Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA)

Measure Methodology Report

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TABLE OF CONTENTS

LIST OF TABLES VI

LIST OF FIGURES VII

1. INTRODUCTION 8
1.1 Purpose and Organization of This Report 8
1.2 Background 8
1.3 Importance of a Complications Measure for Elective Primary THA/TKA 9

2. CURRENT MEASURE SPECIFICATIONS 11
2.1 Overview 11
2.2 Data Sources 12
2.3 Cohort Definition 13
2.3.1 Inclusion Criteria 13
2.3.2 Exclusion Criteria 14
2.4 Outcome Definition 17
2.4.1 Use of Procedure Codes to Identify Significant Surgical Complications 17
2.4.2 Outcome Attribution For Sequential Elective Primary THA/TKA Procedures in Different Calendar Years 18
2.4.3 Outcome Attribution For Sequential Elective Primary THA/TKA Procedures Occurring in the Same Calendar Year 18
2.5 Measure Timeframe 18
2.6 Overview of Risk Adjustment 26
2.7 Model Performance Testing 26
2.8 Statistical Approach to Measure Calculation 27
2.9 Hospital Performance Reporting 28

3. RESULTS 29
3.1 Frequency of Model Variables 29
3.2 Model Parameters and Performance 31
3.3 Distribution of Hospital Volumes and RSCRs 34

4. MAIN FINDINGS / SUMMARY 36

5. REFERENCES 37

6. APPENDIX 39

APPENDIX A: TECHNICAL MEASURE DEVELOPMENT AND VALIDATION PROCESS 40
I. INTRODUCTION TO APPENDIX A 41
II. METHODS FOR MEASURE DEVELOPMENT 42
a. Data Sources (Measure Development) 42
b. Cohort Definition (Measure Development) 42
i. Inclusion Criteria (Measure Development) 43
ii. Exclusion Criteria (Measure Development) 44

iii. Changes to the Original Cohort Exclusions 45
c. Outcome Definition (Measure Development) 47
i. Selection of Complications for Inclusion in Outcome 47
d. Selection of Measure Timeframe (Measure Development) 48
i. Changes to Original Outcome Definition 50
e. Development and Validation Overview (Measure Development) 51
f. Approach to Risk-Adjustment (Measure Development) 51
g. Candidate and Final Variables for Inclusion in Risk-Adjustment (Measure Development) 51
i. Candidate Variable Selection 51
ii. Final Variable Selection 54
h. Statistical Approach to Risk-Adjustment (Measure Development) 56
i. Hospital Performance Reporting 58
i. Creating Interval Estimates 59
ii. Algorithm 59

III. MODEL DEVELOPMENT/VALIDATION RESULTS 61
a. Model Development and Validation Samples 61
b. Risk-Factor Results in Development and Validation Samples 61
c. Risk-Adjustment Model Performance and Validation 63
d. Hierarchical Logistic Regression Model Results 64
e. Unadjusted and Adjusted Complication Rate Distributions (Original Model) 66
f. Measure Testing 67
i. Reliability of the Data Elements 67
ii. Reliability of the Risk-Adjustment Model 71
iii. Validity 71
iv. Medical Record Validation Study of Hospital Risk-Standardized Complication Rate Following Elective Primary THA and/or TKA 71
Appendix B: ICD-9-CM Codes for Hip Fracture, Revision Procedures, Partial Hip Arthroplasty, Resurfacing Procedures, Mechanical Complications, Removal of Implanted Device, and Malignant Neoplasms 73
Appendix C: Conditions Not Adjusted For If Coded Only During Index Admission As They May Represent Adverse Outcomes of Care Received 76
Appendix D: CCs Not Considered for Risk Adjustment 78
Appendix E: Validation Report for Hospital Risk-Standardized Complication Rate following Elective, Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure 79

LIST OF TABLES

Table 1. Measure Specifications for Identification of Complications following THA/TKA 20
Table 2. Frequency of Model Variables (2008-2010) 30
Table 3. Model Variable Adjusted ORs and 95% CIs (2008-2010 – Hierarchical Logistic Regression Model) 32
Table 4. Model Performance (Logistic Regression Model) 33
Table 5. Distribution of Hospital Volumes and RSCRs 34

Table A.1 Procedure Characteristics and Unadjusted Mortality, Readmission, and Complication Rates for THA and TKA (Medicare Inpatient Part A, 2008) 43
Table A.2 THA/TKA Complications Measure Candidate Model Variables 52
Table A.3 THA/TKA Complications Measure Final Model Variables 56
Table A.4 Logistic Regression Model Results for 2008 Development Sample (ROC=0.69) and 2008 Validation Sample (ROC=0.70) 62
Table A.5 Model Performance for Logistic Regression Model 64
Table A.6 Hierarchical Logistic Regression Model Results for Full 2008 Dataset 65
Table A.7 Risk Factor Frequency by Year of Discharge (Logistic Regression Model) 69
Table A.8 Standardized Estimates by Year of Discharge (Logistic Regression Model) 70

LIST OF FIGURES

Figure 1. Measure Cohort (2008-2010 Medicare FFS Patients)..... 16
Figure 2. Distribution of Hospital-Specific Risk-Standardized Complication Rates (2008-2010 Cohort; N=3497 Hospitals) - Hierarchical Logistic Regression Model..... 35

Figure A.1 Cohort for Measure Development (2008 Medicare FFS Patients) 46
Figure A.2 Trend in Mortality and Surgical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)..... 49
Figure A.3 Trend in Medical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)..... 50
Figure A.4 Analysis Steps 60
Figure A.5 Distribution of Unadjusted Hospital Complication Rates (2008 Sample; N=3,311 Hospitals) 66
Figure A.6 Distribution of Hospital Risk-Standardized Complication Rates (2008 Sample; N=3,311 Hospitals) – Hierarchical Logistic Regression Model..... 67

1. INTRODUCTION

1.1 Purpose and Organization of This Report

This report describes the hospital-level risk-standardized elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA) complications measure as it is currently specified for the Center for Medicare & Medicaid Services' (CMS) dry run period in 2012. The body of the report presents the current measure specifications, measure methodology and results. Appendix A details the initial measure development and validation process.

1.2 Background

In 2009 CMS contracted with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop two hospital outcomes measures that reflect the quality of care for patients undergoing elective primary total hip arthroplasty and/or total knee arthroplasty procedures (THA and TKA, respectively). Although these elective procedures dramatically improve quality of life and function, serious complications do sometimes occur. For patients undergoing operations that are elective the associated risks are particularly important to understand and weigh in their decision-making. Current quality improvement measures for patients undergoing elective THA and TKA procedures are generally limited to evidence-based processes of care. Measurement of patient outcomes, such as complications, allows for a more comprehensive view of quality of care, capturing more complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment. To date, there are no outcomes measures comparing hospital performance in the care of patients undergoing elective primary THA/TKA.

YNHHSC/CORE developed two measures: (1) a hospital-level, risk-standardized complication rate (RSCR) following elective primary THA and/or TKA procedures (presented in this report) and (2) a hospital-level 30-day all-cause risk-standardized readmission rate (RSRR) following elective primary THA and/or TKA procedures (presented in a separate technical report, entitled Hospital-level 30-Day All-Cause Risk-Standardized Readmission Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty located at http://www.qualitynet.org > Hospitals-Inpatient > Claims-Based Measures > New Hospital Wide and Hip/Knee Measures In Testing).

The goal of the measures is to improve the quality of care delivered to patients undergoing elective primary THA and/or TKA procedures. They are complementary measures that assess different domains of quality. The complications measure will inform quality improvement efforts targeted toward minimizing medical and surgical complications during surgery and the postoperative period. The readmission measure captures an additional domain of

care provided in the transition to outpatient settings. The premise is that improved quality of care, including coordination and communication among providers and with patients and their caregivers, can favorably influence performance on these measures. Both measures were endorsed by the NQF in 2012.

After YNHHSC/CORE developed both measures, a medical-record validation of the complications in the risk-standardized complications measure was conducted because administrative databases may be subject to coding errors and variation in coding practices within and across care settings. Based on findings from the validation study (Appendix E) and NQF review, YNHHSC/CORE made minor modifications to the codes used to define the outcome and cohort. These changes are detailed in Appendix A, Section II. b. iii.

1.3 Importance of a Complications Measure for Elective Primary THA/TKA

THA and TKA are commonly performed procedures that improve quality of life. In 2003 there were 202,500 THAs and 402,100 TKAs performed[1] and the number of procedures performed has increased steadily over the past decade.[2,3]

Although these procedures dramatically improve quality of life, they are costly. In 2005 annual hospital charges totaled $3.95 billion and $7.42 billion for primary THA and TKA, respectively.[2] These costs are projected to increase by 340% to $17.4 billion for THA and by 450% to $40.8 billion for TKA by 2015.[2] Medicare is the single largest payer for these procedures, covering approximately two-thirds of all THAs and TKAs performed in the US.[3] Combined, THA and TKA procedures account for the largest procedural cost in the Medicare budget.[4]

Because these are commonly performed and costly procedures, it is imperative to address quality of care. Complications increase costs associated with THA and TKA and affect the quality, and potentially quantity, of life for patients. Although complications following elective THA and TKA are rare, the results can be devastating. Rates for periprosthetic joint infection following THA and TKA range from 1.6% to 2.3%, depending upon the population.[5,6] Reported 90-day death rates following THA range from 0.7% [7] to 2.7%.[8] Rates for pulmonary embolism following TKA range from 0.5% to 0.9%.[8-11] Rates for wound infection in Medicare population-based studies vary between 0.3% and 1.0%.[8,9,11] Rates for septicemia range from 0.1%, during the index admission[12] to 0.3%, 90 days following discharge for primary TKA.[8] Rates for bleeding and hematoma following TKA range from 0.94% [12] to 1.7%.[13]

Furthermore, hospitals vary in their rate of complications. Analyses in Medicare fee-for-service (FFS) patients (2008-2010) demonstrate a median hospital-level RSCR of 3.5% (range 1.8% to 8.9%) after elective primary THA and/or TKA, suggesting room for improvement in clinical care.

The variation in complication rates across hospitals suggests there are considerable differences in the quality of care at the hospital level. Measuring and reporting risk-standardized complications rates will inform health care providers about opportunities to improve care, strengthen incentives for quality improvement, and promote improvements in the quality of care received by patients and the outcomes they experience. The measure will also provide patients with information that could guide their choices regarding where they seek care for these elective procedures. Furthermore, the measure will increase transparency for consumers and has the potential to lower health care costs due to costly readmissions associated with these complications.

2. CURRENT MEASURE SPECIFICATIONS

2.1 Overview

This hospital-level risk-standardized complications measure for patients undergoing elective primary THA and/or TKA identifies "index" admissions for inclusion in the measure using Medicare Part A inpatient claims for FFS Medicare beneficiaries hospitalized in calendar years 2008-2010. An "index" admission is any eligible admission to an acute care hospital for an elective primary THA and/or TKA included in the measure. The admission date of the index hospitalization is the starting point for all follow-up, and the hospital that performed the procedure is the one held accountable for the measure outcome (complication or no complication), regardless of whether a patient is transferred to another acute care facility following the procedure.

The measure calculates complication rates using a hierarchical logistic regression model to account for the clustering of patients within hospitals while risk-adjusting for differences in patient case-mix. The measure calculates the hospital RSCR by producing a ratio of the number of "predicted" to the number of "expected" admissions with a complication for each hospital and then multiplying the ratio by the national unadjusted complication rate.

YNHHSC/CORE developed this measure in accordance with national guidelines for publicly reported outcomes measures including the NQF[14], CMS' Measure Management System, and guidance articulated in the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes".[15] Expert and stakeholder input on the measure was obtained through three mechanisms: first, through regular discussions with a working group of clinical and methodological experts; second, through a series of three conference calls with a national Technical Expert Panel (TEP); and third, through a public comment period.

Early in the development phase, YNHHSC/CORE assembled an advisory working group comprised of orthopedic surgeons and experts in orthopedic quality measurement. Regular conference calls were held throughout the development process and YNHHSC/CORE solicited detailed feedback and guidance on key clinical and methodological decisions pertaining to measure development. The working group provided a forum for focused expert review and discussion of technical issues during measure development prior to consideration by the broader TEP.

In alignment with CMS' Measure Management System, YNHHSC/CORE also released a public call for nominations and convened a national TEP. Potential members were also solicited via e-mail in consultation with the working group and CMS. The role of the TEP was to provide feedback on key methodological decisions made in consultation with the working group. The TEP was comprised

of individuals with diverse perspectives and backgrounds and included clinicians, consumers, hospitals, purchasers, and experts in quality improvement. Finally, YNHHSC/CORE solicited public comment on the proposed measure through CMS' Measure Management System Public Comment website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html). Public comments were summarized and publicly posted for 30 days after the close of the public comment period. The resulting content was taken into consideration during the final stages of measure development.

A detailed description of the development of the original measure specifications, including the rationales for the cohort identification and selection of complications, selection of the variables for risk-adjustment, and statistical modeling is provided in Appendix A.

2.2 Data Sources

The measure uses 2008-2010 claims data from the Medicare inpatient, outpatient, and carrier (physician) Standard Analytic Files for the results presented in the main report. (This is the same data that is included in the dry run.) The measure identifies index hospitalizations and complications in Part A inpatient claims data and identifies comorbidities for risk adjustment in Part A inpatient and outpatient and Part B claims data, in the 12 months prior to admission. The measure uses the Medicare Enrollment Database to determine FFS enrollment and post-discharge mortality status, and medical record data was used to validate the complications identified in administrative claims data.

Part A inpatient data - contains final action claims data submitted by inpatient hospital providers for Medicare FFS beneficiaries for reimbursement of facility costs. Information in this file includes ICD-9 diagnosis codes, ICD-9 procedure codes, dates of service, hospital provider ID, and beneficiary demographic information.

Part A outpatient data - contains final action claims data submitted by inpatient hospital providers for Medicare FFS claims paid for the facility component of surgical or diagnostic procedures, emergency room care, and other non-inpatient services performed in a hospital outpatient department or ambulatory surgical/diagnostic center.

Part B data - contains final action claims data for the physician services (regardless of setting) and other outpatient care, services, and supplies for Medicare FFS beneficiaries. For purposes of this project, Part B services included only face-to-face encounters between a care provider and patient. Therefore, the measure does not include information for services such as laboratory tests, medical supplies, or other ambulatory services.

Medicare Enrollment Database - contains Medicare beneficiary demographic, benefit/coverage, and vital status information.

2.3 Cohort Definition

We developed a combined measure for patients undergoing elective primary hip and/or knee procedures because: both procedures are performed in clinically similar patient cohorts and for similar indications (osteoarthritis); hospitals typically develop protocols for lower extremity total joint arthroplasty, rather than for THA or TKA individually; the same surgeons frequently perform both procedures; and outcomes are similar. During measure development YNHHSC/CORE conducted analyses that indicated the types of complications, rates for complications and readmission, and length of stay were similar in both patient cohorts (analyses are in Table A.1, Appendix A, Section II. b.). Furthermore, combining procedures provides greater power to detect hospital-level variation in complication rates

In 2010-2011, YNHHSC/CORE conducted a medical record validation study of the ICD-9 codes used to identify the complications (except death) using a sample of administrative claims for elective primary THA and/or TKA procedures both with and without the indicated complications. The primary goal of the validation study was to determine the overall agreement between patients identified as having a complication (or no complication) in the claims-based measure and those who had a complication (or no complication) also documented in the medical record. After a detailed review of all disagreements, YNHHSC/CORE made minor modifications to the codes used to define the outcome and cohort exclusions. The current measure specifications take these findings into consideration, as well as feedback from public comment during the NQF endorsement process. Details regarding the changes made to the original cohort exclusions and specifications of certain complications based on the NQF comments and medical record validation are provided in the Appendix E.

2.3.1 Inclusion Criteria

Patients eligible for inclusion in the measure are those aged 65 years and older electively admitted to non-federal acute care hospitals, as indicated by an ICD-9-CM procedure code for primary THA and/or TKA in 2008-2010. The flowchart depicting cohort selection is presented in Figure 1.

Eligible index admissions are identified using the following ICD-9 procedure codes in Medicare Part A inpatient claims data:

- 81.51 Total Hip Arthroplasty
- 81.54 Total Knee Arthroplasty

2.3.2 Exclusion Criteria

To identify a homogeneous cohort of patients undergoing elective primary THA and/or TKA procedures, we excluded admissions for patients who on the index admission had a principal discharge diagnosis indicative of a non-elective arthroplasty (e.g., hip fracture, mechanical complication). We also excluded patients who had a procedure code for an arthroplasty procedure that was not an elective primary arthroplasty (e.g., partial hip arthroplasty, revision procedures) or represented a different procedure (e.g., hip resurfacing, removal of implanted device).

In order to identify a cohort of elective THA and/or TKA procedures, the measure excludes admissions for patients:

1. With a femur, hip or pelvic fracture coded in the principal discharge diagnosis field for the index admission
   Rationale: THA procedures are not elective in these patients, and these patients represent a higher risk category for mortality, complication, and readmission.

2. Undergoing partial hip arthroplasty (PHA) procedures (with a concurrent THA/TKA)
   Rationale: Partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions.

3. Undergoing revision procedures (with a concurrent THA/TKA)
   Rationale: Revision procedures may be performed at a disproportionately small number of hospitals and represent a higher risk category for mortality, complication, and readmission.

4. Undergoing resurfacing procedures (with a concurrent THA/TKA)
   Rationale: Resurfacing procedures are a different type of procedure involving only the joint's articular surface. Resurfacing procedures are typically performed on younger, healthier patients.

5. With a mechanical complication coded in the principal discharge diagnosis field for the index admission
   Rationale: A complication coded as the principal discharge diagnosis suggests the procedure was more likely the result of a previous procedure and indicates the complication was present on admission. These patients may require more technically complex arthroplasty procedures and may be at increased risk for complications, particularly mechanical complications.

6. With a 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 for the index admission
   Rationale: Patients with these malignant neoplasms are at increased risk for complications and the procedure may not be elective.

7. With a procedure code for removal of implanted devices / prostheses
   Rationale: Elective procedures performed in these patients may be more complicated.

After excluding the above admissions to select elective primary THA/TKA procedures, the measure also excludes admissions for patients:

8. Without at least 12-months pre-index admission enrollment in Medicare FFS
   Rationale: Appropriate risk adjustment requires uniform data availability of pre-operative comorbidity

9. Who were transferred in to the index hospital
   Rationale: If the patient is transferred from another acute care facility to the hospital where the index procedure occurs, it is likely that the procedure is not elective or that the admission is associated with an acute condition.

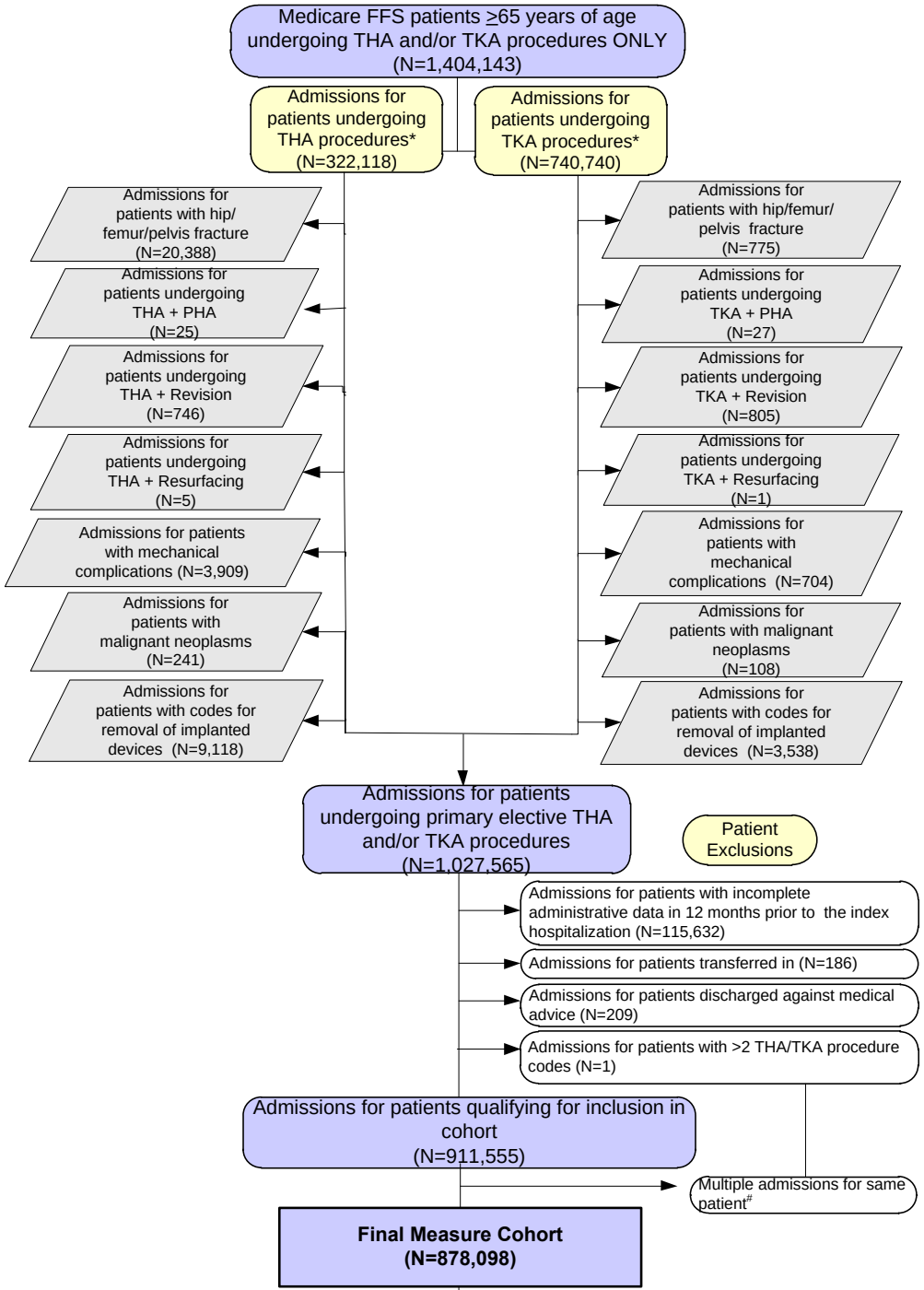
10. Who leave the hospital against medical advice (AMA)
    Rationale: Hospitals and physicians do not have the opportunity to provide the highest quality care for these patients.

11. With more than two THA/TKA procedures codes during the index hospitalization
    Rationale: Although clinically possible, it is highly unlikely that patients would receive more than two elective THA/TKA procedures in one hospitalization, and this may reflect a coding error.

After applying the exclusion criteria above, we randomly select one index admission for patients with multiple index admissions in a calendar year. We therefore exclude the other eligible index admissions in that year.

Appendix B lists the ICD-9 codes for the following exclusion categories: femur, hip and pelvic fractures, revision procedures, partial hip arthroplasty procedures, resurfacing procedures, mechanical complications, removal of implanted device/prosthesis, and malignant neoplasms.

Figure 1. Measure Cohort (2008-2010 Medicare FFS Patients)



Procedure	N (%)
1 THA procedure	250,378 (28.5)
1 TKA Procedure	600,758 (68.4)
THA + THA	821 (0.1)
TKA + TKA	26,023 (2.1)
THA + TKA	118 (0.0)

*THA and TKA are presented separately for illustrative purposes and are not mutually exclusive

#Randomly selected and kept in the cohort one of multiple admissions for the same patient

2.4 Outcome Definition

The goal was to identify medical and surgical complications that could be attributable to the care provided during and after an elective total hip or knee arthroplasty procedure. YNHHSC/CORE identified complications for potential inclusion in the measure from the medical literature and in consultation with the working group and technical expert panel. YNHHSC/CORE then selected complications that could be both attributable to the THA/TKA procedure and subsequent hospital care and were identifiable in claims data. Complications are counted in the measure if they occur during the index admission, or require a readmission. The measure does not count complications that occur in the outpatient setting and do not require a readmission. The complication selection process is detailed in Appendix A, Section II. c. and d.

The outcome for this measure is any one of the specified complications occurring during the index admission or during a readmission within the specified time period for that complication (Table 1). Therefore, if a patient experiences one or more complications in the applicable time period, the outcome variable is coded as a "yes." The measure includes complications that are clinically significant, attributable to the THA/TKA procedure, and identifiable in claims data. The measure includes the following surgical complications: surgical site bleeding, mechanical complications, periprosthetic joint infection/wound infection; and also includes death as a complication. The measure also includes the following medical complications, as they are important in measuring overall quality: acute myocardial infarction (AMI), pneumonia, pulmonary embolism, and sepsis/septicemia/shock. Detailed information on the selection of the final complications included in the measure is available in Appendix A, Section II. c. i.

2.4.1 Use of Procedure Codes to Identify Significant Surgical Complications

Periprosthetic joint infection/wound infection and surgical site bleeds have varying degrees of severity not conveyed in ICD-9 diagnosis codes. For example, an ICD-9 code for a wound infection may represent redness and swelling around the incision site, or a true infection requiring incision and drainage. To capture periprosthetic joint infections/wound infections and surgical site bleeds significant enough to impact clinical care, and to reduce the likelihood of capturing miscoded or minor complications, the measure only counts these conditions as complications when an accompanying ICD-9 procedure code(s) for an intervention is also coded during the same hospitalization (Table 1).

2.4.2 Outcome Attribution For Sequential Elective Primary THA/TKA Procedures in Different Calendar Years

The measure randomly selects one index admission per patient per year, but because the measure as currently specified for the dry run is calculated using three years of data, it is possible that two index admissions are included in the measure that occur in such proximity that a complication requiring a readmission cannot be definitively assigned to the index admission from which it resulted. For example, a patient is admitted on November 15, 2008 for an elective primary THA, and this patient is admitted again on January 15, 2009 for another elective primary THA. The patient is then readmitted for a mechanical complication on January 25, 2009. To avoid assigning the mechanical complication to both index admissions (since it falls within the specified follow-up period for both), the measure will assign the mechanical complication to the second index admission (January 15, 2009). This assignment of the complication outcome is only applicable in cases where a complication occurs after a second elective primary procedure, but occurs within the follow-up period for both the first and second index admissions. If a complication occurs during the index admission, it will be assigned to that index admission. In other words, when two index THA/TKA admissions occur in separate years but their admission dates are fewer than 90 days apart and the second index admission is followed by one or more readmissions, any complications associated with those readmissions will only be attributed to the second index admission.

2.4.3 Outcome Attribution For Sequential Elective Primary THA/TKA Procedures Occurring in the Same Calendar Year

Complications following another elective admission for a THA/TKA in the same year, that was not randomly selected for inclusion in the measure are not attributed to the hospital that performed the index procedure (the admission that is included in the measure), even if the complication(s) is within the specified outcome period for the index procedure. This will avoid incorrectly assigning that complication.

2.5 Measure Timeframe

To determine the appropriate follow-up period, we obtained clinical input and examined 90-day trends in complication rates (details regarding selection of the timeframe and analyses are provided in Appendix A, Section II. d.). Based on these analyses, both the advisory working group and TEP recommended that we establish complication-specific follow-up periods. Accordingly, we reviewed each complication with the working group and TEP and chose either a 7, 30, or 90 day follow-up period by consensus. The measure counts complications occurring

during the index hospitalization or during a readmission that occurs within the given timeframe for a complication. The measure only counts complications that occur in the inpatient setting (during the index admission or readmission) and not those that are minor enough to be treated as an outpatient.

The measure follow-up period is 90 days for mechanical complications and periprosthetic joint infection/wound infection. We selected this time period because clinical experts agreed that mechanical complications and periprosthetic joint infection/wound infections are still attributable to the index THA/TKA for the 90 days following admission for surgery.

The measure follow-up period for death, surgical site bleeding, and pulmonary embolism is 30 days as clinical experts agree these complications are still likely attributable to the hospital performing the procedure.

The measure follow-up period for AMI, pneumonia, and sepsis/septicemia/shock is 7 days from the date of index admission, as these conditions are more likely to be attributable to the procedure if they occur within the first week after the procedure. The list of complications and their associated follow-up periods are listed in Table 1. Table 1 also indicates the required coding placement (i.e., principal or secondary diagnosis) for each ICD-9 complication code.

For complications occurring during the index admission, it is not possible to determine the exact date on which the complication occurred, however it is important to capture such events for quality measurement. Therefore, if the length of stay for the index admission exceeds the follow up period for a specific complication and that complication occurs during the index admission, the measure counts it in the outcome. For example, if a patient has a length of stay of 15 days for the index admission and has an AMI during the index stay, the measure will count the AMI as a complication. Hospitalizations for elective THA/TKA procedures are commonly fewer than seven days in duration and lengthier stays are consistent with potential complications of care. Therefore, the measure includes all complications occurring during the index admission, even if they occur beyond the specified follow-up period for that complication. The working group and TEP agreed with this approach, and it was endorsed by the NQF.

Table 1. Measure Specifications for Identification of Complications following THA/TKA

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
Acute myocardial infarction	During Index Admission or within 7 days of admission date	410 Acute myocardial infarction (excluding 410.x2) 410.0 Acute myocardial infarction of anterolateral wall 410.00 Acute myocardial infarction of anterolateral wall episode of care unspecified 410.01 Acute myocardial infarction of anterolateral wall initial episode of care 410.1 Acute myocardial infarction of other anterior wall 410.10 Acute myocardial infarction of other anterior wall episode of care unspecified 410.11 Acute myocardial infarction of other anterior wall initial episode of care 410.2 Acute myocardial infarction of inferolateral wall 410.20 Acute myocardial infarction of inferolateral wall episode of care unspecified 410.21 Acute myocardial infarction of inferolateral wall initial episode of care 410.3 Acute myocardial infarction of inferoposterior wall 410.30 Acute myocardial infarction of inferoposterior wall episode of care unspecified 410.31 Acute myocardial infarction of inferoposterior wall initial episode of care 410.4 Acute myocardial infarction of other inferior wall 410.40 Acute myocardial infarction of other inferior wall episode of care unspecified 410.41 Acute myocardial infarction of other inferior wall initial episode of care 410.5 Acute myocardial infarction of other lateral wall 410.50 Acute myocardial infarction of other lateral wall episode of care unspecified 410.51 Acute myocardial infarction of other lateral wall initial episode of care 410.6 True posterior wall infarction 410.60 True posterior wall infarction episode of care unspecified 410.61 True posterior wall infarction initial episode of care 410.7 Subendocardial infarction 410.70 Subendocardial infarction episode of care unspecified 410.71 Subendocardial infarction initial episode of care 410.8 Acute myocardial infarction of other specified sites 410.80 Acute myocardial infarction of other specified sites episode of care unspecified 410.81 Acute myocardial infarction of other specified sites initial episode of care 410.9 Acute myocardial infarction of unspecified site 410.90 Acute myocardial infarction of unspecified site episode of care unspecified 410.91 Acute myocardial infarction of unspecified site initial episode of care	• Index admission – principal or secondary discharge diagnosis field • Readmissions - principal discharge diagnosis field only

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
Pneumonia	During Index Admission or within 7 days of admission date	480 Viral pneumonia 480.0 Pneumonia due to adenovirus 480.1 Pneumonia due to respiratory syncytial virus 480.2 Pneumonia due to parainfluenza virus 480.3 Pneumonia due to SARS-associated coronavirus 480.8 Pneumonia due to other virus not elsewhere classified 480.9 Viral pneumonia unspecified 481 Pneumococcal pneumonia 482 Other bacterial pneumonia 482.0 Pneumonia due to Klebsiella pneumoniae 482.1 Pneumonia due to Pseudomonas 482.2 Pneumonia due to *Hemophilus influenzae* (*H. influenzae*) 482.3 Pneumonia due to streptococcus 482.30 Pneumonia due to streptococcus unspecified 482.31 Pneumonia due to streptococcus group a 482.32 Pneumonia due to streptococcus group b 482.39 Pneumonia due to other streptococcus 482.4 Pneumonia due to staphylococcus 482.40 Pneumonia due to staphylococcus unspecified 482.41 Methicillin susceptible pneumonia due to *Staphylococcus aureus* 482.42 Methicillin resistant pneumonia due to *Staphylococcus aureus* 482.49 Other staphylococcus pneumonia 482.81 Pneumonia due to anaerobes 482.82 Pneumonia due to *Escherichia coli* [*E. coli*] 482.83 Pneumonia due to other gram-negative bacteria 482.84 Pneumonia due to Legionnaires' disease 482.89 Pneumonia due to other specified bacteria 482.9 Bacterial pneumonia unspecified 483 Pneumonia due to other specified organism 483.0 Pneumonia due to *Mycoplasma pneumoniae* 483.1 Pneumonia due to *Chlamydia* 483.8 Pneumonia due to other specified organism 485 Bronchopneumonia organism unspecified 486 Pneumonia organism unspecified 487.0 Influenza with pneumonia 488.01 Influenza due to identified avian influenza virus with pneumonia 488.11 Influenza due to identified novel h1n1 influenza virus with pneumonia 507.0 Pneumonitis due to inhalation of food or vomitus	• Index admission - principal or secondary discharge diagnosis fields • Readmissions - principal discharge diagnosis field only

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
Sepsis/ septicemia/ shock	During Index Admission or within 7 days of admission date	038 Septicemia 038.0 Streptococcal septicemia 038.1 Staphylococcal septicemia 038.10 Staphylococcal septicemia unspecified 038.11 Methicillin susceptible staphylococcus aureus septicemia 038.12 Methicillin resistant staphylococcus aureus septicemia 038.19 Other staphylococcal septicemia 038.2 Pneumococcal septicemia 038.3 Septicemia due to anerobes 038.4 Septicemia due to other gram-negative organisms 038.40 Septicemia due to gram negative organisms unspecified 038.41 Septicemia due to h. influenzae 038.42 Septicemia due to e. coli 038.43 Septicemia due to pseudomonas 038.44 Septicemia due to serratia 038.49 Other septicemia due to gram-negative organisms 038.8 Other specified septicemias 038.9 Unspecified septicemia 785.52 Septic shock 785.59 Other shock without trauma 790.7 Bacteremia 995.91 Systemic inflammatory response syndrome due to infectious process w/out organ dysfunction 995.92 Systemic inflammatory response syndrome due to infectious process with organ dysfunction 998.0 Postoperative shock not elsewhere classified	• Index admission - principal or secondary discharge diagnosis fields • Readmissions - principal or secondary discharge diagnosis fields

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
Surgical site bleeding	During Index Admission or within 30 days of admission date	998.1 Hemorrhage or hematoma complicating a procedure not elsewhere classified 998.11 Hemorrhage complicating a procedure 998.12 Hematoma complicating a procedure 998.13 Seroma complicating a procedure 719.10 Hemarthrosis site unspecified 719.16 Hemarthrosis involving lower leg 719.17 Hemarthrosis involving ankle and foot 39.98 Control of hemorrhage NOS **One of the above codes AND the following procedure code:** 86.04 Other incision with drainage of skin and subcutaneous tissue	• Index admission - principal or secondary discharge diagnosis fields • Readmissions - principal or secondary discharge diagnosis fields
Pulmonary embolism	During Index Admission or within 30 days of admission date	415.1 Pulmonary embolism and infarction 415.11 Iatrogenic pulmonary embolism and infarction 415.19 Other pulmonary embolism and infarction	• Index admission - principal or secondary discharge diagnosis fields • Readmissions - principal or secondary discharge diagnosis fields
Death	During Index Admission or within 30 days of admission date	N/A	N/A

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
Mechanical complications	During Index Admission or within 90 days of admission date	996.4 Mechanical complication of internal orthopedic device implant and graft 996.40 Unspecified mechanical complication of internal orthopedic device, implant, and graft 996.41 Mechanical loosening of prosthetic joint 996.42 Dislocation of prosthetic joint 996.44 Peri-prosthetic fracture around prosthetic joint 996.47 Other mechanical complication of prosthetic joint implant 996.49 Other mechanical complication of other internal orthopedic device, implant, and graft	• Index admission - secondary discharge diagnosis field • Readmissions - principal or secondary discharge diagnosis fields
Periprosthetic Joint Infection / Wound Infection	During Index Admission or within 90 days of admission date	998.6 Persistent postoperative fistula not elsewhere classified 998.83 Non-healing surgical wound 998.3 Disruption of wound 998.30 Disruption of wound, unspecified 998.31 Disruption of internal operation (surgical) wound 998.32 Disruption of external operation (surgical) wound 998.33 Disruption of traumatic wound repair 998.5 Postoperative infection not elsewhere classified 998.51 Infected postoperative seroma 998.59 Other postoperative infection 996.67 Infection and inflammatory reaction due to other internal orthopedic device implant and graft 996.66 Infection and inflammatory reaction due to internal joint prosthesis **One of the above codes AND at least one of the following procedure codes:** 86.22 Excisional debridement of wound, infection, or burn 86.28 Non-excisional debridement of wound, infection, or burn 86.04 Other incision with drainage of skin and subcutaneous tissue 81.53 Revise Hip Replacement, NOS 81.55 Revision of Knee replacement, NOS 81.59 Revision of joint replacement of lower extremity, not elsewhere classified 00.70 REV Hip Repl-acetab/fem	• Index admission - principal or secondary discharge diagnosis fields • Readmissions - principal or secondary discharge diagnosis fields

Complication	Follow-up Period in Days*	ICD-9 Codes Defining Complication	Required Coding Placement
		00.71 REV Hip Repl-acetab comp 00.72 REV Hip Repl-fem comp 00.73 REV Hip Repl-liner/head 00.80 Replacement of femoral, tibial, and patellar components (all components) 00.81 Replacement of tibial baseplate and tibial insert (liner) 00.82 Revision of knee replacement, femoral component 00.83 Revision of knee replacement, patellar component 00.84 Revision of total knee replacement, tibial insert (liner) 80.05 Arthrotomy for removal of prosthesis, hip 80.06 Arthrotomy for removal of prosthesis, knee 80.09 Arthrotomy for removal of prosthesis, other unspecified sites 78.65 Removal of implanted devices for femur 78.66 Removal of implanted devices from bone; patella 78.67 Removal of implanted devices from bone; tibia and fibula	

2.6 Overview of Risk Adjustment

The goal of risk adjustment is to account for patient age, whether the patient had one or two procedures, and comorbid conditions that are clinically relevant and have strong relationships with the outcome while illuminating important quality differences between hospitals. The measure adjusts for case-mix differences based on the clinical status of the patient at the time of admission. Conditions that may represent adverse outcomes due to care received during the index admission are not considered for inclusion in the risk adjustment. Although they may increase the risk of mortality and complications, including them as covariates in risk adjustment could attenuate the measure's ability to characterize the quality of care delivered by hospitals. Appendix C lists the conditions not adjusted for if they only appear in the index admission and not in the 12 months prior to admission.

Comorbidities for inclusion in risk adjustment are identified in administrative claims during the 12 months prior to and including the index admission. To assemble the more than 15,000 ICD-9 codes into clinically coherent variables for risk adjustment, the measure employs the publicly available CMS hierarchical condition categories (CCs) to group codes into CCs[16], and selects comorbidities for inclusion in risk adjustment on the basis of clinical relevance and statistical significance. A detailed description of the risk adjustment methodology is provided in Appendix A, Section II. g.

Additionally, the measure does not adjust for the patients' admission source or their discharge disposition (e.g. skilled nursing facility) because these factors are associated with the structure of the health care system, not solely patients' clinical risk factors. Regional differences in resource availability and practice patterns may exert an undue influence on model results. Moreover, the accuracy of these admission and discharge disposition codes is not known. The measure does not adjust for socioeconomic status (SES), race or ethnicity. Variation in quality associated with these characteristics may be indicative of disparities in the quality of the care provided to vulnerable populations, and adjusting for these factors would obscure these disparities. The measure does not adjust for hospital characteristics either (e.g., teaching status) since this would hold different types of hospitals to different quality standards, and because such characteristics may exist on a causal pathway to the outcome, rather than act as confounders. This approach is consistent with NQF guidelines (http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx).

2.7 Model Performance Testing

Two summary statistics were computed to assess model performance in each year of data: discrimination in terms of predictive ability and discrimination in terms of C statistic (area under the receiver operating curve [ROC]). Further

performance testing results from initial measure development are provided in Appendix A.

Discrimination in predictive ability measures the model's ability to distinguish high-risk subjects from low-risk subjects. Good model discrimination is indicated by a wide range between the lowest decile and highest decile.

The C statistic is a measure of the extent a statistical model is able to distinguish between a patient with and without an outcome. A C statistic of 0.50 indicates random prediction, implying all patient risk factors are useless. A C statistic of 1.0 indicates perfect prediction, implying patients' outcomes can be predicted completely by their risk factors, and physicians and hospitals play no role in patients' outcomes. Although a higher C statistic is desirable, we would not want to maximize model discrimination by adjusting for hospital and physician characteristics that may influence the outcome.

To assess model performance across years, we computed model performance statistics for each calendar year of data (2008, 2009, and 2010) and for the three-year combined period (2008-2010). Logistic regression models were used during this step as we are interested in the model's capability of predicting the outcome using selected risk adjusters prior to assessing hospital specific effects.

2.8 Statistical Approach to Measure Calculation

The measure estimates hospital-level RSCRs using a hierarchical logistic regression model. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals. The patient level models the log-odds of a complication adjusting for age, sex, selected clinical covariates, and a hospital-specific intercept. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital specific-intercept represents the underlying risk of a complication at that hospital, after accounting for patient risk. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSCR is calculated as the ratio of the number of "predicted" to the number of "expected" admissions with a complication, multiplied by the national unadjusted complication rate. For each hospital, the numerator of the ratio is the number of admissions with a complication predicted on the basis of the hospital's performance with its observed case-mix, and the denominator is the number of admissions with a complication expected on the basis of the nation's performance with that hospital's case-mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case-mix to an average hospital's performance with the same case-mix. Thus

a lower ratio indicates lower-than-expected complication rate or better quality and a higher ratio indicates higher-than-expected complication rate or worse quality.

After regressing the risk factors and the hospital specific intercept on the risk of a complication, the predicted number of admissions with a complication (the numerator) is calculated by summing the estimated regression coefficients multiplied by the patient characteristics, adding the estimated hospital specific intercept, transforming this value to the probability scale, and then summing over all patients attributed to the hospital to get the predicted value. The expected number of admissions with a complication (the denominator) is obtained by summing the estimated regression coefficients multiplied by the patient characteristics observed in the hospital, adding the estimated average hospital intercept, transforming to the probability scale and then summing over all patients in the hospital to get the expected value.

Please refer to Appendix A, Section II. h. for further technical details.

2.9 Hospital Performance Reporting

For each hospital, we use bootstrapping simulations to compute a 95% interval estimate of the RSCR to characterize the level of uncertainty around the specific point estimate. The point estimate and interval estimate can be used to characterize and compare a hospital's performance (e.g. higher than expected, as expected, or lower than expected) to an average hospital with a similar case-mix. Please refer to Appendix A, Section II. i. for technical details.

3. RESULTS

3.1 Frequency of Model Variables

We examined the temporal variation in both overall complications rates and frequency of clinical and demographic variables. Between 2008 and 2010, the crude complications rate remained stable at approximately 3.6% (Table 2). During this time period, no risk factor frequency changed by more than 1.5 absolute percentage points between 2008 and 2010 (Table 2). The largest relative changes were seen in the percentage of patients with renal failure (CC 131), which increased from 6.7% in 2009 to 7.5% in 2010, the percentage of patients with morbid obesity (ICD-9 code 278.01), which increased from 3.4% in 2008 to 4.1% in 2010, and the percentage of patients having two procedures (versus one), which decreased from 3.3% in 2008 to 2.8% in 2010.

Table 2. Frequency of Model Variables (2008-2010)

Variable	2008 Freq (%)	2009 Freq (%)	2010 Freq (%)	2008-2010 Freq (%)
Number of Admissions	286,442	292,990	298,666	878,098
Number of Hospitals	3,309	3,298	3,325	3,497
Number of Admissions with Complications	10,480	10,452	10,315	31,247
Crude Complications Rate	3.7%	3.6%	3.5%	3.6%
Demographic				
Age-65 (years above 65, continuous)[1]	10.2	10.1	10.1	10.1
Male	35.8	36.0	36.1	36.0
THA/TKA Procedure				
THA procedure	28.2	28.9	28.8	28.6
Number of procedures (two vs. one)	3.3	3.1	2.8	3.1
Comorbid Conditions				
Skeletal deformities (ICD-9 code 755.63)	0.1	0.1	0.2	0.2
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)	0.5	0.5	0.4	0.5
Morbid obesity (ICD-9 code 278.01)	3.4	3.8	4.1	3.8
Metastatic cancer and acute leukemia (CC 7)	0.6	0.5	0.6	0.6
Cancer (CC 8-10)	12.8	12.9	13.0	12.9
Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)	18.0	17.8	17.7	17.8
Diabetes and DM complications (CC 15-20, 119, 120)	27.4	28.0	28.5	27.9
Protein-calorie malnutrition (CC 21)	0.6	0.6	0.7	0.6
Bone/Joint/Muscle Infections/Necrosis (CC 37)	2.8	2.7	2.6	2.7
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)	8.5	8.4	8.7	8.5
Osteoarthritis of Hip or Knee (CC 40)	95.6	95.8	95.8	95.7
Osteoporosis and Other Bone/Cartilage Disorders (CC 41)	24.6	25.1	25.2	25.0
Dementia and senility (CC 49, 50)	4.3	4.3	4.2	4.3
Major psychiatric disorders (CC 54-56)	3.7	3.9	4.1	3.9
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)	1.6	1.6	1.6	1.6
Cardio-Respiratory Failure and Shock (CC 79)	2.0	2.0	2.1	2.0
Chronic Atherosclerosis (CC 83-84)	30.7	30.2	29.4	30.1
Stroke (CC 95, 96)	2.4	2.3	2.3	2.3
Vascular or circulatory disease (CC 104-106)	22.4	22.7	22.7	22.6
COPD (CC 108)	14.6	14.4	14.1	14.3
Pneumonia (CC 111-113)	4.8	4.4	4.3	4.5
Pleural effusion/pneumothorax (CC 114)	1.4	1.5	1.5	1.5
End-stage renal disease or dialysis (CC 129, 130)	0.1	0.1	0.1	0.1
Renal Failure (CC 131)	6.1	6.7	7.5	6.8
Decubitus ulcer or chronic skin ulcer (CC 148, 149)	2.6	2.7	2.6	2.6
Trauma (CC 154-156, 158-161)	4.5	4.6	4.6	4.6
Vertebral Fractures (CC 157)	1.3	1.3	1.3	1.3
Other injuries (CC162)	26.7	27.0	27.4	27.0
Major Complications of Medical Care and Trauma (CC 164)	3.6	3.6	3.6	3.6

[1] Mean number of years over age 65

3.2 Model Parameters and Performance

Table 3 shows the risk-adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for the model variables by individual year and for the combined 2008-2010 calendar year dataset. Overall, the variable effect sizes were relatively constant across years.

Table 4 conveys the model performance statistics. Good discrimination for this model is indicated by a wide range between the lowest decile and highest decile (range is 2% - 8% in all years of data). The C statistic is 0.63 in all three years of data, indicating good discriminant ability.

Table 3. Model Variable Adjusted ORs and 95% CIs (2008-2010 – Hierarchical Logistic Regression Model)

Variable	2008 OR (95% CI)	2009 OR (95% CI)	2010 OR (95% CI)	2008-2010 OR (95% CI)
Demographic				
Age-65 (years above 65, continuous)	1.03 (1.03,1.04)	1.03 (1.03,1.03)	1.03 (1.03,1.03)	1.03 (1.03,1.03)
Male	1.12 (1.08,1.17)	1.14 (1.09,1.19)	1.11 (1.06,1.16)	1.12 (1.10,1.15)
THA/TKA Procedure				
THA procedure	1.47 (1.41,1.53)	1.47 (1.41,1.53)	1.44 (1.38,1.50)	1.46 (1.43,1.50)
Number of procedures (two vs. one)	1.66 (1.51,1.83)	1.65 (1.49,1.83)	1.62 (1.46,1.80)	1.65 (1.56,1.75)
Comorbid Conditions				
Skeletal deformities (ICD-9 code 755.63)	1.47 (0.98,2.19)	1.08 (0.68,1.71)	1.19 (0.79,1.80)	1.25 (0.98,1.60)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)	1.06 (0.81,1.38)	0.77 (0.57,1.05)	1.21 (0.94,1.58)	1.01 (0.86,1.18)
Morbid obesity (ICD-9 code 278.01)	1.33 (1.20,1.46)	1.41 (1.28,1.54)	1.41 (1.30,1.54)	1.38 (1.31,1.46)
Metastatic cancer and acute leukemia (CC 7)	1.09 (0.87,1.36)	1.24 (0.99,1.56)	1.22 (0.98,1.53)	1.19 (1.04,1.36)
Cancer (CC 8-10)	0.98 (0.93,1.04)	0.95 (0.89,1.00)	0.95 (0.90,1.01)	0.96 (0.93,1.00)
Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)	0.90 (0.86,0.95)	0.91 (0.87,0.96)	1.02 (0.97,1.07)	0.95 (0.92,0.97)
Diabetes and DM complications (CC 15-20, 119, 120)	1.15 (1.10,1.20)	1.12 (1.08,1.17)	1.13 (1.08,1.18)	1.13 (1.10,1.16)
Protein-calorie malnutrition (CC 21)	2.88 (2.50,3.31)	2.63 (2.29,3.03)	2.61 (2.28,2.99)	2.66 (2.45,2.88)
Bone/Joint/Muscle Infections/Necrosis (CC 37)	1.18 (1.07,1.30)	1.09 (0.99,1.20)	1.12 (1.01,1.24)	1.13 (1.07,1.20)
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)	1.06 (0.99,1.13)	1.08 (1.01,1.16)	1.06 (0.99,1.13)	1.07 (1.03,1.11)
Osteoarthritis of Hip or Knee (CC 40)	0.89 (0.81,0.97)	0.88 (0.80,0.96)	0.84 (0.77,0.92)	0.87 (0.82,0.92)
Osteoporosis and Other Bone/Cartilage Disorders (CC 41)	0.92 (0.88,0.96)	0.95 (0.91,1.00)	0.94 (0.89,0.98)	0.93 (0.91,0.96)
Dementia and senility (CC 49, 50)	1.24 (1.14,1.34)	1.17 (1.07,1.26)	1.21 (1.11,1.31)	1.20 (1.15,1.26)
Major psychiatric disorders (CC 54-56)	1.26 (1.15,1.37)	1.27 (1.17,1.39)	1.27 (1.17,1.38)	1.26 (1.20,1.33)
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)	1.23 (1.08,1.40)	1.10 (0.96,1.26)	1.07 (0.93,1.23)	1.13 (1.04,1.22)
Cardio-Respiratory Failure and Shock (CC 79)	1.21 (1.09,1.35)	1.17 (1.05,1.30)	1.31 (1.18,1.45)	1.23 (1.15,1.31)
Chronic Atherosclerosis (CC 83-84)	1.29 (1.23,1.34)	1.30 (1.24,1.35)	1.21 (1.16,1.26)	1.27 (1.24,1.30)
Stroke (CC 95, 96)	1.04 (0.94,1.16)	0.98 (0.87,1.10)	0.96 (0.85,1.08)	1.00 (0.93,1.06)
Vascular or circulatory disease (CC 104-106)	1.16 (1.10,1.21)	1.19 (1.14,1.24)	1.20 (1.15,1.25)	1.18 (1.15,1.21)
COPD (CC 108)	1.41 (1.34,1.48)	1.39 (1.32,1.45)	1.39 (1.32,1.46)	1.39 (1.35,1.43)
Pneumonia (CC 111-113)	1.28 (1.19,1.38)	1.31 (1.21,1.41)	1.24 (1.15,1.34)	1.28 (1.22,1.34)
Pleural effusion/pneumothorax (CC 114)	1.02 (0.90,1.16)	1.05 (0.93,1.19)	1.03 (0.91,1.17)	1.03 (0.96,1.11)
End-stage renal disease or dialysis (CC 129, 130)	2.16 (1.63,2.88)	1.57 (1.14,2.18)	1.30 (0.93,1.82)	1.67 (1.39,2.01)
Renal Failure (CC 131)	1.17 (1.09,1.26)	1.23 (1.15,1.32)	1.25 (1.18,1.34)	1.21 (1.17,1.26)
Decubitus ulcer or chronic skin ulcer (CC 148, 149)	1.24 (1.12,1.36)	1.19 (1.08,1.31)	1.37 (1.24,1.50)	1.27 (1.20,1.34)
Trauma (CC 154-156, 158-161)	1.21 (1.12,1.31)	1.23 (1.13,1.33)	1.22 (1.13,1.32)	1.22 (1.16,1.27)
Vertebral Fractures (CC 157)	1.18 (1.02,1.35)	1.19 (1.04,1.37)	1.19 (1.04,1.38)	1.19 (1.09,1.29)
Other injuries (CC162)	1.08 (1.04,1.13)	1.07 (1.03,1.12)	1.03 (0.99,1.08)	1.06 (1.03,1.09)
Major Complications of Medical Care and Trauma (CC 164)	1.18 (1.09,1.29)	1.21 (1.11,1.32)	1.16 (1.06,1.27)	1.19 (1.13,1.25)

Table 4. Model Performance (Logistic Regression Model)

Indices	2008	2009	2010	2008-2010
Discrimination -Predictive Ability (lowest decile %, highest decile %)	(2%, 8%)	(2%, 8%)	(2%, 8%)	(2%, 8%)
Discrimination – Area Under Receiver Operator Curve (C-statistic)	0.63	0.63	0.63	0.63

3.3 Distribution of Hospital Volumes and RSCRs

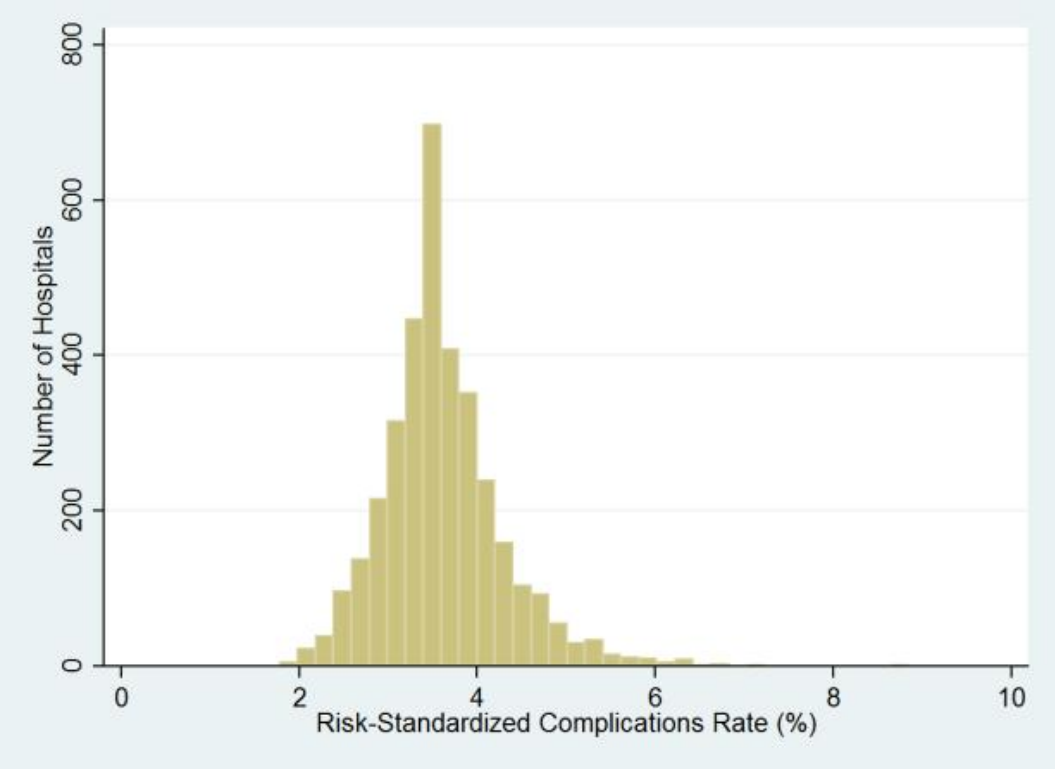
Table 5 shows the distributions of hospital volumes and hospital RSCRs, as well as the between-hospital variance, by individual year and for the combined 2008-2010 calendar year dataset. Between 2008 and 2010, mean elective primary THA/TKA volume increased from 87 to 90 admissions per hospital. The mean RSCR was stable across the three year time period. The mean hospital RSCR in the combined three-year dataset was 3.6% (range: 1.8% to 9.0%). The median RSCR was 3.5%. Between-hospital variance in the combined dataset was 0.11 (SE: 0.01). If there were no systematic differences between hospitals, the between hospital variance would be 0.

Figure 2 shows the overall distribution of the hospital RSCRs for the combined 2008-2010 calendar year dataset. The odds of a complication if treated at a hospital one standard deviation above the national average were 1.93 times higher than the odds of a complication if treated at a hospital one standard deviation below the national average.

Table 5. Distribution of Hospital Volumes and RSCRs

Characteristic	2008	2009	2010	2008-2010
Number of Hospitals	3,309	3,298	3,325	3,497
Hospital Volume				
Mean (SD)	87 (118)	89 (121)	90 (123)	251 (354)
Range (min. – max.)	(1-2,627)	(1-2,724)	(1-2,853)	(1-8,204)
25th percentile	15	16	16	39
50th percentile	47	48	48	130
75th percentile	114	117	119	332
RSCR (%)				
Mean (SD)	3.7 (0.57)	3.6 (0.58)	3.5 (0.54)	3.6 (0.70)
Range (min. – max.)	(1.8-7.6)	(1.9-6.7)	(1.8-7.8)	(1.8-9.0)
25th percentile	3.4	3.3	3.2	3.2
50th percentile	3.6	3.5	3.4	3.5
75th percentile	4.0	3.9	3.7	3.9
Between Hospital Variance (SE)	0.12(0.01)	0.12(0.01)	0.11(0.01)	0.11(0.01)

Figure 2. Distribution of Hospital-Specific Risk-Standardized Complication Rates (2008-2010 Cohort; N=3497 Hospitals) - Hierarchical Logistic Regression Model



4. MAIN FINDINGS / SUMMARY

This NQF-endorsed quality outcomes measure has the potential to significantly improve the quality of care delivered to patients undergoing elective primary THA and/or TKA procedures. It will inform healthcare providers about opportunities to improve care, and strengthen incentives for targeted quality and safety improvement efforts. Improvements in inpatient care and care transitions for this common, costly procedure are likely to reduce complications. The mean hospital RSCR was 3.6%, and there was considerable variation in RSCRs across hospitals, supporting the existence of differences in care quality.

This measure is consistent with the consensus standards for publicly reported outcomes measures, and can be implemented using available data. This measure was developed with input from experts with clinical and methodological expertise relevant to orthopedic quality measurement. The cohort for inclusion in the measure is homogeneous, comprised of patients undergoing elective primary THA and/or TKA and will allow for valid comparisons of hospital quality across institutions. We excluded covariates that are not appropriate for inclusion in a quality measure, such as race, SES, and hospital-level factors (e.g., hospital bed size and volume of arthroplasty cases). The hierarchical modeling accounts for hospital case-mix, the clustering of patients within hospitals, and differences in sample size across hospitals, thereby making the measure suitable for public reporting.

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6. APPENDIX

Appendix A: Technical Measure Development and Validation Process

I. INTRODUCTION TO APPENDIX A

The purpose of this appendix is to provide the detailed methodology used to develop and validate the initial logistic regression model and calculate the RSCRs.

The logistic regression model presented in this appendix report was developed in 2009-2010 using 2008 Medicare administrative claims. The original cohort exclusions and specifications of certain complications were revised in 2011 based on feedback received during NQF review and on findings from a validation study of a sample of administrative elective primary THA and/or TKA claims both with and without complications (full report provided in Appendix E). YNHHSC/CORE conducted the validation study in 2010-2011 under contract with CMS.

Specific topics discussed in this appendix include the original cohort definition for inclusion in the measure (Section II. b.), selection of the individual complications and follow-up periods, (Sections II. c - d.), the risk-adjustment methodology (Section II. f - g), and the methods to test model reliability (Section III. f. ii.) and validity (Section III. f. iii.).

Each section details the decisions made, the rationale for those decisions, and any subsequent changes incorporated into the current measure (described in the main body of the report).

II. METHODS FOR MEASURE DEVELOPMENT

a. Data Sources (Measure Development)

The data sources used to develop the logistic regression model are detailed in the main report Section 2.2. For measure development, using Part A administrative claims data, the measure identified hospitalizations for patients aged 65 years and older who underwent an elective primary THA and/or TKA in 2008. Comorbidities were identified via Part A inpatient and outpatient and Part B outpatient claims in the 12 months prior to and including the index admission. Enrollment and post-discharge mortality status were obtained from Medicare's Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information.

b. Cohort Definition (Measure Development)

We considered whether to develop separate measures for patients undergoing THA and TKA procedures or to combine patients undergoing either procedure into a single hospital quality measure. To inform that decision, we consulted with the working group and conducted analyses to examine the average length of stay, as well as mortality, complication, and readmission rates for each procedure.

Based on those analyses (provided in Table A.1), and in consultation with the working group, we combined these patient cohorts for the complications measure for several reasons including:

- A large proportion of THA and TKA procedures are elective and performed in similar patient cohorts for similar indications (e.g., osteoarthritis)
- The same surgeons frequently perform both procedures
- Both procedures have similar lengths of stay
- The rates and types of complications are similar
- The mortality and readmission rates are similar
- Hospitals develop protocols/programs for lower extremity total joint arthroplasty, rather than for THA and TKA separately
- Combining admissions for both procedures will provide greater power to detect hospital-level variation to enable quality improvement

Table A.1 Procedure Characteristics and Unadjusted Mortality, Readmission, and Complication Rates for THA and TKA (Medicare Inpatient Part A, 2008)

		Total Hip Replacement* (excludes partial hip replacement and hip fractures)	Total Knee Replacement**
Procedure-related characteristics			
Number of Patients Receiving Procedure		97,130	240,517
Mean Length of Stay (SD)		3.8 (2.3)	3.6 (1.7)
Mean Patient Age (SD)		75.2 (6.6)	74.2 (6.1)
Number of Hospitals Performing Procedure		3083	3307
Median Number of Procedures Performed at Each Hospital (Q1-Q3)		16 (6 - 41)	40 (13 - 257)
Mortality		**% (5th-95th)**	**% (5th-95th)**
In-hospital Mortality	Patient level	0.2	0.1
	Hospital level: median	0 (0 - 0.9)	0 (0 - 0.6)
30-day Mortality	Patient level	0.5	0.3
	Hospital level: median	0 (0 - 2.9)	0 (0 - 1.7)
90-day Mortality	Patient level	0.9	0.5
	Hospital level: median	0 (0 - 5.6)	0 (0 - 3.0)
Readmission		**% (5th-95th)**	**% (5th-95th)**
30-day All-cause Readmission	Patient level	6.9	5.9
	Hospital level: median	5 (0 - 25)	5 (0 - 18)
90-day All-cause Readmission	Patient level	12.2	10.7
	Hospital level: median	11 (0 - 38)	10 (0 - 27)
Complications		**% (30-day / 90-day)**	**% (30-day / 90-**
Dislocation		0.8 / 1.1	0.1 / 0.1
DVT		0.1 /0.2	0.2 / 0.2
Hematoma		1.9 / 2.0	1.2 / 1.3
Periprosthetic Joint Infection		0.5 / 0.7	0.4 / 0.6
Postoperative infection		0.8 / 1.0	0.7 / 0.8
Pulmonary Embolism		0.5 / 0.7	0.8 / 1.0
Mechanical complication of internal orthopedic device, implant and graft		2.7 / 3.3	0.3 / 0.4
Venous thrombosis		0.1 / 0.2	0.1 / 0.1
Wound Infection		0.7 / 0.9	0.7 / 0.8
All complications combined		5.8 / 7.0	3.4 / 4.1
* Includes ICD-9 code 81.51 ** Incudes ICD-9 code 81.54			

i. Inclusion Criteria (Measure Development)

Patients eligible for inclusion in the measure were those aged 65 and older electively admitted to non-federal acute care hospitals with an ICD-9 procedure code for THA and/or TKA in 2008.

Eligible index admissions are identified using the following ICD-9-CM procedure codes in Medicare Part A inpatient claims data:

- 81.51 Total Hip Arthroplasty
- 81.54 Total Knee Arthroplasty

ii. Exclusion Criteria (Measure Development)

To identify a cohort of elective THA and/or TKA procedures, the original measure specifications excluded admissions for patients:

1. With hip fractures coded in the principal discharge diagnosis field for the index admission
   Rationale: Patients with hip fractures have higher mortality, complication, and readmission rates and the procedures are not elective.

2. Undergoing partial hip arthroplasty (PHA) procedures (with or without a concurrent THA/TKA)
   Rationale: Partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions.

3. Undergoing revision procedures (with or without a concurrent THA/TKA)
   Rationale: Revision procedures may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication, and readmission rates.

4. Undergoing resurfacing procedures (with or without a concurrent THA/TKA)
   Rationale: Resurfacing procedures are a different type of procedure where only the joint's articular surface is replaced. A THA involves surgical removal of the neck of the femur (thighbone) and insertion of a stem deep inside the bone to connect with the pelvic socket and liner. These procedures are typically performed on younger, healthier patients.

After excluding the above admissions, the measure also excluded the following admissions for patients:

5. Without at least 12 months pre-index admission enrollment in Medicare FFS
   Rationale: Appropriate risk adjustment requires uniform data availability of pre-operative comorbidity

6. Who were transferred in to the index hospital
   Rationale: If the patient is transferred from another acute care facility to the hospital where the index procedure occurs, it is likely that the procedure is not elective or that the admission is associated with an acute condition.

7. Who leave the hospital against medical advice (AMA)
   Rationale: Hospitals and physicians do not have the opportunity to provide the highest quality care for these patients.

8. With more than two THA/TKA procedures codes during the index hospitalization
   Rationale: It is unlikely that patients would receive more than two THA/TKA procedures in one hospitalization, and this may reflect a coding error.

9. Multiple admissions for these procedures for a single patient in the 12 months studied; one hospitalization per patient was randomly selected for inclusion after applying the other exclusion criteria.

The flow chart depicting cohort selection for the measure as originally specified is presented in Figure A.1 . Appendix C lists the ICD-9 codes for hip fracture, revision procedures, partial hip arthroplasty procedures, and resurfacing procedures.

iii. Changes to the Original Cohort Exclusions

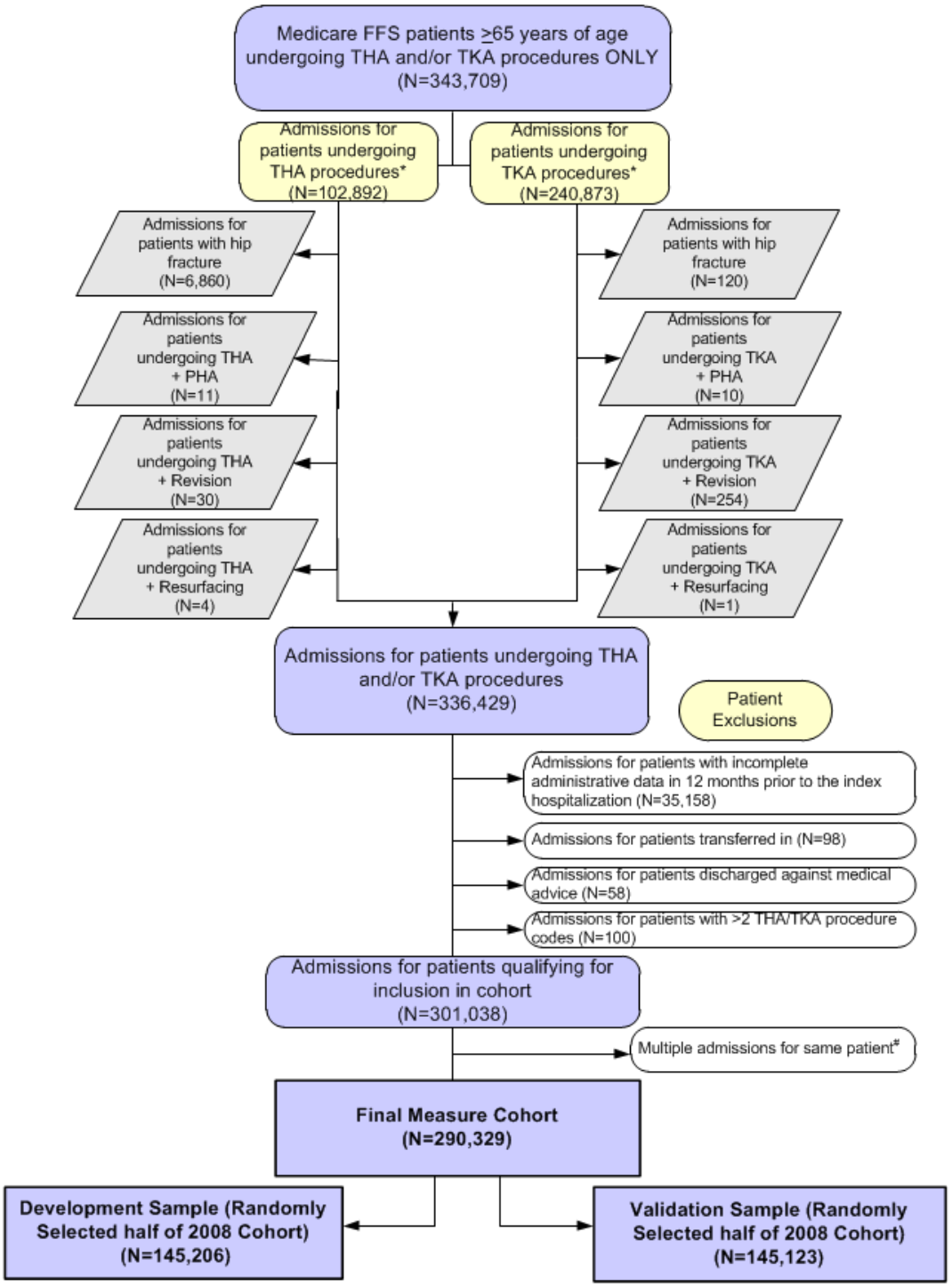
Based on feedback we received during the NQF public comment period and findings from the medical record validation study, we excluded additional patients from the measure cohort. These changes are reflected in the current specifications detailed in the main report. We excluded patients who had an ICD-9 code for one of the following conditions in the principal discharge diagnosis field during the index admission (please see shaded rows in Appendix B):

- mechanical complication;
- femur and pelvic fractures; and
- malignant neoplasm of the pelvic bones, sacrum, coccyx, lower limbs, bone and bone marrow, and disseminated malignant neoplasms.

We also excluded patients who had an ICD-9 code for one of the following procedures in a secondary diagnosis field during the index admission (please see shaded rows in Appendix B):

- removal of implanted device from femur, patella, tibia, fibula; and
- arthrotomy for removal of prosthesis (femur and knee, and non-specified site).

Figure A.1 Cohort for Measure Development (2008 Medicare FFS Patients)



*THA and TKA are presented separately for illustrative purposes and are not mutually exclusive

#Randomly selected and kept in the cohort one of multiple admissions for the same patient

c. Outcome Definition (Measure Development)

The outcome for this measure is binary (yes for any complication(s); no for no complications). Therefore, if a patient experiences one or more complications, the outcome variable is coded as a "yes." We selected complications that were clinically significant, attributable to the THA/TKA procedure and accurately identified in claims data. Please refer to the report Section 2.3 for details regarding the current measure specifications.

i. Selection of Complications for Inclusion in Outcome

We identified complications for potential inclusion in the measure from the medical literature and in consultation with the working group. To be considered as candidates for inclusion in the outcome, the complications had to:

- Represent meaningful complications attributable to the THA/TKA procedures
- Be identifiable in administrative claims data
- Be fair to hospitals and physicians

Based on these criteria and in consultation with the working group, we identified several *candidate* complications for inclusion in a composite complications measure:

- Death
- Mechanical complications
- Periprosthetic joint infection
- Surgical site bleeding
- Wound infection
- Pulmonary embolism
- AMI
- Pneumonia
- Sepsis/septicemia
- Deep vein thrombosis (DVT)
- Urinary tract infection (UTI)

Along with surgical complications, we considered the following medical complications for inclusion in the measure, as they are important in measuring overall quality: AMI, pneumonia, sepsis/septicemia, DVT and UTI. However, DVT and UTI were excluded based on working group feedback and limitations documented in the literature. We excluded DVT because there is wide variability in screening and readmission practices for this complication across hospitals. [17,18] We also excluded UTI because there is similarly wide variability in screening for and diagnosing UTI, and the rates are likely inflated due to over-diagnosis in patients post THA/TKA.[19]

Based on these considerations, we included the following complications in the measure:

- Death
- Mechanical complications
- Periprosthetic joint infection
- Surgical site bleeding
- Wound infection
- Pulmonary embolism
- AMI
- Pneumonia
- Sepsis/septicemia

d. Selection of Measure Timeframe (Measure Development)

Complications are counted if they occur during the index admission, or require a readmission. The measure does not count complications that occur in the outpatient setting and do not require a readmission.

To determine the appropriate follow-up periods, we obtained clinical input and examined 90-day trends in complication rates (Figures A.2 and A.3). Figure A.2 conveys the rates for mortality and surgical complications occurring from the date of index admission to 90 days post the date of the index admission. Figure A.3 conveys the rates for medical complications occurring from the date of index admission to 90 days post the date of the index admission. These analyses indicated that these complications occur most commonly within 7 days following the procedure, but the rates continue to decline, leveling off at approximately 30 days. Although a standardized period of follow-up is ideal, defining a single optimal period of assessment appropriate for a wide range of clinical complications was challenging. For example, the working group and TEP agreed that mechanical complications, wound infection, and periprosthetic joint infection are still attributable to the procedure for up to 90 days following the procedure, while medical complications, such as AMI, are far less likely to be attributable to the procedure after 7 days. Both the working group and TEP advised that we establish complication-specific follow-up periods. Accordingly, we reviewed each complication with the working group and TEP and chose either a 7, 30, or 90 day follow-up period by consensus from clinical experts.

The measure follow-up period is 90 days for the following complications: mechanical complications, wound infection and periprosthetic joint infection as these complications are still attributable to the index THA/TKA for up to 90 days following THA/TKA. Preliminary analyses indicated rates for mechanical complications are elevated until 90 days post admission to the index hospital.

The measure follow-up period is 30 days for: death, surgical site bleeding, and pulmonary embolism as rates of these complications are elevated until

approximately 30 days post admission to the index hospital. This finding was consistent with input from clinical experts.

The measure follow-up period for AMI, pneumonia, and sepsis/septicemia is 7 days after admission to the index hospital. These conditions are more likely to be attributable to the procedure if they occur within the first week after the procedure. Analyses indicated that the rate for these complications decreases sharply 7 days from the date of index admission, and a 7-day follow-up period limits overlap with the 30-day all-cause readmission measure for elective primary THA/TKA.

For complications occurring during the index admission, it is not possible to determine the exact date on which the complication occurred. Therefore, if the length of stay for the index admission exceeds the follow up period for a specific complication and that complication occurs during the index admission, the measure counts it in the outcome. For example, if a patient has a length of stay of 15 days for the index admission and has an AMI on day 10, the measure will count the AMI as a complication, although the specified follow-up period is 7 days.

Figure A.2 Trend in Mortality and Surgical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)

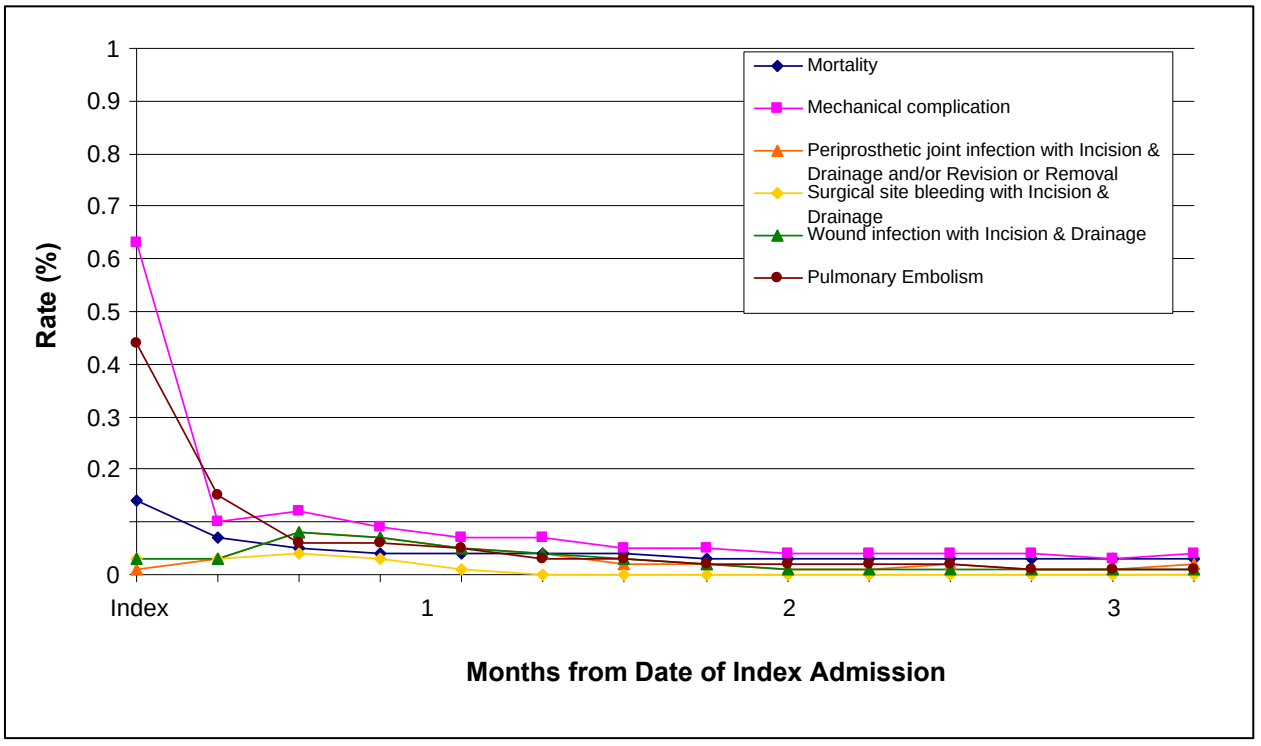
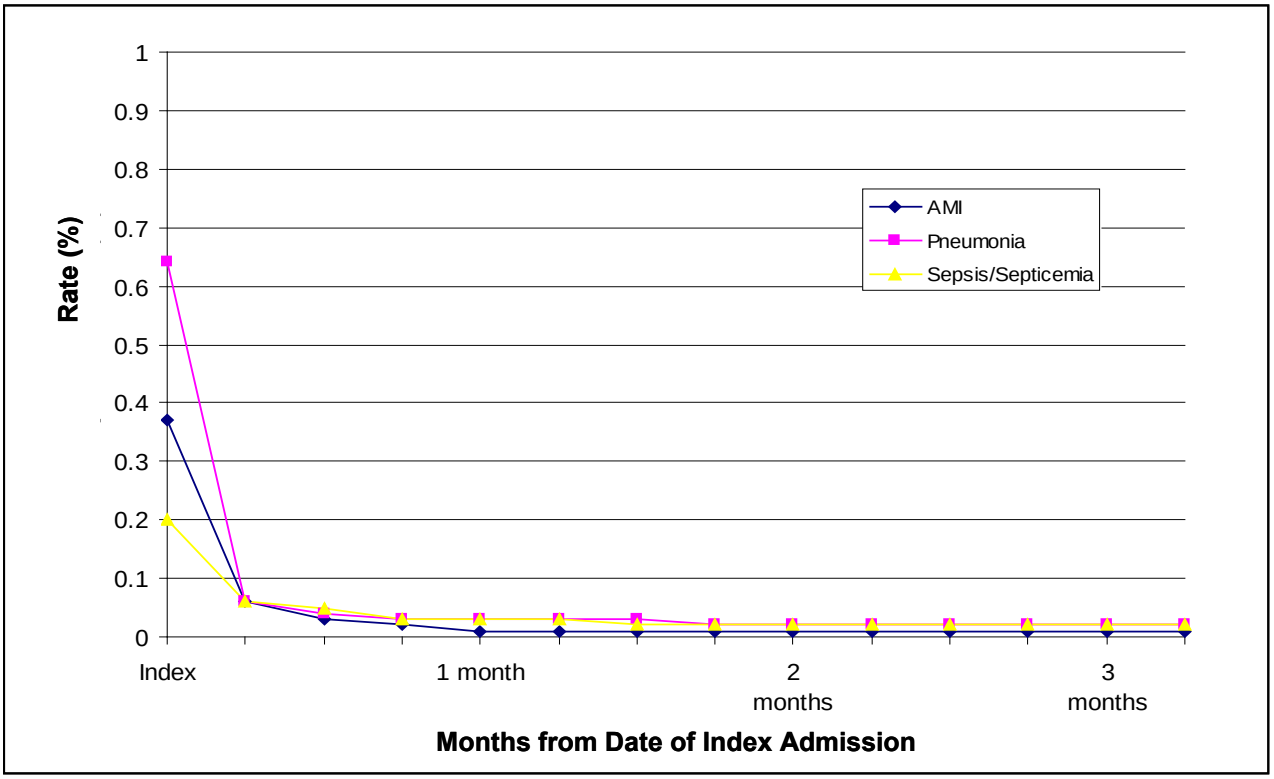


Figure A.3 Trend in Medical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)



i. Changes to Original Outcome Definition

We made the following changes to the original complication specifications based on the medical record validation study (detailed in Appendix E):

- combined periprosthetic joint infection and wound infection into one complication because it is often difficult to distinguish between periprosthetic joint infections and wound infections and the codes for both are frequently used interchangeably;
- removed ICD-9 code 998.59 from the specifications for identifying cases of sepsis because it is a non-specific code that identified cases that were not true cases of sepsis; and
- changed the title of "Sepsis/Septicemia" to Sepsis/Septicemia/Shock" because the measure specifications for sepsis include shock codes, but this was not reflected in the title.

These changes are reflected in the current measure specifications for the dry run, and the ICD-9 codes used to identify these complications and the follow-up periods are listed in Table 1 in Section 2.5.

e. Development and Validation Overview (Measure Development)

We stratified by hospital and randomly selected 50% of the THA and/or TKA admissions in 2008 that met all inclusion and exclusion criteria and created a model "development sample" which we used to select risk-adjustment variables and build the logistic regression model. The performance of the model was then evaluated using patients contained in the other half of the 2008 administrative dataset. To assess stability of the model over time, we also evaluated the model using all eligible THA and/or TKA hospitalizations from 2007.

f. Approach to Risk-Adjustment (Measure Development)

The goal of risk adjustment is to account for patient age and comorbid conditions at the time of admission that are clinically relevant and have strong relationships with the outcome while illuminating important quality differences. Conditions that may represent adverse outcomes due to care received during the index admission are not considered for inclusion in the risk-adjusted model. Although they may increase the risk of mortality and complications, including them as covariates in a risk-adjusted model could attenuate the measure's ability to characterize the quality of care delivered by hospitals. Appendix C lists the conditions not adjusted for if they are coded only during the index admission and not in the 12 months prior to admission.

g. Candidate and Final Variables for Inclusion in Risk-Adjustment (Measure Development)

i. Candidate Variable Selection

The goal of risk adjustment was to develop a parsimonious model that included clinically relevant variables that are strongly associated with risk of complications. The candidate variables for the model were derived from: the index admission, with comorbidities identified from the index admission secondary diagnoses (excluding potential complications), 12-month pre-index Part A inpatient and outpatient data, and Part B outpatient hospital data and physician data.

For model development, YNHHSC/CORE clinicians reviewed the 189 CCs, which are clinically relevant diagnostic groups of the more than 15,000 ICD-9 codes.[16] They used the April 2010 version of the ICD-9 to CC assignment map, which is maintained by CMS and posted at www.qualitynet.org.

To select candidate variables, clinicians reviewed all 189 CCs and excluded those that were not relevant to the Medicare population (Appendix D) or that were not clinically relevant to the complications

outcome (e.g., attention deficit disorder, female infertility, cataract). Clinically relevant CCs were selected as candidate variables. CCs with high clinical relevance to the outcome were broken out and certain conditions within that CC were examined separately when clinically indicated. For example, obesity and morbid obesity are known risk factors for complications following THA/TKA. We examined the effect on the outcome for these conditions after separating them from the CC. Based on these analyses and expert feedback, morbid obesity was separated from CC 24 (obesity and other endocrine/metabolic/nutritional disorders) and included in the risk adjusted model independently. Other CCs were combined into clinically coherent groups. Other candidate variables included age, sex, type of procedure (THA, TKA or both), and number of procedures (1 versus 2) and are listed in Table A.2.

Table A.2 THA/TKA Complications Measure Candidate Model Variables

Category	Variable	ICD-9 Code(s) or CC(s)
Demographic	Age-65 (years above 65, continuous)	
	Sex	
Procedure	Type of procedure	ICD-9-CM 81.51 (THA)
		ICD-9-CM 81.54 (TKA)
	Number of procedures (1 versus 2)	
Comorbidities	Skeletal deformities	ICD-9-CM 755.63
	Post traumatic osteoarthritis	ICD-9-CM 716.15, 716.16
	Morbid obesity	ICD-9-CM 278.01
	History of Infection	CC 1, 3-6
	Septicemia/shock	CC 2
	Metastatic cancer and acute leukemia	CC 7
	Cancer	CC 8-10
	Respiratory/Heart/Digestive/Urinary/Other Neoplasms	CC 11-13
	Benign neoplasms of skin, breast, eye	CC 14
	Diabetes and DM complications	CC 15-20, 119, 120
	Protein-calorie malnutrition	CC 21
	Disorders of Fluid/Electrolyte/Acid-Base	CC 22, 23
	Obesity/disorders of thyroid, cholesterol, lipids	CC 24
	Liver and biliary disease	CC 25-30
	Intestinal Obstruction/Perforation	CC 31
	Pancreatic Disease	CC 32
	Inflammatory Bowel Disease	CC 33
	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	CC 34
	Appendicitis	CC 35
	Other Gastrointestinal Disorders	CC 36
	Bone/Joint/Muscle Infections/Necrosis	CC 37
	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	CC 38
	Disorders of the Vertebrae and Spinal Discs	CC 39
	Osteoarthritis of Hip and Knee	CC 40

Category	Variable	ICD-9 Code(s) or CC(s)
	Osteoporosis and Other Bone/Cartilage Disorders	CC 41
	Congenital/Developmental Skeletal and Connective Tissue Disorders	CC 42
	Other Musculoskeletal and Connective Tissue Disorders	CC 43
	Severe Hematological Disorders	CC 44
	Disorders of Immunity	CC 45
	Coagulation Defects and Other Specified Hematological Disorders	CC 46
	Iron Deficiency and Other/Unspecified Anemias and Blood Disease	CC 47
	Delirium and Encephalopathy	CC 48
	Dementia and senility	CC 49, 50
	Drug/alcohol abuse/dependence/psychosis	CC 51-53
	Major psychiatric Disorders	CC 54-56
	Personality Disorders	CC 57
	Depression	CC 58
	Anxiety Disorders	CC 59
	Other psychiatric disorders	CC 60
	Mental retardation or developmental disability	CC 61-65
	Hemiplegia, paraplegia, paralysis, functional disability	CC 67-69, 100-102, 177-178
	Muscular Dystrophy	CC 70
	Polyneuropathy	CC 71
	Multiple Sclerosis	CC 72
	Parkinson's and Huntington's Diseases	CC 73
	Seizure Disorders and Convulsions	CC 74
	Coma, Brain Compression/Anoxic Damage	CC 75
	Mononeuropathy, Other Neurological Conditions/Injuries	CC 76
	Respirator Dependence/Tracheostomy Status	CC 77
	Respiratory Arrest	CC 78
	Cardio-Respiratory Failure and Shock	CC 79
	Congestive Heart Failure	CC 80
	Acute Coronary Syndrome	CC 81-82
	Chronic Atherosclerosis	CC 83-84
	Heart Infection/Inflammation, Except Rheumatic	CC 85
	Valvular and Rheumatic Heart Disease	CC 86
	Congenital cardiac/circulatory defect	CC 87-88
	Hypertension	CC 89, 91
	Hypertensive heart disease	CC 90
	Arrhythmias	CC 92, 93
	Other and Unspecified Heart Disease	CC 94
	Stroke	CC 95, 96
	Cerebrovascular disease	CC 97-99, 103
	Vascular or circulatory disease	CC 104-106
	Cystic fibrosis	CC 107
	COPD	CC 108
	Fibrosis of lung or other chronic lung disorder	CC 109
	Asthma	CC 110
	Pneumonia	CC 111-113

Category	Variable	ICD-9 Code(s) or CC(s)
	Pleural effusion/pneumothorax	CC 114
	Other lung disorder	CC 115
	Legally Blind	CC 116
	Major eye infections/inflammations	CC 117
	Retinal detachments	CC 118
	Retinal Disorders, Except Detachment and Vascular Retinopathies	CC 121
	Glaucoma	CC 122
	Other Eye Disorders	CC 124
	Significant Ear, Nose, and Throat Disorders	CC 125
	Hearing Loss	CC 126
	Other Ear, Nose, Throat, and Mouth Disorders	CC 127
	Kidney Transplant Status	CC 128
	End-stage renal disease or dialysis	CC 130
	Renal Failure	CC 131
	Nephritis	CC 132
	Urinary Obstruction and Retention	CC 133
	Incontinence	CC 134
	Urinary Tract Infection	CC 135
	Other urinary tract disorders	CC 136
	Pelvic Inflammatory disease	CC 138
	Other female genital disorders	CC 139
	Male genital disorders	CC 140
	Decubitus ulcer or chronic skin ulcer	CC 148, 149
	Extensive burns	CC 150, 151
	Cellulitis, Local Skin Infection	CC 152
	Other Dermatological Disorders	CC 153
	Trauma	CC 154-156, 158-161
	Vertebral Fractures	CC 157
	Other Injuries	CC 162
	Poisonings and Allergic Reactions	CC 163
	Major Complications of Medical Care and Trauma	CC 164
	Other Complications of Medical Care	CC 165
	Major Symptoms, Abnormalities	CC 166
	Minor Symptoms, Signs, Findings	CC 167
	Major Organ Transplant Status	CC 174
	Other organ transplant/replacement	CC 175

ii. Final Variable Selection

To inform final variable selection, a modified approach to stepwise logistic regression was performed. The development sample was used to create 500 “bootstrap” samples. For each sample, we ran a logistic stepwise regression that included all candidate variables. The results were summarized to show the percentage of times that each of the candidate variables was significantly associated with complications ($p<0.001$) in each of the 500 repeated samples (e.g., 70 percent would mean that the

candidate variable was selected as significant at p<0.001 in 70 percent of the estimations). We also assessed the direction and magnitude of the regression coefficients.

The clinical team reviewed these results and decided to retain all risk-adjustment variables above a 70% cutoff, because they demonstrated a relatively strong association with risk for complications and were clinically relevant. Additionally, specific variables with particular clinical relevance to the risk of complications were forced into the model (regardless of % selection) to ensure appropriate risk-adjustment for THA and TKA. These included:

Markers for end of life/frailty:

- decubitus ulcer (CC 148)
- dementia and senility (CC 49 and CC 50, respectively)
- metastatic cancer and acute leukemia (CC 7)
- protein-calorie malnutrition (CC 21)
- hemiplegia/paraplegia/paralysis/functional disability (CC 67-69, 100-102, 177-178)
- stroke (CC 95-96)

Diagnoses with potential asymmetry among hospitals that would impact the validity of the model:

- cancer (CC 8-12)

Final model variables are listed in Table A.3.

There were no changes made to risk adjustment variables based upon the NQF review or validation study.

Table A.3 THA/TKA Complications Measure Final Model Variables

Category	Variable	ICD-9 Code(s) or CC(s)
Demographic	Age-65 (years above 65, continuous)	
	Sex	
Procedure	Type of procedure	ICD-9-CM 81.51 (THA)
	Number of procedures (1 vs. 2)	
Comorbidities	Skeletal deformities	ICD-9-CM 755.63
	Post traumatic osteoarthritis	ICD-9-CM 716.15, 716.16
	Morbid obesity	ICD-9-CM 278.01
	Metastatic cancer and acute leukemia	CC 7
	Cancer	CC 8-10
	Respiratory/Heart/Digestive/Urinary/Other Neoplasms	CC 11-13
	Diabetes and DM complications	CC 15-20, 119, 120
	Protein-calorie malnutrition	CC 21
	Bone/Joint/Muscle Infections/Necrosis	CC 37
	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	CC 38
	Osteoarthritis of Hip or Knee	CC 40
	Osteoporosis and Other Bone/Cartilage Disorders	CC 41
	Dementia and senility	CC 49, 50
	Major psychiatric disorders	CC 54-56
	Hemiplegia, paraplegia, paralysis, functional disability	CC 67-69, 100-102, 177-178
	Cardio-Respiratory Failure and Shock	CC 79
	Chronic Atherosclerosis	CC 83-84
	Stroke	CC 95, 96
	Vascular or circulatory disease	CC 104-106
	COPD	CC 108
	Pneumonia	CC 111-113
	Pleural effusion/pneumothorax	CC 114
	End-stage renal disease or dialysis	CC 130
	Renal Failure	CC 131
	Decubitus ulcer or chronic skin ulcer	CC 148, 149
	Trauma	CC 154-156, 158-161
	Vertebral Fractures	CC 157
	Other injuries	CC 162
	Major Complications of Medical Care and Trauma	CC 164

h. Statistical Approach to Risk-Adjustment (Measure Development)

Two models were fitted, a logistic regression model linking the outcome to the patient-level risk factors and a hierarchical logistic regression model to account for the natural clustering of the patients within hospitals. The logistic regression modeled the log-odds of having a complication as a function of only patient

demographic and clinical characteristics. The hierarchical logistic regression modeled the log-odds of having a complication as a function of not only patient demographic and clinical characteristics but also a random hospital-specific intercept. This strategy accounts for within-hospital correlation of the observed outcomes and models the assumption that underlying differences in quality among the health care facilities being evaluated lead to systematic differences in outcomes.

We then calculated the risk-standardized complication rates as the ratio of the number of "predicted" to the number of "expected" admissions with a complication, multiplied by the national unadjusted complications rate. For each hospital, the numerator of the ratio is the number of admissions with a complication predicted on the basis of the hospital's performance with its observed case-mix, and the denominator is the number of admissions with a complication expected on the basis of the nation's performance with that hospital's case-mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case-mix to an average hospital's performance with the same case-mix. Thus a lower ratio indicates a lower-than-expected complication rate or better quality and a higher ratio indicates a higher-than-expected complication rate or worse quality.

After regressing the risk factors and the hospital specific intercept on the risk of a complication, the predicted number of admissions with a complication (the numerator) is calculated by summing the estimated regression coefficients multiplied by the patient characteristics, adding the estimated hospital specific intercept, transforming this value to the probability scale, and then summing over all patients attributed to the hospital to get the predicted value. The expected number of admissions with a complication (the denominator) is obtained by summing the estimated regression coefficients multiplied by the patient characteristics observed in the hospital, adding the estimated average hospital intercept, transforming to the probability scale and then summing over all patients in the hospital to get the expected value.

More specifically, the logistic regression model links the outcome to the patient-level risk factors.[20] Let Y_{ij} denote the outcome (equal to 1 if the patient dies or has a complication, zero otherwise) for the j^{th} patient who had a THA/TKA procedure at the i^{th} hospital; $\mathbf{Z}_{ij}$ denotes a set of risk factors based on the data. Let I denote the total number of hospitals and n_i the number of index patient stays in hospital i. We assume the outcome is related linearly to the covariates via a known linked function, h, where

$$\text{Logistic regression } h(Y_{ij}) = \alpha + \beta\mathbf{Z}_{ij} \qquad (1)$$

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots, Z_{pij})$ is a set of p patient-specific covariates. In our case, h = the logit link.

To account for the natural clustering of observations within hospitals, we then estimate the hierarchical logistic regression model that links the risk factors to the same outcome and a hospital-specific random effect,

Hierarchical logistic regression $h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij}$ (2)

$\alpha_i = \mu + \omega_i; \quad \omega_i \sim N(0, \tau^2)$ (3)

where α_i represents the hospital-specific intercept, $\mathbf{Z}_{ij}$ is defined as above, μ the adjusted average outcome over all hospitals in the sample, and τ^2 the between-hospital variance component.[21] This model separates within-hospital variation from between-hospital variation. Both the logistic regression model and the hierarchical logistic regression model were estimated using the SAS software system (PROC LOGISTIC and PROC GLIMMIX procedures respectively.)

We first fit the GLM described in Equation (1) using the logit link. Having identified the covariates that remained, we next fit the hierarchical logistic regression described in Equations (2) and (3), again using the logit link function.

i. Hospital Performance Reporting

Using the set of risk factors in the logistic regression model, we fit the hierarchical logistic regression model defined by Equations (2) - (3) and estimate the parameters, $\hat{\mu}$, $\{\hat{\alpha}_i, \hat{\alpha}_2, ..., \hat{\alpha}_I\}$, $\hat{\beta}$, and $\hat{\tau}^2$. We calculate a standardized outcome, s_i, for each hospital by computing the ratio of the number of predicted complications to the number of expected complications, multiplied by the unadjusted overall complication rate, $\bar{y}$. Specifically, we calculate

Predicted $\hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta}\, \mathbf{Z}_{ij})$ (4)

Expected $\hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta}\, \mathbf{Z}_{ij})$ (5)

$$\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \bar{y} \quad (6)$$

If the number of "predicted" admissions with a complication is higher (lower) than the "expected" number of admissions with a complication, then that hospital's $\hat{s}_i$ will be higher (lower) than the unadjusted average. For each hospital, we compute an interval estimate of s_i to characterize the level of uncertainty around the point estimate using bootstrapping simulations. The point estimate and interval estimate can be used to characterize and compare hospital performance (e.g., higher than expected, as expected, or lower than expected).

i. Creating Interval Estimates

Because the statistic described in Equation (6) is a complex function of parameter estimates, we use re-sampling and simulation techniques to derive an interval estimate. In particular, we use bootstrapping procedures to compute confidence intervals. Because the theoretical-based standard errors are not easily derived, and to avoid making unnecessary assumptions, we use the bootstrap to empirically construct the sampling distribution for each hospital-specific RSCR.

ii. Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for b = 1,2,…B times:

1. Sample *I* hospitals with replacement.

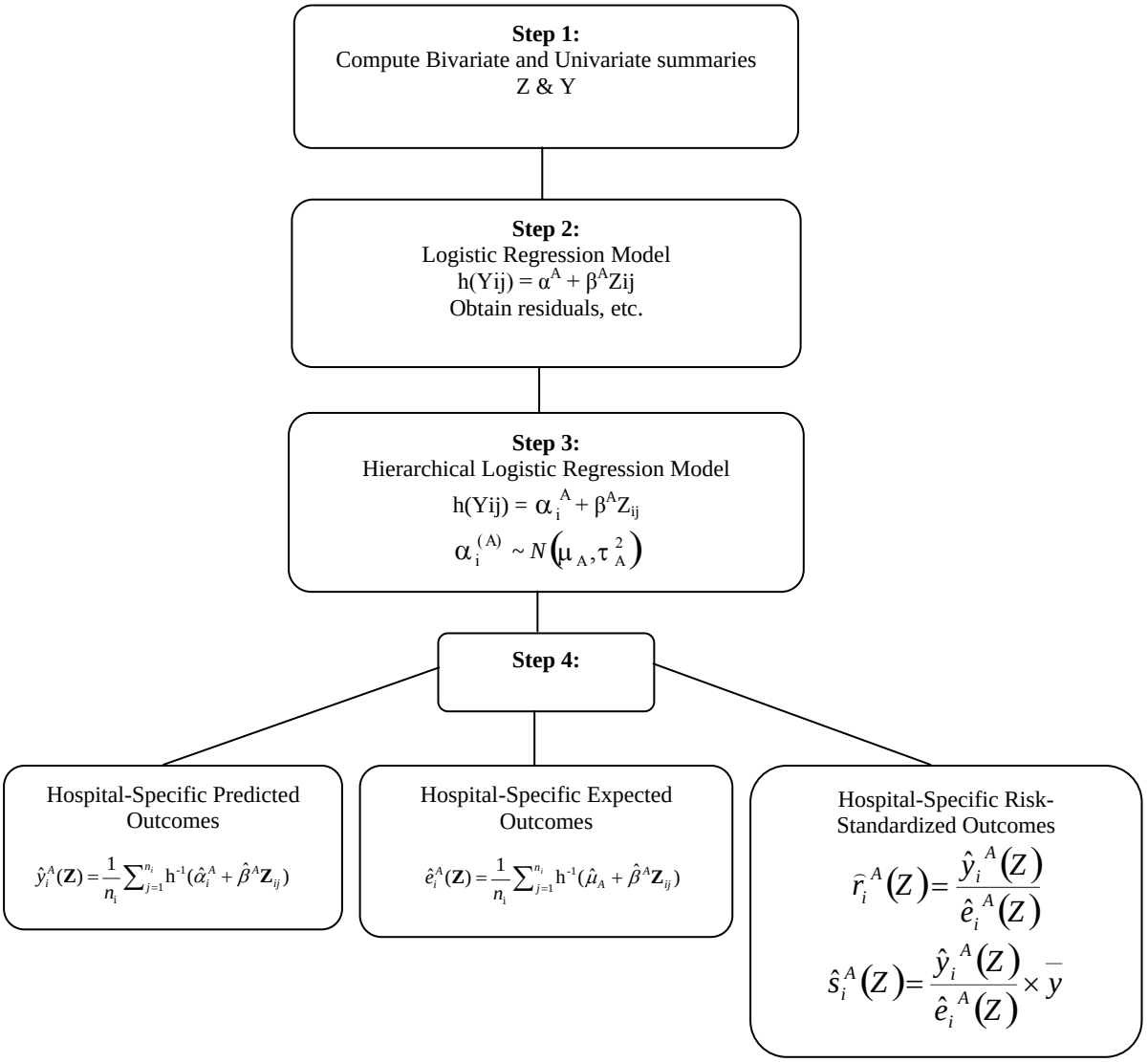
2. Fit the hierarchical logistic regression model using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)}, \hat{\text{var}}(\alpha_i^{(b)}); i = 1,2,\ldots,I\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\text{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i(Z)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5th and 97.5th percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals). [22]

Figure A.4 Analysis Steps



III. MODEL DEVELOPMENT/VALIDATION RESULTS

a. Model Development and Validation Samples

The risk-adjustment model development sample included 145,206 admissions at 3,221 hospitals in 2008.

The 2008 model validation sample included 145,123 admissions at 3,223 hospitals and the 2007 model validation sample included 294,697 admissions at 3,300 hospitals.

b. Risk-Factor Results in Development and Validation Samples

Table A.4 conveys the parameter estimates, standard errors, odds ratios (OR), and 95% confidence intervals for the model risk factors in the 2008 development and validation samples. Odds ratios are similar in both samples.

Table A.4 Logistic Regression Model Results for 2008 Development Sample (ROC=0.69) and 2008 Validation Sample (ROC=0.70)

Description	2008 Development Sample (N=145,206 at 3,221 hospitals)				2008 Validation Sample (N=145,123 at 3.223 hospitals)			
	Estimate	Standard Error	Odds Ratio	95% Confidence Interval for OR	Estimate	Standard Error	Odds Ratio	95% Confidence Interval for OR
Intercept	-3.58	0.06			-3.62	0.06		
Demographics								
Age-65 (years above 65, continuous)	0.03	0.00	1.03	(1.03 – 1.04)	0.03	0.002	1.03	(1.03 - 1.04)
Male	0.09	0.03	1.10	(1.04 – 1.16)	0.11	0.03	1.11	(1.05 - 1.18)
THA/TKA Procedure								
THA procedure	0.53	0.03	1.70	(1.61 – 1.80)	0.56	0.03	1.75	(1.65 - 1.85)
Number of procedures (one vs. two)	0.51	0.07	1.67	(1.46 – 1.91)	0.37	0.07	1.45	(1.26 - 1.68)
Comorbid Conditions								
Skeletal deformities (ICD-9 code 755.63)	0.31	0.30	1.37	(0.77 – 2.45)	0.31	0.27	1.36	(0.80 - 2.31)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)	0.24	0.15	1.27	(0.94 – 1.73)	0.35	0.14	1.42	(1.08 - 1.87)
Morbid obesity (ICD-9 code 278.01)	0.17	0.07	1.19	(1.03 – 1.37)	0.40	0.07	1.50	(1.31 - 1.71)
Metastatic cancer and acute leukemia (CC 7)	0.38	0.13	1.46	(1.12 – 1.89)	0.03	0.15	1.03	(0.76 - 1.39)
Cancer (CC 8-10)	-0.06	0.04	0.94	(0.87 – 1.02)	-0.07	0.04	0.93	(0.86 - 1.01)
Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)	-0.15	0.04	0.86	(0.80 – 0.93)	-0.09	0.04	0.91	(0.85 - 0.98)
Diabetes and DM complications (CC 15-20, 119, 120)	0.15	0.03	1.16	(1.09 – 1.22)	0.12	0.03	1.12	(1.06 - 1.19)
Protein-calorie malnutrition (CC 21)	0.84	0.10	2.32	(1.91 – 2.83)	0.70	0.10	2.02	(1.67 - 2.46)
Bone/Joint/Muscle Infections/Necrosis (CC 37)	0.00	0.06	1.00	(0.88 – 1.13)	0.02	0.07	1.02	(0.90 - 1.16)
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)	0.03	0.05	1.03	(0.94 – 1.12)	-0.04	0.05	0.96	(0.88 - 1.06)
Osteoarthritis of Hip or Knee (CC 40)	-0.61	0.05	0.54	(0.49 – 0.60)	-0.66	0.05	0.52	(0.47 - 0.57)
Osteoporosis and Other Bone/Cartilage Disorders (CC 41)	0.01	0.03	1.01	(0.95 – 1.08)	-0.01	0.03	0.99	(0.93 - 1.05)
Dementia and senility (CC 49, 50)	0.17	0.05	1.19	(1.07 – 1.32)	0.17	0.05	1.19	(1.07 - 1.32)
Major psychiatric disorders (CC 54-56)	0.19	0.06	1.21	(1.07 – 1.36)	0.09	0.06	1.10	(.097 - 1.24)
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)	0.18	0.09	1.20	(1.00 – 1.43)	0.11	0.09	1.11	(0.93 - 1.32)
Cardio-Respiratory Failure and Shock (CC 79)	-0.30	0.08	0.74	(0.64 – 0.86)	-0.25	0.07	0.78	(0.67 - 0.90)
Chronic Atherosclerosis (CC 83-84)	0.21	0.03	1.24	(1.17 – 1.31)	0.19	0.03	1.21	(1.15 - 1.29)
Stroke (CC 95, 96)	-0.10	0.08	0.91	(0.78 – 1.06)	-0.01	0.08	0.99	(0.86 - 1.15)
Vascular or circulatory disease (CC 104-106)	0.11	0.03	1.12	(1.05 – 1.19)	0.11	0.03	1.11	(1.05 - 1.18)
COPD (CC 108)	0.15	0.03	1.17	(1.09 – 1.25)	0.15	0.03	1.16	(1.08 - 1.24)
Pneumonia (CC 111-113)	1.53	0.04	4.61	(4.29 – 4.96)	1.55	0.04	4.72	(4.39 - 5.08)
Pleural effusion/pneumothorax (CC 114)	-0.37	0.09	0.69	(0.59 – 0.82)	-0.26	0.08	0.77	(0.65 - 0.91)
End-stage renal disease or dialysis (CC 129, 130)	0.74	0.20	2.09	(1.41 – 3.10)	0.42	0.20	1.53	(1.03 - 2.27)
Renal Failure (CC 131)	0.01	0.05	1.01	(0.91 – 1.11)	0.12	0.05	1.13	(1.03 - 1.24)
Decubitus ulcer or chronic skin ulcer (CC 148, 149)	0.24	0.13	1.27	(0.99 – 1.64)	0.15	0.13	1.17	(0.90- 1.50)
Trauma (CC 154-156, 158-161)	0.70	0.05	2.02	(1.84 – 2.20)	0.69	0.05	2.00	(1.83 - 2.18)
Vertebral Fractures (CC 157)	0.12	0.09	1.13	(0.94 – 1.36)	0.10	0.09	1.11	(0.93 - 1.32)
Other injuries (CC162)	0.09	0.03	1.09	(1.03 – 1.16)	0.14	0.03	1.15	(1.08 - 1.22)
Major Complications of Medical Care and Trauma (CC 164)	0.45	0.05	1.57	(1.42 – 1.74)	0.56	0.05	1.74	(1.58- 1.93)

c. Risk-Adjustment Model Performance and Validation

Using the development sample, we computed five summary statistics for assessing the risk-adjustment model performance[23], over-fitting indices, predictive ability, area under the receiver operating characteristic (ROC) curve (C statistic), distribution of residuals, and model Chi Square. We then compared the model performance in the development sample with its performance in the 2008 and 2007 model validation samples. Table A.5 conveys the logistic regression model performance for all samples.

Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and outcome well in the development dataset but fails to provide valid predictions in new patients. Estimated values of γ_0 far from 0 and estimated values of γ_1 far from 1 provide evidence of over-fitting (See footnote for Table A.5 for calculation steps). In the development and validation samples, γ_0 is close to zero and the γ_1 is close to one, providing no evidence of over-fitting (Table A.5).

Discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. Good model discrimination is indicated by a wide range between the lowest decile and highest decile, which the models show (Table A.5).

The C statistic is a measure of how accurately a statistical model is able to distinguish between a patient with and without an outcome. For binary outcomes the C statistic is identical to the receiver operator curve (ROC). A C statistic of 0.50 indicates random prediction, implying all patient risk factors are useless. A C statistic of 1.0 indicates perfect prediction, implying patients' outcomes can be predicted completely by their risk factors, and physicians and hospitals play no role in patients' outcomes. While higher C statistic is desirable, we do not want to maximize it by adjusting for factors that should not be adjusted for (e.g. hospital and characteristics). The C statistic for the 2008 development model is 0.69 and 0.70 for the 2008 validation model. The C statistic for the 2007 validation model is 0.69, indicating good discriminant ability

Overall, the model showed good performance consistent across all samples.

Table A.5 Model Performance for Logistic Regression Model

Indices	2008 Development Sample	2008 Validation Sample	2007 Validation Sample
Year	2008 (50%)	2008 (50%)	2007 (100%)
Number of Admissions	145,206	145,123	294,697
Number of Hospitals	3,221	3,223	3,300
Number of Complications	6148	6043	12,707
Calibration ($\gamma 0$, $\gamma 1$)[1]	(0, 1)	(0.04, 1.02)	(0.002, 1.00)
Discrimination -Predictive Ability (lowest decile %, highest decile %)	(2%, 15%)	(2%, 15%)	(2%, 15%)
Discrimination – Area Under Receiver Operator Curve	0.69	0.70	0.69
Residuals Lack of Fit (Pearson Residual Fall %)			
<-2	0	0	0
[-2, 0)	95.8	95.8	95.7
[0, 2)	0.4	0.4	0.4
[2+	3.8	3.7	3.9
Model Wald χ^2 [Number of Covariates]	4401 [33]	4698 [33]	9236 (33)

d. Hierarchical Logistic Regression Model Results

Table A.6 conveys the hierarchical logistic regression model results for the full 2008 dataset.

[1] Over-Fitting Indices (γ_0, γ_1) provide evidence of over-fitting and require several steps to calculate. Let *b* denote the *estimated vector* of regression coefficients. *Predicted Probabilities* ($\hat{p}$) = 1/(1+exp{-Xb}), and *Z* = *Xb* (e.g., the linear predictor that is a scalar value for everyone). A new logistic regression model that includes only an intercept and a slope by regressing the logits on Z is fitted in the validation sample; e.g., Logit(P(Y=1|Z)) = $\gamma_0 + \gamma_1 Z$. Estimated values of γ_0 far from 0 and estimated values of γ_1 far from 1 provide evidence of over-fitting.

Table A.6 Hierarchical Logistic Regression Model Results for Full 2008 Dataset

Description	Estimate	Standard Error	T-Value	Pr > T-Value	Odds Ratio	95% Confidence Interval for OR
Intercept	-3.57	0.06	-61.36	<.0001		
Demographics						
Age-65 (years above 65, continuous)	0.03	0.002	14.54	<.0001	1.03	(1.03 – 1.04)
Male	0.09	0.03	3.31	0.001	1.10	(1.04 – 1.16)
THA/TKA Procedure						
THA procedure	0.54	0.03	19.58	<.0001	1.71	(1.62 – 1.81)
Number of procedures (one vs. two)	0.53	0.07	7.75	<.0001	1.69	(1.48 – 1.93)
Comorbid Conditions						
Skeletal deformities (ICD-9 code 755.63)	0.34	0.29	1.17	0.242	1.40	(0.80 – 2.47)
Post traumatic osteoarthritis (ICD-9	0.26	0.15	1.72	0.086	1.30	(0.96 – 1.74)
Morbid obesity (ICD-9 code 278.01)	0.18	0.07	2.49	0.013	1.19	(1.04 – 1.37)
Metastatic cancer and acute leukemia	0.38	0.13	2.91	0.004	1.46	(1.13 – 1.88)
Cancer (CC 8-10)	-0.06	0.04	-1.54	0.123	0.94	(0.87 – 1.02)
Respiratory/Heart/Digestive/Urinary/Other	-0.14	0.04	-4.02	<.0001	0.87	(0.81 – 0.93)
Diabetes and DM complications (CC 15-	0.14	0.03	4.82	<.0001	1.15	(1.09 – 1.22)
Protein-calorie malnutrition (CC 21)	0.84	0.10	8.54	<.0001	2.31	(1.90 – 2.79)
Bone/Joint/Muscle Infections/Necrosis	-0.01	0.06	-0.11	0.910	0.99	(0.88 – 1.12)
Rheumatoid Arthritis and Inflammatory	0.03	0.04	0.72	0.471	1.03	(0.95 – 1.13)
Osteoarthritis of Hip or Knee (CC 40)	-0.61	0.05	-12.76	<.0001	0.54	(0.49 – 0.59)
Osteoporosis and Other Bone/Cartilage	0.01	0.03	0.41	0.679	1.01	(0.95 – 1.08)
Dementia and senility (CC 49, 50)	0.17	0.05	3.19	0.001	1.18	(1.07 – 1.31)
Major psychiatric disorders (CC 54-56)	0.19	0.06	3.14	0.001	1.21	(1.07 – 1.35)
Hemiplegia, paraplegia, paralysis,	0.18	0.09	2.12	0.034	1.20	(1.01 – 1.43)
Cardio-Respiratory Failure and Shock	-0.30	0.07	-4.05	<.0001	0.74	(0.64 – 0.86)
Chronic Atherosclerosis (CC 83-84)	0.21	0.03	7.63	<.0001	1.24	(1.17 – 1.31)
Stroke (CC 95, 96)	-0.10	0.07	-1.28	0.199	0.91	(0.79 – 1.05)
Vascular or circulatory disease (CC 104-	0.11	0.03	3.84	0.0001	1.12	(1.06 – 1.19)
COPD (CC 108)	0.15	0.03	4.41	<.0001	1.16	(1.09 – 1.24)
Pneumonia (CC 111-113)	1.53	0.04	42.39	<.0001	4.62	(4.31 – 4.96)
Pleural effusion/pneumothorax (CC 114)	-0.37	0.08	-4.36	<.0001	0.69	(0.59 – 0.82)
End-stage renal disease or dialysis (CC	0.73	0.20	3.72	0.0002	2.07	(1.41 – 3.03)
Renal Failure (CC 131)	-0.001	0.05	-0.02	0.988	1.00	(0.91 – 1.10)
Decubitus ulcer or chronic skin ulcer (CC	0.24	0.13	1.90	0.058	1.27	(0.99 – 1.63)
Trauma (CC 154-156, 158-161)	0.70	0.04	15.99	<.0001	2.02	(1.86 – 2.20)
Vertebral Fractures (CC 157)	0.12	0.09	1.39	0.166	1.13	(0.95 – 1.35)
Other injuries (CC162)	0.08	0.03	2.84	0.005	1.09	(1.03 – 1.15)
Major Complications of Medical Care and Trauma (CC 164)	0.45	0.05	8.80	<.0001	1.56	(1.41 – 1.72)

e. Unadjusted and Adjusted Complication Rate Distributions (Original Model)

Figures A.5 and A.6 display the frequency distributions of the hospital-specific complication rates, with and without risk adjustment and standardization for the full 2008 cohort. The unadjusted mean complication rate was 4.98 and ranges from 0 to 100% (Figure A.5). The median unadjusted complication rate was 3.70%.

After adjusting for patient and clinical characteristics, accounting for the clustering of patients within hospitals, and including a hospital-specific effect, the risk-standardized rates are more normally distributed (Figure A.6) with a mean of 4.23%, ranging from 2.20% to 8.88%. The median adjusted complication rate was 4.16%.

Figure A.5 Distribution of Unadjusted Hospital Complication Rates (2008 Sample; N=3,311 Hospitals)

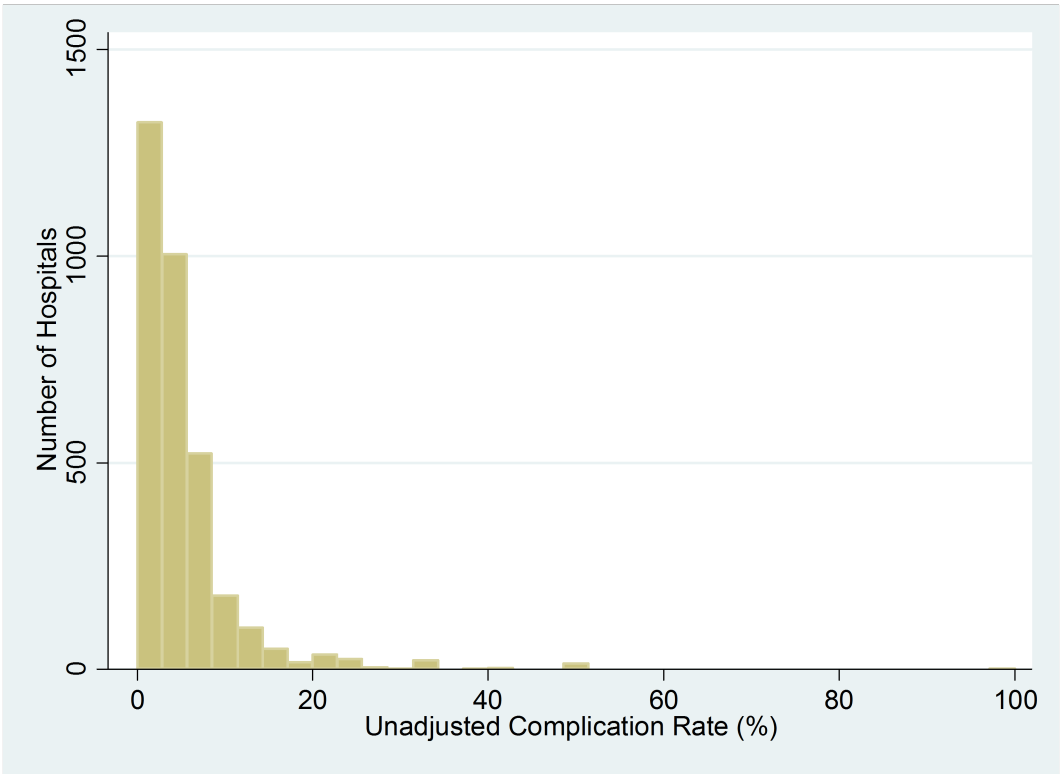
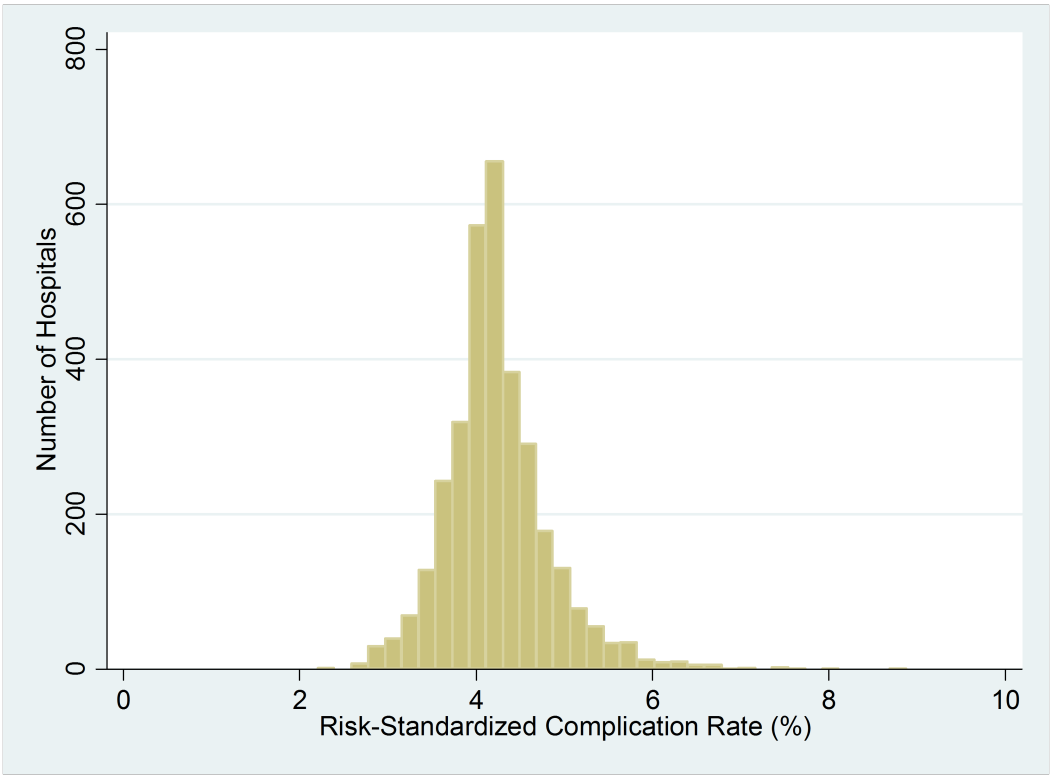


Figure A.6 Distribution of Hospital Risk-Standardized Complication Rates (2008 Sample; N=3,311 Hospitals) – Hierarchical Logistic Regression Model



f. Measure Testing

i. Reliability of the Data Elements

For measure development, we only use data elements in claims that have both face validity and reliability. We do not use fields that are inconsistently coded across providers, and only use fields that are consequential for payment and which are audited. We identify these variables through empiric analyses and our understanding of CMS auditing and billing policies and do not use variables which do not meet this standard. For example, “discharge disposition” is a variable in Medicare claims data that is not consistently coded across hospitals. Thus, we construct an indicator variable as a surrogate for “discharge disposition” to identify patients that are transferred using variables in the claims data with greater reliability, including admit date and discharge date.

In addition, CMS has in place several hospital auditing programs used to assess overall claims code accuracy, ensure appropriate billing, and for overpayment recoupment. CMS routinely conducts data analysis to identify potential problem areas and detect fraud,

and audits important data fields used in our measures, including diagnosis and procedure codes, and other elements that are consequential to payment.

The data elements we use are stable over time. We used data from 2007 and 2008 to assess the stability of the data elements over time: 145,206 admissions from 3,221 hospitals in 2008 development sample, 145,123 admissions and 3,223 hospitals in 2008 validation sample and 294,697 admissions from 3,300 hospitals in 2007 validation sample. Table A.7 conveys the model risk factor frequencies in these samples. There were no notable changes in risk factor frequencies.

Table A.8 shows the adjusted odds ratios for the logistic regression (patient-level) model variables in the 2007 and 2008 data samples. There are no notable differences in the odds ratios across the samples. The consistency in the rates of the risk-adjustment variables, and their relationship to the outcome across two years of data all demonstrate the reliability of the measure data elements.

Table A.7 Risk Factor Frequency by Year of Discharge (Logistic Regression Model)

Description	2008 Development Sample	2008 Validation Sample	2007 Validation Sample
Male	35.8	35.6	35.5
THA procedure	28.8	28.7	28.6
Number of procedures (one vs. two)	3.3	3.3	3.6
Skeletal deformities	0.1	0.1	0.1
Post traumatic osteoarthritis	0.5	0.6	0.5
Morbid obesity	3.4	3.4	2.9
Metastatic cancer and acute leukemia	0.6	0.6	0.7
Cancer	12.8	12.8	12.8
Respiratory/Heart/Digestive/Urinary/Other Neoplasms	17.9	18.0	17.8
Diabetes and DM complications	27.3	27.4	26.8
Protein-calorie malnutrition	0.6	0.7	0.5
Bone/Joint/Muscle Infections/Necrosis	3.0	2.8	3.1
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	8.5	8.6	8.3
Osteoarthritis of Hip or Knee	95.3	95.4	95.3
Osteoporosis and Other Bone/Cartilage Disorders	24.8	25.1	24.2
Dementia and senility	4.4	4.4	4.2
Major psychiatric disorders	3.7	3.8	3.6
Hemiplegia, paraplegia, paralysis, functional disability	1.5	1.6	1.5
Cardio-Respiratory Failure and Shock	2.1	2.1	2.0
Chronic Atherosclerosis	30.7	30.7	31.1
Stroke	2.5	2.4	2.5
Vascular or circulatory disease	22.5	22.6	22.1
COPD	14.7	14.7	15.2
Pneumonia	5.4	5.5	5.5
Pleural effusion/pneumothorax	1.5	1.5	1.5
End-stage renal disease or dialysis	0.1	0.2	0.2
Renal Failure	6.0	6.2	5.5
Decubitus ulcer or chronic skin ulcer	0.4	0.5	0.4
Trauma	5.1	5.1	5.0
Vertebral Fractures	1.3	1.4	1.3
Other injuries	27.6	27.7	27.7
Major Complications of Medical Care and Trauma	3.9	3.9	3.9

Table A.8 Standardized Estimates by Year of Discharge (Logistic Regression Model)

Description	2008 (100%)			2007 (100%)		
	Standardized Estimates	Odds Ratio	95% Confidence Interval for OR	Standardized Estimates	Odds Ratio	95% Confidence Interval for OR
Demographics						
Age-65 (years above 65, continuous)	0.11	1.03	(1.03 - 1.04)	0.10	1.03	(1.03 – 1.04)
Male	0.03	1.11	(1.06 - 1.15)	0.02	1.10	(1.04 – 1.16)
THA/TKA Procedure						
THA procedure	0.14	1.73	(1.66 - 1.80)	0.13	1.70	(1.61 – 1.80)
Number of procedures (one vs. two)	0.04	1.56	(1.42 - 1.73)	0.05	1.67	(1.46 – 1.91)
vComorbid Conditions						
Skeletal deformities (ICD-9 code 755.63)	0.01	1.36	(0.92 - 2.02)	0.01	1.37	(0.77 – 2.45)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)	0.01	1.35	(1.10 - 1.66)	0.01	1.27	(0.94 – 1.73)
Morbid obesity (ICD-9 code 278.01)	0.03	1.34	(1.21 - 1.47)	0.02	1.19	(1.03 – 1.37)
Metastatic cancer and acute leukemia (CC 7)	0.01	1.24	(1.02 - 1.51)	0.02	1.46	(1.12 – 1.89)
Cancer (CC 8-10)	-0.01	0.94	(0.89 - 0.99)	-0.01	0.94	(0.87 – 1.02)
Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)	-0.03	0.89	(0.85 - 0.93)	-0.03	0.86	(0.80 – 0.93)
Diabetes and DM complications (CC 15-20, 119, 120)	0.03	1.14	(1.09 - 1.19)	0.04	1.16	(1.09 – 1.23)
Protein-calorie malnutrition (CC 21)	0.03	2.16	(1.88 - 2.48)	0.04	2.32	(1.91 – 2.83)
Bone/Joint/Muscle Infections/Necrosis (CC 37)	0.00	1.01	(0.92 - 1.11)	0.00	1.00	(0.88 – 1.13)
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)	0.00	1.00	(0.93 - 1.06)	0.00	1.03	(0.94 – 1.12)
Osteoarthritis of Hip or Knee (CC 40)	-0.07	0.53	(0.49 - 0.57)	-0.07	0.54	(0.49 – 0.60)
Osteoporosis and Other Bone/Cartilage Disorders (CC 41)	0.00	1.00	(0.96 - 1.05)	0.00	1.01	(0.95 – 1.08)
Dementia and senility (CC 49, 50)	0.02	1.19	(1.10 - 1.28)	0.02	1.19	(1.07 – 1.32)
Major psychiatric disorders (CC 54-56)	0.01	1.15	(1.06 - 1.25)	0.02	1.21	(1.07 – 1.36)
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)	0.01	1.15	(1.02 - 1.30)	0.01	1.20	(1.01 – 1.43)
Cardio-Respiratory Failure and Shock (CC 79)	-0.02	0.76	(0.69 - 0.85)	-0.02	0.74	(0.64 – 0.86)
Chronic Atherosclerosis (CC 83-84)	0.05	1.23	(1.18 - 1.28)	0.05	1.24	(1.17 – 1.31)
Stroke (CC 95, 96)	0.00	0.95	(0.85 - 1.06)	-0.01	0.91	(0.78 – 1.06)
Vascular or circulatory disease (CC 104-106)	0.03	1.12	(1.07 - 1.17)	0.03	1.12	(1.05 – 1.19)
COPD (CC 108)	0.03	1.16	(1.11 - 1.22)	0.03	1.17	(1.09 – 1.25)
Pneumonia (CC 111-113)	0.19	4.67	(4.43 - 4.91)	0.19	4.61	(4.29 – 4.96)
Pleural effusion/pneumothorax (CC 114)	-0.02	0.73	(0.65 - 0.82)	-0.02	0.69	(0.59 – 0.82)
End-stage renal disease or dialysis (CC 129, 130)	0.01	1.79	(1.35 - 2.36)	0.02	2.09	(1.41 – 3.10)
Renal Failure (CC 131)	0.01	1.07	(1.00 - 1.14)	0.00	1.01	(0.91 – 1.11)
Decubitus ulcer or chronic skin ulcer (CC 148, 149)	0.01	1.21	(1.01 - 1.45)	0.01	1.27	(0.99 – 1.64)
Trauma (CC 154-156, 158-161)	0.08	2.01	(1.88 - 2.14)	0.08	2.02	(1.84 – 2.20)
Vertebral Fractures (CC 157)	0.01	1.12	(0.98 - 1.27)	0.01	1.13	(0.94 – 1.36)
Other injuries (CC162)	0.03	1.12	(1.07 - 1.17)	0.02	1.09	(1.03 – 1.16)
Major Complications of Medical Care and Trauma (CC 164)	0.05	1.65	(1.54 - 1.78)	0.05	1.57	(1.42 – 1.74)

ii. Reliability of the Risk-Adjustment Model

As stated previously we evaluated model performance in the development sample and validation samples. The results of these analyses were consistent in all samples indicating good reliability (See Section III. c. for detailed results). Additionally, no notable differences were observed in risk factor ORs across the years of data (Table A.8), indicating reliable model estimation.

iii. Validity

CMS has validated the six NQF-endorsed measures currently used in public reporting (mortality and readmission measures for AMI, heart failure, and pneumonia). They validated the claims-based measures by building comparable models using medical record data for risk adjustment for heart failure patients (National Heart Failure data), AMI patients (Cooperative Cardiovascular Project data), and pneumonia patients (National Pneumonia Project dataset). When the medical record-based models were applied to the corresponding patient population, the hospital risk-standardized rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based models for public reporting.

In 2010 YNHHSC/CORE conducted a national, multi-site validation study for a procedure-based complications measure, it developed in 2009 (Hospital Risk-Standardized Complication Rate Following Implantation of Implantable Cardioverter Defibrillator (ICD)). That study demonstrated strong agreement between complications coded in claims and those documented in the medical record, suggesting that claims data variables are valid and therefore can be used reliably for developing new claims-based outcome measures.

iv. Medical Record Validation Study of Hospital Risk-Standardized Complication Rate Following Elective Primary THA and/or TKA

In 2010 – 2011 YNHHSC/CORE conducted a medical record validation study of this measure. The goal of that study was to determine the overall agreement between arthroplasty patients identified as having a complication (or no complication) in the claims-based measure and those who had a complication (or no complication) also documented in the medical record.

Overall measure agreement was 93% (598/644 patients) before any changes were made to the model specifications. After the

measure specifications were changed based upon both the results of this validation study, the measure agreement between claims data and the medical record was 99% (635/644).

The full report from the validation study is provided in Appendix E.

Appendix B: ICD-9-CM Codes for Hip Fracture, Revision Procedures, Partial Hip Arthroplasty, Resurfacing Procedures, Mechanical Complications, Removal of Implanted Device, and Malignant Neoplasms[1]

Femur, Hip, and Pelvic Fracture Codes	
733.10	Pathological fracture unspecified site
733.14	Pathological fracture of neck of femur
733.15	Pathological fracture of other specified part of femur
733.19	Pathological fracture of other specified site
733.8	Malunion and nonunion of fracture
733.81	Malunion of fracture
733.82	Nonunion of fracture
733.95	Stress fracture of other bone
733.96	Stress fracture of femoral neck
733.97	Stress fracture of shaft of femur
808.0	Closed fracture of acetabulum
808.1	Open fracture of acetabulum
808.2	Closed fracture of pubis
808.3	Open fracture of pubis
808.41	Closed fracture of ilium
808.42	Closed fracture of ischium
808.43	Multiple closed pelvic fractures w/ disruption of pelvic circle
808.49	Closed fracture of other specified part of pelvis
808.50	Open fracture of other specified part of pelvis
808.51	Open fracture of ilium
808.52	Open fracture of ischium
808.53	Multiple open pelvic fractures w/ disruption of pelvic circle
808.8	Unspecified closed fracture of pelvis
820	Fracture of neck of femur
820.0	Transcervical fracture closed
820.00	Fracture of unspecified intracapsular section of neck of femur closed
820.01	Fracture of epiphysis (separation) (upper) of neck of femur closed
820.02	Fracture of midcervical section of femur closed
820.03	Fracture of base of neck of femur closed
820.09	Other transcervical fracture of femur closed
820.1	Transcervical fracture open
820.10	Fracture of unspecified intracapsular section of neck of femur open
820.11	Fracture of epiphysis (separation) (upper) of neck of femur open
820.12	Fracture of midcervical section of femur open
820.13	Fracture of base of neck of femur open
820.19	Other transcervical fracture of femur open
820.2	Pertrochanteric fracture of femur closed
820.20	Fracture of unspecified trochanteric section of femur closed
820.21	Fracture of intertrochanteric section of femur closed
820.22	Fracture of subtrochanteric section of femur closed
820.3	Pertrochanteric fracture of femur open

[1] Shaded rows refer to ICD-9 codes that were added as exclusions based on NQF review of the measure and on the medical record validation study.

Femur, Hip, and Pelvic Fracture Codes	
820.30	Fracture of unspecified trochanteric section of femur open
820.31	Fracture of intertrochanteric section of femur open
820.32	Fracture of subtrochanteric section of femur open
820.8	Fracture of unspecified part of neck of femur closed
820.9	Fracture of unspecified part of neck of femur open
821	Fracture of other and unspecified parts of femur
821.0	Fracture of shaft or unspecified part of femur closed
821.00	Fracture of unspecified part of femur closed
821.01	Fracture of shaft of femur closed
821.1	Fracture of shaft or unspecified part of femur open
821.10	Fracture of unspecified part of femur open
821.11	Fracture of shaft of femur open
821.2	Fracture of lower end of femur closed
821.20	Fracture of lower end of femur unspecified part closed
821.21	Fracture of femoral condyle closed
821.22	Fracture of lower epiphysis of femur closed
821.23	Supracondylar fracture of femur closed
821.29	Other fracture of lower end of femur closed
821.3	Fracture of lower end of femur open
821.30	Fracture of lower end of femur unspecified part open
821.31	Fracture of femoral condyle open
821.32	Fracture of lower epiphysis of femur open
821.33	Supracondylar fracture of femur open
821.39	Other fracture of lower end of femur open

THA and TKA Revision Codes	
81.53	Revise Hip Replacement, NOS
81.55	Revision of Knee replacement, NOS
81.59	Revision of joint replacement of lower extremity, not elsewhere classified
00.70	REV Hip Repl-acetab/fem
00.71	REV Hip Repl-acetab comp
00.72	REV Hip Repl-fem comp
00.73	REV Hip Repl-liner/head
00.80	Replacement of femoral, tibial, and patellar components (all components)
00.81	Replacement of tibial baseplate and tibial insert (liner)
00.82	Revision of knee replacement, femoral component
00.83	Revision of knee replacement, patellar component
00.84	Revision of total knee replacement, tibial insert (liner)

Partial Hip Replacement	
81.52	Partial Hip Replacement

THA Resurfacing Procedure Codes	
00.85	Resurfacing hip, total, acetabulum and femoral head, hip resurfacing arthroplasty, total

[1] Shaded rows refer to ICD-9 codes that were added as exclusions based on NQF review of the measure and on the medical record validation study.

Femur, Hip, and Pelvic Fracture Codes	
00.86	Resurfacing hip, partial, femoral head, hip resurfacing arthroplasty, NOS, hip resurfacing arthroplasty, partial, femoral head
00.87	Resurfacing hip, partial, acetabulum, hip resurfacing arthroplasty, partial, acetabulum

Mechanical Complications Codes	
996.4	Mechanical complication of internal orthopedic device implant and graft
996.40	Unspecified mechanical complication of internal orthopedic device, implant and graft
996.41	Mechanical loosening of prosthetic joint
996.42	Dislocation of prosthetic joint
996.43	Broken prosthetic joint implant
996.44	Peri prosthetic fracture around prosthetic joint
996.45	Peri prosthetic osteolysis
996.46	Articular bearing surface wear of prosthetic joint
996.47	Other mechanical complication of prosthetic joint implant
996.49	Other mechanical complication of other internal orthopedic device, implant, and graft
996.77	Other complications due to internal joint prosthesis
996.78	Other complications due to other internal orthopedic device implant and graft

Removal of Implanted Devices/Prosthesis Codes	
78.65	Removal of implanted devices from femur
78.66	Removal of implanted devices from bone; patella
78.67	Removal of implanted devices from bone; tibia and fibula
80.05	Arthrotomy for removal of prosthesis - femur
80.06	Arthrotomy for removal of prosthesis without replacement, knee
80.09	Arthrotomy For Removal Of Prosthesis Without Replacement, Other Specified Sites

Malignant Neoplasms Codes	
170.6	Malignant neoplasm of pelvic bones sacrum and coccyx
170.7	Malignant neoplasm of long bones of lower limb
170.9	Malignant neoplasm of bone and articular cartilage site unspecified
195.3	Malignant neoplasm of pelvis
195.5	Malignant neoplasm of lower limb
198.5	Secondary malignant neoplasm of bone and bone marrow
199.0	Disseminated malignant neoplasm

[1] Shaded rows refer to ICD-9 codes that were added as exclusions based on NQF review of the measure and on the medical record validation study.

Appendix C: Conditions Not Adjusted For If Coded Only During Index Admission As They May Represent Adverse Outcomes of Care Received

CC	Description
2	Septicemia/Shock
6	Other Infectious Diseases
17	Diabetes with Acute Complications
23	Disorders of Fluid/Electrolyte/Acid-Base
24	Other Endocrine/Metabolic/Nutritional Disorders
28	Acute Liver Failure/Disease
31	Intestinal Obstruction/Perforation
34	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders
36	Other Gastrointestinal Disorders
37	Bone/Joint/Muscle Infections/Necrosis
43	Other Musculoskeletal and Connective Tissue Disorders
46	Coagulation Defects and Other Specified Hematological Disorders
47	Iron Deficiency and Other/Unspecified Anemias and Blood Disease
48	Delirium and Encephalopathy
51	Drug/Alcohol Psychosis
75	Coma, Brain Compression/Anoxic Damage
76	Mononeuropathy, Other Neurological Conditions/Injuries
77	Respirator Dependence/Tracheostomy Status
78	Respiratory Arrest
79	Cardio-respiratory failure and shock
80	Congestive heart failure
81	Acute myocardial infarction
85	Heart Infection/Inflammation, Except Rheumatic
92	Specified Heart Arrhythmias
93	Other Heart Rhythm and Conduction Disorders
95	Cerebral Hemorrhage
96	Ischemic or Unspecified Stroke
97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia
100	Hemiplegia/Hemiparesis
101	Cerebral Palsy and Other Paralytic Syndromes
102	Speech, Language, Cognitive, Perceptual
104	Vascular Disease with Complications
105	Vascular Disease
106	Other Circulatory Disease
111	Aspiration and Specified Bacterial Pneumonias
112	Pneumococcal Pneumonia, Emphysema, Lung Abscess
113	Viral and Unspecified Pneumonia, Pleurisy
114	Pleural Effusion/Pneumothorax
130	Dialysis Status
131	Renal failure
132	Nephritis
133	Urinary Obstruction and Retention
135	Urinary Tract Infection
148	Decubitus Ulcer of Skin
152	Cellulitis, Local Skin Infection

CC	Description
154	Severe Head Injury
155	Major Head Injury
156	Concussion or Unspecified Head Injury
158	Hip Fracture/Dislocation
159	Major Fracture, Except of Skull, Vertebrae, or Hip
160	Internal Injuries
161	Traumatic Amputation
162	Other Injuries
163	Poisonings and Allergic Reactions
164	Major Complications of Medical Care and Trauma
165	Other Complications of Medical Care
175	Other Organ Transplant/Replacement
177	Amputation Status, Lower Limb/Amputation
178	Amputation Status, Upper Limb

Appendix D: CCs Not Considered for Risk Adjustment

CC	Description	Rationale
66	Attention Deficit Disorder	Pediatric ; Low frequency
123	Cataracts	Marker of clinical practice, not clinical relevant
137	Female Infertility	Irrelevant to Medicare FFS Population
141	Ectopic Pregnancy	Irrelevant to Medicare FFS Population
142	Miscarriage/Abortion	Irrelevant to Medicare FFS Population
143	Completed Pregnancy with Major Complications	Irrelevant to Medicare FFS Population
144	Completed Pregnancy with Complications	Irrelevant to Medicare FFS Population
145	Completed Pregnancy without Complication	Irrelevant to Medicare FFS Population
146	Uncompleted Pregnancy with Complications	Irrelevant to Medicare FFS Population
147	Uncompleted Pregnancy with No or Minor Complications	Irrelevant to Medicare FFS Population
168	Extremely Low Birthweight Neonates	Fetal Effects; Irrelevant to Medicare FFS Population
169	Very Low Birthweight Neonates	Fetal Effects; Irrelevant to Medicare FFS Population
170	Serious Perinatal Problems Affecting Newborn	Fetal Effects; Irrelevant to Medicare FFS Population
171	Other Perinatal Problems Affecting Newborn	Fetal Effects; Irrelevant to Medicare FFS Population
172	Normal, Single Birth	Fetal Effects; Irrelevant to Medicare FFS Population
173	Major Organ Transplant	Not included in CMS-HCC Model
176	Artificial Openings for Feeding or Elimination	CC too heterogeneous; Mix of disparate codes
179	Post-Surgical States/Aftercare/Elective	CC too heterogeneous; Mix of disparate codes
180	Radiation Therapy	CC too heterogeneous; Mix of disparate codes
181	Chemotherapy	CC too heterogeneous; Mix of disparate codes
182	Rehabilitation	CC too heterogeneous; Mix of disparate codes
183	Screening/Observation/Special Exams	CC too heterogeneous; Mix of disparate codes
184	History of Disease	CC too heterogeneous; Mix of disparate codes
185	Oxygen	Not included in CMS-HCC Model; DME
186	CPAP/IPPB/Nebulizers	Not included in CMS-HCC Model; DME
187	Patient Lifts, Power Operated Vehicles, Beds	Not included in CMS-HCC Model; DME
188	Wheelchairs, Commodes	Not included in CMS-HCC Model; DME
189	Walkers	Not included in CMS-HCC Model; DME

Appendix E: Validation Report for Hospital Risk-Standardized Complication Rate following Elective, Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure

Background

In 2009 - 2010, under contract with the Centers for Medicare & Medicaid Services (CMS), Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) developed two hospital outcome measures of quality of care for patients undergoing elective total hip arthroplasty (THA) and/or total knee arthroplasty (TKA). YNHHSC/CORE, in consultation with a group of nationally recognized experts in orthopedic quality improvement, developed a hospital risk-standardized complications measure and a hospital risk-standardized readmission measure for patients undergoing THA and/or TKA. YNHHSC/CORE developed these measures using Medicare administrative claims data for beneficiaries 65 years of age or older.

We identified complications via International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9 CM) codes in Medicare claims. The follow-up periods for the complications vary from 7 to 90 days after the date of the index admission, depending on the complication.
We obtained index admission and comorbidity data from Medicare Part A inpatient and outpatient, and Part B physician office Medicare claims in the 12 months prior to admission. Enrollment and post-discharge mortality status were obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

Complications included in the measure represent meaningful complications attributable to the THA/TKA procedures that are identifiable in administrative claims data. The following complications were included in the measure:

- Death
- Mechanical complications
- Periprosthetic joint infection
- Surgical site bleeding
- Wound infection
- Pulmonary embolism
- Acute myocardial infarction (AMI)
- Pneumonia
- Sepsis/septicemia

The goal of the measure is to improve the quality of care delivered to patients undergoing THA and TKA procedures and inform quality improvement efforts targeted towards reducing medical and surgical complications associated with these procedures.

Study Objectives

Administrative databases may be subject to coding errors and variation in coding practices within and across care settings. Therefore, YNHHSC/CORE chose to conduct a medical record validation study. The primary goal of this validation study was to

determine the overall agreement between patients identified as having a complication (or no complication) in the claims-based measure and those who had a complication (or no complication) also documented in the medical record. We conducted a secondary analysis of agreement of individual specific complications to identify opportunities for measure improvement.

Methods

Hospital Recruitment

In order to review a broad range of medical records and to efficiently conduct the study, we aimed to recruit 9 hospitals, the maximum allowed without triggering a requirement for Office of Management and Budget clearance. Recruitment began November 1, 2010 and continued until June 2011.
To select hospitals for recruitment, we ranked all hospitals included in the measure by the number of patients having at least one of the included complications, except for those whose only complication was death. We did not validate the complication of death because death is reliably identified in the Medicare Enrollment Database. Once hospitals were ranked according to the number of patients with complications, we focused recruitment efforts on the 25 hospitals with the most patients with complications and one local hospital.

YNHHSC/CORE team contacted each hospital via the quality improvement, performance management, or orthopedic departments to solicit participation. YNHHSC/CORE sent a letter of introduction and written summary of the validation study to the contact person at each interested hospital by email or US mail. Thereafter, the YNHHSC/CORE team followed up with contacts at each hospital to answer hospitals' questions about the project, implications of the validation study, participation logistics, and resources available to assist them with Institutional Review Board (IRB) applications and Business Associate Agreements (BAA). We recruited nine hospitals for the validation study. Each hospital determined whether their participation required institutional review board (IRB) and/or a BAA. One hospital required IRB approval and 4 required a BAA.

Medical Record Acquisition

Given the number of eligible cases at each hospital and in order to maximize the reviewed cases while staying within a budgeted number of medical records, we requested between 40 and 48 medical records for randomly-selected patients with complications from each participating hospital. We also requested from each hospital a randomly-selected identical number of patients whom the measure identified as having no complications. Complications were identified via ICD-9-CM diagnosis and procedure codes in the claims data based on the measure specifications (Appendix C). For each hospital, YNHHSC/CORE selected approximately 96 medical records (half with and half without complications) for patients who underwent a THA and/or TKA in 2007 and 2008.

Inclusion/Exclusion Criteria

We included Medicare beneficiaries 65 years of age or older who had a THA or TKA between January 1, 2007 and December 31, 2008 who were in the cohort for the hospital risk-standardized complications measure.

We excluded patients whose only complication was death because the death outcome was identified via the Medicare Enrollment Database and was verified in prior analyses conducted by YNHHSC/CORE.

We also excluded *readmissions* for patients who were readmitted to a hospital which did not perform the index procedure because we had to limit medical record acquisition to participating hospitals. We could not access medical records for readmissions to non-participating hospitals. If a patient was readmitted to the hospital that performed the index procedure and was readmitted again to a non-participating hospital, only the readmission to the non-participating hospital was excluded from the validation study.

Medical Record Abstraction and Data Security

A CMS-approved subcontractor, Information Collection Enterprises, LLC (ICE) requested copies (paper and/or electronic) of all eligible patient records from each hospital and conducted the medical record abstraction. YNHHSC/CORE analysts provided ICE with a list of patient stays for the randomly selected patients, including the following information:

- Patient HIC number
- Date of admission
- Date of discharge
- Gender
- Date of Birth

The list was derived from Medicare inpatient claims data based on measure specifications.

The YNHHSC/CORE team developed an abstraction tool (Appendix A) and trained the ICE team of abstractors on the use of the tool. The team also developed abstraction guidelines that accompanied the tool (Appendix B). Furthermore, we provided ongoing support to answer questions and address specific issues with the tool and data abstraction as they arose during the abstraction phase.
For each randomly selected patient in the validation study, YNHHSC/CORE provided ICE with the dates for the index admission and for each readmission (to the same hospital that performed the procedure) up to 90 days after the date of the index admission. The claims-based measure identified complications requiring a readmission up to 90 days after the date of the index admission.

ICE abstracted data onto a hardcopy of the abstraction tool and then uploaded the data into an electronic database maintained by ICE. All electronic data is maintained on a

secure server, connected to password protected computers and password protected files at ICE. Abstracted data was sent to YNHHSC/CORE on encrypted and password protected CDs and then loaded onto secure servers that are password protected and stored in a locked room.

YNHHSC/CORE requested copies of medical records for some cases where there were disagreements between the medical record and claims data. ICE sent hardcopies of those records to YNHHSC/CORE via overnight FedEx. Copies of medical records were stored in a locked cabinet in a locked room at YNHHSC/CORE.

Complications following THA/TKA procedures were selected and defined during the measure development process by the YNHHSC/CORE team in conjunction with a working group comprised of individuals with expertise relevant to orthopedic quality measurement. Complications were identified during 7, 30, or 90 days following THA and/or TKA procedures depending on the type of complication. Detailed measure specifications for each complication are in Appendix C.

Data Analysis

A senior statistician at YNHHSC/CORE conducted a detailed analysis of each abstracted patient record received from ICE and compared the findings to the patient results found in the claims-based measure. If any disagreement between the medical record abstraction and the claims data was found, the disagreement was documented and explored in further detail with the YNHHSC/CORE team. In some instances, YNHHSC/CORE requested that the medical record be re-abstracted by ICE in order to confirm the disagreement and/or to obtain more clinical information. Yale clinicians also reviewed some medical records to further determine the nature of disagreement.
To determine overall measure agreement, we calculated the percentage of patients for whom both the claims and medical record identified at least one complication or neither identified a complication. For each case where there was a disagreement between the medical record and claims-based measure, we verified and characterized each disagreement. We then conducted a detailed review of all disagreements between the specific complications documented (or not documented) in the claims data and the medical records, even if such disagreements did not result in overall measure disagreement. We then calculated the percentage of patients where the exact complication(s) coded in claims was also documented in the medical record and vice versa (referred to throughout as “one-to-one agreement”).

Results

Hospital Recruitment

We recruited nine hospitals but one hospital was excluded from the study because they did not submit the required BAA to YNHHSC/CORE in time to participate.
Characteristics for the eight participating hospitals are described in Table 1. Nearly all hospitals are not-for-profit (n=7) and most are large hospitals (n=5 with more than 600

beds) with teaching status (n=5). The number of hip and knee arthroplasty procedures performed in 2007-2008 across hospitals ranged from 167 – 4,953. Half of all hospitals are located in the Mid-Atlantic region.

Table 1. Hospital Characteristics* (n=8)

Description	Number of Hospitals
Total Number of Hospitals	8
Number of THA and TKA procedures performed in 2007-	
> 3,000 ≤ 5,000	1
> 1,000 ≤ 3,000	3
≥ 500 ≤ 1,000	3
< 500	1
Ownership	
Government	1
For Profit	0
Not-For-Profit	7
Teaching Status	
Teaching	5
Non Teaching	3
Safety Net Status	
Safety-Net	2
Non-Safety Net	6
Number of Beds	
>600	5
>300 <=600	2
<300	1
Region	
New England	1
Middle Atlantic	4
East North Central	1
South Atlantic	2

*Based on 2008 American Hospital Association Data

Study Sample

The study included 644 patients - 319 patients who the claims-based measure identified as having one or more complications and 325 who the measure identified as having no complications. The medical record acquisition rate for these 644 patients was 96% (644 patient records received / 674 patient records requested).

Overall Measure Agreement

Overall measure agreement was 93% (598/644 patients). More specifically, there were 598 patients who either had a complication coded in the claims and a complication was also documented in the medical record or who had no complication documented in both

claims and medical record data. When we examined overall agreement in patients with and without complications, initial agreement was 86% for patients with a complication compared with 99% for patients without a complication. As discussed in detail below we are proposing some minor changes to the measure on the basis of this validation study. After the proposed measure changes are implemented, measure agreement between claims data and the medical record will increase to 99% (635/644).

Agreement of Individual Complications and Characterization of Each Complication-specific Disagreement

One-to-one agreement of the actual complication was 87% (558/644 patients); 558 patients had the same complication(s) coded in claims and in the medical record or had no complication coded in claims and no complication documented in the medical record.

Of the 644 patients in the study, 86 patients had at least one disagreement between a complication identified (or not identified) in claims data versus the medical record (although not all of these resulted in overall measure disagreement). For these 86 patients, there were a total of 97 disagreements between complications coded in claims data and those documented in the medical record. Table 2 characterizes each of the 97 disagreements.

Twenty-two percent of the disagreements were related to mechanical complications captured by the claims-based measure that were actually present on admission to the index hospital (they preceded the index hip or knee arthroplasty) and thus were not the result of the index procedure. In the vast majority of these cases the mechanical complications were coded in the principal discharge diagnosis field (which indicates the condition was present on admission). For example, a patient had a prior fracture of the lower femur which required stabilization with a metal rod in the past. After time, the metal rod caused a new fracture, and the patient was admitted (measure index admission) for removal of the rod and a total hip arthroplasty. This admission was captured in the measure as a “mechanical complication of internal orthopedic device”, but the complication was related to a prior procedure and not to the total hip arthroplasty which identified the patient for the measure. In only two instances when the complication was present on admission (2% of such disagreements) the measure identified a mechanical complication during the index admission via a secondary diagnosis field. YNHHSC/CORE recommends that patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission be excluded from the measure cohort (see below). Mechanical complications coded in a secondary diagnosis field during the index admission cannot be reliably identified as present on admission and therefore, we are not recommending excluding those patients from the measure cohort.

Twenty-one percent of the disagreements occurred in patients who the claims-based measure identified as having sepsis based on ICD-9 code 998.59, “Other postoperative infection.” We determined that this code is not sufficiently specific to sepsis, and the measure identified cases of sepsis that were not documented in the medical record.

Therefore, YNHHSC/CORE recommends removal of this code from the measure specifications.

Two disagreements occurred because the claims-based measure identified sepsis via ICD-9 codes 998.0 (postoperative shock) or 785.59 (other shock) but the patients did not have true infectious sepsis per the medical records (2% of all disagreements). Both medical records indicated that the patients experienced shock due to blood loss after surgery. The measure specifications for sepsis currently include ICD-9 codes 998.0 and 785.59 (Appendix C), but shock is not reflected in the title of that complication. YNHHSC/CORE recommends changing the title of the sepsis complication to include shock, as it more accurately reflects the current specifications and appropriately identifies patients with severe post-operative complications.

Twenty percent of disagreements occurred because the measure identified a wound infection or a periprosthetic joint infection, and the medical record indicated the other. These two complications can be clinically difficult to differentiate. Therefore, YNHHSC/CORE recommends combining wound infection and periprosthetic joint infection as a single complication in the measure specifications.

Thirty-one percent of complications were due to “true” inconsistencies in claims data and medical records. For example, claims data indicated a wound infection, but there was documentation in the medical record instead of a surgical site bleed. A subset of these disagreements occurred because the complication identified by the claims-based measure was documented in the medical record but not related to the index procedure (5%). For example a patient who had a hip replacement was readmitted to the hospital for a mechanical complication that was related to a prior knee replacement. In a few cases (n=3) the claims-based measure did not identify pneumonia during a readmission because it was coded in a secondary diagnosis field (3%) which are not captured per the measure specifications. Despite disagreement at the complication level for these patients, there was overall measure agreement between the claims data and the medical record on the measure outcome in 90% of the above cases (yes/no for any complication).

Table 2. Characterization of Disagreements

Disagreement (n=97)	Number (%)*	Proposed Change to Measure	Rationale
Measure identified a mechanical complication during the index admission, but it was actually present on admission	21 (22%) (19 coded in principal field and 2 coded in secondary field)	Exclude these patients from measure cohort if in principal discharge diagnosis field	These are most often patients with a distant fracture that has been treated surgically (with open reduction and internal fixation). These patients represent more technically complex arthroplasty procedures and as such may be at increased risk for complications, particularly mechanical complications.
Measure identified sepsis via ICD-9 code 998.59 (other postoperative infection) but was not truly sepsis	20 (21%)	Remove ICD-9 code 998.59 from measure specifications for sepsis	The code is not specific enough to identify true cases of sepsis.
Measure identified sepsis via ICD-9 codes 998.0 (postoperative shock) or 785.59 (other shock) but patient did not have true infectious sepsis; they experienced shock due to blood loss	2 (2%)	Change complication name to "Sepsis/Shock" (measure specifications unchanged)	The measure specifications for sepsis complication include shock codes but shock is not reflected in the title. Shock is a similarly significant clinical event to sepsis and should be assessed as a complication.
Measure identified wound infection and/or periprosthetic joint infection but the other was coded in the medical record	19 (20%)	Combine wound infection and periprosthetic joint infection outcomes	It is often difficult to distinguish between wound infections and periprosthetic joint infection. The codes for both are used interchangeably. The interventions and follow-up periods are the same. There will still be overall measure agreement.
Complication documentation inconsistent between claims and medical record (e.g. complication documented in medical record but not coded in	30 (31%)	None (True disagreement)	

Disagreement (n=97)	Number (%)*	Proposed Change to Measure	Rationale
claims)			
Complication was not related to the procedure	5 (5%)	None (True disagreement)	
TOTAL	**97**		

*Percentages do not add to 100 due to rounding

Proposed Changes to the Measure

After categorizing and conducting a detailed review of all disagreements, YNHHSC/CORE proposes the following changes to the measure specifications. The first two are minor changes to the cohort or outcome identification. The second two are simply changes in the naming of complications without having any impact on the patients included in the measure or the complications captured:

1. Exclude patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission.
   Rationale: A complication coded in the principal field indicates it was present on admission. Furthermore, these patients represent more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications.

2. Remove sepsis code 998.59 from the specifications for identifying cases of sepsis.
   Rationale: This is a non-specific code that identified cases that were not true cases of sepsis.

3. Change the title of "Sepsis" complication to "Sepsis/Shock."
   Rationale: The measure specifications for sepsis include shock codes (785.59, 998.0), but this was not reflected in the title.

4. Combine wound infection and periprosthetic joint infection outcomes into a single complication of wound infection/periprosthetic joint infection.
   Rationale: It is often difficult to distinguish between wound infections and periprosthetic joint infections and the codes for both are frequently used interchangeably. Furthermore, the follow-up periods for periprosthetic joint infection and wound infection are the same.

Effect of Proposed Changes on the Risk-standardized Complication Rate

To determine the effects of the proposed modifications to the measure, we recalculated the risk-standardized complication rate after removing ICD-9 code 998.59 from the sepsis specifications and after excluding from the measure cohort all patients who had a mechanical complication coded in the principal discharge diagnosis field on the index admission. Of note, ICD-9 code 998.59 is also in the measure specifications for wound infection, but was only removed from the sepsis specifications.

There were 627 patients whose only complication was sepsis identified by ICD-9 code 998.50. After removing sepsis code 998.59 there were still 290,329 patients in the measure, but the total number of patients with complications decreased by 627. After excluding from the measure cohort the patients who had a mechanical complication coded in the principal discharge diagnosis field on the index admission, the number of patients in the cohort decreased by 930 patients to 289,399 patients.

Prior to these two changes, there were 290,329 patients in the measure and the risk-standardized mean complication rate was 4.23% (range 2.20 to 8.88%). The risk-standardized mean complication rate after implementing these two changes is 3.84% (range 1.87 to 7.60%).The proposed changes will have a small effect on the risk-standardized complication rate and the measure will not include patients who had an arthroplasty due to a complication from a prior orthopedic procedure. Removal of the non-specific sepsis code (998.59) will eliminate cases of sepsis that were not a true infectious sepsis complication.