NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1550 **NQF Project:** Surgery Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)
De.2 **Brief description of measure***:* This measure estimates hospital risk-standardized complication rates (RSCRs) associated with primary elective THA and TKA in patients 65 years and older. The measure uses Medicare claims data to identify complications occurring from the date of index admission to 90 days post date of the index admission.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** This measure is paired with a readmission measure for THA and TKA.
De.4 **National Priority Partners Priority Area:** Care coordination, Safety De.5 **IOM Quality Domain**: Effectiveness, Patient-centered, Efficiency, Safety De.6 **Consumer Care Need:** Getting better, Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary A.4 **Measure Steward Agreement attached:**	**A** Y☐ N☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, High resource use, Other 1a.2 High cost 1a.3 **Summary of Evidence of High Impact:** High complication rate We conducted analyses using 2008 Medicare Part A inpatient claims data and found a median 30-day unadjusted hospital complication rate of 6.7%. This rate is high considering these are elective procedures typically performed on younger, healthier patients, compared to other Medicare patients. Complication rates following THA and TKA warrant investigation as these procedures are elective, costly, and projected to increase over the coming years (Kurtz et al., 2007). Complication rates have been shown to vary across hospitals, suggesting care can be improved. Prospective studies show risk adjusted rates for periprosthetic joint infection, a rare but devastating complication, vary between 2.3 to 1.6 percent after 1 and 2 years of follow-up respectively (Kurtz et al., 2010; Bongartz et al., 2008). Ninety-day death rates following THA also range from 0.7 to 2.7 percent and are high for an elective procedure (Cram et al., 2007; Soohoo et al., 2010). Rates for pulmonary embolism following TKA range from 0.5 and 0.9 percent (Cram et al., 2007; Mahomed et al., 2003; Khatod et al., 2008; Solomon et al., 2006;). Rates for wound infection in Medicare population based studies vary between 0.3 and 1.0 percent (Cram et al., 2007; Mahomed et al., 2003; Solomon et al., 2006). Rates for septicemia range from 0.1%, during the index admission (Browne et al., 2010) to 0.3%, 90 days following discharge for primary TKA (Cram et al.,	**1a** C☐ P☐ M☐ N☐

2007). Rates for bleeding and hematoma following TKA range from 0.94 (Browne et al., 2010) to 1.7% (Huddleston et al., 2009).

The variation in complication rates across hospitals indicates there is room for quality improvement and targeted efforts to reduce these complications could result in better patient care and potential cost savings.

High volume
THA and TKA are priority areas for outcomes measure development, as they are commonly performed procedures in the US. In 2003 there were 202,500 primary hip arthroplasties and 402,100 primary total knee arthroplasties performed (Kurtz et al., 2007). The number of procedures performed has increased steadily over the past decade (Kurtz et al., 2007; Ong et al., 2006) and complications may increase the risk of revision procedures which are even more costly and associated with higher resource utilization (Ong et al., 2006).

High cost
Although these procedures can dramatically improve health-related 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 (Kurtz et al., 2007). 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 (Kurtz et al., 2007). Medicare is the single largest payer for these procedures, covering approximately two-thirds of all THAs and TKAs performed in the US (Ong et al., 2006). THA and TKA procedures combined account for the largest procedural cost in the Medicare budget (Bozic et al., 2008).

1a.4 Citations for Evidence of High Impact: Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713-1720.

Bozic KJ, Rubash HE, Sculco TP, Berry DJ. An analysis of medicare payment policy for total joint arthroplasty. Journal of Arthroplasty. 2008;23(6 Suppl 1):133-138.

Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152-156.

Cram P,Vaughan-Sarrazin MS,Wolf B,Katz JN,Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675-1684.

Huddleston JI,Maloney WJ,Wang Y,Verzier N,Hunt DR,Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95-100.

Khatod M,Inacio M,Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812-819.
Kurtz S,Ong K,Lau E,Bozic K,Berry D,Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.
Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780-785.
Kurtz SM, Ong KL, Schmier J, et al. Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:144-151.
Mahomed NN,Barrett JA,Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. Jan 2003;85-A(1):27-32.
Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. Clin Orthop Relat Res. May 2006;446:22-28.
Solomon DH,Chibnik LB,Losina E, et al. Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536-1542.
Soohoo NF,Farng E,Lieberman JR,Chambers L,Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363-2371.

1b. Opportunity for Improvement

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1b.1 Benefits (improvements in quality) envisioned by use of this measure: Measuring and reporting complication rates will inform health care providers about opportunities to improve care, strengthen

incentives for quality improvement, and ultimately improve the quality of care for Medicare patients. The measure will also provide patients with information that could guide their choices. In addition, it has the potential to lower health care costs associated with complications. The measure will increase transparency for consumers.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
There is considerable variation in practice patterns, patient outcomes, and adherence to payer-defined practice guidelines for both THA and/or TKA (Bozic et al., 2008). The unadjusted mean complication rate was 4.98% and ranged from 0% to 100% across 3,311 hospitals in 2008. After adjustment for patient and clinical characteristics, the mean hospital-level complication rate was 4.23% ranging from 2.20-8.88%. The variation observed for complications suggested there are differences in the quality of care delivered across hospitals that result in variation in outcomes.

Primary elective THA and TKA are beneficial procedures that greatly improve the quality of life for patients who choose to undergo these procedures (Hawker et al., 1998). Understanding and addressing causes of complications in this elective group of patients may improve the quality of care and reduce costs associated with THA and TKA.

1b.3 Citations for data on performance gap:
Bozic KJ, Chiu V. Quality Measurement and Public Reporting in Total Joint Replacement. The Journal of Replacement. 2008; 23:146-149.

Hawker GJ, Wright J, Coyte P, Paul J, Dittus R, Croxford B, et al. Health-related quality of life after knee replacement. J Bone Joint Surg Am. 1998; 80:163-73.

1b.4 Summary of Data on disparities by population group:
We conducted analyses to explore disparities by SES. We used Medicaid eligibility status identified in the Medicare claims enrollment database (EDB) as a proxy for SES. This approach is consistent with prior research as well as NQF recommendations (http://www.nysna.org/images/pdfs/practice/nqf_ana_outcomes_draft10.pdf). Patients were categorized into two groups, based on their eligibility status for Medicaid (yes/no). The Medicaid eligible population represents lower SES status. Analyses demonstrated that although SES is a significant predictor of readmission at the patient level, it does not affect overall hospital performance in the risk-adjusted readmission model. Consistent with NQF guidelines, this measure does not risk-adjust for SES factors.

1b.5 Citations for data on Disparities:
N/A

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure will calculate hospital-level complication rates following elective primary THA and/or TKA with the goal to reduce complication rates. It addresses a priority condition (osteoarthritis) and will lead to reduced morbidity and mortality post THA and TKA.

1c.2-3. Type of Evidence: Expert opinion, Systematic synthesis of research

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Complications following primary elective THA and/or TKA are important patient outcomes that may reflect quality of care delivered to patients undergoing these procedures. However, the evidence available on the relationship between healthcare processes and complication outcomes from primary elective THA and/or TKA is sparse. Most of the research into complications of primary elective THA and/or TKA estimate rates and patient level characteristics that predict outcomes. Few studies examine hospital and provider level characteristics associated with complications from THA and/or TKA. However, a working group and technical expert panel (TEP) of orthopedists, rheumatologists, consumer and purchaser perspective, disparities experts, and quality improvement experts were consulted in determining which complications are likely

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attributable to care processes (see section 2c for details) and can be reduced.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):** N/A (outcome measure)

1c.6 Method for rating evidence: N/A (outcome measure)

1c.7 Summary of Controversy/Contradictory Evidence: Defining Complications
After conducting a comprehensive literature review and in consultation with the working group, YNHHSC/CORE identified complications for potential inclusion in a complications measure. 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
? Acute myocardial infarction (AMI)
? Pneumonia
? Sepsis/septicemia
? Deep vein thrombosis (DVT)
? Urinary tract infection (UTI)

DVT and UTI were excluded based on working group feedback and the literature. We excluded DVT because there is wide variability across hospitals in screening (Geerts et al., 2004; Pierce et al., 2008) and readmission practices for this complication. We excluded UTI because there is wide variability in diagnosing UTI, and the rates are likely inflated due to overdiagnosis in patients post THA/TKA (Woodford et al., 2009).

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

A potential area of controversy may be the varying degrees of severity for some of the complications. Degrees of severity are not conveyed in the ICD-9 diagnosis codes, specifically, wound infection, periprosthetic joint infection, and surgical site bleeding. For example, the diagnosis codes used to identify wound infection may reflect redness and swelling around the incision site, or a true wound infection, requiring incision and drainage. Thus, to capture clinically important complications and to reduce the likelihood of capturing miscoded complications, working group and TEP members recommended only counting these complications in the outcome if they are associated with accompanying ICD-9 procedure codes indicating that they were severe enough to require specific interventions. We therefore imposed additional coding requirements for these complications to set an appropriate threshold for severity.

Complication-specific follow-up periods
We identified the follow-up period for each complication based on preliminary data analyses and expert clinical input. Our empirical analyses indicated that the rates for all complications were elevated during the

index admission and returned to baseline within 30 to 90 days post the index date of admission, depending on the complication. We confirmed the follow-up periods with an expert panel that included orthopaedic surgeons, a rheumatologist, and experts in quality measurement.
The inclusion of medical complications (acute myocardial infarction, pneumonia, and sepsis) may be controversial because some clinicians may feel these medical conditions are not attributable to the procedure. Our data indicated, however, that the rates for these medical complications are elevated during the index admission period and decrease sharply 7 days from admission, returning to baseline within 30 days of the index admission date. Therefore, the follow-up period for these medical complications was limited to 7 days post index admission date, as they are more likely to be attributable to the procedure if they occur within 7 days of the index date of admission. Restricting the follow-up period to 7 days also limits overlap with the 30-day all-cause readmission measure.

Use of Hierarchical Generalized Linear Modeling
Hierarchical modeling for hospital outcomes measurement is the appropriate statistical approach for hospital outcomes measures given the structure of the data and the underlying assumption of such measures, which is that hospital quality of care influences complication rates. However, CMS frequently receives comments and questions about this approach, so we are concisely reiterating the rationale for and merits of using hierarchical logistic regression. Patients are clustered within hospitals and, as such, have a shared exposure to the hospital quality and processes. The use of hierarchical modeling accounts for the clustering of patients within hospitals. Second, hierarchical models distinguish within-hospital variation and between-hospital variation to estimate the hospital's contribution to the risk of complications. This allows for an estimation of the hospital's influence on patient outcomes. Finally, within hierarchical models we can account for both differences in case mix and sample size to fairly profile hospital performance. If we did not use hierarchical modeling we could overestimate variation and potentially misclassify hospitals' performance. Accurately estimating variation is an important objective for models used in public reporting and potentially used in value-based purchasing programs.

1c.8 Citations for Evidence (*other than guidelines***):** Geerts WH,Pineo GF,Heit JA, et al. Prevention of Venous Thromboembolism. Chest. September 1, 2004 2004;126(3 suppl):338S-400S.

Pierce C,Haut E,Kardooni S, et al. Surveillance bias and deep vein thrombosis in the national trauma data bank: the more we look, the more we find. J Trauma. 2008;64:6.

Woodford HJ,George J. Diagnosis and Management of Urinary Tract Infection in Hospitalized Older People. Journal of the American Geriatrics Society. 2009;57(1):107-114.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
N/A - We did not set any clinical practice guidelines as this is an outcomes measure, not a process of care measure.

1c.10 Clinical Practice Guideline Citation: N/A
1c.11 National Guideline Clearinghouse or other URL: N/A

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
N/A

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)*:
N/A

1c.14 Rationale for using this guideline over others:
N/A

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met? **Rationale:**	**1** **Y☐**

	N☐
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1c tests per year); thus, we are using this field to define the outcome (i.e. adverse events) following THA and/or TKA procedures. The composite complication is a binary outcome (yes for any complication(s); no for no complications). Therefore, if a patient experiences 1 or more complications, the outcome variable will get coded as a "yes." Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complications captured in the numerator are identified during the index admission or associated with a readmission up to 90 days post date of index admission, depending on the complication. The follow-up period for complications from date of index admission is as follows: 1) Mechanical complications - 90 days 2) Wound infection/Periprosthetic joint infection (PJI) - 90 days 3) Surgical site bleeding - 30 days 4) Pulmonary embolism - 30 days 5) Death - 30 days 6) AMI - 7 days 7) Pneumonia - 7 days 8) Sepsis/septicemia/shock - 7days **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** The specific time frame for the complication varies (depending on the complication) from 7 to 90 days post date of the index admission (see “Numerator Details”). **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** Complications are identified using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes. The complications listed below are counted in the measure if coded in the principal or secondary diagnosis fields during either the index admission or a readmission as indicated below. Multiple complications count only once toward the numerator. For example, if a patient experiences a mechanical complication and also has an acute myocardial infarction, the combined events will be counted only once in the measure. ICD-9 diagnosis and procedure codes used to identify complications are listed below: Complications identified from the date of index admission to 7 days post date of index admission: 1. Acute Myocardial Infarction – counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is only counted when coded in the principal discharge diagnosis field. Presence of one of the following diagnosis codes: 410.xx excluding 410.x2	**2a-specs** C☐ P☐ M☐ N☐

2. Pneumonia – counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is only counted when coded in the principal discharge diagnosis field.
Presence of one of the following diagnosis codes: 480, 480.0, 480.1, 480.2, 480.3, 480.8, 480.9, 481, 482, 482.0, 482.1, 482.2, 482.3, 482.30,482.31, 482.32, 482.39, 482.4, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, 482.89, 482.9, 483, 483.0, 483.1, 483.8, 485, 486, 487.0, 507.0

3. Sepsis/Septicemia/Shock* - counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is counted if coded in the principal or secondary discharge diagnosis field.
Presence of one of the following diagnosis codes: 038, 038.0, 038.1, 038.10, 038.11, 038.12, 038.19, 038.2, 038.3, 038.4, 038.40, 038.41, 038.42, 038.43, 038.44, 038.49, 038.8, 038.9, 785.52, 785.59, 790.7, 995.91, 995.92, 998.0, 790.7

Complications identified from date of index admission to 30 days post date of index admission:
4. Pulmonary Embolism - counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is counted if coded in the principal or secondary discharge diagnosis field.
Presence of one of the following diagnosis codes: 415.1, 415.11, 415.19

5. Surgical Site Bleeding - counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is counted if coded in the principal or secondary discharge diagnosis field.
Presence of one of the following diagnosis codes: 998.1,998.11, 998.12, 998.13, 286.5, 719.10, 719.16, 719.17

AND the following procedure code:
Incision and Drainage: 86.04

6. Death (Source: Medicare Enrollment Database)

Complications identified from date of index admission to 90 days post date of index admission:
7. Wound Infection/Periprosthetic Joint Infection** - counted in the measure if coded in the principal or secondary discharge diagnosis field on the index admission. For readmissions, it is counted if coded in the principal or secondary discharge diagnosis field.
Presence of one of the following diagnosis codes: 998.6, 998.83, 998.3, 998.30, 998.31, 998.32, 998.33, 998.5, 998.51, 998.59, 996.67, 996.66

AND at least one of the following procedure codes:
Incision and Drainage: 86.22, 86.28, 86.04
Revision: 81.53, 81.55, 81.59, 00.70, 00.71, 00.72, 00.73, 00.80, 00.81, 00.82, 00.83, 00.84
Removal: 80.05, 80.06, 80.09

8. Mechanical Complication - counted in the measure if coded in the secondary diagnosis field during the index admission. For readmissions, it is counted if coded in the principal or secondary diagnosis fields.
Presence of one of the following diagnosis codes: 996.4, 996.40, 996.41, 996.42, 996.44, 996.47, 996.49

* Following a medical record validation study of this measure, we renamed the title of this complication to "Sepsis/Septicemia/Shock" because the measure specifications for sepsis include shock codes (ICD-9 codes 785.59 and 998.0) but this was not reflected in the title.
Based on the validation study, we also removed ICD-9 code 998.59 from the specifications because it is a non-specific code that identified cases that were not true cases of sepsis. Please refer to section 2c, Validity Testing for details regarding the validation study.

** Based on the validation study, we combined wound infection and periprosthetic joint infection outcomes into a single complication of wound infection/periprosthetic joint infection because it is often difficult to distinguish between the two complications, and the codes for both are used interchangeably. Furthermore,

the follow-up periods for wound infection and periprosthetic joint infection are the same (90 days). Please refer to section 2c, Validity Testing for details regarding the validation study.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
The target population for this measure includes admissions for patients at least 65 years of age undergoing elective primary THA and/or TKA procedures.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: 65 years of age and older

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
This measure was developed using claims data from calendar year 2007 and 2008. The time period for public reporting has not been determined.

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
The denominator includes patients aged 65 and older admitted to non-federal acute care hospitals for an elective, primary THA and/or TKA in 2007 and 2008. Patients are eligible for inclusion in the denominator if they had a THA and/or a TKA AND had continuous enrollment in Medicare FFS one year prior to the date of index admission.

This cohort is defined using the following ICD-9-CM procedure codes identified in Medicare Part A Inpatient claims data:
81.51 Total Hip Arthroplasty
81.54 Total Knee Arthroplasty

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Patients will be excluded from the cohort if they meet any of the followed criteria:

1. Patients with hip fractures
   Presence of one of the following diagnosis codes: 733.1, 733.10, 733.14, 733.15, 733.19, 733.8, 733.81, 733.82, 733.95, 733.96, 733.97, 808.0, 808.1, 820.00, 820.01, 820.02, 820.03, 820.09, 820.10, 820.11, 820.12, 820.13, 820.19, 820.20, 820.21, 820.22, 820.30, 820.31, 820.32, 820.8, 820.9, 821, 821.0, 821.00, 821.01, 821.1, 821.10, 821.11, 808.xx
   Rationale: Patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is not elective.

2. Patients undergoing revision procedures (with or without a concurrent THA/TKA)
   Presence of one of the following diagnosis codes: 81.53, 81.55, 81.59, 00.70, 00.71, 00.72, 00.73, 00.80, 00.81, 00.82, 00.83, 00.84
   Rationale: Revision procedures may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication and readmission rates.

3. Patients undergoing partial hip arthroplasty procedures (with or without a concurrent THA/TKA)
   Presence of the following diagnosis code: 81.52
   Rationale: Partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions.

4. Patients undergoing resurfacing procedures (with or without a concurrent THA/TKA)
   Presence of one of the following diagnosis codes: 00.85, 00.86, 00.87
   Rationale: Resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients.

5. 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, and these patients underwent an arthroplasty due to a complication related to a prior procedure. Furthermore, these

patients may require more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications.

6. Patients who are 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.

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

8. Patients with more than two THA/TKA procedure codes during the index hospitalization
Rationale: Patients with more than two procedure codes for THA/TKA are excluded because it is rare that a patient would have 3 arthroplasty procedures done at one time. This is likely to be a coding error.

9. Patients with multiple admissions for THA/TKA in the 12 months studied; one hospitalization per patient was randomly selected for inclusion after applying the other exclusion criteria
Rationale: Observations are not independent; a patient is not eligible for the death outcome during the first admission if admitted later in the year for another procedure

* Based on a medical record validation study of this measure, we also excluded patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission because 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. Please refer to section 2c, Validity Testing for details regarding the validation study.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
See "Denominator Exclusion" section

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
This measure is not stratified.

2a.12-13 Risk Adjustment Type: Risk-adjustment devised specifically for this measure/condition

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
The measure estimates hospital-level RSCRs using hierarchical logistic regression models. In brief, the approach simultaneously models outcomes at two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals (Normand et al., 2007). At the patient level, the model adjusts the log-odds of a complication for age, sex, and selected clinical covariates. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of complication at the hospital, after accounting for case mix. If there were no differences among hospitals, then after adjusting for case mix, the hospital intercepts should be identical across all hospitals.

The measure adjusts for key variables that were clinically relevant and had strong relationships with the outcome (e.g. demographic factors, disease severity indicators, and indicators of frailty). For each patient, covariates are obtained from Medicare claims extending 12 months prior to and including the index admission. The model adjusts for case mix differences based on the clinical status of the patient at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis and procedure codes. 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. Hence, these conditions are not adjusted for if they only appear in the index admission and not in the 12 months prior to admission.
The risk adjustment model included 33 variables which are listed below:

Demographic
1. Age-65 (years above 65, continuous)
2. Sex

THA/TKA Procedure
3. THA procedure
4. Number of procedures performed

Clinical Risk Factors
5. Skeletal deformities (ICD-9 code 755.63)
6. Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)
7. Morbid obesity (ICD-9 code 278.01)
8. Metastatic cancer and acute leukemia (CC 7)
9. Cancer (CC 8-10)
10. Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)
11. Diabetes and DM complications (CC 15-20,119,120)
12. Protein-calorie malnutrition (CC 21)
13. Bone/Joint/Muscle Infections/Necrosis (CC 37)
14. Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)
15. Osteoarthritis of hip and knee (CC 40)
16. Osteoporosis and Other Bone/Cartilage Disorders (CC 41)
17. Dementia and senility (CC 49, 50)
18. Major psychiatric disorders (CC 54-56)
19. Hemiplegia, paraplegia, paralysis, function disability (CC 67-69, 100-102, 177-178)
20. Cardio-respiratory failure and shock (CC 79)
21. Chronic atherosclerosis (CC 83-84)
22. Stroke (CC 95, 96)
23. Vascular or circulatory disease (CC 104-106)
24. COPD (CC 108)
25. Pneumonia (CC 111-113)
26. Pleural effusion/pneumothorax (CC 114)
27. End-stage renal disease or dialysis (CC 129, 130)
28. Renal Failure (CC 131)
29. Decubitus ulcer or chronic skin ulcer (CC 148, 149)
30. Trauma (CC 154-156,158-161)
31. Vertebral Fractures (CC 157)
32. Other injuries (CC 162)
33. Major complications of medical care and trauma (CC 164)

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment THA-TKA Complications Technical Report.pdf

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Lower score

2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
The RSCR is calculated as the ratio of the number of "predicted" to the number of "expected" complications, multiplied by the national unadjusted complication rate. For each hospital, the "numerator" of the ratio is the number of complications predicted on the basis of the hospital's performance with its observed case mix, and the "denominator" is the number of complications 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 or better quality and a higher ratio indicates higher-than-expected complication or worse quality.

The predicted hospital outcome (the numerator) is calculated by regressing the risk factors and the hospital-specific intercept on the risk of complications, multiplying the estimated regression coefficients by the patient characteristics in the hospital, transforming, and then summing over all patients attributed to the

hospital to get a value. The expected number of complications (the denominator) is obtained by regressing the risk factors and a common intercept on the complications outcome using all hospitals in our sample, multiplying the subsequent estimated regression coefficients by the patient characteristics observed in the hospital, transforming, and then summing over all patients in the hospital to get a value.

Please see attachment for more details on the calculation algorithm.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)*:
The method for discriminating hospital performance has not been determined. For the 6 publicly reported measures of hospital outcomes developed with similar methodology and reported on the CMS website www.hospitalcompare.hhs.gov, CMS currently estimates an interval estimate for each risk-standardized rate to characterize the amount of uncertainty associated with the rate, compares the interval estimate to the national crude rate for the outcome, and categorizes hospitals as "better than the US national rate," "worse than the US national rate," or "no different than the US national rate." However, the decision to publicly report this measure and the approach has not been determined.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
This measure is not based on a survery or sample.

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Administrative claims

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The datasets used to create the measures are described below.

1. 2008 Part A (inpatient) data
   Part A inpatient data includes claims paid for Medicare inpatient hospital care, skilled nursing facility care, some home health agency services, and hospice care. For purposes of this project, Part A is used to refer to inpatient services only and includes data from 2 time periods:
   a. Index admission: Index admission data are based on the inclusion/exclusion criteria for THA/TKA, and comorbidities (if any) are identified from the secondary diagnoses associated with the index admission.
   b. Pre-index: 12 months prior to the index admission ("pre-index").

2. 2008 Part A (outpatient) data – 12 months pre-index
   Hospital outpatient refers to Medicare 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.

3. Part B data – 12 months pre-index
   Part B data refers to Medicare claims for the services of physicians (regardless of setting) and other outpatient care, services, and supplies. For purposes of this project, Part B services included only face-to-face encounters between a care provider and patient. We thus do not include services such as laboratory tests, medical supplies, or other ambulatory services.

4. 2008 Medicare Enrollment Database
   This database contains Medicare beneficiary demographic, benefit/coverage, enrollment status on admission, and vital status information. These data have previously been shown to accurately reflect patient vital status (Fleming Fisher et al., 1992).

Fleming C., Fisher ES, Chang CH, Bubolz D, Malenda J. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs Hospitals. Medical Care. 1992; 30(5): 377-91.

2a.26-28 Data source/data collection instrument reference web page URL or attachment:

2a.29-31 Data dictionary/code table web page URL or attachment: URL N/A
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1182785083979

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital/Acute Care Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: Medicare Part A inpatient claims data for calendar year 2007 and 2008 were used to test reliability. The 2008 cohort included 290,329 admissions and the 2007 cohort included 294,697 admissions.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
The reliability of the model was tested using identical cohort inclusion/exclusion criteria for patients who underwent THA and/or TKA. We randomly selected 50% of the THA and/or TKA admissions that met all inclusion and exclusion criteria in 2008 and created a development sample, which we used to build the model. We used the remaining 50% of THA/TKA admissions in 2008 as the validation sample. We also used all qualifying THA and/or TKA admissions in 2007 data as an additional sample to validate the model. Model performance was assessed in the development dataset and both validation datasets. In addition, we will run the model in addtional datasets and compare the risk-standardized complication rates for each hospital.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Preliminary results indicate similar model performance in both cohorts (e.g., ROC=0.69 in the development cohort, 0.70 in the 2008 validation cohort, and 0.69 in the 2007 validation cohort).

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2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: External Validity

We included Medicare beneficiaries 65 years of age or older who had a primary elective total hip and/or total knee arthroplasty 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.
Eight hospitals participated in the medical record validation study. The study sample included 644 patients who underwent elective total hip arthroplasty or total knee arthroplasty in 2007-2008. Of the 644 patients, there were 319 whom the claims-based measure identified as having one or more complications and 325 whom 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).

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:
Face Validity

During measure development, we consulted with representatives from potential users of this measure including clinicians, professional societies, payers, and consumers. We use this field to describe the role that these representatives played on the working group and Technical Expert Panel (TEP). We used a structured measure evaluation tool to assess face validity and other measure properties.

We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside experts, and with the public. The measure is consistent with the technical approach to outcomes measurement set forth in National Quality Forum (NQF) guidance for outcomes measures (National Quality Forum, 2010), CMS Measure Management System guidance, and the guidance articulated in

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the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes" (Krumholz et al., 2006). We obtained expert and stakeholder input on the measure through three mechanisms: first, through regular discussions with a working group; 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, we assembled a working group that included individuals with clinical and methodological expertise relevant to orthopedic quality measurement. We held regular conference calls throughout the development process, and the Yale team 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 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 including clinicians, consumers, hospitals, purchasers, and experts in quality improvement. Finally, we solicited public comment on the proposed measure through CMS' Measure Management System Public Comment site (https://www.cms.gov/MMS/17_CallforPublicComment.asp#TopOfPage). Public comments were summarized and publicly posted for 30 days. The resulting content was taken into consideration during the final stages of measure development.

National Quality Forum. National voluntary consensus standards for patient outcomes, first report for phases 1 and 2: A consensus report http://www.nysna.org/images/pdfs/practice/nqf_ana_outcomes_draft10.pdf. Accessed August 19, 2010.

Krumholz HM,Brindis RG,Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation. January 24, 2006 2006;113(3):456-462.

External Validity

Administrative databases may be subject to coding errors and variation in coding practices within and across care settings. We therefore conducted a medical record validation study 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. In addition, we conducted a secondary analysis of agreement of individual specific complications to identify opportunities for measure improvement.

YNHHSC/CORE developed a standardized abstraction tool, and a CMS-approved subcontractor, Information Collection Enterprises, LLC (ICE), conducted the medical record abstraction. A senior statistician at YNHHSC/CORE conducted a detailed analysis of each abstracted patient record received from ICE and compared the findings to the patients results found in the claims-based measure. YNHHSC/CORE conducted an iterative review of each case where the claims-based measure differed from the medical record, and physicians at YNHHS/CORE adjudicated differences.

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. This assessment led us to propose minor modifications to the measure, as detailed in the "Testing Results" section below.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test*

conducted):
Face Validity

The experts agree the measure accurately reflects the quality of care and distinguishes levels of quality for patients undergoing THA and/or TKA.

External Validity

The overall measure agreement was 93% based on the original measure specifications. More specifically, there were 598 patients (of the 644 total) 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. 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 a result of the detailed review of the discrepancies between complications, we made some minor changes to the measure. After the proposed measure changes are implemented, measure agreement between claims data and the medical record will increase to 99%.
1) Remove sepsis code 998.59, "Other postoperative infection," from the measure specifications for sepsis. This excludes patients who did not have true cases of sepsis complication. This code, ICD-9 code 998.59, is appropriately included in the measure specifications for wound infection, and will only be removed from the sepsis specifications.
2) Exclude patients with a mechanical complication coded in the principal discharge diagnosis field of the index admission. This excludes from the measure cohort patients who were undergoing a non-elective arthroplasty due to a complication related to a prior procedure. Furthermore, these patients represent more technically complex arthroplasty procedures, and may be at increased risk for complications, particularly mechanical complications.
3) Change the title of "Sepsis/Septicemia" complication to "Sepsis/Septicemia/Shock" to reflect the presence of shock codes in this complication category.
4) Combine wound infection and periprosthetic joint infection outcomes into a single complication of "Wound Infection/Periprosthetic Joint Infection." This will have minimal effect on the measure because periprosthetic joint infection and wound infection are clinically similar, and the follow-up periods for the two are the same.

Quantitative Impact of Changes to the Measure

Numerator and Denominator Effects
Prior to modifications 1 and 2 stated above, there were 290,329 patients in the measure cohort, and the measure identified 12,556 patients as having one or more complications in 2008-2009. Of the patients with complications, there were 627 patients whose only complication was sepsis identified by ICD-9 code 998.59 (5.0% of all patients with at least one complication). After removing sepsis code 998.59 (as per modification 1), there were still 290,329 patients in the measure, but the total number of patients with complications decreased by 627 to 11,929.
After excluding from the measure cohort the patients who had a mechanical complication coded in the principal discharge diagnosis field on the index admission (as per modification 2), the number of patients in the cohort decreased by 930 patients to 289,399 patients (a less than 0.5% decrease), and 10,992 had one or more complications.

Overall Impact on Measure Score
Prior to the measure modifications, the hospital risk-standardized mean complication rate was 4.23% (range 2.20 to 8.88%). After implementing the modifications, the hospital risk-standardized mean complication rate decreased to 3.84% (range 1.87 to 7.60%). Thus, the proposed modifications have a small effect on the hospital risk-standardized mean complication rate, but the range of the rate still shows significant variation in hospital complication rates.

Overall Impact on Model Performance
Given the small effect on the complication rate and the cohort size, we would not expect these changes to have a meaningful impact on the model performance. We have not made structural changes to the model,

but have only refined our approach to the cohort composition and complication identification in order to make the measure more accurate.	
2d. Exclusions Justified **2d.1 Summary of Evidence supporting exclusion(s):** Rationale for exclusions is described in "Denominator Exclusions **2d.2 Citations for Evidence:** See "Denominator Exclusions" **2d.3 Data/sample** *(description of data/sample and size)*: N/A **2d.4 Analytic Method** *(type analysis & rationale)*: N/A **2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)*: N/A	**2d** C☐ P☐ M☐ N☐ NA ☐
2e. Risk Adjustment for Outcomes/ Resource Use Measures **2e.1 Data/sample** *(description of data/sample and size)*: 2008 Medicare Part A (inpatient) data, hospital outpatient data, and Part B data were used to identify candidate variables for risk adjustment. Specifically, Medicare Part A inpatient data was used to identify variables for risk adjustment in the index admission, while Part A outpatient and Part B data were used to identify variables for risk adjustment in the 12-month period preceding the index date of admission. As described in section 2b, we developed and validated the model in three separate cohorts to assess and compare model performance: (1) development sample of 145,206 admissions in 2008 data; (2) validation sample of 145,123 admissions in 2008 data; and (3) validation sample of 294,697 admissions in 2007 data. **2e.2 Analytic Method** *(type of risk adjustment, analysis, & rationale)*: This measure was fully risk-adjusted using a hierarchical logistic regression model to calculate hospital risk-standardized complication rates (RSCR). (see "risk adjustment methodology/variables" for additional details). Approach to assessing model performance: For the development and validation cohort, we computed five summary statistics for assessing model performance (Harrell, 2001): (1) over-fitting indices (over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients) (2) predictive ability (3) area under the receiver operating characteristic (ROC) curve (4) distribution of residuals (5) model chi-square (A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation. F.E. Harrell and Y.C.T. Shih, Using full probability models to compute probabilities of actual interest to decision makers, Int. J. Technol. Assess. Health Care 17 (2001), pp. 17–26. **2e.3 Testing Results** *(risk model performance metrics)*: Performance Metrics in Development Cohort: Development cohort consisted of 145,206 patient stays at 3,221 hospitals (half of 2008 cohort), with a risk-adjusted median complication rate of 4.2%. The development model has strong discrimination and fit. The risk-standardized complication rate ranges from 2.5% to 8.6%, a range of 6.1%. Results are summarized below:	**2e** C☐ P☐ M☐ N☐ NA ☐

Over-fitting indices: (0,1)
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 95.8%; [0, 2) = 0.4%; [2+ = 3.8%
Model Chi-square [# of covariates]: 4401 [33]
Predictive ability (lowest decile %, highest decile %): (2, 15)
Area under the ROC curve = 0.69 (GLM)

The discrimination and the explained variation of the model are consistent with those of models currently used to publicly report condition specific rates of both mortality and readmission.

Model Validation using 2008 Validation Cohort: 2008 validation cohort consisted of 145,123 admissions (other half of the 2008 cohort) randomly selected from 3,223 hospitals, with a risk-standardized median complication rate of 4.1%. The model performance was not substantively different in this validation sample, as compared to the development sample. Results are summarized below:

Over-fitting indices: (0.04, 1.02)
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 95.8%; [0, 2) = 0.4%; [2+ = 3.7%
Model Chi-square[# of covariates]: 4698 [33]
Predictive ability (lowest decile %, highest decile %):(2, 15)
Area under the ROC curve = 0.70

Model Validation using 2007 Validation Cohort: 2007 validation cohort consisted of 294,697 admissions from 3,300 hospitals. The model performance was not substantively different in this validation sample, as compared to the development sample. Results are summarized below:

Over-fitting indices: (0.002, 1.00)
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 95.7%; [0, 2) = 0.4%; [2+ = 3.9%
Model Chi-square[# of covariates]: 9236 [33]
Predictive ability (lowest decile %, highest decile %):(2, 15)
Area under the ROC curve = 0.69

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models. The frequencies and regression coefficients are fairly consistent over the two cohorts.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: 2008 Medicare Part A inpatient claims data.

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Unadjusted median hospital-level complication rates following THA and/or TKA were assessed across hospitals.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Median hospital-level risk-standardized complication rate was 4.2% with a range from 2.2-8.9%. This is likely a signal of differences in the quality of care received for patients undergoing THA and/or TKA. Total hip replacement and TKA are elective procedures typically performed on healthy patients. Therefore, complication rates are expected to be lower than that for an emergent procedure. The variation observed for complications is likely a signal that though rates may be relatively low there are differences in the quality of care delivered across hospitals that result in variation in outcomes.

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2g. Comparability of Multiple Data Sources/Methods

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2g.1 Data/sample *(description of data/sample and size)*: No comparable data source is available at this time. We will perform validity testing of the development model in data from a different time frame. **2g.2 Analytic Method** *(type of analysis & rationale)*: N/A **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*: N/A	**P**☐ **M**☐ **N**☐ **NA**☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: This measure is not stratified. **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** There were no disparities detected during measure development. Please see "Summary of Data on Disparities by Population Group" for additional details.	**2h** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met? **Rationale:**	***2*** **C**☐ **P**☐ **M**☐ **N**☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** Not in use but testing completed **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): CMS plans to use the measures for public reporting and will propose the measures through rulemaking process. **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** This measure is not currently in use. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)*: N/A **3a.5 Methods** *(e.g., focus group, survey, QI project)*: No consumer or other field testing has been completed at this time. However, this measure was systematically evaluated by an expert group of orthopedists and Technical Expert Panel (TEP) over a period of 8 months. Regular meetings were held throughout the development of this measure, during which we received input and feedback on key methodological and other measure decisions (see section 2c - Validity Testing for more details on process of TEP input). **3a.6 Results** *(qualitative and/or quantitative results and conclusions)*: The TEP agreed that the measure would be useful in informing consumers and hospitals.	**3a** **C**☐ **P**☐ **M**☐ **N**☐

3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?**	**3b** C☐ P☐ M☐ N☐ NA ☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** N/A	**3c** C☐ P☐ M☐ N☐ NA ☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA ☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and**	**4d** C☐ P☐

describe how these potential problems could be audited. If audited, provide results.

Using administrative claims variables for risk adjustment

This measure uses variables from claims data submitted by hospitals to CMS for payment as "clinical" risk adjusters. Prior research has demonstrated that administrative claims data can be used to develop risk-adjusted outcomes measures for mortality following admission for myocardial infarction, heart failure, and death and that the models produce estimates of risk-standardized mortality rates (RSMRs) that are very similar to rates estimated by models based on chart data. This high level of agreement between the clinical and claims-based models supports the use of the claims-based models for public reporting. The models have also demonstrated consistent performance across years of claims data. The approach to identifying risk factors for patients also mitigates the potential limitations of claims data. Because not every diagnosis is coded at every visit, we identified comorbid conditions for risk adjustment in inpatient, outpatient, and physician claims data coded in the year prior to admission, as well as those coded in the secondary diagnosis fields during the index admission. This strategy allows for comprehensive review of patients' medical histories. If a diagnosis appeared only once, in some visits and not others, it was included, minimizing the effect of incomplete coding.

We were careful, however, to include information about each patient's status at admission and not to adjust for possible complications of the admission. Although some codes, by definition, represent conditions that are present before admission (e.g. cancer), other codes and conditions cannot be distinguished from complications occurring during the index hospitalization (e.g. infection or shock). If these are secondary diagnoses from the index admission, then they are not adjusted for in the analysis.

Using administrative claims codes to define complications

This measure identifies complications in claims data. This approach is similar to that used in an ICD complications measure recently approved by NQF. In consultation with a technical expert panel, it was agreed that the codes and restrictions applied to certain complication definitions (i.e., requiring an intervention/procedure code in addition to the diagnosis code for the complication itself) were adequate for identifying clinically significant adverse events (outcomes). To further assess the accuracy of the administrative claims codes, we plan to conduct a validation study to determine whether the specific codes used to identify complications in Medicare claims reliably identify hip/knee complications documented in charts.

Potentially creating access barrier

Because THAs and TKAs are elective procedures, publicly reporting the measure could potentially reduce access to care for certain patients who may be healthy enough to undergo the procedure but who carry a higher risk for complications.

M☐ N☐

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:

N/A

4e.2 Costs to implement the measure (*costs of data collection, fees associated with proprietary measures*)**:**

This measure uses claims data submitted by hospitals to CMS for payment, There are no costs associated with data collection, as hospitals are mandated by CMS to submit claims for reimbursement purposes. There is no additional cost/burden on hospitals.

4e.3 Evidence for costs:

N/A

4e.4 Business case documentation: Key points as noted in various sections of this document are as follows:

1. The median 30-day all-cause risk-standardized complication rate is high (4.2%)
2. There is substantial variation in risk-standardized complication rates across hospitals, ranging from 2.2-8.9%, respectively) (based on preliminary analysis of 2008 Part A inpatient claims data).
3. Quality of care should be addressed as THA and TKA procedures are associated with high volume and cost

4e C☐ P☐ M☐ N☐

(relative to other elective procedures performed in the Medicare population).	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility?*	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

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Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION

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Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
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Richard E. White, Jr., MD
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Ad.2 If adapted, provide name of original measure:

Ad.3-5 If adapted, provide original specifications URL or attachment
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** **Ad.7 Month and Year of most recent revision:** **Ad.8 What is your frequency for review/update of this measure?** **Ad.9 When is the next scheduled review/update for this measure?**
Ad.10 Copyright statement:
Ad.11 Disclaimers:
Ad.12 -14 Additional Information web page URL or attachment: Attachment Complication calculation algorithm.pdf
Date of Submission (*MM/DD/YY*)**:** 12/14/2010

THA/TKA Complication Calculation Algorithm

We estimate a generalized linear model and a hierarchical generalized linear model which accounts for the clustering of observations within hospitals. The generalized linear model (GLM) links the outcome to the patient-level risk factors,[20] Let Y_{ij} denote the outcome (equal to 1 if 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

GLM $h(Y_{ij}) = \alpha + \beta\mathbf{Z}_{ij}$ (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 an HGLM that links the risk factors to the same outcome and a hospital-specific random effect,

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

$\alpha_i = \mu + \omega_i;\ \omega_i \sim N(0, \tau^2)$ (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 HGLMs and GLMs are estimated using the SAS software system (GLIMMIX and LOGISTIC procedures, respectively).

We first fit the GLM described in Equation (1) using the logit link.

Having identified the covariates that were selected, we next fit the HGLM described in Equations (2) and (3), again using the logit link function; e.g.,

Logit $(P(Y_{ij} = 1)) = \alpha_i + \beta\ \mathbf{Z}_{ij}$

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

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the GLM model. As before, $Y_{ij} = 1$ if patient j treated at hospital i had the event; 0 otherwise.

Hospital performance reporting

Using the set of risk factors in the GLM, we fit the HGLM defined by Equations (2) - (3) and estimate the parameters, $\hat{\mu}$, $\{\hat{\alpha}_i, \hat{\alpha}_2, \ldots, \hat{\alpha}_I\}$, $\hat{\beta}$, 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)

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

If more (fewer) "predicted" cases than "expected" cases have the outcome in a hospital, then $\hat{s}_i$ 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).

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. The bootstrapping simulation has the advantage of avoiding unnecessary distributional assumptions.

Calculation 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.

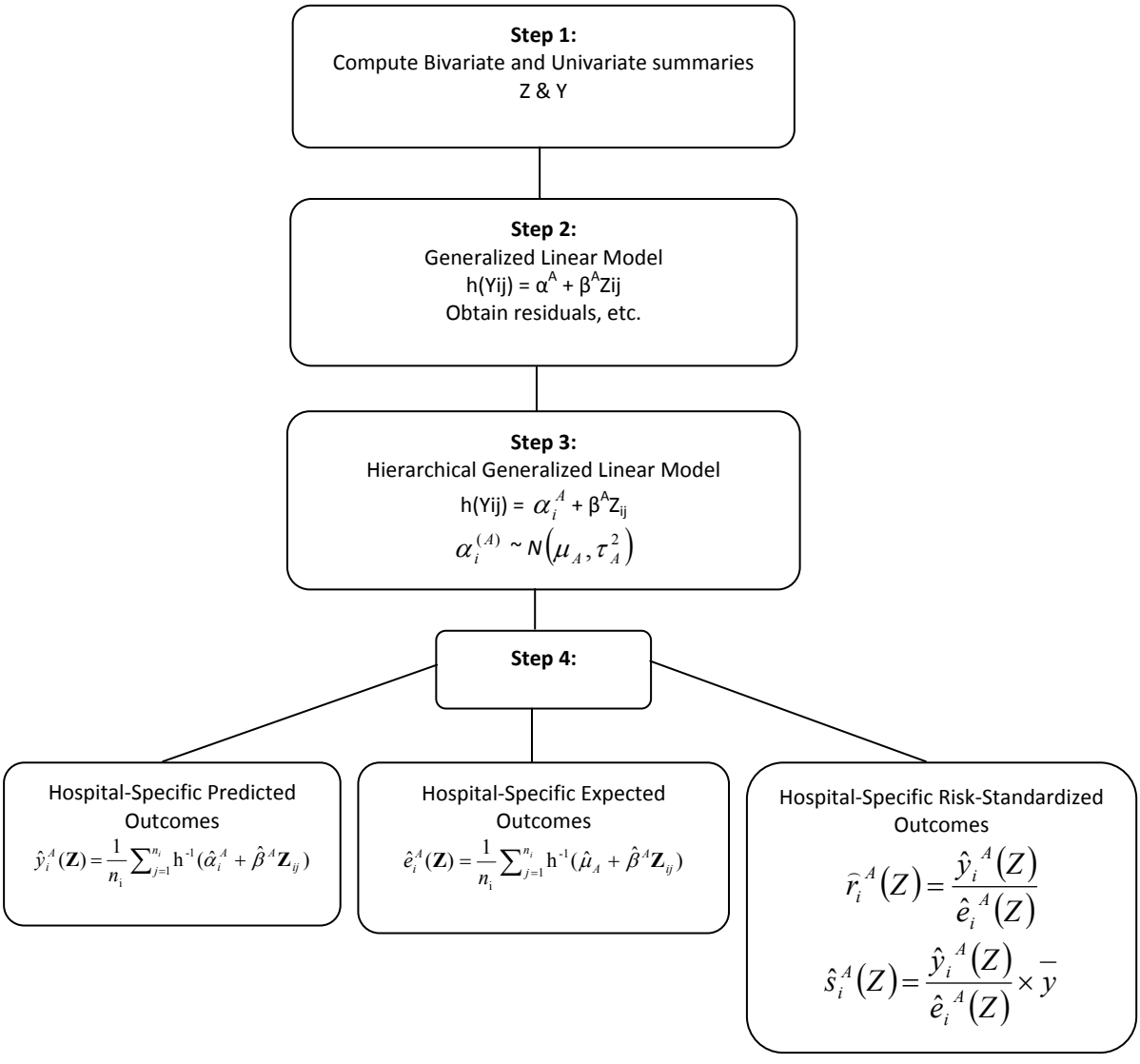
2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate 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, $\{\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}(\alpha_i^{(b)}); i = 1,2,\ldots,I\}$.

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 $\alpha_i^{(b*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ 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 the B estimates (or the percentiles corresponding to the alternative desired intervals).

Figure 1. Analysis Steps



Outcomes Measure: Hospital-level Risk-Standardized Complication Rates following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)

Measure Methodology Report

Submitted By Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE):

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Submitted September 29, 2010

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1. INTRODUCTION

1.1 Overview of Measure

Total hip and knee arthroplasties (THA and TKA, respectively) 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]

Given the high volume and cost associated with these procedures (relative to other elective procedures performed in the Medicare population), 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. A quality measure to address complications following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures.

CMS contracted with Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop hospital outcomes measures that reflect the quality of care for patients undergoing elective THA and TKA procedures and are suitable for public reporting. YNHHSC/CORE, in consultation with CMS and a working group of leading national orthopedic surgeons active in quality improvement, developed a hospital-level, risk-standardized measure of complication rates following elective THA and TKA procedures. The goal of the measure is to improve the quality of care delivered to patients undergoing THA and TKA procedures.

This report provides the background and detailed technical information on the measure. In brief, we developed a model that estimates hospital-specific, risk-standardized, complication rates following THA/TKA. We used Medicare claims data and linked it to CMS claims and enrollment data to identify complications after THA/TKA. To account for the clustering of observations within hospitals and differences in the number of admissions across hospitals, we used hierarchical logistic regression to estimate the risk-standardized complication rates (RSCRs).

This measure was developed concurrently with a second CMS outcomes measure – 30-day all-cause readmission following THA and/or TKA. These are complementary measures that assess separate domains of quality. The complications measure will inform quality improvement efforts targeted toward minimizing medical and surgical complications during surgery and in the recovery phase. The readmission measure captures an additional domain of care provided in the transition to outpatient settings. The readmission measure is presented in a separate technical report.

These two measures expand a set of hospital outcomes measures CMS has developed to improve hospital quality and meet its mandate under the Deficit Reduction Act (DRA) of 2005 to publicly report outcomes and efficiency measures on the consumer site, Hospital Compare (http://www.hospitalcompare.hhs.gov). CMS began publicly reporting acute myocardial infarction (AMI) and heart failure (HF) 30-day mortality measures as outcomes measures in June 2007, and added a pneumonia 30-day mortality measure in August 2008. In addition, CMS began publicly reporting 30-day readmission measures for AMI, HF, and pneumonia in July 2009.

1.2 Approach to Measure Development

We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside expert and public input. The measure is consistent with the technical approach to outcomes measurement set forth in National Quality Forum (NQF) guidance for outcomes measures [5], CMS Measure Management System guidance, and the guidance articulated in the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes". [6] We obtained expert and stakeholder input on the measure through three mechanisms: first, through regular discussions with a working group; 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, we assembled a working group that included individuals with clinical and methodological expertise relevant to orthopedic quality measurement. We held regular conference calls throughout the development process and the Yale team 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 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, we solicited public comment on the proposed measure through CMS' Measure Management System Public Comment site (https://www.cms.gov/MMS/17_CallforPublicComment.asp#TopOfPage). Public comments were summarized and publicly posted for 30 days. The resulting content was taken into consideration during the final stages of measure development.

1.3 Importance of a Complications Measure

Measuring and reporting complication rates will inform health care providers about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care for Medicare patients. The measure will also provide patients with information that could guide their choices. In addition, it has the potential to lower health care costs associated with complications. The measure will increase transparency for consumers.

Complication rates have been shown to vary across hospitals, suggesting care can be improved. Prospective studies show risk adjusted rates for periprosthetic joint infection, a rare but devastating complication, vary between 2.3 to 1.6 percent after 1 and 2 years of follow-up respectively.[7-8] Ninety-day death rates following THA also range from 0.7 to 2.7 percent and are high for an elective procedure.[9-10] Rates for pulmonary embolism following TKA range from 0.5 and 0.9 percent.[10-13] Rates for wound infection in Medicare population based studies vary between 0.3 and 1.0 percent.[10, 12-13] Rates for septicemia range from 0.1%, during the index admission[14] to 0.3%, 90 days following discharge for primary TKA.[10] Rates for bleeding and hematoma following TKA range from 0.94[14] to 1.7%.[15]

The variation in complication rates across hospitals indicates there is room for quality improvement and targeted efforts to reduce these complications could result in significant cost savings.

2. METHODS

2.1 Overview

We developed a hospital-level complications quality measure for patients undergoing THA and TKA procedures. The model estimates hospital-level RSCRs using hierarchical generalized linear modeling (HGLM), to account for the clustering of patients within hospitals. To adjust for differences in hospital case mix, the model adjusts for patient risk factors, including age and comorbidities present at the time of admission.

We identified index admissions for inclusion in the measure via ICD-9 procedure codes for THA and TKA in 2008 Medicare Part A inpatient claims. Because there are no dates associated with procedure codes in Part A data, we use the date of the index admission as the starting point for all follow-up. We used Medicare Part A data for years 2008 and 2009 to identify complications associated with these claims. We identified Information on comorbid conditions for risk adjustment using ICD-9 codes in inpatient, outpatient, and part B Medicare claims data in the 12 months prior to the date of the index admission.

The measure calculates the hospital risk-standardized complication rate (RSCR) by producing a ratio of the number of "predicted" to the number of "expected" complications for each hospital and then multiplying the ratio by the national raw complication rate. For each hospital, the "numerator" of the ratio is the number of complications predicted on the basis of the hospital's performance with its observed case mix (using a hospital-specific estimate intercept term), and the "denominator" is the number of expected complications, based on the nation's performance using the hospital's observed case mix and the national intercept term. In other words, we estimate the complication rate based on each hospital's particular experience and divide it by the estimated complication rate had the hospital performed at the average level for all the hospitals.

The model estimates the hospital-specific intercept term used in the numerator based on how well each hospital performs relative to other hospitals with a similar case mix. Among hospitals with similar case mixes, hospitals that have a lower rate of complications will have a lower intercept term; hospitals that have a higher rate of complications will have a higher intercept term.

2.2 Data Sources

We obtained index admission and in-hospital comorbidity data from Medicare's Standard Analytic File (SAF). Comorbidities were also assessed using Part A inpatient and outpatient, and Part B physician office and hospital 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.

2.3 Outcome Definition

After conducting a comprehensive literature review and in consultation with the working group, YNHHSC/CORE identified complications for potential inclusion in a complications measure. 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
- Acute myocardial infarction (AMI)
- Pneumonia
- Sepsis/septicemia
- Deep vein thrombosis (DVT)
- Urinary tract infection (UTI)

DVT and UTI were excluded based on working group feedback documented in the literature. We excluded DVT because experts advised that there is wide variability across hospitals in screening [16-17] and readmission practices for this complication. We excluded UTI because there is wide variability in diagnosing UTI, and the rates are likely inflated due to overdiagnosis in patients post THA/TKA [18] Working group members also noted that there is wide variability in readmission for UTI in US hospitals and wide variability in treatment for it.

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

Some of these complications have varying degrees of severity not conveyed in the ICD-9 codes, specifically, wound infection, periprosthetic joint infection, and surgical site bleeding. For example, the claims codes used to identify wound infection may reflect redness and swelling around the incision site, or a true wound infection, requiring incision and drainage. Thus, to capture clinically important complications and to reduce the likelihood of capturing miscoded complications, working group and TEP members recommended only counting these complications in the outcome if they are associated with accompanying ICD-9 procedure codes indicating that they were severe enough to require specific interventions. We therefore imposed additional coding requirements for these complications to set an appropriate threshold for severity.

We include the following complications in the outcome only if they are accompanied by the following procedure codes listed during the admission in which the complication occurred:

Periprosthetic joint infection

Presence of a periprosthetic joint infection code AND the presence of <u>at least one</u> of the following procedure codes

- Incision and drainage
- Revision
- Removal

Wound infection

Presence of a wound infection code AND the presence of <u>at least one</u> of the following procedure codes:

- Incision and drainage
- Revision
- Removal

Surgical site bleeding

Presence of a surgical site bleeding code AND the presence of the following procedure code:

- Incision and drainage

Please refer to Appendix A for complication-specific measure specifications.

2.4 Measure Timeframe

To determine the appropriate follow-up period, we obtained clinical input and examined 90-day trends in complication rates (Figures 1 and 2). Figure 1 conveys the week-by-week rates for mortality and surgical complications occurring from the date of index admission to 90 days post date of index admission. Figure 2

conveys the week-by-week rates for medical complications. These analyses indicate that most complications occur 7 days following the procedure, but level off at 30 days. Although a standardized period of follow-up is ideal, defining a single optimal period of assessment appropriate for a wide range of complications was challenging. For example, the working group and TEP agreed that mechanical complications 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.

We observe two complications for 90 days: mechanical complications and periprosthetic joint infection as these complications are still attributable to the index THA/TKA for up to 90 days afterwards. Preliminary analyses indicate rates for mechanical complications are elevated until 90 days post the date of index admission. We observe four complications for 30 days: death, surgical site bleeding, wound infection, and pulmonary embolism as rates of these complications are elevated until approximately 30 days post the date of index admission. This finding was consistent with input from clinical experts. AMI, pneumonia, and sepsis/septicemia are followed to 7 days post date of index admission (Figure 2). These conditions are more likely to be attributable to procedure if they occur within the first week after the procedure.

Analyses indicate 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. The list of complications and their associated follow-up periods are listed in Table 1.

Figure 1. Trend in Mortality and Surgical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)

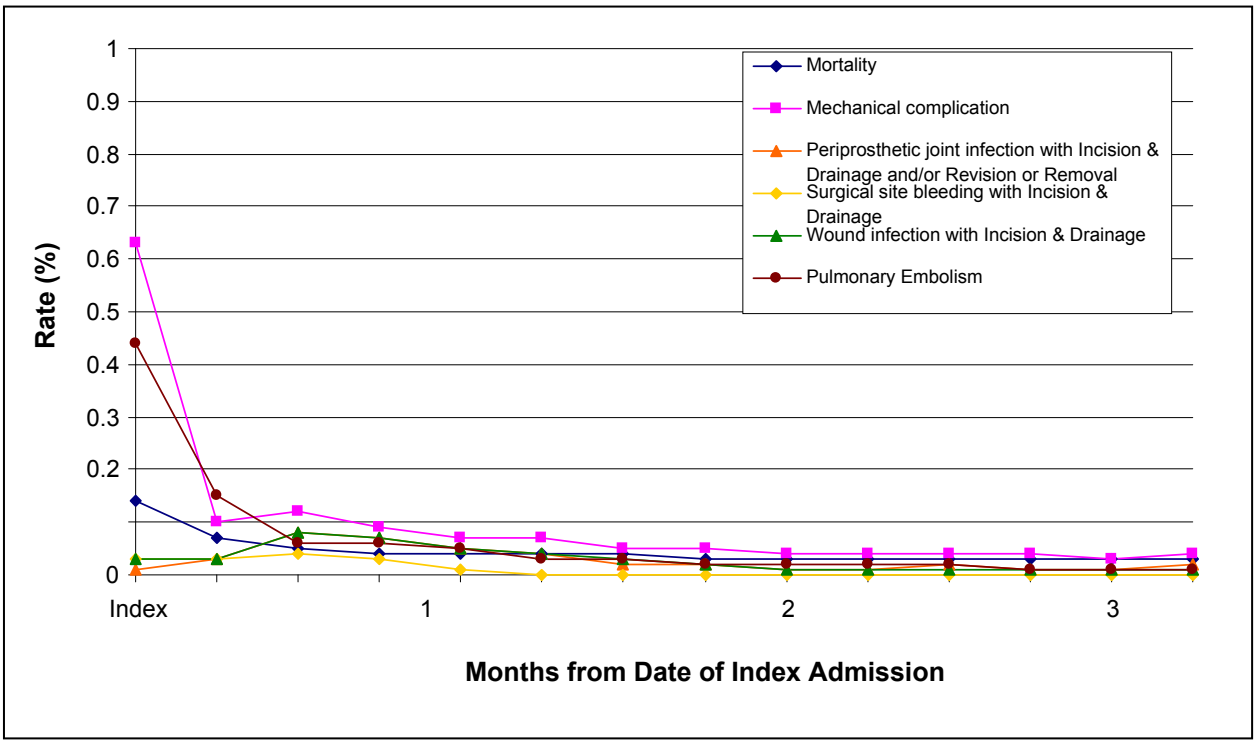


Figure 2. Trend in Medical Complication Rates (Medicare FFS Part A Inpatient Data, 2008)

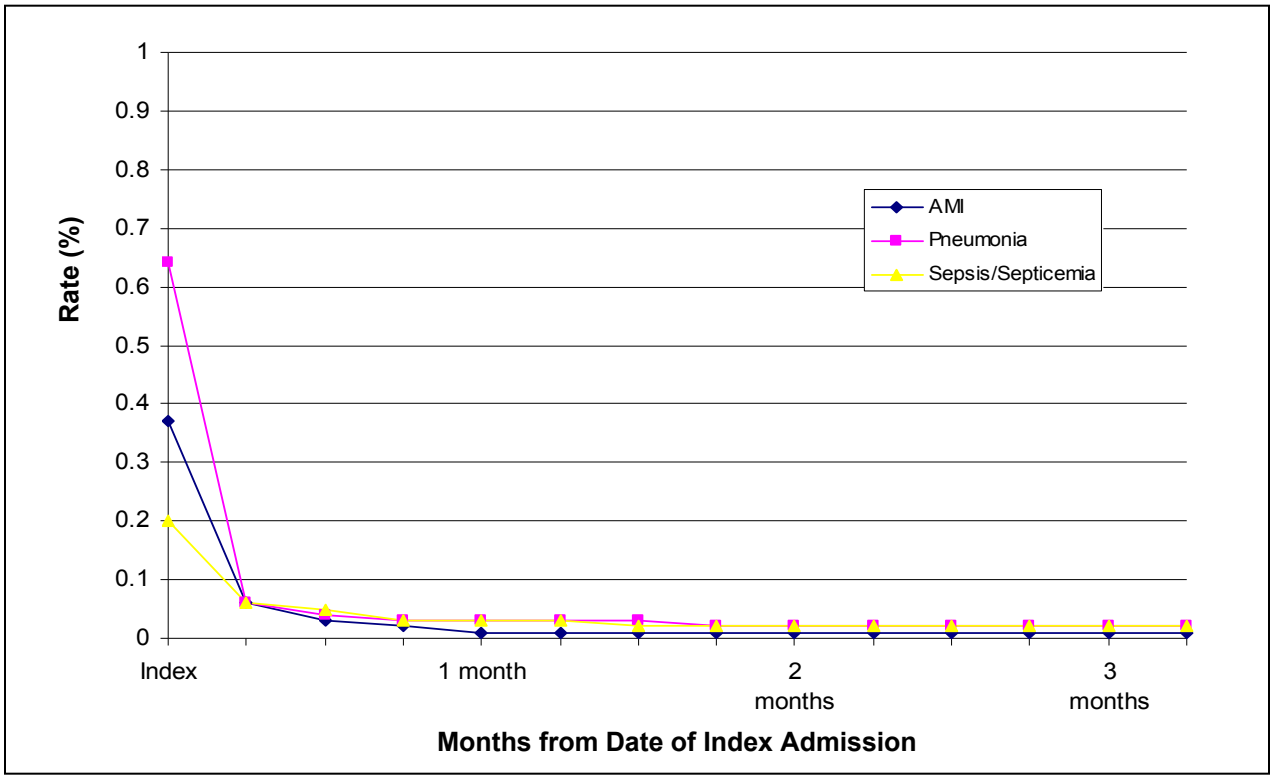


Table 1. Complication Follow-up Periods

Complication	Follow-up Period	Rationale
Death	30 days	• Still attributable to procedure
Mechanical complications	90 days	• Mechanical complications occurring 90 days post procedure can still be attributable to the index procedure • Data indicate that the rate is elevated until 90 days post procedure
Periprosthetic joint infection (PJI)	90 days	• Periprosthetic joint infections occurring 90 days post procedure can still be attributable to the index procedure • Although the rate tapers off after approximately 6 weeks, it remains slightly elevated until 90 days post procedure
Surgical site bleeding	30 days	• Consistent with clinical course • Data indicate that rate decreases after 30 days
Wound infection	30 days	• Consistent with clinical course • Data indicate that rate decreases after 30 days
Pulmonary embolism	30 days	• Consistent with clinical course • Data indicate that rate decreases after 30 days
AMI	7 days	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases sharply 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure
Pneumonia	7 days	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases sharply 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure
Sepsis/septicemia	7 days	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure

The working group and TEP recognized that a model using complication-specific timeframes may make measure interpretation more complex, but there was agreement that this potential disadvantage was offset by improvements to face validity and acceptability of the measure.

2.5 Cohort Definition

In consultation with the working group, 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. 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 (Table 2)
- The mortality and readmission rates are similar (Table 2)
- 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 2. 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			

Patients undergoing non-elective THA or TKA have greater risk of complications and receive a wider variety of surgical procedures than individuals undergoing elective THA or TKA. In consultation with the working group and with the goal of defining a comprehensive yet reasonably homogeneous cohort for quality assessment, we selected inclusion and exclusion criteria in order to identify patients undergoing elective THA and TKA for degenerative (either primary or secondary) arthritis.

Patients eligible for inclusion in the measure are those aged 65 and older admitted to non-federal acute care hospitals with an ICD-9 code for THA and/or TKA. Patients must have had continuous enrollment in Medicare fee-for-service (FFS) for one year prior to the date of index admission to ensure full data availability for risk adjustment. The flow chart depicting cohort selection is presented in Figure 3.

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

2.6 Exclusion Criteria

We excluded the following patient stays from the cohort:

1. Patients with hip fractures
   Rationale: Patients with hip fractures have higher mortality, complication and readmission rates and the procedures are not elective

2. Patients 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

3. Patients 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, more frail, and with more comorbid conditions

4. Patients 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

5. Patients 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

6. Patients who leave the hospital against medical advice (AMA)
   Rationale: Hospitals and physicians do not have the opportunity to provide the highest quality care

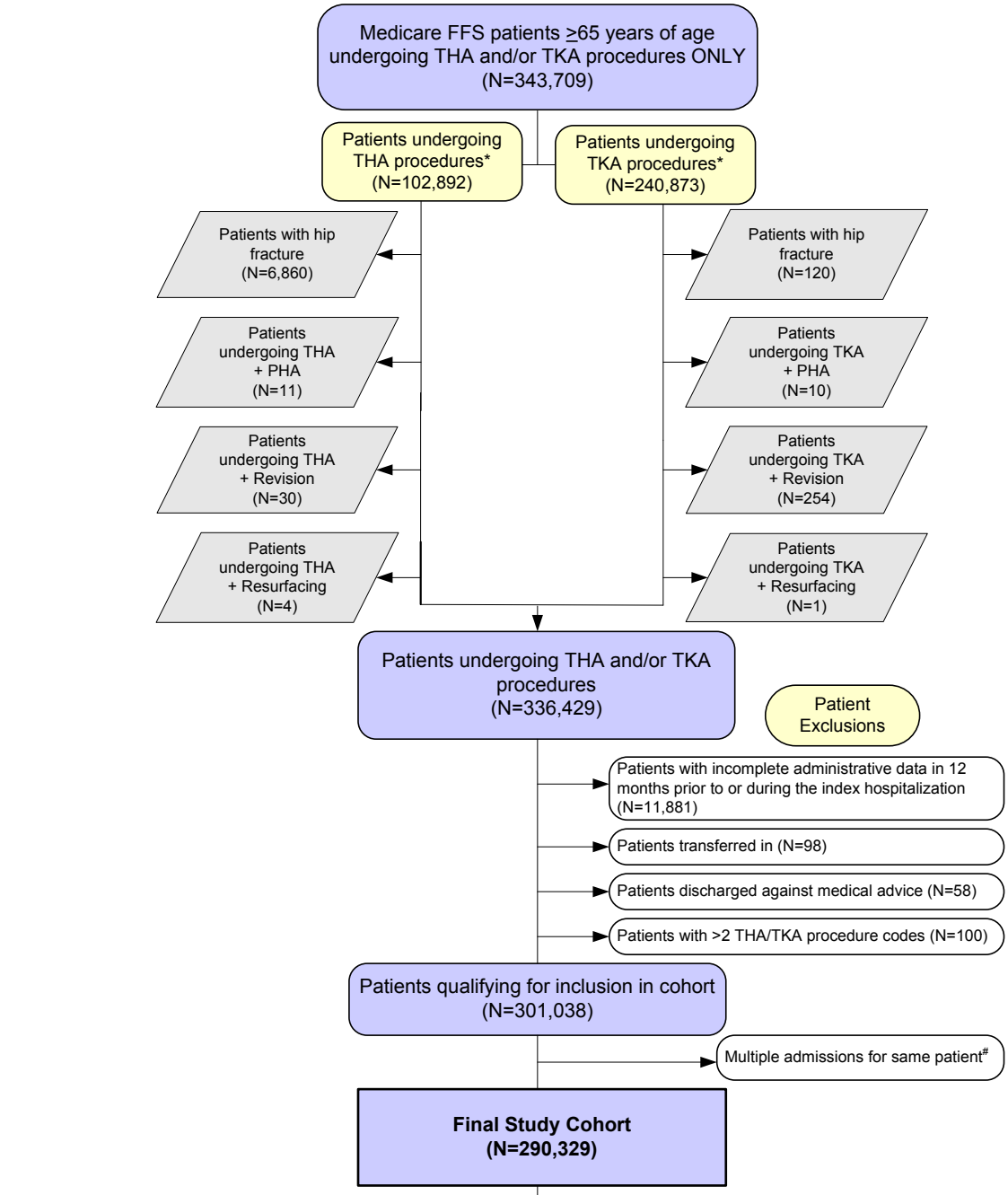
7. Patients with more than two THA/TKA procedures codes during the index hospitalization
   Rationale: It is unlikely that patients would receive more than two THA/TKA procedures in one hospitalization, and this may reflect a coding error

8. Patients with inconsistent or unknown mortality status or other unreliable data (e.g. date of death precedes admission date)
   Rationale: Outcome status is unreliable, although this is rare

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
   Rationale: Observations are not independent; a patient is not eligible for the death outcome during the first admission, admitted later in the year for another procedure

Appendix B lists the ICD-9 codes for hip fracture, revision procedures, partial hip arthroplasty procedure, and resurfacing procedures.

Figure 3. Cohort for Model Development



Procedure	N (%)
1 THA procedure	83,066
1 TKA Procedure	197,646
THA + THA	305
TKA + TKA	9263
THA + TKA	49

*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

2.7 Approach to Risk Adjustment

The goal of risk adjustment is to account for patient demographic and clinical characteristics while illuminating important quality differences. The model 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 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 only appear in the index admission and not in the 12 months prior to admission. This methodology is consistent with NQF guidelines.

Consistent with NQF guidelines, the model does not adjust for socioeconomic status (SES), race, or ethnicity because risk-adjusting for SES would hold hospitals with a large proportion of low SES patients to a different standard of care than hospitals treating a larger proportion of high SES patients. Model does not adjust for patients' admission source and their discharge disposition either (e.g. skilled nursing facility) because these factors are associated with structure of the health care system.

2.8 Candidate and Final Risk-Adjustment Variables

Our goal 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 inpatient Part A data, outpatient hospital data, and Part B physician data.

For administrative model development, we started with the 189 Condition Categories (CCs). CCs are clinically relevant diagnostic groups of the more than 15,000 ICD-9 codes.[19] We 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, a team of 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 reviewed these comorbidities and 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 3.

Table 3. THA/TKA Complications Model Candidate 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
	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	CC 47

Category	Variable	ICD-9 Code(s) or CC(s)
	Disease	
	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
	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

Category	Variable	ICD-9 Code(s) or CC(s)
	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 129, 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

To inform final variable selection, a modified approach to stepwise logistic regression was performed. A subsample of the data was used to create 500 “bootstrap” samples. For each sample, we ran a logistic stepwise regression that included the 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 4.

Table 4. THA/TKA Complications Model 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 129, 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

2.9 Statistical Approach to Model Development

We randomly selected 50% of the THA and/or TKA admissions that met all inclusion and exclusion criteria and created a development sample, which we used to build the model. We used the remaining 50% of THA/TKA admissions as the validation sample. We also used all qualifying THA and/or TKA admissions in

2007 data as an additional sample to validate the model. Model performance was assessed in the development dataset and both validation datasets.

Due to the natural clustering of hospitalizations within hospitals, we used hierarchical generalized linear models (HGLMs) to model the log-odds of death and complications. Death and complications were modeled as a function of patient-level demographic and clinical characteristics and 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 hospital risk-standardized complication rates (RSCRs) using a hierarchical logistic regression model (given the hierarchical nature of the data). These rates are calculated as the ratio of the predicted number of complications to the expected number of complications, multiplied by the national unadjusted complication rate. The expected number of complications for each hospital was estimated using that hospital's patient mix and the national intercept. Specifically, for each patient in the data set, the estimated regression coefficients are multiplied by the observed characteristics and the average of the hospital-specific intercepts is added to this quantity. Then, the quantity is transformed to the probability scale. For each patient within a hospital, these probabilities are summed. The predicted number of complications in each hospital employs a similar calculation. The predicted number of complications for each hospital is calculated by summing the predicted complication rates for all patients in the hospital. The predicted complication rate for each patient is calculated through the hierarchical model by applying the estimated regression coefficients to the patient characteristics observed and adding the hospital-specific intercept. In order to assess hospital performance in any specific year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.

More specifically, we estimate a generalized linear model and a hierarchical generalized linear model which accounts for the clustering of observations within hospitals. The generalized linear model (GLM) links the outcome to the patient-level risk factors,[20] Let Y_{ij} denote the outcome (equal to 1 if 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

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

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 an HGLM that links the risk factors to the same outcome and a hospital-specific random effect,

HGLM $h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij}$ (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 HGLMs and GLMs are estimated using the SAS software system (GLIMMIX and LOGISTIC 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 HGLM described in Equations (2) and (3), again using the logit link function; e.g.,

Logit $(P(Y_{ij} = 1)) = \alpha_i + \beta \mathbf{Z}_{ij}$

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

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the GLM model. As before, Y_{ij} = 1 if patient *j* treated at hospital *i* had the event; 0 otherwise.

2.10 Hospital Performance Reporting

Using the set of risk factors in the GLM, we fit the HGLM 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 more (fewer) "predicted" cases than "expected" cases have the outcome in a hospital, then $\hat{s}_i$ 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).

2.10.1 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. The bootstrapping simulation has the advantage of avoiding unnecessary distributional assumptions.

2.10.2 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.

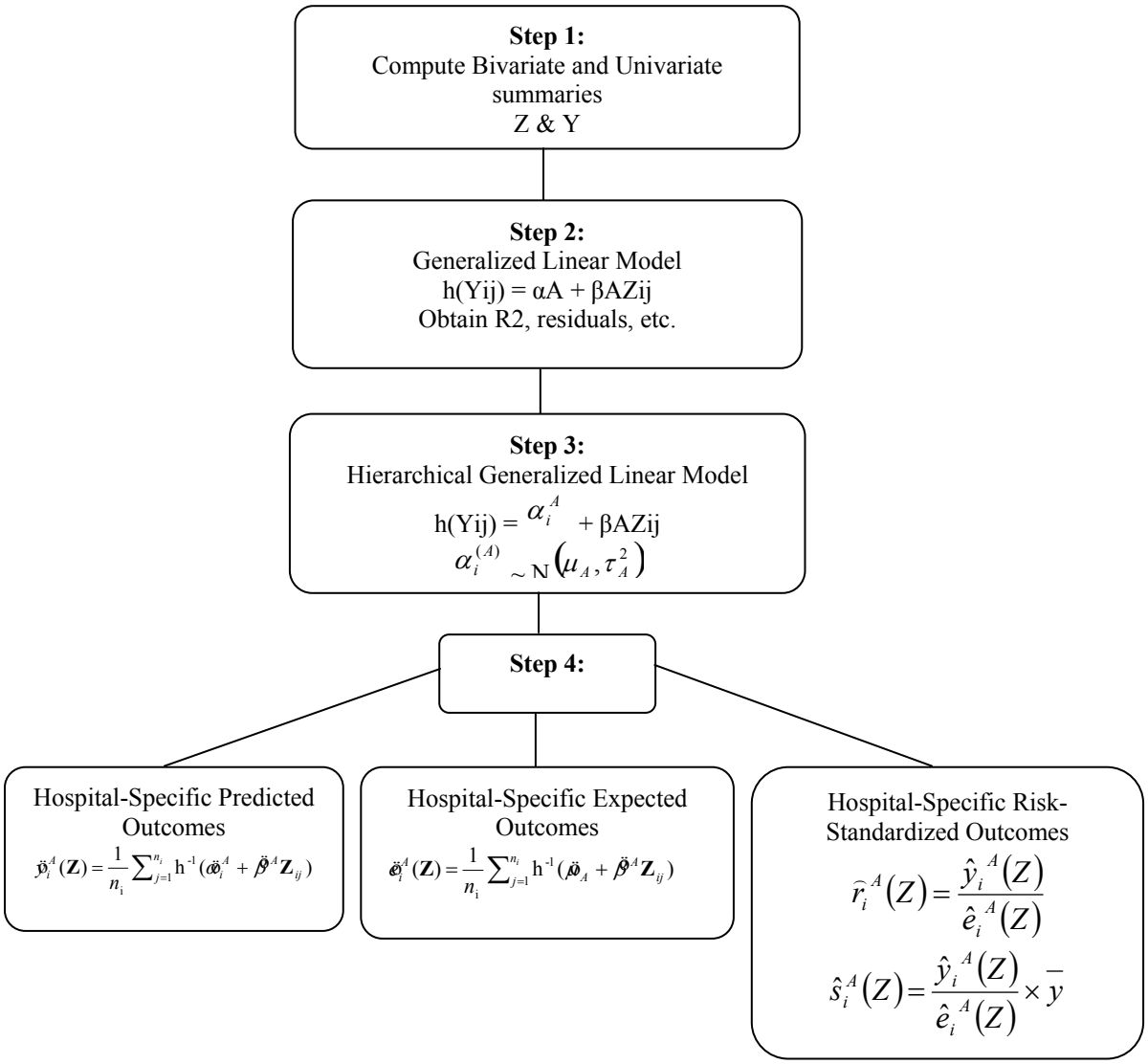
2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate 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, $\{\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}(\alpha_i^{(b)}); i = 1,2,\ldots,I\}$.

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 $\alpha_i^{(b*)} \sim N(\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}(\hat{\alpha}_i^{(b)}))$ 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 2.5^{th} and 97.5^{th} percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals). [22]

Figure 4. Analysis Steps



3. RESULTS

3.1 Model Results

3.1.1 Development and Validation Models

Tables 5 and 6 convey the developmental sample model results for GLM and HGLM analyses respectively. The standardized estimates are regression coefficients expressed in units of standard deviations and can range between -1 and 1, with ±1 indicating a perfect linear relationship and 0 indicating no linear relationship.[1] The estimated between-hospital variance in the adjusted log-odds of a complication(s) is 0.105, based on the 2008 full dataset. This result implies that the odds of a complication(s) for a high-complication hospital (+1 SD) are 1.91 times that in a low-complication hospital (-1 SD). If there were no differences between hospitals, the between-hospital variance would be 0 and the odds ratio would be 1.0.Table 7 conveys the GLM results for the validation sample.

3.1.2 Model Performance

We computed 6 summary statistics for assessing model performance [23] over-fitting indices[2], predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square[3]. Table 8 conveys GLM model performance results for both the developmental and validation samples.

The models for both the development and validation samples have strong discrimination and fit. Model predictive ability ranges from 2% in the lowest predictive decile to 15% in the highest decile in both samples, indicating

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[1] Standardized estimates are like correlation coefficients. We compute them in order to compare the size of the coefficients by standardizing the coefficients to be unitless.

[2] Over-fitting refers to the phenomenon in which a model well describes the relationship between predictive variables and outcome in the development dataset, but fails to provide valid predictions in new patients.

[3] Chi-Square – A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation. The formula for computing the chi-square is as follows:

$$\sum \frac{(O-E)^2}{E}$$

where O = observed value
E = expected value, and
degrees of freedom (df) = (rows-1)(columns-1)

the model can reasonably classify patients on the outcome, based on their risk. The area under the ROC curve (C statistic) is 0.69 for the development model and 0.70 for the validation model (Table 8).The discrimination ability is consistent with models currently used to publicly report condition specific rates of both mortality and readmission.

Table 9 conveys the standardized estimates by year of discharge in the full datasets for 2007 and 2008. There are no notable differences in the standardized estimates between the two years. Table 10 conveys the risk factor frequency for the development and validation samples by year of discharge. The prevalence of morbid obesity increased slightly to 3.36% in 2008, compared with 2.91% in 2007. There were no other notable changes in risk factor frequency over the two-year period.

Table 5. GLM Model Results for 2008 Development Sample (ROC=0.69)

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

Table 6. HGLM Model Results for 2008 Development Sample

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‡ (mean)	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)

Table 7. GLM Model Results for 2008 Validation Sample (ROC=0.70)

Label	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	Odds Ratio	95 % Confidence Interval for OR
Intercept	-3.62	0.06	3744.33	<.0001			
Demographics							
Age-65‡ (mean)	0.03	0.002	224.72	<.0001	0.11	1.03	(1.03 - 1.04)
Male	0.11	0.03	13.08	0.0003	0.03	1.11	(1.05 - 1.18)
THA/TKA Procedure							
THA procedure	0.56	0.03	384.24	<.0001	0.14	1.75	(1.65 - 1.85)
Number of procedures (one vs. two)	0.37	0.07	25.24	<.0001	0.04	1.45	(1.26 - 1.68)
Comorbid Conditions							
Skeletal deformities (ICD-9 code 755.63)	0.31	0.27	1.28	0.259	0.01	1.36	(0.80 - 2.31)
Post traumatic osteoarthritis (ICD-9 codes 716.15, 716.16)	0.35	0.14	6.26	0.01	0.01	1.42	(1.08 - 1.87)
Morbid obesity (ICD-9 code 278.01)	0.40	0.07	35.90	<.0001	0.04	1.50	(1.31 - 1.71)
Metastatic cancer and acute leukemia (CC 7)	0.03	0.15	0.03	0.85	0.001	1.03	(0.76 - 1.39)
Cancer (CC 8-10)	-0.07	0.04	2.81	0.094	-0.01	0.93	(0.86 - 1.01)
Respiratory/Heart/Digestive/Urinary/Other Neoplasms (CC 11-13)	-0.09	0.04	6.33	0.012	-0.02	0.91	(0.85 - 0.98)
Diabetes and DM complications (CC 15-20, 119, 120)	0.12	0.03	14.93	0.000	0.03	1.12	(1.06 - 1.19)
Protein-calorie malnutrition (CC 21)	0.70	0.10	50.97	<.0001	0.03	2.02	(1.67 - 2.46)
Bone/Joint/Muscle Infections/Necrosis (CC 37)	0.02	0.07	0.12	0.734	0.00	1.02	(0.90 - 1.16)
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC 38)	-0.04	0.05	0.62	0.429	-0.01	0.96	(0.88 - 1.06)
Osteoarthritis of Hip or Knee (CC 40)	-0.66	0.05	180.53	<.0001	-0.08	0.52	(0.47 - 0.57)
Osteoporosis and Other Bone/Cartilage Disorders (CC 41)	-0.01	0.03	0.11	0.743	0.00	0.99	(0.93 - 1.05)
Dementia and senility (CC 49, 50)	0.17	0.05	9.99	0.002	0.02	1.19	(1.07 - 1.32)
Major psychiatric disorders (CC 54-56)	0.09	0.06	2.15	0.143	0.01	1.10	(.097 - 1.24)
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177-178)	0.11	0.09	1.39	0.238	0.01	1.11	(0.93 - 1.32)
Cardio-Respiratory Failure and Shock (CC 79)	-0.25	0.07	11.51	0.001	-0.02	0.78	(0.67 - 0.90)
Chronic Atherosclerosis (CC 83-84)	0.19	0.03	44.25	<.0001	0.05	1.21	(1.15 - 1.29)
Stroke (CC 95, 96)	-0.01	0.08	0.01	0.917	0.00	0.99	(0.86 - 1.15)
Vascular or circulatory disease (CC 104-106)	0.11	0.03	11.57	0.001	0.02	1.11	(1.05 - 1.18)
COPD (CC 108)	0.15	0.03	18.16	<.0001	0.03	1.16	(1.08 - 1.24)
Pneumonia (CC 111-113)	1.55	0.04	1754.99	<.0001	0.20	4.72	(4.39 - 5.08)
Pleural effusion/pneumothorax (CC 114)	-0.26	0.08	9.85	0.002	-0.02	0.77	(0.65 - 0.91)
End-stage renal disease or dialysis (CC 129, 130)	0.42	0.20	4.35	0.037	0.01	1.53	(1.03 - 2.27)
Renal Failure (CC 131)	0.12	0.05	6.69	0.010	0.02	1.13	(1.03 - 1.24)
Decubitus ulcer or chronic skin ulcer (CC 148, 149)	0.15	0.13	1.38	0.240	0.01	1.17	(0.90- 1.50)
Trauma (CC 154-156, 158-161)	0.69	0.05	234.27	<.0001	0.08	2.00	(1.83 - 2.18)
Vertebral Fractures (CC 157)	0.10	0.09	1.22	0.269	0.01	1.11	(0.93 - 1.32)
Other injuries (CC162)	0.14	0.03	21.49	<.0001	0.03	1.15	(1.08 - 1.22)
Major Complications of Medical Care and Trauma (CC 164)	0.56	0.05	119.55	<.0001	0.06	1.74	(1.58- 1.93)

Table 8. Model Performance for GLM Model

Indices	Development Sample	Validation Sample	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 (γ0, γ1)[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][4]	4401 [33]	4698 [33]	9236 (33)

[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)) = γ_0 + γ_1Z. Estimated values of γ_0 far from 0 and estimated values of γ_1 far from 1 provide evidence of over-fitting.

Table 9. Standardized Estimates for GLM Model by Year of Discharge (GLM)

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‡ (mean)	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)
Comorbid 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)

Table 10. Risk Factor Frequency by Year of Discharge (GLM)

Description	2008 Development Sample	2008 Validation Sample	2007 Validation Sample
Male	35.76	35.62	35.49
THA procedure	28.76	28.67	28.63
Number of procedures (one vs. two)	3.32	3.30	3.61
Skeletal deformities	0.13	0.14	0.14
Post traumatic osteoarthritis	0.49	0.56	0.49
Morbid obesity	3.36	3.40	2.91
Metastatic cancer and acute leukemia	0.64	0.58	0.65
Cancer	12.84	12.76	12.77
Respiratory/Heart/Digestive/Urinary/Other Neoplasms	17.87	18.02	17.75
Diabetes and DM complications	27.31	27.38	26.75
Protein-calorie malnutrition	0.58	0.67	0.54
Bone/Joint/Muscle Infections/Necrosis	2.97	2.84	3.12
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	8.52	8.56	8.31
Osteoarthritis of Hip or Knee	95.26	95.35	95.31
Osteoporosis and Other Bone/Cartilage Disorders	24.81	25.11	24.19
Dementia and senility	4.39	4.36	4.22
Major psychiatric disorders	3.66	3.79	3.57
Hemiplegia, paraplegia, paralysis, functional disability	1.54	1.63	1.51
Cardio-Respiratory Failure and Shock	2.05	2.07	1.98
Chronic Atherosclerosis	30.74	30.72	31.05
Stroke	2.45	2.44	2.50
Vascular or circulatory disease	22.47	22.61	22.09
COPD	14.65	14.65	15.16
Pneumonia	5.38	5.49	5.46
Pleural effusion/pneumothorax	1.47	1.49	1.47
End-stage renal disease or dialysis	0.14	0.15	0.15
Renal Failure	6.02	6.18	5.51
Decubitus ulcer or chronic skin ulcer	0.44	0.47	0.43
Trauma	5.08	5.13	5.00
Vertebral Fractures	1.30	1.37	1.30
Other injuries	27.57	27.71	27.66
Major Complications of Medical Care and Trauma	3.88	3.93	3.88

3.1.3 Unadjusted and Adjusted Complication Rate Distributions

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

After adjusting for patient and clinical characteristics, the risk-standardized rates are more normally distributed (Figure 6) with a mean of 4.23, ranging from 2.20 to 8.88%. The median adjusted complication rate is 4.16%.

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

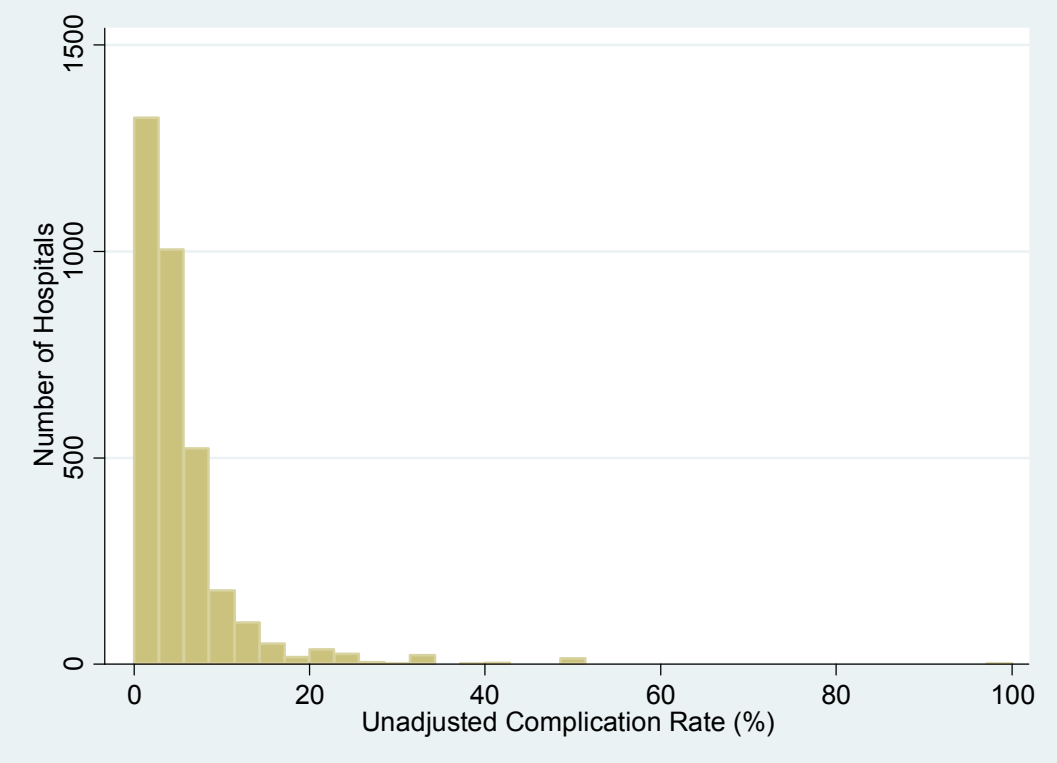
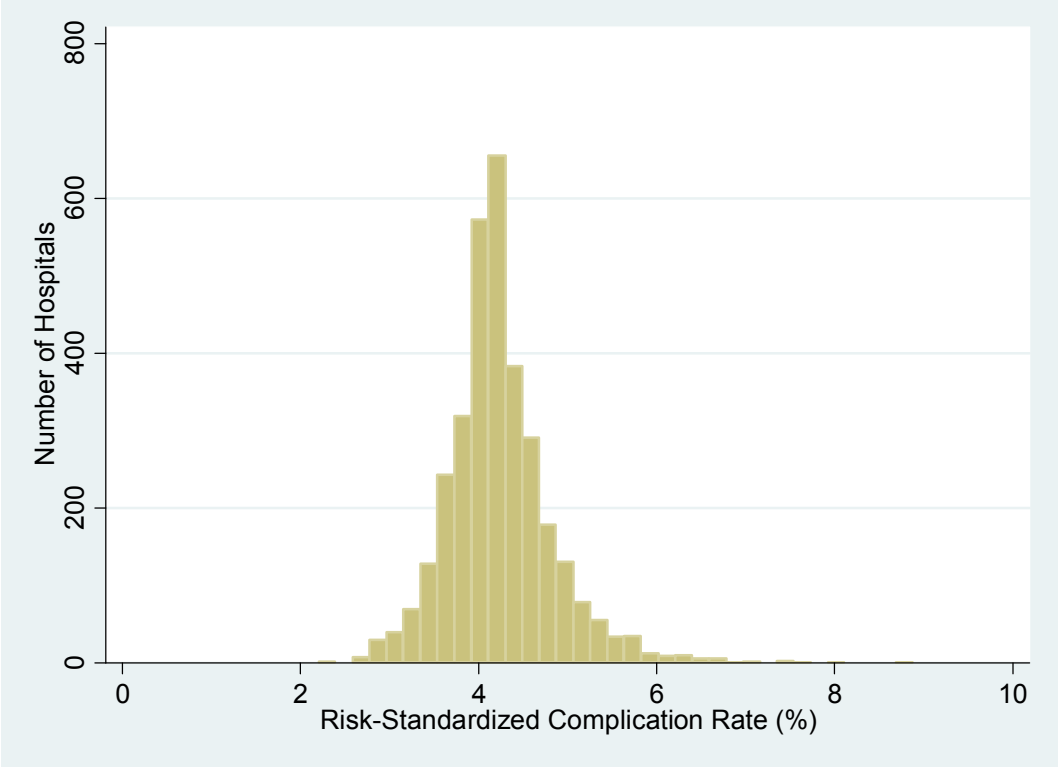


Figure 6. Distribution of Hospital Risk-Standardized Complication Rates (2008 Sample; N=3,311 Hospitals) – HGLM



4. MAIN FINDINGS / SUMMARY

The proposed measure of death and complications has the potential to significantly improve the quality of care delivered to patients undergoing elective primary THA and TKA procedures. Risk-standardized complication rates can be used for targeted quality improvement efforts by hospitals to decrease rates for death and complications post THA and TKA. The risk standardized model meets recognized standards for outcomes measurement and was developed with extensive input from clinicians and experts in measure development. The cohort for inclusion in the measure is appropriately defined, consisting of patients undergoing elective primary THA and/or TKA. The definitions for the complications, the complication-specific follow-up periods, and the risk-adjustment methodology all have strong face validity, which may facilitate physician acceptance. We excluded covariates that are not appropriate for inclusion in a quality measure, including race, socioeconomic status, and physician and hospital-level variables (e.g., procedural volume). The hierarchical modeling accounts for the clustering of patients within hospitals and differences in sample size across hospitals, thereby allowing for valid comparisons across hospitals. In summary, we present a claims-based model of death and complications post THA/TKA that is suitable for public reporting.

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6. APPENDIX

6.1 Appendix A: Complication-Specific Measure Specifications

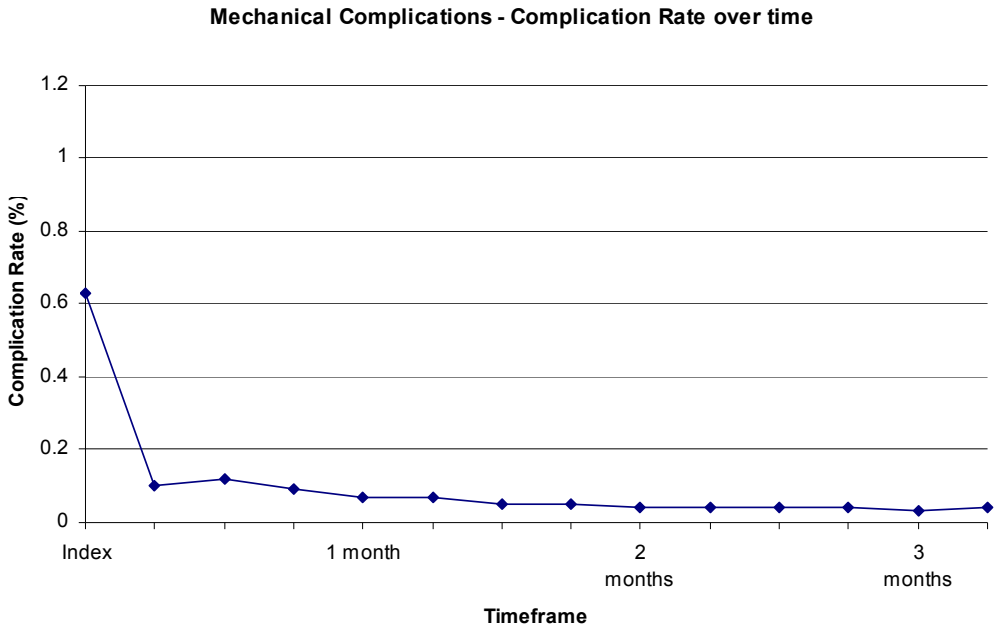
MECHANICAL COMPLICATIONS

Complication ICD-9 Code*	Description
996.4[1]	Mechanical complication of internal orthopedic device implant and graft
996.40[2]	Unspecified mechanical complication of internal orthopedic device, implant, and graft
996.41[2]	Mechanical loosening of prosthetic joint
996.42[2]	Dislocation of prosthetic joint
996.44[2]	Peri-prosthetic fracture around prosthetic joint
996.47[2]	Other mechanical complication of prosthetic joint implant
996.49[2]	Other mechanical complication of other internal orthopedic device, implant, and graft

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any mechanical complication code listed above in a primary or secondary diagnosis field	• These codes identify mechanical complications related to the index procedure
Readmission	
• Presence of any mechanical complication code listed above in a primary or secondary diagnosis field	• These codes identify all mechanical complications, including those identified at the time of a readmission (even though mechanical complication may not be the primary reason for that readmission), since all are likely to be procedure-related
Follow-up Period for Complications Measure	
• During index admission or within 90 days from admission date	• Data indicate that the rate is elevated until 90 days post procedure • Mechanical complications occurring 90 days post procedure can still be attributable to the index procedure

[1] Weaver F, Hynes D, Hopkinson W, Wixson R, Khuri S, Daley J, Henderson W. (2003). Preoperative risks and outcomes of hip and knee arthroplasty in the Veterans Health Administration. *J Arthroplasty*, 18(6): 693-708.
[2] Memtsoudis S, Gonzalez Ella Valle A, Besculides M, Gaber L, Sculco T. (2008). In-hospital complications and mortality of unilateral, bilateral, and revision TKA. *Clin Orthop Relat Res*, 466:2617-2627.

*NOTE: Mechanical complication codes not used: 996.43, 996.45, 996.46



Data Source: Medicare Part A Inpatient Data, 2008

PERIPROSTHETIC JOINT INFECTION

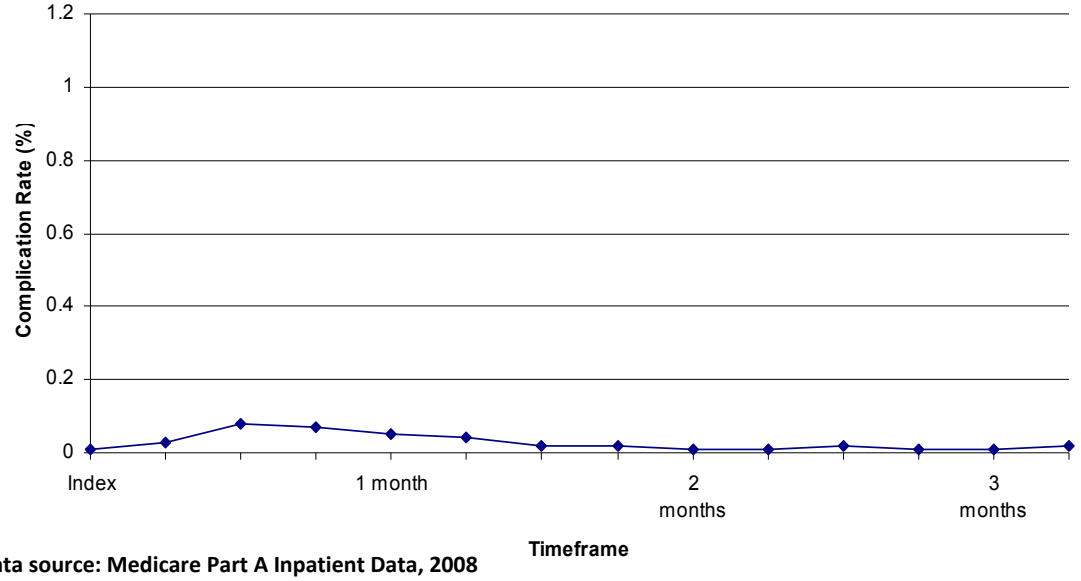
Complication ICD-9 Code	Description
996.66[3]	Infection and inflammatory reaction due to internal joint prosthesis

Intervention ICD-9 Code	Description
86.22	Excisional debridement of wound, infection, or burn
86.28	Nonexcisional 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
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

[3] Thomas C, Cadwallader HL, Riley TV. (2004). Surgical-site infections after orthopaedic surgery: statewide surveillance using linked administrative databases. *J Hosp Infect*, (57(1): 25-30.

When to Count as Complication	
Index Admission	**Rationale**
• Presence of periprosthetic joint infection code listed above in a primary or secondary diagnosis field AND the presence of <u>at least one</u> of the following procedure codes: o Incision and drainage o Revision o Removal	• These codes identify periprosthetic joint infection related to the index procedure • Requiring an intervention sets an appropriate threshold for severity and will therefore more likely capture true joint infections and reduce false positives
Readmission	
• Presence of periprosthetic joint infection code listed above in a primary or secondary diagnosis field AND the presence of <u>at least one</u> of the following procedure codes: o Incision and drainage o Revision o Removal	• These codes identify all periprosthetic joint infections, including those identified at the time of a readmission (even though PJI may not be the primary reason for that readmission), since all are likely to be procedure-related
Follow-up Period for Complications Measure	
• During index admission or within 90 days from admission date	• Although the rate tapers off after approximately 6 weeks, it remains slightly elevated until 90 days post procedure • Periprosthetic joint infections occurring 90 days post procedure can still be attributable to the index procedure

Periprosthetic joint infection with Incision & Drainage and/or Revision/Removal - Complication Rate over Time



Data source: Medicare Part A Inpatient Data, 2008

SURGICAL SITE BLEEDING

Complication ICD-9 Code	Description
998.1[4,5,6]	Hemorrhage or hematoma complicating a procedure not elsewhere classified
998.11[1,3,7,8]	Hemorrhage complicating a procedure
998.12[1,3,4,5]	Hematoma complicating a procedure
998.13[3]	Seroma complicating a procedure
286.5[5]	Bleeding from anticoagulation
719.10[1]	Hemarthrosis site unspecified
719.16[1]	Hemarthrosis involving lower leg
719.17[1]	Hemarthrosis involving ankle and foot

Intervention ICD-9 Code	Description
86.04	Other incision with drainage of skin and subcutaneous tissue

When to Count as Complication	Rationale
Index Admission	
• Presence of any bleeding code listed above in a primary or secondary diagnosis field AND: o procedure code for incision and drainage	• These codes identify surgical site bleeding related to the index procedure • Requiring an intervention sets an appropriate threshold for severity and will therefore more likely capture true surgical site bleeding and reduce false positives
Readmission	
• Presence of any bleeding code listed above in the primary or secondary diagnosis fields AND: o procedure code for incision and drainage	• These codes identify all surgical site bleeds, including those identified at the time of a readmission (even though bleeding may not be the primary reason for that readmission), since all are likely to be procedure-related
Follow-up Period for Complications Measure	
• During index admission or within 30 days from admission date	• Data indicate that rate decreases after 30 days • Consistent with clinical course

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[6] Deyo R, Martin B, Kreuter W, Jarvik J, Mirza S. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*, 303(13): 1259-65.
[7] *Version 4.1 technical documentation* AHRQ Quality Indicators. December, 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/TechnicalSpecs41.htm
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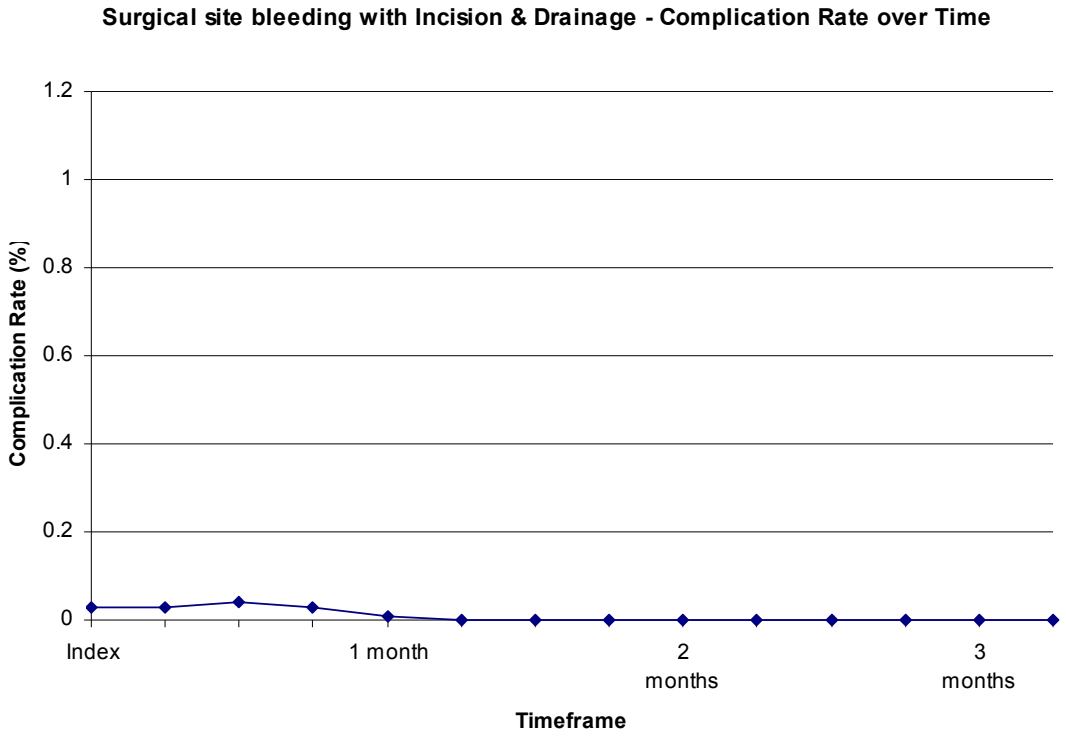

Data Source: Medicare Inpatient Part A Data, 2008

WOUND INFECTION

Complication ICD-9 Code*	Description
998.6[2,9]	Persistent postoperative fistula not elsewhere classified
998.83[2,3,10]	Non-healing surgical wound
998.3[4]	Disruption of wound
998.30[2,3,4]	Disruption of wound, unspecified
998.31[2,3,4]	Disruption of internal operation (surgical) wound
998.32[2,3,4]	Disruption of external operation (surgical) wound
998.33	Disruption of traumatic wound repair
998.5[2,3,4,11]	Postoperative infection not elsewhere classified
998.51[4]	Infected postoperative seroma
998.59[4,12]	Other postoperative infection
996.67[7]	Infection and inflammatory reaction due to other internal orthopedic device implant and graft

Intervention ICD-9 Code	Description
86.22	Excisional debridement of wound, infection, or burn
86.28	Nonexcisional 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
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)
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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

[9] Memtsoudis S, Gonzalez Ella Valle A, Besculides M, Gaber L, Sculco T. (2008). In-hospital complications and mortality of unilateral, bilateral, and revision TKA. *Clin Orthop Relat Res*, 466:2617-2627.

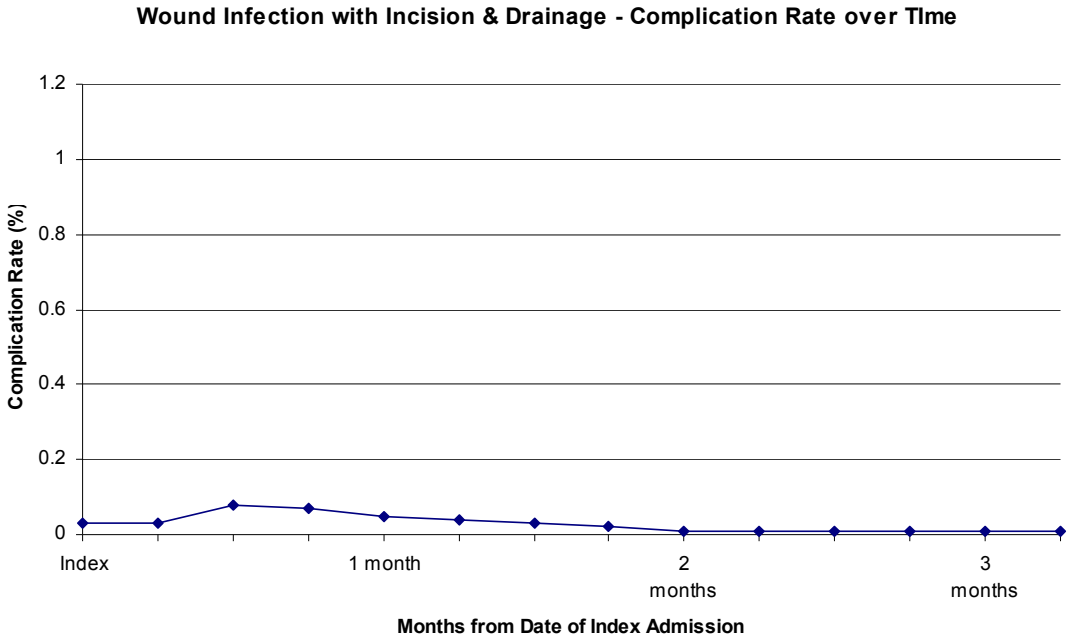
[10] Deyo R, Martin B, Kreuter W, Jarvik J, Mirza S. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*, 303(13): 1259-65.

[11] Thomas C, Cadwallader HL, Riley TV. (2004). Surgical-site infections after orthopaedic surgery: statewide surveillance using linked administrative databases. *J Hosp Infect*, (57(1): 25-30.

[12] Centers for Medicare and Medicaid Services No-Pay List

*NOTE: Wound infection codes not used: 890.0, 890.1, 890.2, 891.0, 891.1, 891.2, 894.1, 894.2, 998.89, 999.3, 999.31, 999.39, 686.9, 682.5, 682.6

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any wound infection code listed above in a primary or secondary diagnosis field AND the presence of <u>at least one</u> of the following procedure codes: o Incision and drainage o Revision o Removal	• These codes identify wound infection related to the index procedure • Requiring an intervention sets an appropriate threshold for severity and will therefore capture true wound infections and reduce false positives
Readmission	
• Presence of any wound infection code listed above in a primary or secondary diagnosis field AND the presence of <u>at least one</u> of the following procedure codes: o Incision and drainage o Revision o Removal	• These codes identify all wound infections, including those identified at the time of a readmission (even though wound infection may not be the primary reason for that readmission), since all are likely to be procedure-related
Follow-up Period for Complications Measure	
• During index admission or within 30 days from admission date	• Data indicate that rate decreases after 30 days • Consistent with clinical course



Data Source: Medicare Inpatient Data, 2008

PULMONARY EMBOLISM (PE)

Complication	ICD-9 Code	Description
	415.1[13,14,15,16,17,18]	Pulmonary embolism and infarction
	415.11[1,2,3,6]	Iatrogenic pulmonary embolism and infarction
	415.19[1,2,3,6]	Other pulmonary embolism and infarction

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any pulmonary embolism code listed in the primary or secondary diagnosis fields	• These codes identify PE related to the index procedure
Readmission	
• Presence of any pulmonary embolism code listed above in the primary or secondary diagnosis fields	• These codes identify all PEs, including those identified at the time of a readmission (even though PE may not be the primary reason for that readmission), since all are likely to be procedure-related
Follow-up Period for Complications Measure	
• During index admission or within 30 days from admission date	• Data indicate that rate decreases after 30 days • Consistent with clinical course

[13] *Version 4.1 technical documentation* AHRQ Quality Indicators. December, 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/TechnicalSpecs41.htm

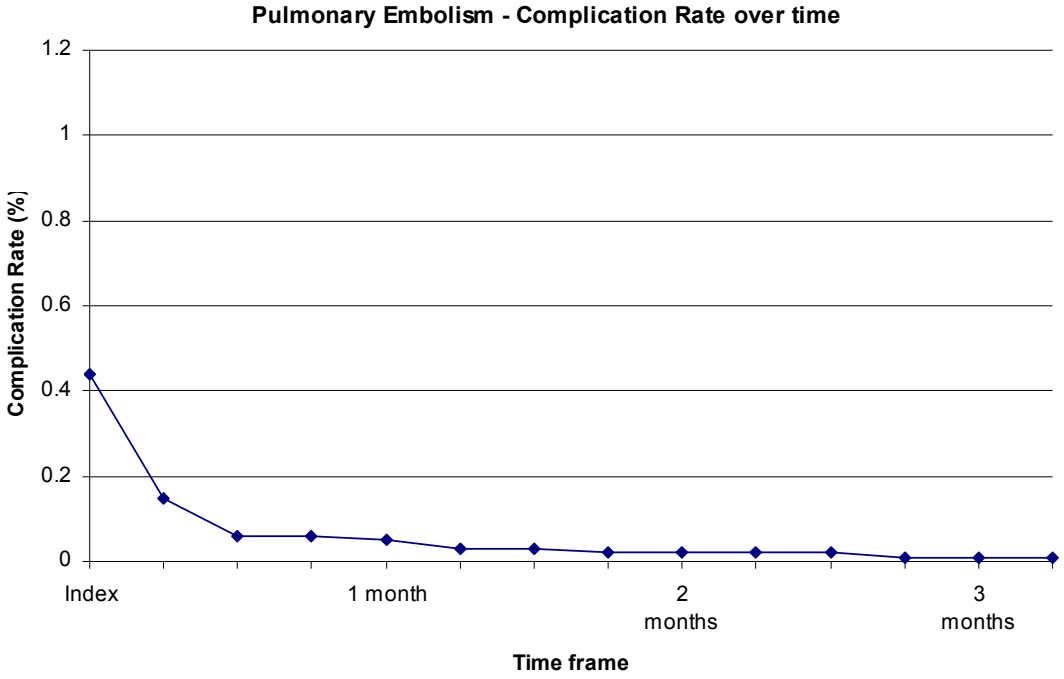
[14] Solomon D, Chibnik L, Losina E, Huang J, Fossel A, Husni E, Katz J. (2006). Development of a preliminary index that predicts adverse events after total knee replacement. *Arthritis Rheum*, 54(5): 1536-1542.

[15] Huddleston J, Maloney W, Wang Y, Verzier N, Hunt D, Herndon J. (2009). Adverse events after total knee arthroplasty. J Arthroplasty, 24(6): 95-100.

[16] Memtsoudis S, Gonzalez Ella Valle A, Besculides M, Gaber L, Sculco T. (2008). In-hospital complications and mortality of unilateral, bilateral, and revision TKA. *Clin Orthop Relat Res*, 466:2617-2627.

[17] Weaver F, Hynes D, Hopkinson W, Wixson R, Khuri S, Daley J, Henderson W. (2003). Preoperative risks and outcomes of hip and knee arthroplasty in the Veterans Health Administration. *J Arthroplasty*, 18(6): 693-708.

[18] Deyo R, Martin B, Kreuter W, Jarvik J, Mirza S. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*, 303(13): 1259-65.



Data Source: Medicare Inpatient Part A Data, 2008

ACUTE MYOCARDIAL INFARCTION (AMI)

Complication ICD-9 Code	Description
*410[19,20]	Acute myocardial infarction
410.0[1,21]	Acute myocardial infarction of anterolateral wall
410.00[1]	Acute myocardial infarction of anterolateral wall episode of care unspecified
410.01[1]	Acute myocardial infarction of anterolateral wall initial episode of care
410.1[1,3]	Acute myocardial infarction of other anterior wall
410.10[1]	Acute myocardial infarction of other anterior wall episode of care unspecified
410.11[1]	Acute myocardial infarction of other anterior wall initial episode of care
410.2[1,3]	Acute myocardial infarction of inferolateral wall
410.20[1]	Acute myocardial infarction of inferolateral wall episode of care unspecified
410.21[1]	Acute myocardial infarction of inferolateral wall initial episode of care
410.3[1,3]	Acute myocardial infarction of inferoposterior wall
410.30[1]	Acute myocardial infarction of inferoposterior wall episode of care unspecified
410.31[1]	Acute myocardial infarction of inferoposterior wall initial episode of care
410.4[1,3]	Acute myocardial infarction of other inferior wall
410.40[1]	Acute myocardial infarction of other inferior wall episode of care unspecified
410.41[1]	Acute myocardial infarction of other inferior wall initial episode of care
410.5[1,3]	Acute myocardial infarction of other lateral wall
410.50[1]	Acute myocardial infarction of other lateral wall episode of care unspecified
410.51[1]	Acute myocardial infarction of other lateral wall initial episode of care
410.6[1,3]	True posterior wall infarction
410.60[1]	True posterior wall infarction episode of care unspecified
410.61[1]	True posterior wall infarction initial episode of care
410.7[1,3]	Subendocardial infarction
410.70[1]	Subendocardial infarction episode of care unspecified
410.71[1]	Subendocardial infarction initial episode of care
410.8[1,3]	Acute myocardial infarction of other specified sites
410.80[1]	Acute myocardial infarction of other specified sites episode of care unspecified
410.81[1]	Acute myocardial infarction of other specified sites initial episode of care
410.9[1,3]	Acute myocardial infarction of unspecified site
410.90[1]	Acute myocardial infarction of unspecified site episode of care unspecified
410.91[1]	Acute myocardial infarction of unspecified site initial episode of care

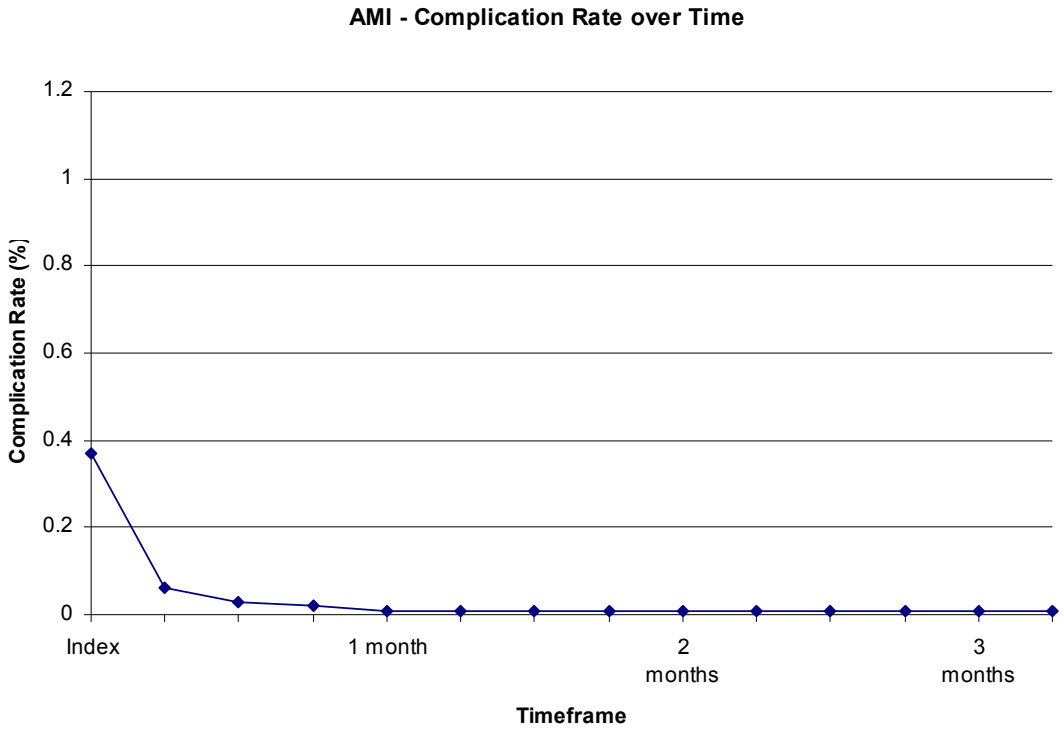
[19] Yale/CORE cohort definition for pneumonia

[20] Weaver F, Hynes D, Hopkinson W, Wixson R, Khuri S, Daley J, Henderson W. (2003). Preoperative risks and outcomes of hip and knee arthroplasty in the Veterans Health Administration. *J Arthroplasty*, 18(6): 693-708.

[21] Deyo R, Martin B, Kreuter W, Jarvik J, Mirza S. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*, 303(13): 1259-65.

* **NOTE: Excludes the following code: 0**410.x2

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any AMI code listed above in a primary or secondary diagnosis field	• These codes identify AMI related to the index procedure
Readmission	
• Presence of any AMI code listed above in a primary field only	• These codes identify AMI's that were the primary reason for a readmission • AMIs that are secondary diagnoses in readmissions may represent a history of AMI or a complication of the second admission
Follow-up Period for Complications Measure	
• During index admission or within 7 days from index admission date	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases sharply 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure



Data source: Medicare Part A Inpatient Data, 2008

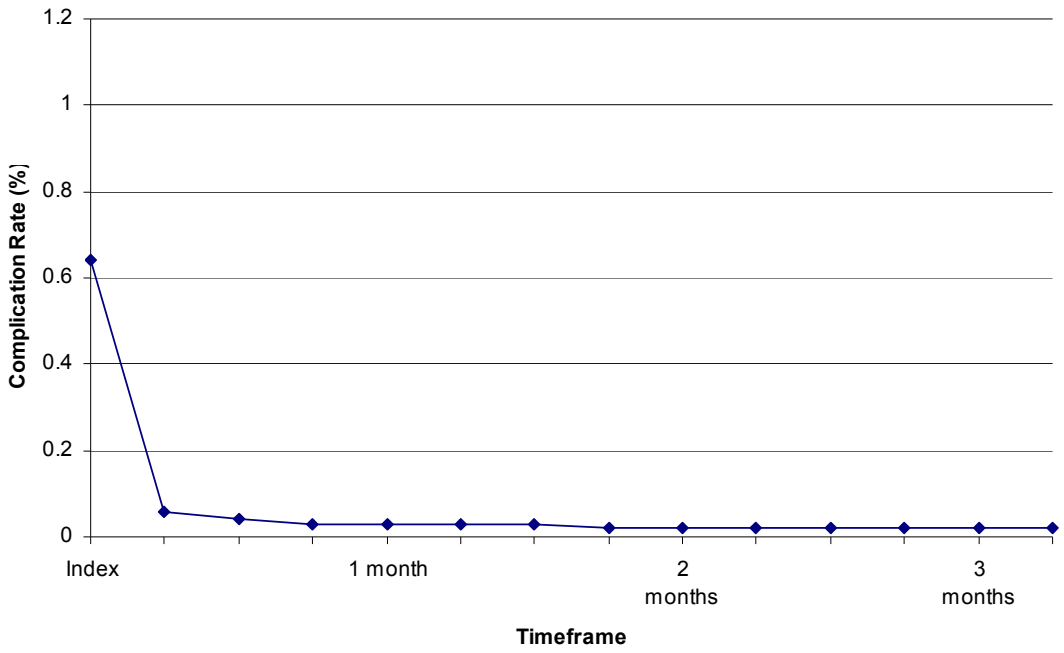
PNEUMONIA

Complication ICD-9 Code	Description
480[22]	Viral pneumonia
480.0[1]	Pneumonia due to adenovirus
480.1[1]	Pneumonia due to respiratory syncytial virus
480.2[1]	Pneumonia due to parainfluenza virus
480.3[1]	Pneumonia due to sars-associated coronavirus
480.8[1]	Pneumonia due to other virus not elsewhere classified
480.9[1]	Viral pneumonia unspecified
481[1,23,24,25,26]	Pneumococcal pneumonia
482[4,5]	Other Bacterial Pneumonia
482.0[1,5]	Pneumonia due to klebsiella pneumoniae
482.1[1,5]	Pneumonia due to pseudomonas
482.2[1,2,3,5]	Pneumonia due to hemophilus influenzae (h. influenzae)
482.3	Pneumonia due to streptococcus
482.30[1,2,3,5]	Pneumonia due to streptococcus unspecified
482.31[1,2,3,5]	Pneumonia due to streptococcus group a
482.32[1,2,3,5]	Pneumonia due to streptococcus group b
482.39[1,2,3,5]	Pneumonia due to other streptococcus
482.4	Pneumonia due to staphylococcus
482.40[1,5]	Pneumonia due to staphylococcus unspecified
482.41[1,2,3,5]	Methicillin susceptible pneumonia due to staphylococcus aureus
482.42[5]	Methicillin resistant pneumonia due to staphylococcus aureus
482.49[1,5]	Other staphylococcus pneumonia
482.81[1,5]	Pneumonia due to anaerobes
482.82[1,5]	Pneumonia due to escherichia coli [e.coli]
482.83[1,5]	Pneumonia due to other gram-negative bacteria
482.84[1,5]	Pneumonia due to legionnaires' disease
482.89[1,5]	Pneumonia due to other specified bacteria
482.9[1,2,3,5]	Bacterial pneumonia unspecified
483[1,2,3]	Pneumonia due to other specified organism
483.0[1]	Pneumonia due to mycoplasma pneumoniae
483.1[1]	Pneumonia due to chlamydia
483.8[1]	Pneumonia due to other specified organism
485[1-5]	Bronchopneumonia organism unspecified
486[1-5]	Pneumonia organism unspecified
487.0[1]	Influenza with pneumonia
507.0[4]	Pneumonitis due to inhalation of food or vomitus

[22] Yale/CORE cohort definition for pneumonia
[23] *Version 4.1 technical documentation* AHRQ Quality Indicators. December, 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/TechnicalSpecs41.htm
[24] National Quality Forum Endorsed Standard-Bacterial Pneumonia.
[25] Weaver F, Hynes D, Hopkinson W, Wixson R, Khuri S, Daley J, Henderson W. (2003). Preoperative risks and outcomes of hip and knee arthroplasty in the Veterans Health Administration. *J Arthroplasty*, 18(6): 693-708.
[26] Deyo R, Martin B, Kreuter W, Jarvik J, Mirza S. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*, 303(13): 1259-65.

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any pneumonia code listed above in a primary or secondary diagnosis field	• These codes identify pneumonia related to the index procedure
Readmission	
• Presence of any pneumonia code listed above in a primary diagnosis field only	• These codes identify pneumonias that were the primary reason for a readmission • Pneumonias that are secondary diagnoses in readmissions may represent a history of pneumonia or a complication of the second admission
Follow-up Period for Complications Measure	
• During index admission or within 7 days from index admission date	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases sharply 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure

Pneumonia - Complication Rate over Time



Data source: Medicare Part A Inpatient Data, 2008

SEPSIS/SEPTICEMIA

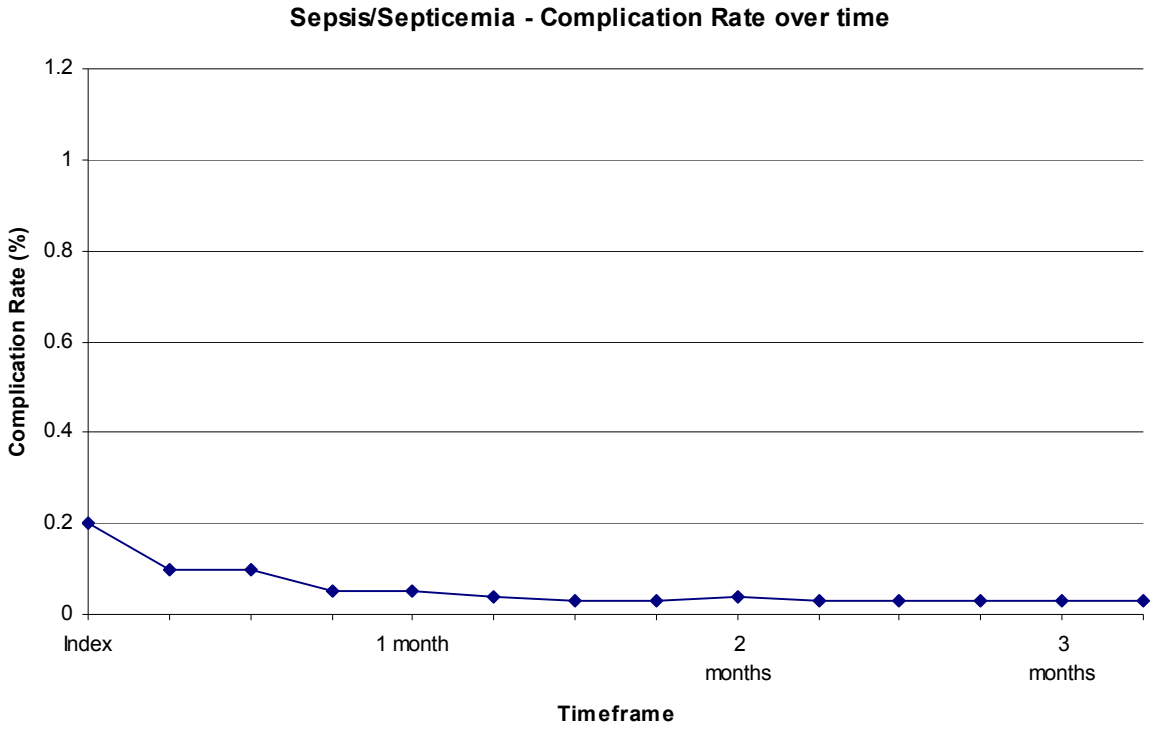
Complications	ICD-9 Code	Description
038[27]		Septicemia
	038.0[28,29]	Streptococcal septicemia
	038.1[2,3]	Staphylococcal septicemia
	038.10[2,3]	Staphylococcal septicemia unspecified
	038.11[2,3]	Methicillin susceptible staphylococcus aureus septicemia
	038.12[2,3]	Methicillin resistant staphylococcus aureus septicemia
	038.19[2,3]	Other staphylococcal septicemia
	038.2[2,3]	Pneumococcal septicemia
	038.3[2,3]	Septicemia due to anerobes
	038.4[2,3]	Septicemia due to other gram-negative organisms
	038.40[2,3]	Septicemia due to gram negative organisms unspecified
	038.41[2,3]	Septicemia due to h. influenzae
	038.42[2,3]	Septicemia due to e. coli
	038.43[2,3]	Septicemia due to pseudomonas
	038.44[2,3]	Septicemia due to serratia
	038.49[2,3]	Other septicemia due to gram-negative organisms
	038.8[2,3]	Other specified septicemias
	038.9[2,3]	Unspecified septicemia
785.52[2,3]		Septic shock
785.59[2,3]		Other shock without trauma
790.7		Bacteremia
995.91[2,3]		Systemic inflammatory response syndrome due to infectious process w/out organ dysfunction
995.92[2,3]		Systemic inflammatory response syndrome due to infectious process with organ dysfunction
998.0[2,3]		Postoperative shock not elsewhere classified
998.59		Post procedural sepsis

[27] Weaver F, Hynes D, Hopkinson W, Wixson R, Khuri S, Daley J, Henderson W. (2003). Preoperative risks and outcomes of hip and knee arthroplasty in the Veterans Health Administration. *J Arthroplasty*, 18(6): 693-708.

[28] *Version 4.1 technical documentation* AHRQ Quality Indicators. December, 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/TechnicalSpecs41.htm

[29] Solomon D, Chibnik L, Losina E, Huang J, Fossel A, Husni E, Katz J. (2006). Development of a preliminary index that predicts adverse events after total knee replacement. *Arthritis Rheum*, 54(5): 1536-1542.

When to Count as Complication	
Index Admission	**Rationale**
• Presence of any sepsis/septicemia code listed above in a primary or secondary diagnosis field	• These codes identify sepsis/septicemia related to the index procedure
Readmission	
• Presence of any sepsis/septicemia code listed above in a primary diagnosis or secondary diagnosis field	• Sepsis/septicemia rates will be underestimated if identified using primary diagnosis field only, as these codes are found more frequently in the secondary diagnosis fields • Primary field may indicate the source of sepsis/septicemia
Follow-up Period for Complications Measure	
• During index admission or within 7 days from index admission date	• More likely to be attributable to procedure if it occurs within 7 days of procedure • Rate decreases 7 days from admission and returns to baseline within 30 days • Limits overlap with 30-day all-cause readmission measure



Data source: Medicare Part A Inpatient Data, 2008

6.2 Appendix B: ICD-9-CM Codes for Hip Fracture, Revision Procedures, Partial Hip Arthroplasty, and Resurfacing Procedure

ICD-9-CM Codes for Hip Fracture	
733.1	Pathologic fracture
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
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
820.10	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
820.20	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
820.30	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

ICD-9-CM Codes for THA and TKA Revision Procedures	
00.70	REV Hip Repl-acetab/fem OCT05
00.71	REV Hip Repl-acetab comp OCT05
00.72	REV Hip Repl-fem comp OCT05
00.73	REV Hip Repl-liner/head OCT05

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)
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

ICD-9-CM Code for Partial Hip Arthroplasty Procedure	
81.52	Partial Hip Replacement

ICD-9-CM Codes for THA Resurfacing Procedure	
00.85	Resurfacing hip, total, acetabulum and femoral head, hip resurfacing arthroplasty, total
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

6.3 Appendix C Conditions That May Represent Adverse Outcomes of Care Received During Index Admission.

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
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
82	Unstable angina
85	Heart Infection/Inflammation, Except Rheumatic
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
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
154	Severe Head Injury
155	Major Head Injury
156	Concussion or Unspecified Head Injury

CC	Description
157	Vertebral Fractures
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

6.4 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
129	End Stage Renal Disease	Not included in CMS-HCC Model
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