA/TKA was done inpatient Complication was coded as principal discharge diagnosis	THA/TKA was done inpatient Complication was coded as secondary diagnosis and POA	THA/TKA was done inpatient Complication was coded as secondary diagnosis and NOT POA	THA/TKA was done in HOPD Complication was coded as principal discharge diagnosis	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and POA	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and NOT POA
Acute Myocardial Infarction (During index admission or within 7 days of admission date)	Coded in an obs stay	No	No	No	No	No	No
Acute Myocardial Infarction (During index admission or within 7 days of admission date)	Coded in an ASC	No	No	No	No	No	No
Pneumonia and Other Respiratory Complications (During index admission or within 7 days of admission date)	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)
Pneumonia and Other Respiratory Complications (During index admission or within 7 days of admission date)	Coded in a readmission	YES	YES	No	YES	YES	No
Pneumonia and Other Respiratory Complications (During index admission or within 7 days of admission date)	Coded in an ED visit	No	No	No	No	No	No
Pneumonia and Other Respiratory Complications (During index admission or within 7 days of admission date)	Coded in an obs stay	No	No	No	No	No	No

Complication	Setting of Complication	**THA/TKA was done inpatient** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and NOT POA**	**THA/TKA was done in HOPD** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and NOT POA**
Pneumonia and Other Respiratory Complications (During index admission or within 7 days of admission date)	Coded in an ASC	No	No	No	No	No	No
Sepsis/ septicemia/ shock (During index admission or within 7 days of admission date)	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)
Sepsis/ septicemia/ shock (During index admission or within 7 days of admission date)	Coded in a readmission	YES	YES	YES	YES	YES	YES
Sepsis/ septicemia/ shock (During index admission or within 7 days of admission date)	Coded in an ED visit	No	No	No	No	No	No
Sepsis/ septicemia/ shock (During index admission or within 7 days of admission date)	Coded in an obs stay	No	No	No	No	No	No
Sepsis/ septicemia/ shock (During index admission or within 7 days of admission date)	Coded in an ASC	No	No	No	No	No	No
Pulmonary Embolism (During index admission or within 30 days of admission date)	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)

Complication	Setting of Complication	**THA/TKA was done inpatient** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and NOT POA**	**THA/TKA was done in HOPD** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and NOT POA**
Pulmonary Embolism (During index admission or within 30 days of admission date)	Coded in a readmission	YES	YES	YES	YES	YES	YES
Pulmonary Embolism (During index admission or within 30 days of admission date)	Coded in an ED visit	No	No	No	No	No	No
Pulmonary Embolism (During index admission or within 30 days of admission date)	Coded in an obs stay	YES	YES	YES	YES	YES	YES
Pulmonary Embolism (During index admission or within 30 days of admission date)	Coded in an ASC	No	No	No	No	No	No
Surgical Site Bleeding and Other Surgical Site Complications (During index admission or within 30 days of admission date) *Must have relevant procedure coded to be YES	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)

Complication	Setting of Complication	THA/TKA was done inpatient Complication was coded as principal discharge diagnosis	THA/TKA was done inpatient Complication was coded as secondary diagnosis and POA	THA/TKA was done inpatient Complication was coded as secondary diagnosis and NOT POA	THA/TKA was done in HOPD Complication was coded as principal discharge diagnosis	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and POA	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and NOT POA
Surgical Site Bleeding and Other Surgical Site Complications (During index admission or within 30 days of admission date) *Must have relevant procedure coded to be YES	Coded in a readmission	YES	YES	YES	YES	YES	YES
Surgical Site Bleeding and Other Surgical Site Complications (During index admission or within 30 days of admission date) *Must have relevant procedure coded to be YES	Coded in an ED visit	No	No	No	No	No	No
Surgical Site Bleeding and Other Surgical Site Complications (During index admission or within 30 days of admission date) *Must have relevant procedure coded to be YES	Coded in an obs stay	YES	YES	YES	YES	YES	YES

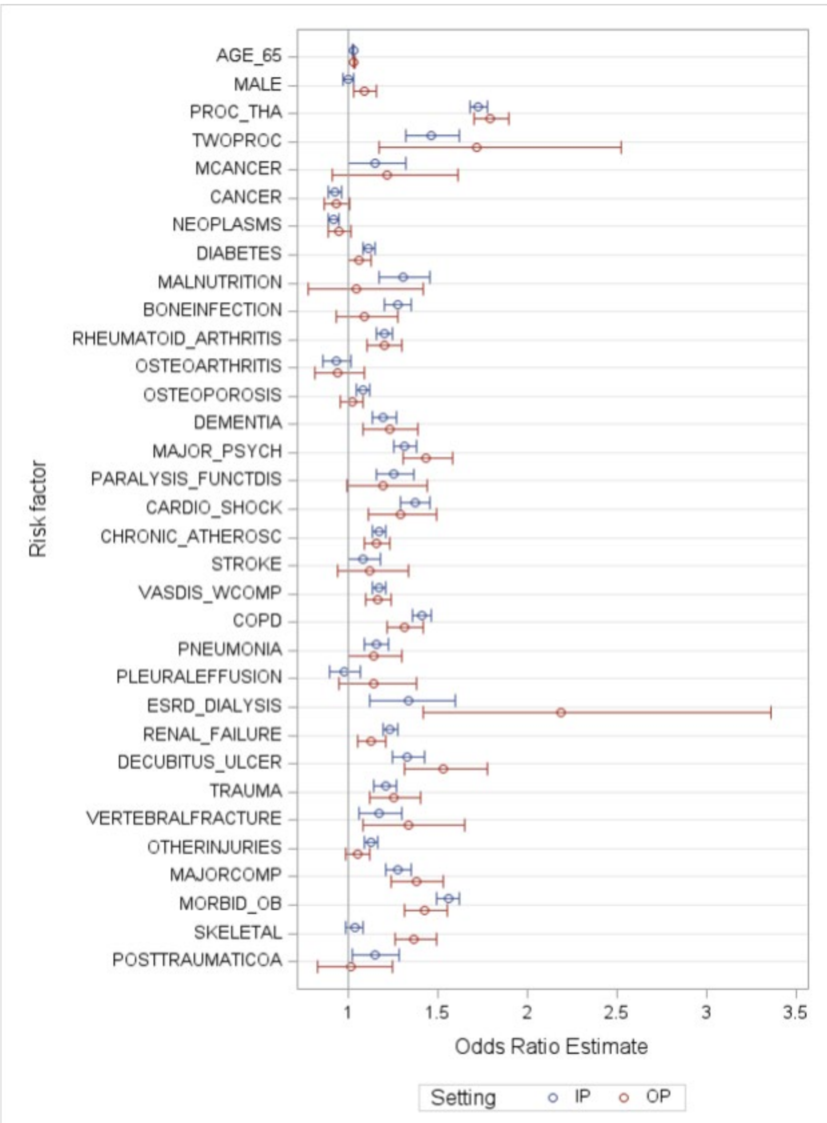
Complication	Setting of Complication	**THA/TKA was done inpatient** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and NOT POA**	**THA/TKA was done in HOPD** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and NOT POA**
Surgical Site Bleeding and Other Surgical Site Complications (During index admission or within 30 days of admission date) *Must have relevant procedure coded to be YES	Coded in an ASC	YES	YES	YES	YES	YES	YES
Mechanical Complications (During index admission or within 90 days of admission date)	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)
Mechanical Complications (During index admission or within 90 days of admission date)	Coded in a readmission	YES	YES	YES	YES	YES	YES
Mechanical Complications (During index admission or within 90 days of admission date)	Coded in an ED visit	YES	YES	YES	YES	YES	YES
Mechanical Complications (During index admission or within 90 days of admission date)	Coded in an obs stay	YES	YES	YES	YES	YES	YES
Mechanical Complications (During index admission or within 90 days of admission date)	Coded in an ASC	YES	YES	YES	YES	YES	YES

Complication	Setting of Complication	THA/TKA was done inpatient Complication was coded as principal discharge diagnosis	THA/TKA was done inpatient Complication was coded as secondary diagnosis and POA	THA/TKA was done inpatient Complication was coded as secondary diagnosis and NOT POA	THA/TKA was done in HOPD Complication was coded as principal discharge diagnosis	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and POA	THA/TKA was done in HOPD Complication was coded as secondary diagnosis and NOT POA
Periprosthetic Joint Infection/ Wound Infection and Other Wound Complications (During index admission or within 90 days of admission date) *Must have relevant procedure coded to be YES	Coded in the index procedure	No	No	YES	No	YES (assumes NOT POA)	YES (assumes NOT POA)
Periprosthetic Joint Infection/ Wound Infection and Other Wound Complications (During index admission or within 90 days of admission date) *Must have relevant procedure coded to be YES	Coded in a readmission	YES	YES	YES	YES	YES	YES
Periprosthetic Joint Infection/ Wound Infection and Other Wound Complications (During index admission or within 90 days of admission date) *Must have relevant procedure coded to be YES	Coded in an ED visit	No	No	No	No	No	No

Complication	Setting of Complication	**THA/TKA was done inpatient** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done inpatient** **Complication was coded as secondary diagnosis and NOT POA**	**THA/TKA was done in HOPD** **Complication was coded as principal discharge diagnosis**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and POA**	**THA/TKA was done in HOPD** **Complication was coded as secondary diagnosis and NOT POA**
Periprosthetic Joint Infection/ Wound Infection and Other Wound Complications (During index admission or within 90 days of admission date) *Must have relevant procedure coded to be YES	Coded in an obs stay	YES	YES	YES	YES	YES	YES
Periprosthetic Joint Infection/ Wound Infection and Other Wound Complications (During index admission or within 90 days of admission date) *Must have relevant procedure coded to be YES	Coded in an ASC	YES	YES	YES	YES	YES	YES

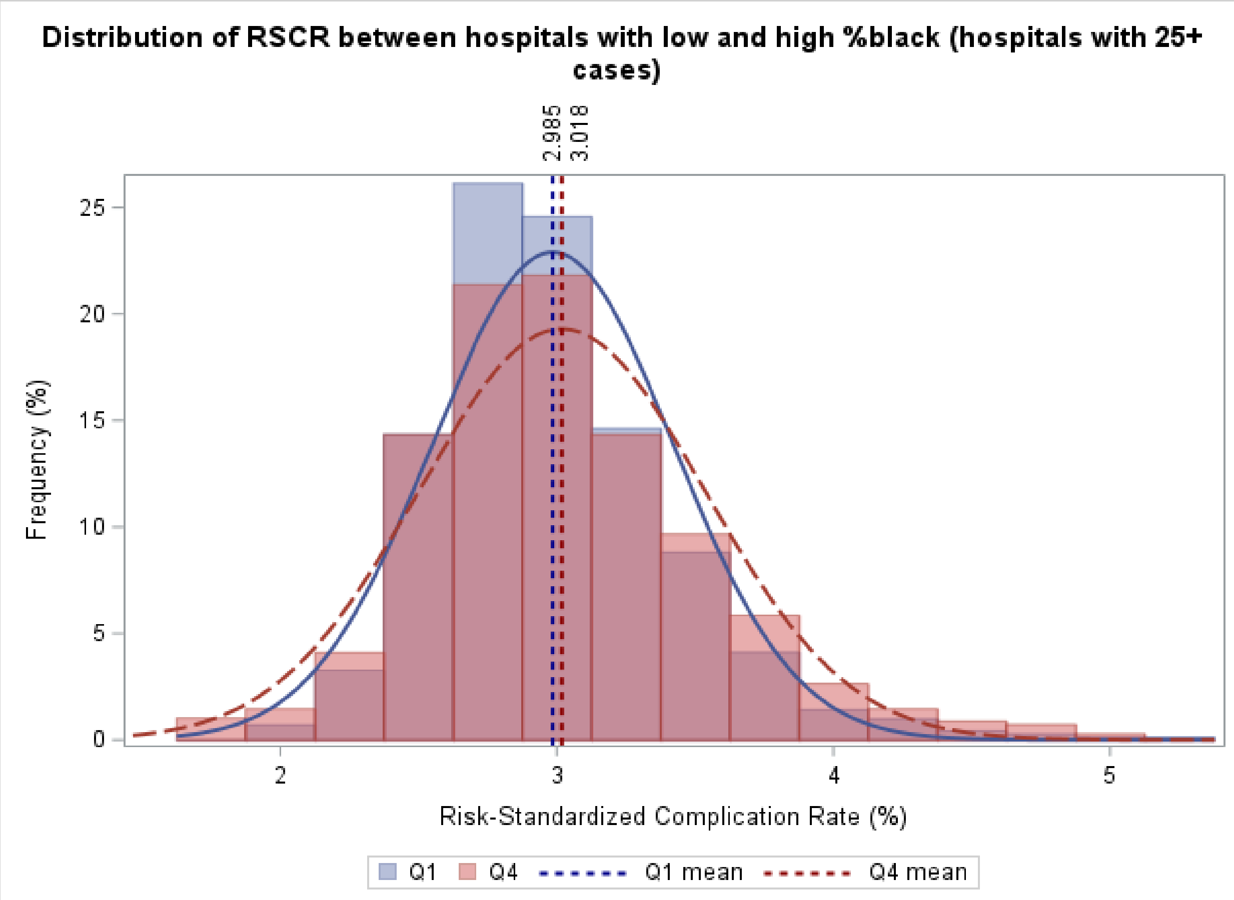
[Appendix Figure 1](#) displays a forest plot of the odds ratios of all the risk variables in the existing Hospital-level THA/TKA Complication measure risk model among inpatients only and outpatients only. With few exceptions, the risk variables perform similarly across settings. All risk variables are directionally concordant across setting with differences found only in the strength of association. The exceptions generally reflect low case volumes and/or unstable estimates in the outpatient setting.

Appendix Figure 1: Multivariate ORs and 95% CI from IP-only (blue) and OP-only (red) models

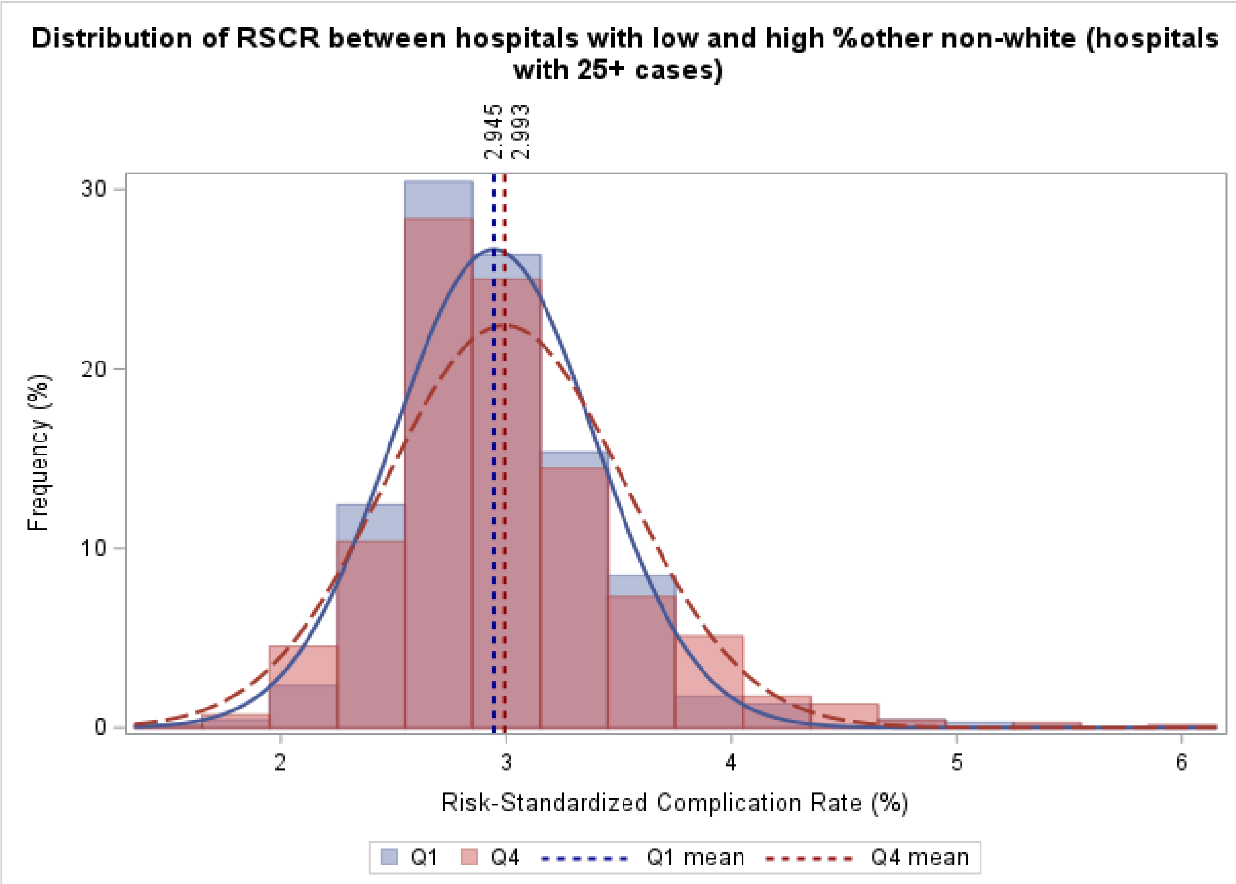


[Appendix Figure 2](#) and [Appendix Figure 3](#) display the distribution of hospital-level RSCRs for hospitals with the highest (Q4) and lowest (Q1) proportions of Black and other non-White patients, respectively. The histograms show that the 4th quartile (Q4) mean is similar but slightly higher (worse) than the first quartile (Q1) mean. This indicates that hospitals with a higher proportion of Black (Q4 in Appendix Figure 2) or other non-White Beneficiaries (Q4 in Appendix Figure 3) have a slightly higher (worse) average RSCR.

Appendix Figure 2: RSCR between Hospitals with Low and High % Black Beneficiaries

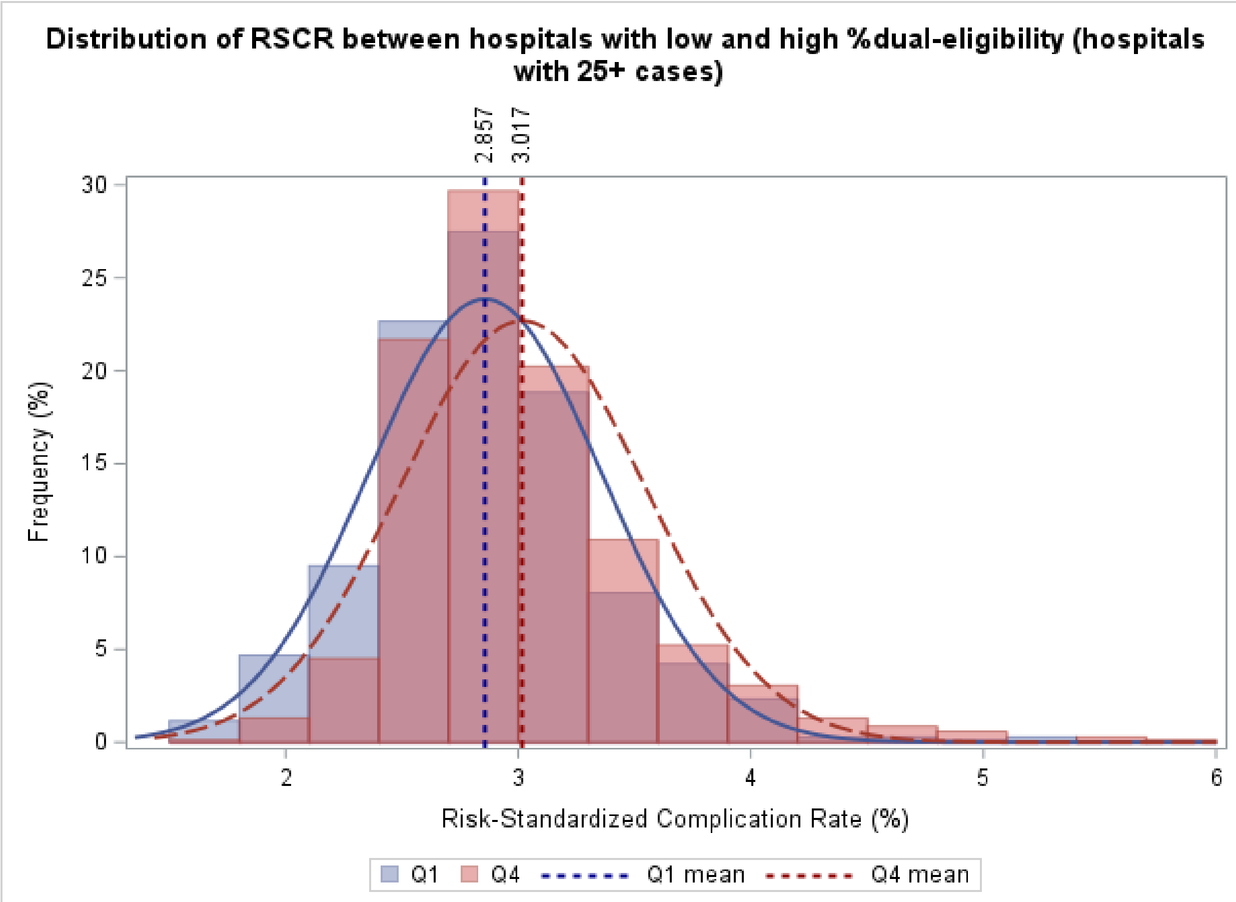


Appendix Figure 3: RSCR between Hospitals with Low and High % Other Non-White Beneficiaries

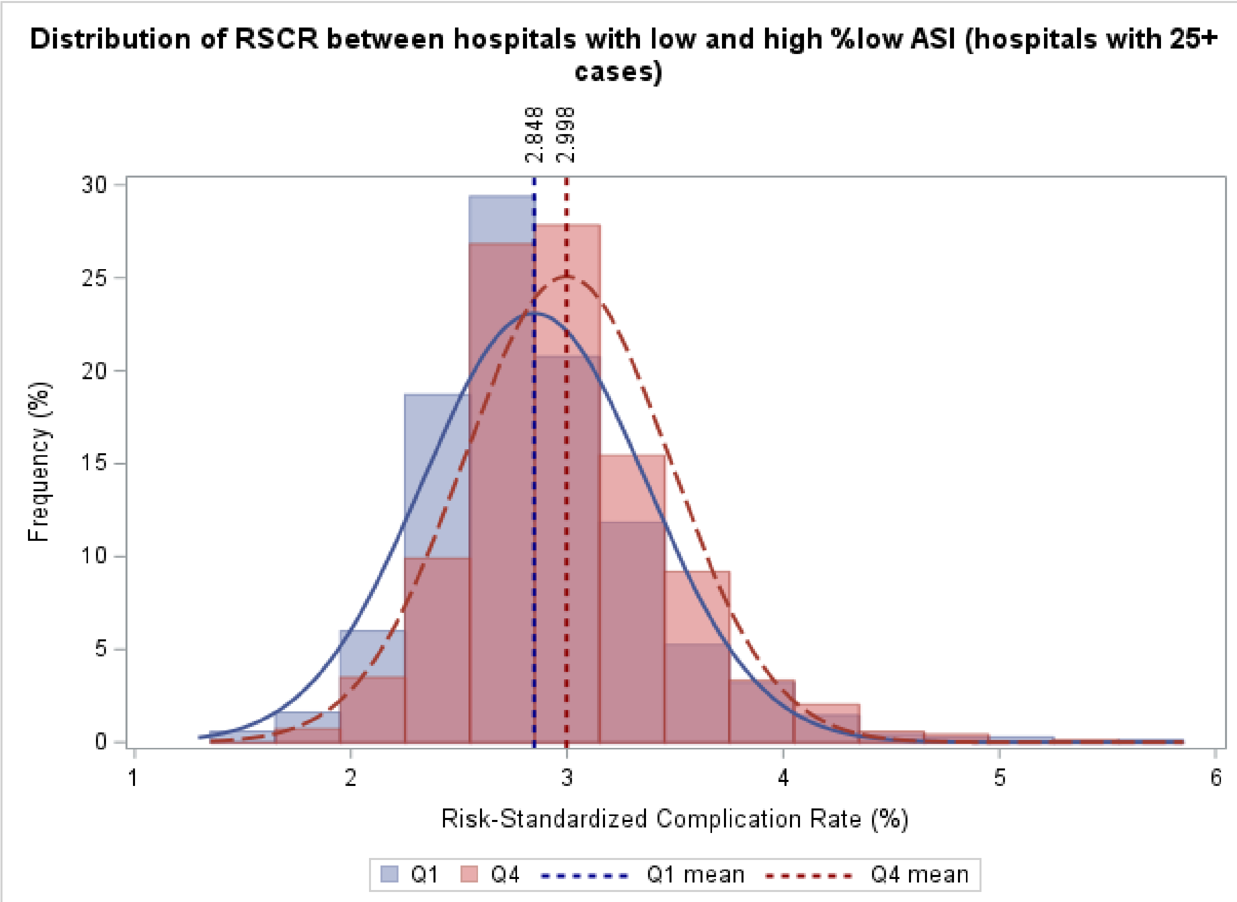


Appendix Figure 4 and Appendix Figure 5 display the distribution of hospital-level RSCRs for hospitals with the highest (Q4) and lowest (Q1) proportions of dual eligible patients and low ASI index score patients, respectively. The histograms show that the 4th quartile (Q4) mean is similar but slightly higher (worse) than the first quartile (Q1) mean. This indicates that hospitals with a higher proportion of dually eligible (Q4 in Appendix Figure 4) or low ASI Beneficiaries (Q4 in Appendix Figure 5, indicating high patient social drivers of health) have a slightly higher (worse) average RSCR.

Appendix Figure 4: Distribution of RSCRs between Hospitals with Low and High % Dual-Eligibility (Hospitals with 25+ cases)

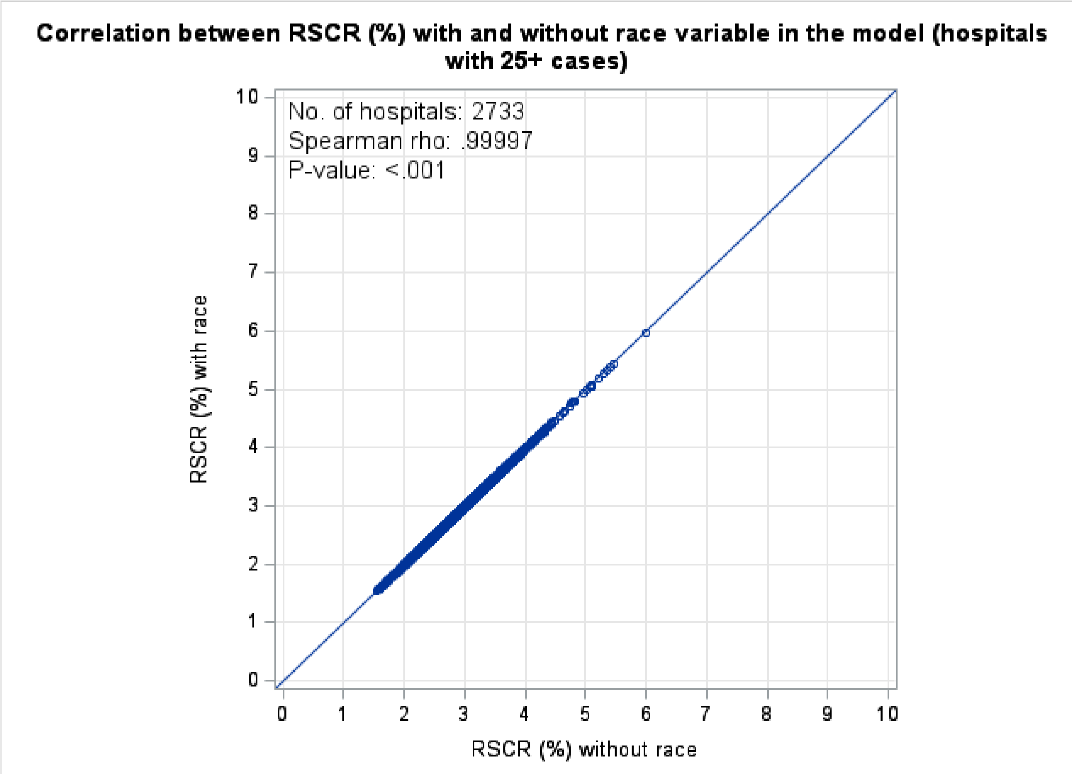


Appendix Figure 5: Distribution of RSCRs between Hospitals with Low and High % Low ASI (Hospitals with 25+ cases)



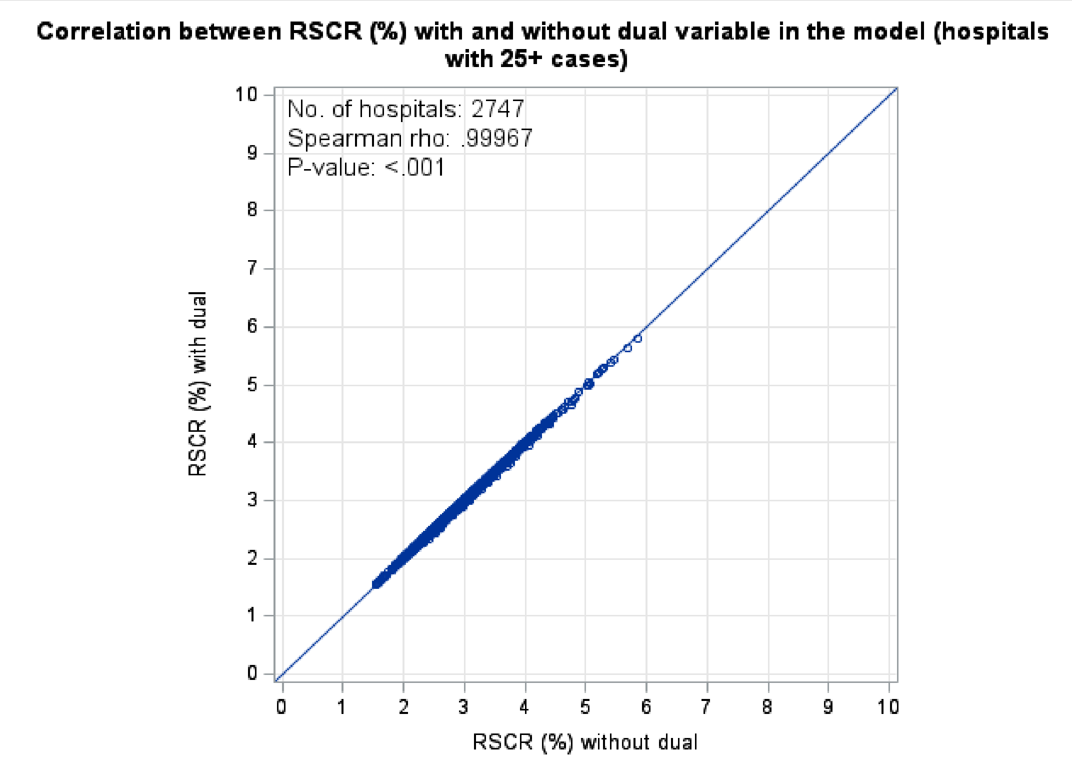
The scatterplot in Appendix Figure 6 shows the correlation between hospital-level RSCRs calculated with and without including race in the risk model. This figure is in support of the previous finding of a small difference between these two models, as evidenced by the near perfect correlation between the RSCRs from these two models.

Appendix Figure 6: Correlation between RSCRs with and without Adjusting for Race



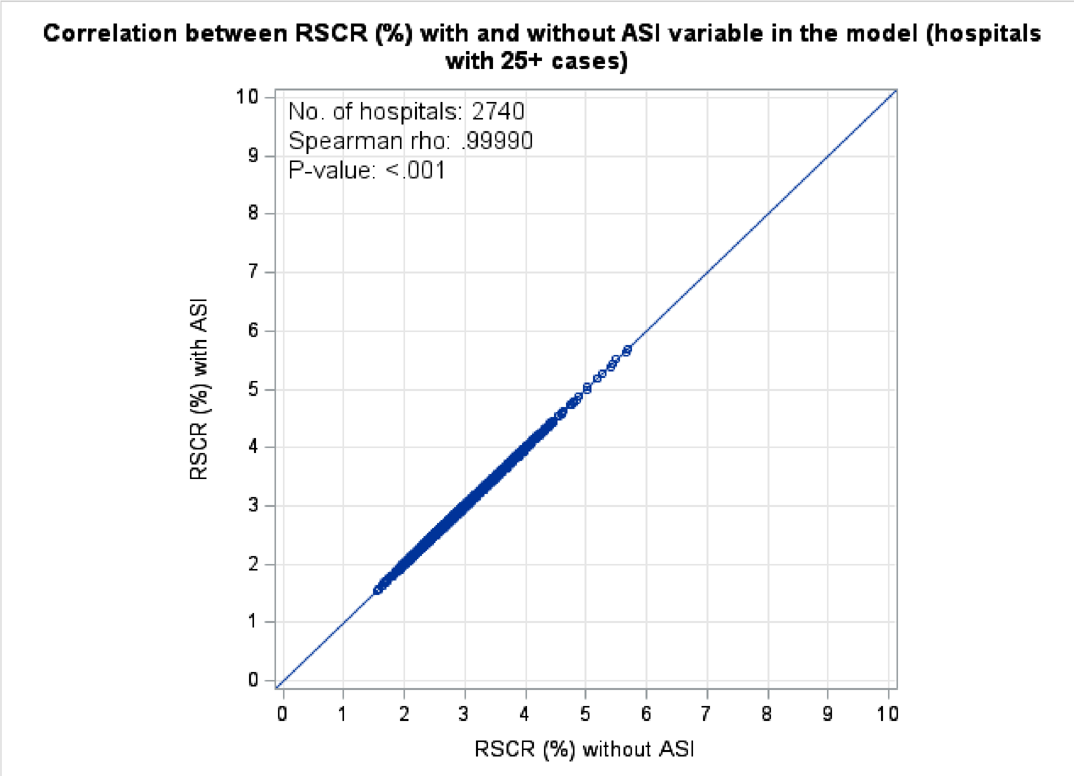
The scatterplot in Appendix Figure 7 shows the correlation between hospital-level RSCRs calculated with and without including dual eligibility in the risk model. This figure is in support of the previous finding of a small difference between these two models, as evidenced by the near perfect correlation between the RSCRs from these two models.

Appendix Figure 7: Correlation between RSCRs with and without Adjusting for Dual Eligibility

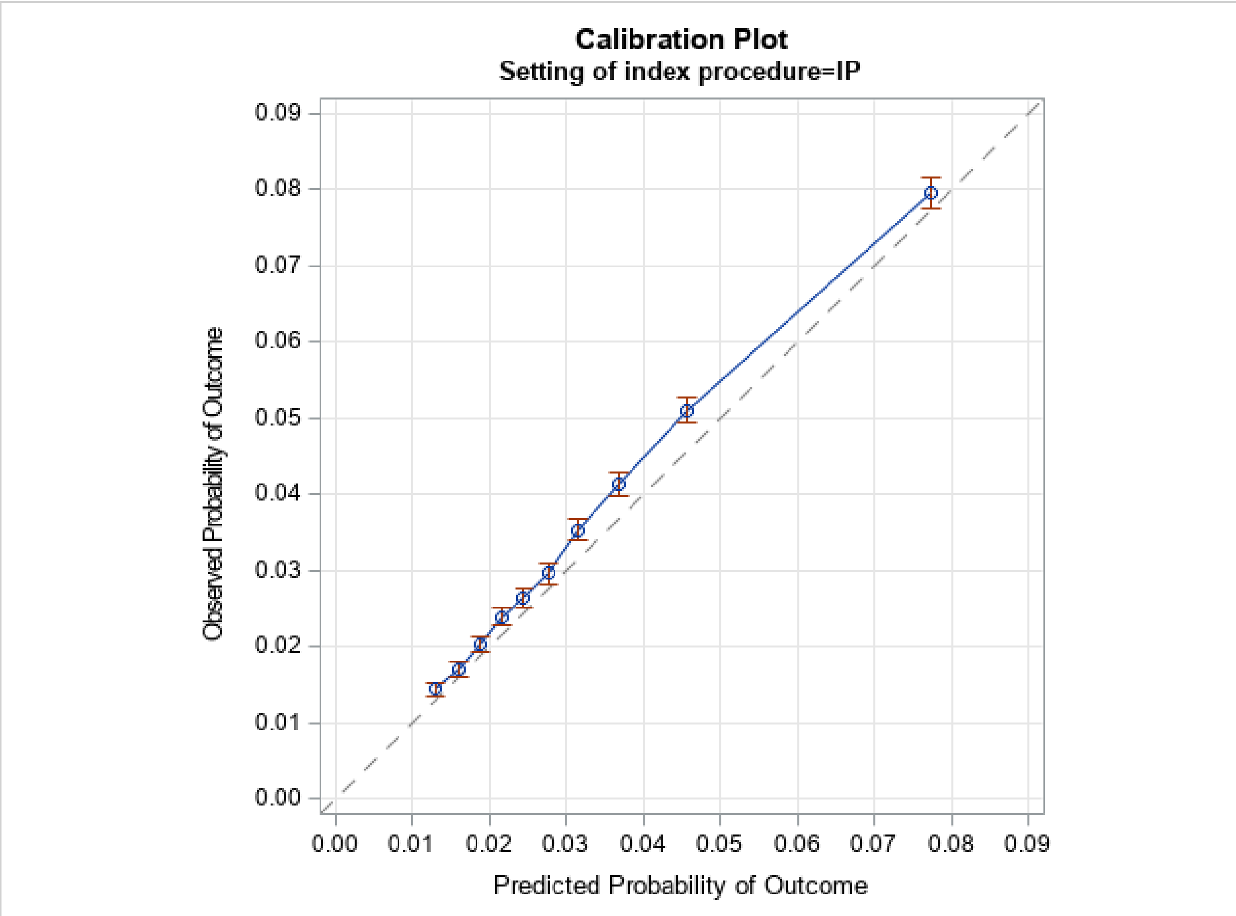


The scatterplot in Appendix Figure 8 shows the correlation between hospital-level RSCRs calculated with and without including AHRQ SES Index in the risk model. This figure is in support of the previous finding of a small difference between these two models, as evidenced by the near perfect correlation between the RSCRs from these two models.

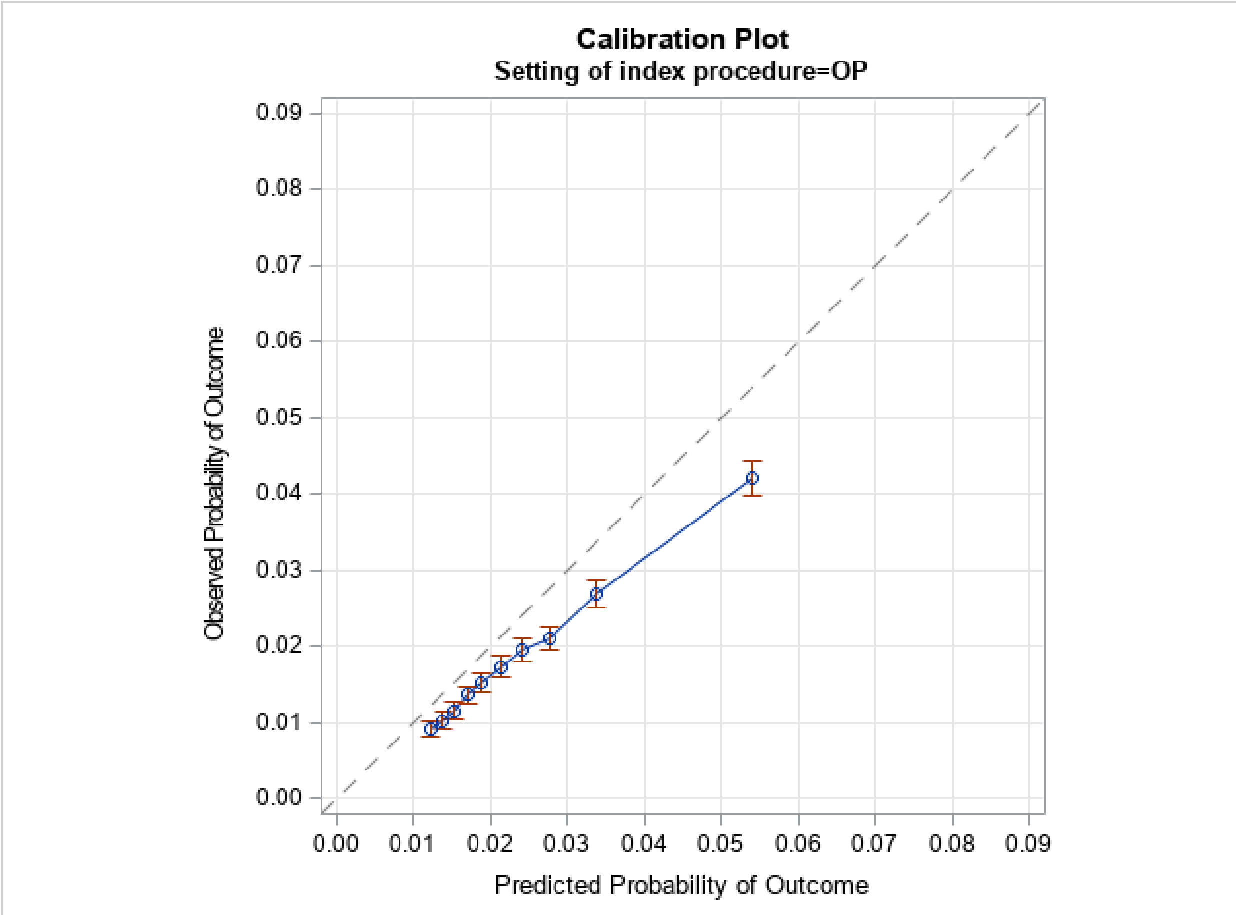
Appendix Figure 8: Correlations between RSCRs with and without Adjusting for ASI



Appendix Figure 9: Calibration Plot for the Inpatient Subgroup in the Single Combined Model



Appendix Figure 10: Calibration Plot for the Outpatient Subgroup in the Single Combined Model



Appendix Figure 11: Calibration Plot for the Combined Inpatient and Outpatient Group in the Single Combined Model