MINI-SENTINEL SYSTEMATIC EVALUATION OF HEALTH OUTCOME OF INTEREST DEFINITIONS FOR STUDIES USING ADMINISTRATIVE DATA

ORTHOPEDIC IMPLANT REMOVAL AND REVISION REPORT

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June 4, 2011

Mini-Sentinel Systematic Evaluation Of Health Outcome Of Interest Definitions For Studies Using Administrative Data

Orthopedic Implant Removal and Revision Report

I. EXECUTIVE SUMMARY

A. OVERVIEW OF PROJECT

The Food and Drug Administration (FDA) Mini-Sentinel contract is a pilot program that aims to conduct active surveillance to detect and refine safety signals that emerge for marketed medical products. To perform this surveillance, it is necessary to develop and understand the validity of algorithms for identifying health outcomes of interest in administrative data. Thus, the goal of this project was to identify algorithms used to detect selected health outcomes of interest using administrative data sources and describe the performance characteristics of these algorithms as reported by the studies in which they were used. This report summarizes the process and findings of the orthopedic implant removal and revision algorithm review.

B. SUMMARY OF FINDINGS

Of all the articles included for the review, we found five articles with validated database algorithms (defined as those tested against a gold standard such as documentation in medical records). Three studies validated International Classification of Diseases- ninth version clinical modification (ICD-9-CM) codes or Common Procedural Terminology (CPT) codes against an independent medical record abstraction for occurrence of revision total hip arthroplasty (THA) in the U.S. Medicare population. The positive predictive values (PPVs; defined as the proportion of patients with a positive test that have the condition of interest) of ICD-9-CM/CPT codes for revision total hip arthroplasty in these studies were 92%, 71%, and 91%, respectively. In the fourth study of the U.S. Medicare population, multiple ICD- 9 codes for underlying diagnoses (complications) for revision total knee arthroplasty (TKA) were compared to newly available single ICD-9-CM codes for revision arthroplasty and found a sensitivity of 87% and specificity of 99% (PPV not provided). The fifth study validated the ICD-9-CM codes for revision total knee arthroplasty (TKA) against Ontario health insurance physician fee service claims as the gold standard and found a PPV of 32%. All other studies of implant removal or revision failed to provide any validation of the algorithm used to identify patients.

In summary, one group of authors has provided validation data with regards to ICD-9-CM/CPT codes for revision total hip arthroplasty in the Medicare population in three separate publications, using medical records as the gold standard. The findings have not been replicated independently by other authors. No validated algorithms have been published for total knee arthroplasty, or for primary arthroplasty. None of the studies have provided any algorithm use of any other database-derived definitions, except looking at additional codes from claims. More validation studies are needed for ICD-9/CPT codes and other database approaches to define these cohorts.

C. RECOMMENDATION FOR ALGORITHMS AND SUGGESTION FOR FUTURE RESEARCH

In this systematic review, we found that two algorithms using ICD-9-CM/CPT codes to identify patients with revision total hip arthroplasty in the Medicare population had consistently high PPV compared to medical record review in two studies. In these two studies, by Katz, et al. in 2001 and Mahomed, et al. in 2003, revision total hip arthroplasty patients were identified by presence of CPT codes 27134, 27137, or 27138 and primary total hip arthroplasty by presence of ICD-9 code 81.51 with/without CPT code 27130. The PPV was 99% for primary THA and 92% for revision THA in the Katz 2001 study. The PPV was 99% for primary THA and 91% for revision THA in the Mahomed study.

Due to the absence of more than one group of investigators that have evaluated these approaches, we recommend that more research is needed to validate these algorithms and to develop new, improved algorithms.

II. PROJECT OBJECTIVES

The primary objective of this project was to identify studies that have validated algorithms used to identify various health outcomes of interest (HOIs) using administrative data from the United States or Canada, and to summarize the results of those validation studies. If fewer than five validation studies were identified, a secondary objective was to identify non-validated algorithms that have been used to identify the HOIs using administrative data. This report deals with the HOI of orthopedic implant removal or revision.

III. BACKGROUND

The Food and Drug Administration (FDA) Mini-Sentinel contract is a pilot program that aims to conduct active surveillance to detect and refine safety signals that emerge for marketed medical products. In order to perform this work, the program needed to identify algorithms used to detect various health outcomes of interest using administrative data sources and identify the performance characteristics of these algorithms as measured in the studies in which they were used. The data sources of interest were limited to those from the United States or Canada to increase their relevance to the Mini-Sentinel data sources, which are all from the United States. The Mini-Sentinel Protocol Core developed a preliminary list of approximately 140 potential health outcomes of interest, based on several criteria. These criteria included: (a) previous validation studies identified in a textbook chapter reviewing the validity of drug and diagnosis data used in pharmacoepidemiologic studies[1]; (b) a list of designated medical events from a proposed FDA rule on the safety reporting requirements for human drug and biological products[2]; (c) the Observational Medical Outcomes Partnership (OMOP) commissioned reports on algorithms used to identify the health outcome using administrative data[3].

From the original list of 140 HOIs, the Protocol Core worked with FDA to select 20 for which reviews of algorithms would be completed. HOIs for which OMOP had already commissioned reports were purposefully excluded in order to avoid duplication of effort.

Implant removal and revision was one of the 20 HOIs selected for review. This report describes the review process and findings for the implant removal and revision definition algorithms.

IV. METHODS

A. SEARCH STRATEGY

The general search strategy was developed based on prior work by OMOP and its contractors, and modified slightly for these reports. Originally, OMOP contracted with two organizations to perform reviews of 10 HOIs. Because the search strategies used by each organization resulted in very different sets of articles, OMOP investigators reviewed the PubMed indexing of the articles deemed useful in final reports and developed a strategy that would identify the majority of these citations while maintaining efficiency in the number of abstracts that would need to be reviewed. Mini-Sentinel investigators made minor changes to this strategy that would result in the identification of more citations, and confirmed

empirically that the majority of relevant articles from one set of OMOP reports[4-5] would be identified using this approach. The base search strategy was then combined with PubMed terms representing the HOIs. Medical subject heading (MeSH) terms were generally preferred as HOI search terms due to their likely specificity. Text word searches were sometimes used, particularly when the MeSH search resulted in a small number of citations for review. The workgroup also searched the database of the Iowa Drug Information Service (IDIS) using a similar search strategy to identify other relevant articles that were not found in the PubMed search. For a limited number of outcomes where very few citations were identified from PubMed and IDIS searches, Embase searches were conducted. Search results were restricted to articles published on or after January 1, 1990.

University of Iowa investigators compiled the search results from different databases and eliminated duplicate results using a citation manager program. The results were then output into two sets of files, one containing the abstracts for review and the other for documenting abstract review results.

The search strategy and results for Implant revision and removal are detailed in the Results section. The PubMed search was conducted on May 14, 2010, and the IDIS search on June 11, 2010. The PubMed search was updated on July 20, 2010.

B. ABSTRACT REVIEW

1. Abstract Review Methods

Each abstract was reviewed independently by two investigators to determine whether the full-text article should be reviewed. Exclusion criteria were documented sequentially (i.e., if exclusion criterion 1 was met then the other criteria were not documented). If the reviewers disagreed on whether the full-text should be reviewed, then it was selected for review. Inter-rater agreement on whether to include or exclude an abstract was calculated using a Cohen's kappa statistic. Before starting the full title and abstract review, a trial consensus exercise was undertaken for a random subset of 35 articles. Both reviewers independently selected the same 4 articles for inclusion (Lyman 2009, Ong 2008, Kurtz 2007 and Cooney 2006) with an agreement of 100% and kappa of 1. Once the list of full-text articles to review had been compiled, each reviewer independently abstracted data from each article. Abstractions were compared and any disagreements on data were resolved by discussion. The goal was to review any administrative database study that used data from the United States or Canada and studied the HOI, as validation components of studies are not necessarily included in the abstract and other relevant citations might be identified from the references of such studies.

2. Abstract Exclusion Criteria

1. Did not study the HOI.

2. Not an administrative database study. Eligible sources included insurance claims databases as well as other secondary databases that identify health outcomes using billing codes.

3. Data source not from the United States or Canada.

C. FULL-TEXT REVIEW

1. Full-Text Review Methods

Full-text articles were reviewed independently by two investigators, with a goal of identifying validation studies described in the article itself or from the reference section of the article. Citations from the article's references were selected for full-text review if they were cited as a source for the HOI algorithm, or were otherwise deemed likely to be relevant. Full-text review exclusion criteria were applied sequentially, since if fewer than 5 validation studies were identified, up to 10 of the articles excluded based on the second criterion would need to be incorporated into the final report. If there was disagreement on whether a study should be included, the two reviewers attempted to reach consensus on inclusion by discussion. If the reviewers could not agree, a third investigator would be consulted to make the final decision.

2. Full-Text Exclusion Criteria

1. Poorly described HOI identification algorithm that would be difficult to operationalize.

2. No validation of outcome definition or reporting of validity statistics.

D. MINI-SENTINEL INVESTIGATOR SURVEY

Mini-Sentinel investigators were surveyed to request information on any published or unpublished studies that validated an algorithm to identify an HOI in administrative data. Studies that would not be excluded by one of the aforementioned criteria were included in the final report.

E. EVIDENCE TABLE CREATION

A single investigator created tables for the final evidence table using the validated data derived from the consensus data sheet, which was generated based on independent data abstractions by two abstractors from each study. The data included in the tables were confirmed by a second investigator for accuracy.

F. CLINICIAN OR TOPIC-EXPERT CONSULTATION

A clinician or topic-expert was consulted to review the results of the evidence table and discuss how they compare and contrast to diagnostic methods currently used in clinical practice. This included whether certain diagnostic codes used in clinical practice were missing from the algorithms, and the appropriateness of the validation definitions compared to diagnostic criteria currently used in clinical practice. A summary of this consultation was included in the results.

V. RESULTS

A. SEARCH STRATEGY AND RESULTS

The following summarizes the search results obtained from the initial PubMed search on 5/14/2010 (Table 1), the updated PubMed search on 7/20/2010 (Table 2), and the IDIS search on 6/11/10 (Table 3). The initial PubMed search identified 580 citations, updated PubMed search identified 5 additional

articles, and the IDIS search identified no unique citations. The total number of unique citations from the combined searches was 585 (580+5). Two additional references were sent by Mini-Sentinel investigators, of which one article was already included in previous searches, leading to a total of 586 articles (580 original + 7 in the updated search with one duplicate article).

Table 1. Initial PubMed Search Strategy (5/14/10) and Results

Search	Query	Duration	Results
#20	Search #11 and #19 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:52:09	580
#19	Search #18 and #12 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:36:19	7424
#18	Search #17 or #13 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:36:04	81888
#17	Search "Arthroplasty"[Mesh] Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:35:51	19033
#13	Search "Orthopedic Procedures"[Mesh] Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:34:45	81888
#12	Search ("Reoperation"[Mesh] OR "Second-Look Surgery"[Mesh]) OR "Device Removal"[Mesh] Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:34:19	38911
#11	Search #3 not #4 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:32:17	391622
#7	Search #6 and #1 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:28:42	966
#6	Search #5 not #4 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:28:30	116479
#5	Search #2 and #3 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:28:15	118108
#4	Search Search ("Clinical Trial"[pt] OR "Editorial"[pt] OR "Letter"[pt] OR "Meta-Analysis"[pt] OR "Randomized Controlled Trial"[pt] OR "Clinical Trial, Phase I"[pt] OR "Clinical Trial, Phase II"[pt] OR "Clinical Trial, Phase III"[pt] OR "Clinical Trial, Phase IV"[pt] OR "Comment"[pt] OR "Controlled Clinical Trial"[pt] OR "case reports"[pt] OR "Clinical Trials as Topic"[Mesh] OR "double-blind"[All] OR "placebo-controlled"[All] OR "pilot study"[All] OR "pilot projects"[Mesh] OR "Review"[pt] OR "Prospective Studies"[Mesh]) Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01	15:27:55	39297
#3	Search ("Premier"[All] OR "Solucient"[All] OR "Cerner"[All] OR "Ingenix"[All] OR "LabRx"[All] OR "IHCIS"[All] OR "marketscan"[All] OR "market scan"[All] OR "Medstat"[All] OR "Thomson"[All] OR "pharmetrics"[All] OR "healthcore"[All] OR "united healthcare"[All] OR "UnitedHealthcare"[All] OR "UHC"[All] OR "GPRD"[All] OR "general practice research database"[All] OR "Research Database"[All] OR "Group Health"[All] OR "HCUP"[All] OR ("Healthcare Cost"[All] AND "Utilization Project"[All]) OR ("Health Care Cost"[All] AND "Utilization Project"[All]) OR "MEPS"[All] OR "Medical Expenditure Panel Survey"[All] OR "NAMCS"[All] OR "National Hospital Ambulatory Medical Care Survey"[All] OR "National	15:27:36	395576

Ambulatory Medical Care Survey"[All] OR "NHIS"[All] OR "National Health Interview Survey"[All] OR "Kaiser"[All] OR "HMO Research"[All] OR "Health Maintenance Organization"[All] OR "HMO"[All] OR "Cleveland Clinic"[All] OR "Lovelace"[All] OR "Department of Defense"[All] OR "Henry Ford"[All] OR ("Denmark"[All] AND "Epidemiology"[All]) OR "i3 Drug Safety"[All] OR "i3"[All] OR "Aetna"[All] OR "Humana"[All] OR "Wellpoint"[All] OR "IMS"[All] OR "Intercontinental Marketing Services"[All] OR "IMS Health"[All] OR "Geisinger"[All] OR "GE Healthcare"[All] OR "MQIC"[All] OR "PHARMO"[All] OR "Institute for Drug Outcome Research"[All] OR "Pilgrim"[All] OR "Puget Sound"[All] OR "Regenstrief"[All] OR "Saskatchewan"[All] OR "Tayside"[All] OR "MEMO"[All] OR "Medicines Monitoring Unit"[All] OR "Veterans Affairs"[All] OR "Partners Healthcare"[All] OR "Mayo Clinic"[All] OR "Rochester Epidemiology"[All] OR "Indiana Health Information Exchange"[All] OR "Indiana Health"[All] OR "Intermountain"[All] OR "THIN"[All] OR "The health improvement network"[All] OR "blue cross"[All] OR "health partners"[All] OR "health plan"[All] OR "health services"[All] OR "Nationwide Inpatient Sample"[All] OR "National Inpatient Sample"[All] OR "medicaid"[All] OR "medicare"[All] OR "MediPlus"[All] OR "Outcome Assessment"[All] OR "insurance database"[All] OR "insurance databases"[All] OR "Data Warehouse"[All] OR "ICD-9"[All] OR "international statistical classification"[All] OR "international classification of diseases"[All] OR "ICD-10"[All] OR "Database Management Systems"[Mesh] OR "Medical Records Systems, Computerized"[Mesh] OR "CPT"[All] OR "Current procedural terminology"[All] OR "drug surveillance"[All] OR ("claims"[tw] AND "administrative"[tw]) OR ("data"[tw] AND "administrative"[tw]) OR "Databases, Factual"[Mesh] OR "Databases as topic"[Mesh] OR "Medical Record Linkage"[Mesh] OR "ICD-9-CM"[All Fields] OR "ICD-10-CM"[All Fields] Limits: Humans, English, Publication Date from 1990/01/01 to 2011/01/01		

Table 2. Updated PubMed Search Strategy and Results (7/20/10)

Search	Query	Duration	Results
#7	Search #5 and #6 Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	13:08:21	5
#6	Search ("Reoperation"[Mesh] OR "Second-Look Surgery"[Mesh] OR "Device Removal"[Mesh]) AND ("Orthopedic Procedures"[Mesh] OR "Arthroplasty"[Mesh]) Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	12:06:32	9182
#5	Search #4 not #1 Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	12:05:39	2824
#4	Search #3 not #2 Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	12:05:26	4312
#3	Search (TennCare [tiab]) OR (RAMQ [tiab]) OR (Cigna [tiab]) OR ((british columbia[tiab]) AND ((health[tiab]) OR (data[tiab]) OR (database[tiab]) OR (population[tiab]))) OR (CIHI [All Fields]) OR ((manitoba[tiab]) AND ((center for health policy[all fields]) OR (population[tiab]) OR (health insurance[tiab]))) OR ((ontario[tiab]) AND ((population[tiab]) OR (OHIP[tiab]) OR (registered persons database[tiab]) OR (health insurance [tiab]) OR (ICES[All Fields]) OR (Institute for Clinical Evaluative Sciences[All Fields]))) OR ((Alberta[tiab]) AND ((health[tiab]) OR (data[tiab]) OR (database[tiab]) OR (population[tiab]) OR (Alberta Health and Wellness[All Fields])))) Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	12:05:05	5162
#2	Search ("Clinical Trial"[pt] OR "Editorial"[pt] OR "Letter"[pt] OR "Meta-Analysis"[pt] OR "Randomized Controlled Trial"[pt] OR "Clinical Trial, Phase I"[pt] OR "Clinical Trial, Phase II"[pt] OR "Clinical Trial, Phase III"[pt] OR "Clinical Trial, Phase IV"[pt] OR "Comment"[pt] OR "Controlled Clinical Trial"[pt] OR "case reports"[pt] OR "Clinical Trials as Topic"[Mesh] OR "double-blind"[All] OR "placebo-controlled"[All] OR "pilot study"[All] OR "pilot projects"[Mesh] OR "Review"[pt] OR "Prospective Studies"[Mesh]) Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01	12:03:23	3211319
#1	Search ("Premier"[All] OR "Solucient"[All] OR "Cerner"[All] OR "Ingenix"[All] OR "LabRx"[All] OR "IHCIS"[All] OR "marketscan"[All] OR "market scan"[All] OR "Medstat"[All] OR "Thomson"[All] OR "pharmetrics"[All] OR "healthcore"[All] OR "united healthcare"[All] OR "UnitedHealthcare"[All] OR "UHC"[All] OR "GPRD"[All] OR "general practice research database"[All] OR "Research Database"[All] OR "Group Health"[All] OR "HCUP"[All] OR ("Healthcare Cost"[All] AND "Utilization Project"[All]) OR ("Health Care Cost"[All] AND "Utilization Project"[All]) OR "MEPS"[All] OR "Medical Expenditure Panel Survey"[All] OR "NAMCS"[All] OR "National Hospital Ambulatory Medical Care Survey"[All] OR "National Ambulatory Medical Care Survey"[All] OR "NHIS"[All] OR "National Health Interview Survey"[All] OR "Kaiser"[All] OR "HMO Research"[All] OR "Health Maintenance Organization"[All] OR "HMO"[All] OR "Cleveland Clinic"[All] OR "Lovelace"[All] OR "Department of Defense"[All] OR "Henry Ford"[All] OR ("Denmark"[All] AND "Epidemiology"[All]) OR "i3 Drug Safety"[All] OR "i3"[All] OR "Aetna"[All] OR "Humana"[All] OR "Wellpoint"[All] OR "IMS"[All] OR "Intercontinental Marketing Services"[All] OR "IMS Health"[All] OR "Geisinger"[All] OR "GE Healthcare"[All] OR "MQIC"[All] OR "PHARMO"[All] OR "Institute for Drug Outcome Research"[All] OR "Pilgrim"[All] OR "Puget Sound"[All] OR "Regenstrief"[All] OR "Saskatchewan"[All] OR "Tayside"[All] OR "MEMO"[All] OR "Medicines Monitoring Unit"[All] OR "Veterans Affairs"[All] OR "Partners Healthcare"[All] OR "Mayo Clinic"[All] OR "Rochester Epidemiology"[All] OR "Indiana Health Information Exchange"[All] OR "Indiana Health"[All] OR "Intermountain"[All] OR "THIN"[All] OR "The health improvement network"[All] OR "blue cross"[All] OR "health partners"[All] OR "health plan"[All] OR "health services"[All] OR "Nationwide Inpatient Sample"[All] OR "National Inpatient Sample"[All] OR "medicaid"[All] OR "medicare"[All] OR "MediPlus"[All] OR "Outcome Assessment"[All] OR "insurance database"[All] OR "insurance databases"[All]	12:03:12	429430

OR "Data Warehouse"[All] OR "ICD-9"[All] OR "international statistical classification"[All] OR "international classification of diseases"[All] OR "ICD-10"[All] OR "Database Management Systems"[Mesh] OR "Medical Records Systems, Computerized"[Mesh] OR "CPT"[All] OR "Current procedural terminology"[All] OR "drug surveillance"[All] OR ("claims"[tw] AND "administrative"[tw]) OR ("data"[tw] AND "administrative"[tw]) OR "Databases, Factual"[Mesh] OR "Databases as topic"[Mesh] OR "Medical Record Linkage"[Mesh] OR "ICD-9-CM"[All Fields] OR "ICD-10-CM"[All Fields] Limits: Humans, Publication Date from 1990/01/01 to 2011/01/01

Table 3. IDIS Search Strategy (6/11/10) and Results

ADVANCED SEARCH

All Fields:

ortho* and ("Premier" OR "Solucient" OR "Cerner" OR "Ingenix" OR "LabRx" OR "IHCIS" OR "marketscan" OR "market scan" OR "Medstat" OR "Thomson" OR "pharmetrics" OR "healthcore" OR "united healthcare" OR "UnitedHealthcare" OR "UHC" OR "GPRD" OR "general practice research database" OR "Research Database" OR "Group Health" OR "HCUP" OR ("Healthcare Cost" AND "Utilization Project") OR ("Health Care Cost" AND "Utilization Project") OR "MEPS" OR "Medical Expenditure Panel Survey" OR "NAMCS" OR "National Hospital Ambulatory Medical Care Survey" OR "National Ambulatory Medical Care Survey" OR "NHIS" OR "National Health Interview Survey" OR "Kaiser" OR "HMO Research" OR "Health Maintenance Organization" OR "HMO" OR "Cleveland Clinic" OR "Lovelace" OR "Department of Defense" OR "Henry Ford" OR ("Denmark" AND "Epidemiology") OR "i3 Drug Safety" OR "i3" OR "Aetna" OR "Humana" OR "Wellpoint" OR "IMS" OR "Intercontinental Marketing Services" OR "IMS Health" OR "Geisinger" OR "GE Healthcare" OR "MQIC" OR "PHARMO" OR "Institute for Drug Outcome Research" OR "Pilgrim" OR "Puget Sound" OR "Regenstrief" OR "Saskatchewan" OR "Tayside" OR "MEMO" OR "Medicines Monitoring Unit" OR "Veterans Affairs" OR "Partners Healthcare" OR "Mayo Clinic" OR "Rochester Epidemiology" OR "Indiana Health Information Exchange" OR "Indiana Health" OR "Intermountain" OR "THIN" OR "The health improvement network" OR "blue cross" OR "health partners" OR "health plan" OR "health services" OR "Nationwide Inpatient Sample" OR "National Inpatient Sample" OR "medicaid" OR "medicare" OR "MediPlus" OR "Outcome Assessment" OR "insurance database" OR "insurance databases" OR "Data Warehouse" OR "ICD-9" OR "international statistical classification" OR "international classification of diseases" OR "ICD-10" OR "Database Management Systems" OR "Medical Records Systems, Computerized" OR "CPT" OR "Current procedural terminology" OR "drug surveillance" OR ("claims" AND "administrative") OR ("data" AND "administrative") OR "Databases, Factual" OR "Databases" OR "Medical Record Linkage" OR "ICD-9-CM" OR "ICD-10-CM"

AND **Disease**:

996. (NOTE: COMPLICATION, DEVICE/IMPLANT 996.)

AND NOT **Descriptor**:

"CASE REPORT ADULT 0" or "FDA APPROVAL PACKAGE 155" OR "FDA BLACK BOX WARNING 165" OR "PIVOTAL STUDY 162" OR "FDA ADVISORY COMMITTEE 164" or "CASE REPORT PEDIATRIC 1" or "CASE REPORT GERIATRIC 2" or "REVIEW ADULT 6" or "STUDY NON-CLINICAL 8" or "REVIEW PEDIATRIC 21" or "REVIEW GERIATRIC 23" or "STUDY RANDOMIZE ADULT 135" or "STUDY RANDOMIZE PEDIATRIC 136" or "STUDY RANDOMIZE GERIATRIC 137" or "CROSS-OVER 144" or "META-ANALYSIS 145" or "N-OF-ONE TRIAL 146" or "PRACTICE GUIDELINE 156" or "SYSTEMATIC REVIEW 161" or "ANNOTATED BIBLIOGRAPHY 167" or "PRIORITY CLIN PRACT GUIDE 168"

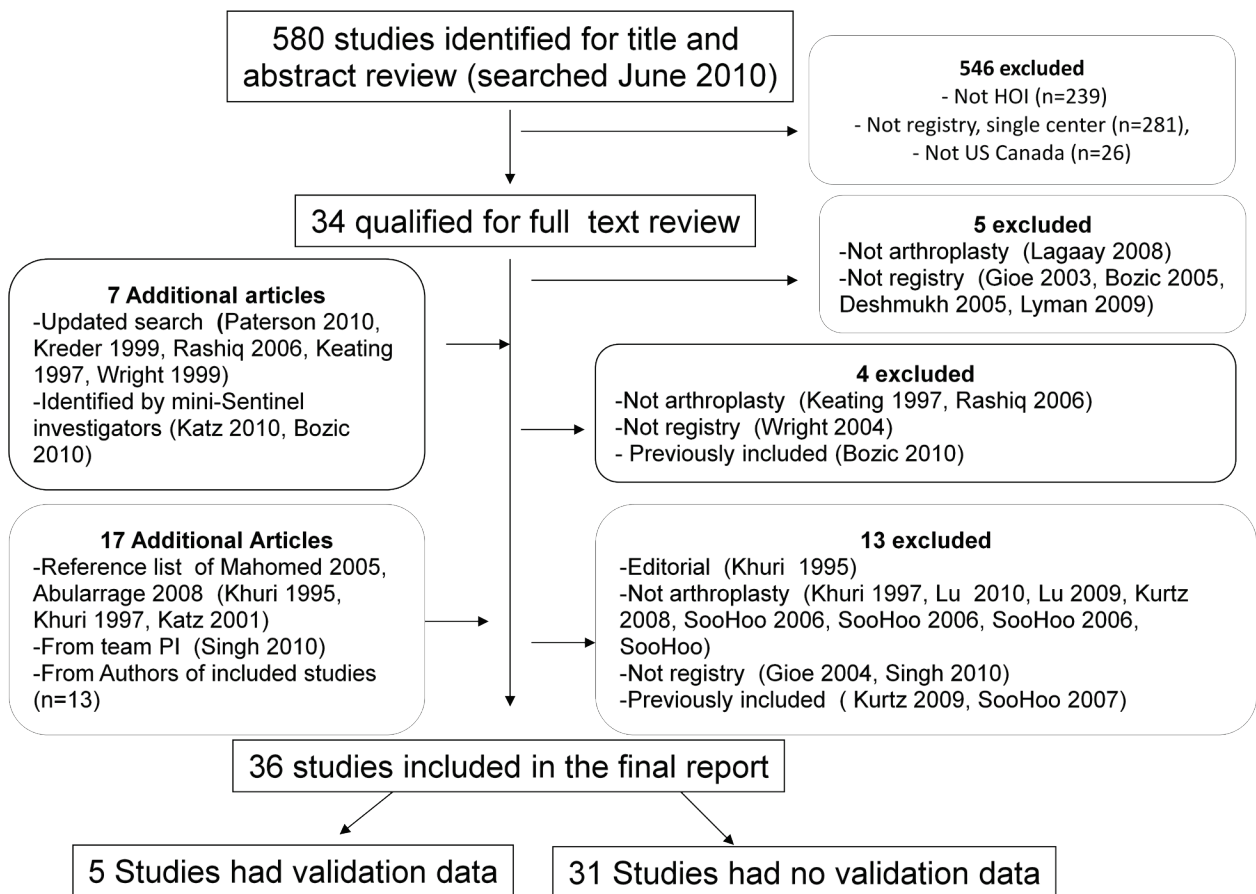Years: 1990-2010

Result is 0

B. ABSTRACT REVIEWS

Of the 580 abstracts reviewed, 546 were excluded. Details are provided below in Figure 1. The reasons for exclusion were as follows: 239 were excluded because they did not study the HOI, 281 were excluded because they were not administrative database studies, and 26 were excluded because the data source was not from the United States or Canada.

Cohen's kappa for agreement between the two reviewers on inclusion versus exclusion of abstracts was 0.95 (standard error, 0.028; reviewer 1 selected 31 articles of the 580; reviewer 2 selected 34 out of 580, which included all 31 from reviewer 1).

An updated search on 07/2010 resulted in 5 additional articles, of which 2 qualified for a full review. The Mini-Sentinel investigators found 2 additional articles, of which one was new and was included for full text review (Katz 2010).

Figure 1. Flow Chart for Included and Excluded Studies

580 studies identified for title and abstract review (searched June 2010)

546 excluded
- Not HOI (n=239)
- Not registry, single center (n=281),
- Not US Canada (n=26)

34 qualified for full text review

5 excluded
-Not arthroplasty (Lagaay 2008)
-Not registry (Gioe 2003, Bozic 2005, Deshmukh 2005, Lyman 2009)

7 Additional articles
-Updated search (Paterson 2010, Kreder 1999, Rashiq 2006, Keating 1997, Wright 1999)
-Identified by mini-Sentinel investigators (Katz 2010, Bozic 2010)

4 excluded
-Not arthroplasty (Keating 1997, Rashiq 2006)
-Not registry (Wright 2004)
- Previously included (Bozic 2010)

17 Additional Articles
-Reference list of Mahomed 2005, Abularrage 2008 (Khuri 1995, Khuri 1997, Katz 2001)
-From team PI (Singh 2010)
-From Authors of included studies (n=13)

13 excluded
-Editorial (Khuri 1995)
-Not arthroplasty (Khuri 1997, Lu 2010, Lu 2009, Kurtz 2008, SooHoo 2006, SooHoo 2006, SooHoo 2006, SooHoo)
-Not registry (Gioe 2004, Singh 2010)
-Previously included (Kurtz 2009, SooHoo 2007)

36 studies included in the final report

5 Studies had validation data

31 Studies had no validation data

C. FULL-TEXT REVIEWS

The original search identified 34 articles for full text review. 24 additional articles were identified from various other sources including the updated search on July 20th, 2010, those found by Mini-Sentinel investigators, those culled from reference lists of the articles, and unpublished work from the HOI Principal Investigator (Singh) (see Figure 1), of which 10 qualified for full text review. Thus, we reviewed full text for 55 unique articles[6-10] [11-20] [21-36] [37-38] [39-41] [42] [43-52] [53-59] [60] (3 duplicates; total 58 =34 +24), of which 43 were relevant. 36 unique articles were included in the final evidence tables. The reasons for exclusion of 22 (19 unique and 3 duplicate) articles were as follows: not related to HOI, n=11[42] [43] [44] [45]

(46) (47) (48) (49) (50) (51) (52); not registry, n=7(53) (54) (55) (56) (57) (58-59); and editorial article, n=1(60). None were excluded based on whether the data source was from the United States or Canada.

Of the 36 articles included in the tables, 5 provided some validation of the database algorithm(6) (7) (8) (9) (10). The abstracts of these studies are provided in Appendix A. Details of the 22 excluded studies and reasons for exclusion are provided in Appendix B. The codes used in five studies with validated algorithms are provided in Appendix C. Among the 31 articles without validation of the algorithm, we chose ten most recently published non-validated studies of unique databases or types of arthroplasty, as specified by our protocol a priori(11) (12) (13) (14) (15) (16) (17) (18) (19) (20). The remaining 21 non-validated algorithms are briefly summarized in Appendix D and include articles from: original search, n=16(21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36); updated search, n=2(37) (38); and those from emails from authors of included articles(39) (40) (41).

D. MINI-SENTINEL INVESTIGATOR SURVEY

Mini-Sentinel investigators provided 0 published and 1 unpublished report of validation studies (unpublished at the time of search; published online now) that had been completed by their teams(58). The single study referred to was a study by Singh, et al. from a single VA medical center(58). We searched for email addresses for all 34 included studies that qualified for the full text review and found email contact information for 20 lead/senior authors. We emailed these authors; 4 responded and provided us with 13 articles (11 published and 2 unpublished). Of the 11 published reports, 9 had not been previously identified through our search. From the total of 13 articles, none qualified for inclusion as validated algorithms; 3 had unvalidated algorithms and 10 did not meet inclusion criteria. These three articles with non-validated algorithms were included in the evidence tables.

E. EVIDENCE INCLUDED IN TABLE

Of the 36 studies included in the tables, 29 were identified from the initial search strategy, 1 was identified through references of articles that underwent full-text review, 3 from the updated search, and 3 were provided by the contact authors of the included studies (Table 4).

1. From Initial Search

Coyte, et al. used the Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures codes and ICD-9-CM codes to study the Canadian Institute for Health Information Abstract Master File in order to determine revision rates after total knee arthroplasty (TKA) for 18,530 patients in Ontario, Canada, from 1984 to 1991. The algorithm was validated by the use of the Ontario Health Insurance physician fee service claims database(6). Heck, et al. used the Health Care Financing Administration (HCFA) Medicare Provider Analysis and Review (MEDPAR) Part A files from 1985 to 1990 to study revision rates after TKA, using a validated algorithm involving ICD-9-CM codes(7). In another study, the Medicare database was used by Katz, et al. to study complications after primary and revision total hip arthroplasty (THA) in 71,477 patients, identified by an algorithm using ICD-9-CM and CPT-4 codes and validated through medical chart review(8). Mahomed, et al. used a similar validated algorithm involving ICD-9-CM and CPT-4 codes to identify 1995 to 1996 Medicare Part A and Part B data from 75,501 patients to study complications after primary and revision THA(9). In 2010, Katz, et al. used a validated algorithm involving ICD-9-CM codes to identify 1995 to 1996 Medicare A data from 58,521 Medicare patients who

underwent primary THA and subsequent revision THA[10]. Specific codes used in these studies are provided in Appendix C.

In addition to summarizing 5 validation studies, we also summarized 10 studies that did not include validation of the outcome or reporting of validity statistics in the evidence table, per Mini-Sentinel protocol[11] [12] [13] [14] [15] [16] [17] [18] [19] [20]. The following paragraph briefly describes these 10 studies (Table 5). The remaining 21 non-validated algorithms were briefly summarized in Appendix D and included articles from: original search, n=16[21] [22] [23] [24] [25] [26] [27] [28] [29] [30] [31] [32] [33] [34] [35] [36]; updated search, n=2[37] [38]; and those from emails from authors of included articles[39] [40] [41]. The 21 studies with unvalidated algorithms were not discussed any further, per Mini-Sentinel protocol (Appendix D).

Abularrage, et al. developed a non-validated algorithm to utilize the National Surgical Quality Improvement Program (NSQIP) registry of the Veterans Affairs Medical Centers to identify via CPT codes a total of 41,633 arthroplasties (THA and TKA) from 1996 to 2003 and to study arterial complications after surgery[11]. Bolognesi, et al. used ICD-9-CM codes and the National Inpatient Sample (NIS) from 1988-2003 of 751,340 patients with THA and TKA to study underlying reasons for revision surgery/trends in revision surgery, without providing any algorithm or validation[12]. Bozic, et al. also used the NIS to study the epidemiology of revision TKA in 60,355 revision TKA patients from October 1, 2005, through December 31, 2006, via a non-validated algorithm involving ICD-9-CM codes[13]. Hervey, et al. used the 1997 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP NIS) of 55,510 patients with TKA and ICD-9-CM codes to study complications, without providing any algorithm or validation[14]. Koval et al. developed a non-validated algorithm to utilize the Medicare National Claims History to identify via ICD-9-CM and CPT codes a total of 11,127 ankle arthroplasties from 1998 to 2001 to study implant removal, implant revision, and other complications after surgery[15]. Manley, et al. used a Medicare registry to develop a non-validated algorithm using ICD-9-CM and CPT-4 codes to identify 53,971 patients undergoing TKA surgery from 1997 to 2004 in order to study complications after primary and revision surgery[16]. Ong, et al. studied revision rates after THA and TKA surgery by developing a non-validated algorithm using ICD-9-CM and CPT-4 codes for a Medicare database from 1997-2004[17]. Rastogi, et al. identified 5,479 patients undergoing THA or TKA from 2005 to 2006 by using a US commercial database and a non-validated algorithm involving the use of ICD-9-CM and CPT-4 codes in order to study revision rates[18]. SooHoo, et al. utilized a non-validated algorithm involving the use of ICD-9-CM codes to identify 480 patients from 1995 to 2004 in a California hospital discharge database who underwent total ankle arthroplasty in order to study revision rates[19]. Zhan, et al. used the 2003 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS) and five state inpatient databases from 2003 of 71,081 THA procedures using the ICD-9-CM codes to study underlying reasons for revision surgery/trends in revision surgery, without providing any algorithm or validation[20].

2. From Updated Search in July 2010

On July 20, 2010, a second PubMed search was performed. The search provided an additional 5 articles, of which 2 met inclusion criteria. Both articles provided non-validated algorithms. Kreder, et al. used ICD-9-CM and CIHI codes to search the Canadian Institute for Health Information (CIHI) and Ontario Health Insurance databases to identify 40 THA and 18 TKA patients who had undergone conversion from fusion procedures from 1993 to 1996 in order study rates of revision and other complications[37]. Using a combination of ICD-9-CM, CCP (Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures), ICD-10, and CCI (Canadian Classification of Health Interventions) codes, Paterson, et al.

found 20,290 THA and 27,217 TKA patients in the Canadian Institute for Health Information (CIHI) and Ontario Health Insurance databases from April 2000 to March 2004 in order to study rates of revision[38].

F. SUMMARY AND DISCUSSION OF ALGORITHMS AND VALIDATION

Codes Used in Algorithms. Of the five studies that had validated algorithms, only the Coyte 1999 study utilized Canadian administrative and claims data[6]; the rest used U.S. data. The first algorithm defined by Coyte, et al. involved the simultaneous use of Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures code and ICD-9-CM codes to identify revision arthroplasty from 1984 to 1991. Coyte, et al. used Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures code 93.41 (total knee arthroplasty, primary or revision) to obtain 18,530 hospitalizations for knee replacement (primary and revision). Since the procedure code was not sufficient to differentiate primary from revision surgery, the group developed an algorithm to identify revisions as any procedure that simultaneously had code 93.41 and one of the following ICD-9-CM codes: 996.4 (mechanical complication of internal orthopedic device, implant and graft), 996.6 (infection and inflammatory reaction due to internal prosthetic device, implant and graft), or 996.7 (other complications of internal prosthetic device, implant and graft). All other surgeries were classified as primary.

The remainder of the four studies used U.S. administrative and claims data, with three (Heck 1998, Katz 2001, and Mahomed 2003) using Medicare databases and ICD-9-CM/CPT codes. One study (Katz 2010) used Medicare data using ICD-9-CM codes for revision THA and ICD-9-CM and CPT codes for primary THA.

Heck, et al. (1998) used the MEDPAR Part A files to study knee arthroplasties from 1985 to 1990[7]. Starting October 1, 1989, separate ICD-9-CM codes were used for primary surgery (81.54) and revision (81.55). However, before 1989, all TKA were coded as 81.41. Thus, an algorithm was developed and validated that used an additional list of 996.xx complication diagnostic codes that often occurred with revision in order to identify TKA revision before 1989. Thus, a revision before 1989 was identified as having the ICD-9-CM code 81.41 (for TKA) and a 996.xx complication code (for revision). Any revision after 1989 used the code 81.55.

Katz, et al. (2001) and Mahomed, et al. used similar algorithms involving ICD-9-CM codes and CPT-4 codes to study complications after THA in Medicare patients. Katz, et al. (2001) used a Medicare database to identify 71,477 THA patients from July 1995 to June 1996[8]. The algorithm for revision THA used presence of a single claim for CPT-4 codes 27134, 27137, or 27138 for patients with inpatient stay on that day; for others presence of a single claim for CPT-4 codes 27134, 23137, or 27138, plus an additional ICD-9-CM or CPT code for revision of THA or removal of device was required(Appendix C). Medical record was the gold standard. Only surgeries that were found and confirmed by the above algorithm were validated by medical record. Using a similar algorithm, Mahomed, et al. used Medicare Part A and Part B files to identify 75,501 patients who underwent THA surgery from July 1995 to June 1996[9]. Revision THA was identified with CPT codes 27134, 27137, or 27138. Primary THA was identified in both studies by the presence of an ICD-9-CM code of 81.51 or CPT code 27130.

Katz, et al. (2010) used a Medicare database to identify 58,521 THA patients from July 1995 to June 1996, who then underwent revision THA and resided in one of seven U.S. states[10]. The group used ICD-9-CM codes 81.51 and/or a CPT code of 27130 to identify primary THA. They used ICD-9-CM code 81.53 (up to October 1st, 2005) and 00.70-00.73 (after October 1st, 2005) to identify revision THA.

Validation Criteria and Method. In the study by Coyte, et al., the Ontario Health Insurance physician fee service claims, which can differentiate between primary and revision TKA, were used as the gold standard to validate the algorithm. Specific fee service claims that identified revision knee replacements included: R244A (revision total knee arthroplasty) or the simultaneous occurrence of E564A (revision of arthroplasty) and any one of the following fee service codes: R248A (total knee replacement with take-down fusion), R441A (total replacement — both compartments), R482A (hemiarthroplasty — single component), or R483A hemiarthroplasty — double component).

In order to verify the algorithm, Heck, et al. used ICD-9-CM codes for primary surgery (81.54) and revision (81.55) as the gold standard for validation of the algorithm. Since post-1989 revision surgery was recorded separately, the algorithm that used code 81.41 and 996.xx complication codes could be verified. Thus, the 15-month period from October 1, 1989 to December 31, 1990 was used to determine the accuracy of using complication codes to obtain rates of revision surgery from the Medicare database.

Katz 2010, et al. used medical record review for validation. The algorithm yielded a revision rate of 7.62% (4,460 revision patients/58,521 THA patients). They used a sample of 374 (29%) of the 1,309 primary procedures restricted to seven states. The PPV was 71% for revision THA on the same side as the index THA (10).

To examine the validity of the algorithm in both the Katz 2001 study and the Mahomed study, a medical record review was performed by trained nurse abstractors as the gold standard.

The five unique algorithms were validated in the five studies shown in Appendix C.

Validation Algorithms. The algorithm by Coyte, et al. yielded a revision rate of 7.0% (1,301 revision patients/18,530 TKA patients)[6]. Comparing the algorithm with the gold standard of the fee service claims, the algorithm had a sensitivity of 77.7% and a specificity of 97.6% (6). Since raw numbers were provided, we calculated 95% CIs – sensitivity (95% confidence interval, 75.0%, 80.3%) and specificity (95% confidence interval, 97.3%, 97.8%). We also calculated predictive values. The positive predictive value for the algorithm was 66.9% (95% CI: 64.1%, 69.6%) and negative predictive value was 98.6% (95% CI: 98.4%, 98.8%).

Heck, et al. (2010) obtained rates of revision based on two ways of modeling (shortest versus longest time to revision). This was done because in a given instance a revision could have followed the most recent primary (shortest time) or the primary that was furthest (longest time) from the time of revision, since the side of implant is not captured in most databases. Based on these definitions, the revision rates for shortest versus longest time to revision were as follows: 0.4% vs 2.2% at 2-years; 0.7% versus 3.2% at 3-years; and 1% versus 4.3% at 4-years. The algorithm was validated with a sensitivity of 87.2% and a specificity of 99.0%[7]. No positive or negative predictive values were provided.

The algorithm by Katz, et al. (2010) yielded a revision rate of 7.62% (4,460 revision patients/58,521 THA patients). They used a sample of 374 (29%) of the 1,309 primary procedures restricted to seven states. The PPV was 71% for revision THA[10].

The algorithm by Katz, et al. (2001) yielded a revision rate of 18.1% (12,956 revision patients/71,477 THA patients). They used a random sample of 1031 (1.8%) of the primary procedures and 671 (5.2%) revision procedures. The PPV was 99% for primary THA and 92% for revision THA[8].

Mahomed, et al. found a revision rate of 18.0% (12,483 revision patients/75,051 THA patients). A random sample of 900 primary and 550 revision THA was chosen for validation with medical records as the gold standard. The PPV was 99% for primary THA and 91% for revision THA[9].

In summary, four studies used Medicare databases (except Coyte, et al.), four focused on revision THA (except Heck, et al. that focused on revision TKA) and four tested algorithms for revision surgery (except in Katz 2010, where the algorithm was developed for laterality of revision THA).

We found five studies which provided five unique algorithms from U.S. and Canadian administrative and claims databases. Important differences existed in the gold standards used in these validation studies. Coyte, et al. used a physician fee service claims database as the gold standard. Katz 2001, and Mahomed 2003, used medical record documentation as the gold standard, the most preferred validation method. Katz 2010 used medical record documentation to examine the accuracy of determining laterality of revision THA. Heck, at al. validated one set of codes against a specific revision diagnosis code as the gold standard. This study by Heck was not a true validation study since it considered a specific code as the gold standard, which arguably is not an acceptable gold standard. In addition, some codes used in this study are now outdated. Similarly, to some extent, the findings from Coyte, et al. may not be directly comparable to those of the Katz 2001 and Mahomed 2003 studies, since the gold standards were different (physician fee claim database versus medical record documentation).

In addition, Coyte, et al. excluded 6% of the miscoded revisions by using an algorithm that excluded patients with <3-day stay and discharge to home or with surgeries at nonacute-care settings, while Katz 2001 and Mahomed 2003 used different exclusion criteria for the algorithm. These exclusion criteria likely impacted the performance characteristics of each of the algorithms. The time frames for the studies were also different: 1984-1990 for Coyte, 1989-90 for Heck, 1995-96 for Katz 2001, 1995-96 for Mahomed 2003, and 1995-2006 for the Katz 2010 study. Further, Coyte used the Canadian Institute for Health Information Abstract Master File, whereas the other studies used Medicare data. Thus, several differences between the Coyte 1999 versus the Katz 2001/Mahomed 2003 studies may explain the differences in validation statistics. These were better and more consistent for the latter studies and slightly lower for Coyte, et al. It is also important to note that Katz 2001 and Mahomed 2003 used the same cohort.

Among the two validation studies that used medical records as the gold standard (i.e., Katz, et al.[8] and Mahomed, et al.[9]), some differences existed in the algorithm. The PPV for revision THA in the Katz 2001 was 92%[8] and in the Mahomed study was 91%[9]. The first algorithm by Katz 2001 included presence of one of the CPT codes (27134, 27137, or 27138), plus presence of an additional CPT or ICD-9-CM code (details in Table 4). The PPV of this approach was 91%. The second algorithm by Mahomed, et al. used presence of one of the CPT codes (27134, 27137, or 27138) to identify revision THA. Both used ICD-9-CM/CPT codes in the same Medicare cohort, were performed by the same group of investigators, and used random samples of patients with primary and revision THA. These might explain the consistency of results between the two studies.

Among the five validated studies, three studies included THA (Katz 2001, Katz 2010, and Mahomed 2003) while the other two studied TKA (Coyte 1999 and Heck 1998). Both Katz and Mahomed also studied complications of revision surgery such as death, dislocation, deep infection, and pulmonary embolism while the remaining two studies focused on revision rates. One similarity among all the algorithms was the use of ICD-9-CM codes.

In conclusion, the five validated studies provided five unique algorithms for the retrieval of implant revision from American and Canadian administrative and claims data. Coyte and Heck, et al. used codes in a database as the gold standard, while Katz 2001, Mahomed, and Katz 2010 used medical record review as the gold standard. One may question the use of database codes as a gold standard. Use of medical records as the gold standard is appropriate and well-accepted. The number of patients for medical record review seemed appropriate.

Selected Patient Populations. Another variation among the studies was the difference in the number of patients included in the validation algorithms. The Coyte study validated data for all the patient records while both Katz and the Mahomed studies validated data for a small sample, usually less than 5% of the total patient population. Also, the revision rates varied somewhat: 7% in Coyte; 2%-4% in Heck; 18% in Katz 2001; 18% in Mahomed; and 7.6% in Katz 2010. This explains the low PPV in Coyte as compared to the very high PPV values in Katz 2001, Katz 2010, and Mahomed 2003, since PPV depends on prevalence.

Age and Sex of Study Population. Age was not reported in three studies[7][9][10] and gender was not reported in two studies[9][10]. Coyte, et al. reported mean age of 68.9 years with 63.3% female in their cohort[6]. Heck, et al. reported that 68.3% of the cohort was female; age was not reported[7]. Katz, et al. reported that their cohort was 74.7$\pm$6.09 years old and 64% female[8].

Time Period of Data Collection. The Coyte and Heck studies included cohorts over an extended duration of 84 months and 60 months, respectively. In contrast, both Katz studies and the Mahomed study were significantly shorter, with each at 12 months. In addition to differences in validation methods and statistics, the studies varied in the length of the validation period. Coyte examined cohorts over 84 months, whereas both Katz (2001 and 2010) and the Mahomed 2003 studies each examined cohorts over 12 months. The Heck study had a validation period of 15 months.

Incident vs Prevalent Outcome Validation. All studies examined incident procedures only.

Principal vs Secondary Diagnosis. Coyte mentioned that diagnosis was searched in any field, while other studies did not explicitly mention this detail.

Hospitalization Diagnosis vs Outpatient Encounter. Since all implant removals and revisions are accompanied by hospitalization, this was not relevant to our study.

G. SUMMARY OF EXCLUDED POPULATIONS AND DIAGNOSES

Coyte, et al. excluded patients who were not residents of Ontario, Canada, patients with missing date of birth or the place of residence, or miscoded procedures such as those performed in a nonacute-care facility (unlikely they were knee replacements) or procedures associated with a discharge to home with self-care within three days after the procedure (patients were never discharged home with self-care within three days after knee replacement during this study period in Ontario)[6].

In studies that looked at Medicare databases (Heck, Katz 2001, Mahomed, and Katz 2010)[7][8][9][10], several patient groups were excluded. Heck, et al. excluded patients for whom a Health Maintenance Organization (HMO) was the primary payer (due to likelihood of incomplete Medicare records), those with end stage renal disease or disability at the time of enrollment, residence outside the United States, those for whom a single knee replacement was accompanied by a diagnosis indicating the procedure

was not done due to contraindication or patient preference (code V.64), those for whom it appeared certain that a knee replacement was not performed (unusually short length of stay, low charges, no diagnoses related to knee replacement) or those at psychiatric, rehabilitation, or drug treatment facilities[7]. Katz 2001, et al. excluded patients younger than 65 years, those enrolled in HMOs, patients not enrolled in both parts of Medicare, or non-residents of the United States, due to the lack of detailed and complete information from these patients[8]. Katz 2001, et al. also excluded patients with codes for infection, metastatic or bone cancer, conversion of hemiarthroplasty or other hip surgery to total hip replacement, or fracture of the hip or the femur[8]. Mahomed, et al. used similar exclusions as Katz 2001 for their study[9]. For primary THA, they excluded patients with codes for hip infection, metastatic or bone cancer, conversion of a hemiarthroplasty (or another type of hip surgery) to a total hip replacement, or fracture of the hip or femur. For patients with revision THA, they excluded those with fracture involving cancer (but not femoral fracture not associated with cancer). They also excluded patients enrolled in health maintenance organizations, under 65 years of age, those who were not residents of the United States, and those not enrolled in both parts of Medicare (for both revision and primary THA). Katz 2010 study excluded the following: Medicare THA recipients younger than 65 years old; codes indicating bilateral THA, hemiarthroplasty, conversion of hemiarthroplasty to THA; a diagnosis of hip fracture, cancer, or infection[10].

Coyte, et al. excluded 1,144 patients (5.8% of the population) (6). Heck, et al. did not describe how many patients were excluded[7]. Katz, et al. (2001) excluded 18,106 primary surgery patients (24% of the population) and 961 revision patients (7% of the population)[8]. Mahomed, et al. excluded 19.6% and 3.1% of primary and revision cohorts, respectively. The Katz 2010 study did not mention how many patients were excluded[10]. Coyte and Heck did not mention the fraction of the population used for the validation studies. Katz 2001 used a random sample of 1031 (1.8%) of the primary procedures and 671 (5.2%) revision procedures for validation purposes. Mahomed used a random sample of 900 (1.5%) primary and 550 revision THA (4%) for validation. Katz 2010 used a sample of 374 THA (29%) of Medicare patients with initial primary and revision THA in seven states for validation.

H. EVIDENCE TABLES

Table 4. Positive Predictive Values and Other Validation Statistics by Algorithm for Validated Algorithms

Citation/Country (US vs. Canada)	Study Population and Time Period	Description of Outcome Studied	Algorithm	Validation/Adjudication Procedure, Operational Definition, and Validation Statistics
Coyte 1999 (6)/ Canada	18,530 TKA patients in Ontario, Canada from April 1, 1984 to March 31, 1991 (84 months) Excluded: Hospitalizations were excluded if the patient was not a resident of Ontario, if pertinent data (such as date of birth or place of residence) were missing, or if a knee-replacement procedure either was not performed or was miscoded. 1,144 patients were excluded (5.8% of population). 68.9 years old (standard deviation (SD), not reported (NR)), 63.3% female, BMI was NR, Race was NR, 85.2% had osteoarthritis, 80% had a Charlson index of 0.	Revision Rate (1301/18530 underwent revision)	Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures code, 93.41 plus one of the ICD-9-CM codes- 996.4, 996.6 or 996.7	Ontario Health Insurance physician fee service claims were used to validate. Sensitivity of 77.7%, specificity of 97.6%, PPV of 66.9%, and NPV of 98.6% were obtained.
Heck 1998 (7)/ U.S.	Medicare Provider Analysis and Review (MEDPAR)-Part A patients who underwent TKA from 1985 to 1990 (60 months). For validation, the 15 month period (October 1, 1989 to December 31, 1990) was used. Excluded: Patients less than 65 years old, infection of the hip, metastatic or bone cancer, conversion of hemiarthroplasty (or other hip surgery) to total hip replacement, fracture of the hip or femur, HMO, not enrolled in both parts of Medicare, and non-residents of the United States. Age was NR, 68.3% female, BMI was NR, Race was NR, 88.5% had osteoarthritis, Co-morbidity was NR	Revision Rate (varied between 1.0-4.2% at 4-years depending on definition used of shortest versus longest time to revision)	One or more of the 996.xx complication codes with a previous ICD-9-CM code of 81.41	Presence of a specific revision code (81.55) during the 15 month period (October 1, 1989 to December 31, 1990) was the gold standard for validation. Sensitivity of 87.2% and a specificity of 99.0% were obtained.
Katz 2001 (8)/ U.S.	71,477 THA patients from a Medicare database from July 1995 to June 1996 (12 months) Excluded: Less than 65 years old, infection of the hip, metastatic or bone cancer, conversion of hemiarthroplasty (or other hip surgery) to total hip replacement, fracture of the hip or femur, HMO, not enrolled in both parts of Medicare, and	Complications leading to revision (12956/71477 underwent revision)	CPT codes for revision (27134, 27137, or 27138) were required in order to be labeled a revision case PLUS other CPT or ICD-9-CM	A medical record review was performed by trained nurse abstractors. A random sample of 1031 (1.8%) of the primary procedures and 671 (5.2%) revision procedures was used. The PPV was 99% for

			codes for revision (Appendix C). A single claim for CPT 27134, 27137 or 27138 was accepted as a case only if the patient was in the hospital on that date.	primary THA and 92% for revision THA.
	non-residents of the United States. 18,106 primary patients (24% of the population) were excluded and 961 revision patients were excluded (7%). 74.7±6.09 years, 64% female, BMI is NR, 94% Caucasian, 94% had osteoarthritis, Co-morbidity was NR			
Mahomed 2003 (9)/ U.S.	75,501 THA patients from a Medicare Part-A or Part-B database from July 1995 to June 1996 (12 months) Excluded: Less than 65 years old, infection of the hip, metastatic or bone cancer, conversion of hemiarthroplasty (or other hip surgery) to total hip replacement, fracture of the hip or femur, HMO, not enrolled in both parts of Medicare, and non-residents of the United States. 19.6% of primary and 3.1% of revision patients were excluded. Age was NR, Gender was NR, BMI was NR, 94% had osteoarthritis, Co-morbidity was NR	Complications leading to revision (13483/75051 underwent revision)	CPT codes for revision (27134, 27137, or 27138) were required to be labeled a revision case; 81.51 or CPT code 27130 to identify primary THA case	A medical record review was performed by trained nurse abstractors. A random sample of 900 primary and 550 revision THA was used. The PPV was 99% for primary THA and 91% for revision THA.
Katz 2010 (10) / U.S.	58,521 THA patients from a Medicare Part-A database from July 1995 to June 1996 (12 months) Excluded: Less than 65 years old, infection of the hip, metastatic or bone cancer, conversion of hemiarthroplasty (or other hip surgery) to total hip replacement, fracture of the hip or femur. Age was NR, Gender was NR, BMI was NR, Osteoarthritis was NR, Co-morbidity is NR	Revision Rates (4460/58521 underwent revision)	ICD-9-CM codes for revision (81.53 up to October 2005 and 00.70-00.73 after October)	A medical record review was performed. A sample of 374 THA was selected. The PPV was 71% (95% CI: 66, 76) for revision THA on the same side as the index THA.

NR, not reported; SD, standard deviation

Table 5. Non-Validated Algorithms from 10 Selected Studies Per Protocol

Citation	Study Population and Time Period	Description of Outcome Studied	Algorithm
Abularrage 2008 (11)	National Surgical Quality Improvement Program (NSQIP) registry of the Veterans Affairs Medical Centers to identify a total of 41,633 arthroplasties (THA and TKA) from 1996 to 2003 Exclusions: Not reported 64.9±0.5 years, 4% female, BMI was NR; 76% Caucasian, 13% Black, 0.2% Asian, 0.5% Native Americans	Lower extremity arterial injury	CPT Codes (specifics not reported)
Bolognesi 2008 (12)	National Inpatient Sample (NIS) from year 1988-2003 of 751,340 patients with THA and TKAwas Exclusions: ICD-9-CM diagnosis codes indicating pathologic fractures; metastatic cancer; infection of the knee or thigh, including acute or chronic osteomyelitis; infections of a device, implant, or graft; or primary malignant bone neoplasms. Patients with codes for femoral neck fractures were excluded from the analysis of primary THA. Diagnosis codes associated with internal device failures or complications were also excluded. 67.9±11.49 years, 61.13% female, BMI was NR; 62.31% Caucasian, 4.34% Black, 2.57% Hispanic, 1.60% other	Revision rates	ICD-9-CM-CM codes: primary THA (81.51), revision THA (81.53), primary TKA (81.54), or revision TKA (81.55).
Bozic 2010 (13)	NIS to study revision TKA in 60,355 revision TKA patients from October 1, 2005 and December 31, 2006 Exclusions: NR 65.8 years (SD was NR), 57.4% female, BMI was NR; 83.3% Caucasian	Epidemiology of revision TKA	Diagnosis codes: Mechanical loosening of prosthetic joint (996.41), Dislocation of prosthetic joint (996.42), Prosthetic joint implant failure/breakage (996.43), Periprosthetic fracture around prosthetic joint (996.44), Periprosthetic osteolysis (996.45), Articular bearing surface wear of a prosthetic joint (996.46), Other mechanical complication of prosthetic joint implant (996.47), Other mechanical complication of other internal orthopedic device, implant, or graft (996.49). Procedure codes: 00.80 Revision of tibial, patellar, and femoral components, 00.81 Revision of tibial component, 00.82 Revision of femoral component, 00.83 Revision of patellar component, 00.84 Isolated revision of tibial insert, 80.06 Arthrotomy/removal of prosthesis, 81.55 Revision of knee, NOS

Hervey 2003 (14)	1997 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP NIS) of 55,510 patients with TKA Exclusions: The analysis of the primary total knee arthroplasties, patients with a primary or secondary diagnosis of osteomyelitis, periostitis, or another type of bone infection; a pathological fracture secondary to a malignant neoplasm; or codes suggestive of complications of a previous arthroplasty. 69.1 years (SD was NR), 62.6% female, BMI was NR; 70.2% Caucasian	Complications after surgery	ICD-9-CM codes: Primary total knee arthroplasty (81.54) or revision total knee arthroplasty (81.55)
Koval 2007 (15)	Medicare National Claims History to identify a total of 11,127 ankle arthroplasties from 1998 to 2001 Exclusions: NR 76 years (SD was NR), 77% female, BMI was NR; 93% Caucasian	Implant removal, implant revision, and other complications after surgery	ICD-9-CM and CPT codes
Manley 2009 (16)	Medicare registry to identify 53,971 patients undergoing TKA surgery from 1997 to 2004 Exclusions: Patients diagnosed with knee fractures (ICD-9-CM codes 821.2, 821.3, 822-823). Age was NR, %Female was NR, BMI was NR; %Caucasian was NR	Complications after primary and revision surgery	ICD-9-CM and CPT-4 codes: The CPT code 27447 (arthroplasty, knee, condyle, and plateau; medial and lateral compartments with or without patella resurfacing) was used to identify the primary surgery. Revisions were identified by the CPT-4 codes 27486 and 27487.
Ong 2008 (17)	THA and TKA surgery for a Medicare database from 1997-2004 Exclusions: All patients who were younger than 65 years old, who were not enrolled in both Part A and Part B of Medicare, who were enrolled in a HMO, or who had been diagnosed with bone cancer, metastatic cancer, or joint infection were excluded from the study. The study population was further limited to patients who had undergone elective arthroplasty. Age was NR, %Female was NR, BMI was NR; %Caucasian was NR	Revision rates	ICD-9-CM and CPT-4 codes. Primary THA was identified with ICD-9-CM code 81.51 and CPT code 27130. Primary TKA was identified with ICD-9-CM code 81.54 and CPT code 27447.
Rastogi 2009 (18)	5,479 patients undergoing THA or TKA from 2005 to 2006 by using a US commercial database Exclusions: Younger than 18 or older than 65, in-hospital death, more than 1 condition code, major surgery, HIV,	Revision rates	ICD-9-CM and CPT-4 codes: Hip arthroplasty: 81.51, knee arthroplasty: 81.54 and any of these ICD-9-CM diagnosis codes as the principal diagnosis: Hip arthroplasty: 820.yx, y = 0,2,8; 733.14; 714.0x; 715.xy, y = 5,9; 719.95; 711.05;

			716.xy, y = 5,9; 730.y5,y = 0,1,2; 733.4y, y = 2,3; 733.8x; 736.3x; 736.89; 170.7; 171.3; 198.5
	suicide, pregnancy, newborn condition, continuous enrollment requirement not met, discharge status was left against medical advice. Age was NR, %Female was NR, BMI was NR; %Caucasian was NR		Knee arthroplasty: 714.0x; 715.xy, y = 6,9; 716.xy, y = 6,9; 719.96; 730.y6, y = 0,1,2; 736.89; 736.yx, y = 4,5,6; 711.06; 170.7; 171.3; 198.5
SooHoo 2007 (19)	480 patients from 1995 to 2004 in a California hospital discharge database who underwent total ankle arthroplasty Exclusions: Patients with a non-California ZIP code were excluded. 59 years (SD was NR), 51% Female, BMI was NR; 84% Caucasian	Revision rates	ICD-9-CM codes (specifics not reported)
Zhan 2003 (20)	2003 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS) and five state inpatient databases from 2003 of 71,081 THA procedures Exclusions: Not reported. Age was NR, 63% Female, BMI was NR; %Caucasian was NR	Revision rates	ICD-9-CM: 81.51 for total hip replacement, 81.52 for partial hip replacement, and 81.53 for revision hip replacement

I. CLINICIAN OR TOPIC-EXPERT CONSULTATION

This report summarizes the current body of evidence guiding validation algorithms for implant outcome studies, or revision surgery, based on administrative databases. Rates of revision surgery are important to both surgeons and patients because revision surgery is a major event that can have a substantial impact on health care resource utilization and health related quality of life.

There is a paucity of validated algorithms and considerable variability in approaches utilized. Revisions in total joint arthroplasty are largely the consequence of failure of the implant (breakage, dislocation, loosening), infection at the bone implant interface, or major clinical symptoms, such as pain and functional decline, associated with an improperly sized or inserted implant. The studies have captured the key criteria in their algorithms to satisfy identification of these events. Coyte, et al.'s algorithm identified a 7% rate of revision surgeries in the Canadian Registry, compared to studies based on US registries that identified rates approximating 18% (over 2.5-fold higher). The PPV for the Canadian study was significantly lower than respective PPVs for US-based studies. Coyte, et al. used fewer exclusion criteria. This likely led to a more heterogeneous population contributing to lower predictive values compared to other studies. Variability in prevalence across the studies may have affected the stability of the PPVs.

While most algorithms have been tested in Medicare populations, about a third of all arthroplasties are performed in those younger than 65 years of age. As the indications for arthroplasty expand to include both younger and older populations, future studies should include younger populations, as well, to avoid systematic bias in algorithms to identify these cohorts.

VI. SUMMARY AND CONCLUSIONS

A. RECOMMENDATIONS FOR ALGORITHMS

Katz, et al.[8], Mahomed, et al.[9], and Katz, et al.[10] provided validation data with regard to ICD-9-CM/CPT codes for revision total hip arthroplasty in the Medicare population in three separate publications based on the same or similar cohorts, using medical record reviews as the gold standard. The positive predictive values (PPVs) in the Katz 2001 and Mahomed 2003 studies for revision total hip arthroplasty were 92% and 91%, respectively. The PPV for correct laterality of revision in Katz 2010 was 71%. Though the PPV of the algorithm is moderate to high, additional data by other groups and/or data on similar approaches in these databases are needed before we feel confident in recommending the use of this algorithm by the FDA to query databases for implant removal or revision. These findings have not been replicated independently by other authors. Data regarding reproducibility of the algorithms are needed. Further, the algorithms need to be tested in populations with differing revision rates. Similar algorithms should be also be developed and tested for other joint arthroplasties, such as knee or shoulder.

B. SUGGESTIONS FOR FUTURE RESEARCH BASED ON EVIDENCE GAPS

Currently, no validated algorithms have been published for total knee or shoulder arthroplasty. Both procedures contribute to the volume of total joint arthroplasties performed. Algorithms that identify cohorts of knee, shoulder, and other arthroplasties would be beneficial. None of the studies have provided any algorithms using database-derived definitions other than those including codes (alone or combination) from claims data. The validated studies have been limited to the use of ICD-9-CM or CPT codes for revision hip arthroplasty. More validation studies are needed for ICD-9-CM/CPT codes and other database approaches to confirm these findings. Future research endeavors need to provide validated algorithms for Medicare and other similar databases.

VII.   REFERENCES

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VIII. APPENDICES

A. APPENDIX A: ABSTRACTS OF STUDIES INCLUDED IN EVIDENCE TABLE

Coyte PC, Hawker G, Croxford R, Wright JG. Rates of revision knee replacement in Ontario, Canada. *J Bone Joint Surg Am*. 1999; 81(6): 773-82.

BACKGROUND: The present study was designed to measure the longevity of knee replacements and to assess the determinants of revision knee replacements in order to enhance the potential for informed decision-making. METHODS: Data on all hospitalizations for knee replacement that occurred in Ontario, Canada, between April 1, 1984, and March 31, 1991, were acquired. To calculate the rates of revision knee replacement, two algorithms were developed: one distinguished primary knee replacements from revision knee replacements and the second linked revision knee replacements to primary knee replacements. The Kaplan-Meier method was used to assess survivorship (absence of a revision) for primary knee replacement. A proportional-hazards regression model was estimated to assess the role of independent variables on the survival of primary knee replacements. RESULTS: During the period of the study, 7.0 percent (1301) of 18,530 knee replacements were classified as revisions. Significant differences were identified between hospitalizations for primary and revision knee replacements in terms of the patient and hospital characteristics. Patients who were more than fifty-five years old, lived in a rural area, or had a diagnosis of rheumatoid arthritis had a significantly (p < 0.05) longer duration before revision than did other patients. Primary knee replacements performed in a teaching or specialty hospital had a significantly (p < 0.05) shorter duration before revision than did those performed in a non-teaching hospital. The long-term rates of revision were uniformly low. Estimates of the proportion of knee replacements that would need to be revised within seven years ranged from a low of 4.3 percent, with use of the algorithm for the longest time to revision, to a high of 8.0 percent, with use of the algorithm for the shortest time to revision. CONCLUSIONS: Revision of a primary knee replacement was a rare event that depended on a patient's age, gender, and place of residence as well as on the hospital where the primary knee replacement was performed. Estimates of the rates of revision knee replacement after almost seven years ranged from a low of 4.3 percent to a high of 8.0 percent.

Heck DA, Melfi CA, Mamlin LA, Katz BP, Arthur DS, Dittus RS, et al. Revision rates after knee replacement in the United States. *Medical Care*. 1998; 36(5): 661-9.

OBJECTIVES: Each year approximately 100,000 Medicare patients undergo knee replacement surgery. Patients, referring physicians, and surgeons must consider a variety of factors when deciding if knee replacement is indicated. One factor in this decision process is the likelihood of revision knee replacement after the initial surgery. This study determined the chance that a revision knee replacement will occur and which factors were associated with revision. METHODS: Data on all primary and revision knee replacements that were performed on Medicare patients during the years 1985 through 1990 were obtained. The probability that a revision knee replacement occurred was modeled from data for all patients for whom 2 full years of follow-up data were available. Two strategies for linking revisions to a particular primary knee replacement for each patient were developed. Predictive models were developed for each linking strategy. ICD-9-CM codes were used to determine hospitalizations for primary knee replacement and revision knee replacement. RESULTS: More than 200,000 hospitalizations for primary knee replacements were performed, with fewer than 3% of them requiring revision within 2 years. The following factors increase the chance of revision within 2 years of primary knee replacement: (1) male gender, (2) younger age, (3) longer

length of hospital stay for the primary knee replacement, (4) more diagnoses at the primary knee replacement hospitalization, (5) unspecified arthritis type, (6) surgical complications during the primary knee replacement hospitalization, and (7) primary knee replacement performed at an urban hospital. CONCLUSIONS: Revision knee replacement is uncommon. Demographic, clinical, and process factors were related to the probability of revision knee replacement.

Katz J, Losina E, Barrett J, Phillips C, Mahomed N, Lew R, et al. Association between hospital and surgeon procedure volume and outcomes of total hip replacement in the United States Medicare population. *J Bone Joint Surg Am*. 2001; 83-A(11): 1622-9.

BACKGROUND: The mortality and complication rates of many surgical procedures are inversely related to hospital procedure volume. The objective of this study was to determine whether the volumes of primary and revision total hip replacements performed at hospitals and by surgeons are associated with rates of mortality and complications. METHODS: We analyzed claims data of Medicare recipients who underwent elective primary total hip replacement (58,521 procedures) or revision total hip replacement (12,956 procedures) between July 1995 and June 1996. We assessed the relationship between surgeon and hospital procedure volume and mortality, dislocation, deep infection, and pulmonary embolus in the first ninety days postoperatively. Analyses were adjusted for age, gender, arthritis diagnosis, comorbid conditions, and income. Analyses of hospital volume were adjusted for surgeon volume, and analyses of surgeon volume were adjusted for hospital volume. RESULTS: Twelve percent of all primary total hip replacements and 49% of all revisions were performed in centers in which ten or fewer of these procedures were carried out in the Medicare population annually. In addition, 52% of the primary total hip replacements and 77% of the revisions were performed by surgeons who carried out ten or fewer of these procedures annually. Patients treated with primary total hip replacement in hospitals in which more than 100 of the procedures were performed per year had a lower risk of death than those treated with primary replacement in hospitals in which ten or fewer procedures were performed per year (mortality rate, 0.7% compared with 1.3%; adjusted odds ratio, 0.58; 95% confidence interval, 0.38, 0.89). Patients treated with primary total hip replacement by surgeons who performed more than fifty of those procedures in Medicare beneficiaries per year had a lower risk of dislocation than those who were treated by surgeons who performed five or fewer of the procedures per year (dislocation rate, 1.5% compared with 4.2%; adjusted odds ratio, 0.49; 95% confidence interval, 0.34, 0.69). Patients who had revision total hip replacement done by surgeons who performed more than ten such procedures per year had a lower rate of mortality than patients who were treated by surgeons who performed three or fewer of the procedures per year (mortality rate, 1.5% compared with 3.1%; adjusted odds ratio, 0.65; 95% confidence interval, 0.44, 0.96). CONCLUSIONS: Patients treated at hospitals and by surgeons with higher annual caseloads of primary and revision total hip replacement had lower rates of mortality and of selected complications. These analyses of Medicare claims are limited by a lack of key clinical information such as operative details and preoperative functional status.

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

BACKGROUND: Information on the epidemiology of primary total hip replacement is limited, and we are not aware of any reports on the epidemiology of revision total hip replacement. The objective of this study was to characterize the rates and immediate postoperative outcomes of primary and revision total hip replacement in persons sixty-five years of age and older residing in the United States. METHODS: We used Medicare claims submitted by hospitals, physicians, and outpatient

facilities between July 1, 1995, and June 30, 1996, to identify individuals who had undergone elective primary total hip replacement for a reason other than a fracture (61,568 patients) or had had revision total hip replacement (13,483 patients). Annual incidence rates of primary and revision total hip replacement were calculated, and multivariate modeling was used to evaluate the association between patient characteristics and surgical rates. The rates of occurrence of five complications within ninety days postoperatively were also evaluated, and relationships between those outcomes and patient characteristics were assessed with use of multivariate models adjusted for hospital and surgeon volume. RESULTS: The rates of primary total hip replacement were three to six times higher than the rates of revision total hip replacement. Women had higher rates than men, and whites had higher rates than blacks. The rates of primary and revision total hip replacement increased with age until the age of seventy-five to seventy-nine years and then declined. The rates of complications occurring within ninety days after primary total hip replacement were 1.0% for mortality, 0.9% for pulmonary embolus, 0.2% for wound infection, 4.6% for hospital readmission, and 3.1% for hip dislocation. The rates after revision total hip replacement were 2.6%, 0.8%, 0.95%, 10.0%, and 8.4%, respectively. Factors associated with an increased risk of an adverse outcome included increased age, gender (men were at higher risk than women), race (blacks were at higher risk than whites), a medical comorbidity, and a low income. CONCLUSIONS: Analysis of United States Medicare population data showed that the rates of total hip replacement increased with age up to the age of seventy-five to seventy-nine years and that blacks had a significantly lower rate of total hip replacement than whites. The overall rates of adverse outcomes were relatively low, but they were significantly higher after revision than after primary total hip replacement. LEVEL OF EVIDENCE: Prognostic study, Level II-1 (retrospective study). See p. 2 for complete description of levels of evidence.

Katz JN, Wright EA, Baron JA, Corbett KL, Nti AA, Malchau H, et al. Predictive value of Medicare claims data for identifying revision of index hip replacement was modest. *J Clin Epidemiol*. 2010 Aug 26.
OBJECTIVE: To determine the positive predictive value of Medicare claims for identifying revision of total hip replacement (THR), a frequent marker of THR quality and outcome. STUDY DESIGN AND SETTING: We obtained Medicare Part A (Hospital) claims from seven states on patients that had primary THR from July 1995 through June 1996. We searched claims to determine whether these THR recipients had a subsequent revision THR through December 2006. We selected a sample of subjects with codes indicating both index primary and subsequent revision THR. We obtained medical records for both procedures to establish whether the revision occurred on the same side as index primary THR. RESULTS: Three hundred seventy-four subjects had codes indicating primary THR in 1995-96 and subsequent revision. Seventy-one percent (95% confidence interval: 66, 76) of the revisions were performed on the index joint and would be correctly attributed as revisions of the index THR, using Medicare claims data. CONCLUSION: Claims data on revision THR that do not contain information on the side that was operated on are ambiguous with respect to whether the revision was performed on the index or contralateral side. Claims-based analyses of revisions after an index THR should acknowledge and adjust for this source of potential misclassification.

Abularrage C J, Weiswasser JM, et al. Predictors of lower extremity arterial injury after total knee or total hip arthroplasty. *Journal of Vascular Surgery*. 2008; 47(4): 803-807, discussion 807-808.
OBJECTIVE: Lower extremity arterial injury is a rare complication following total knee (TKA) or total hip arthroplasty (THA). To date, no multi-institutional study has identified preoperative factors that may portend increased risk for these injuries. We queried a large clinical database for the incidence and predictors of arterial injury and/or compromise following lower extremity arthroplasty.

METHODS: Prospectively collected preoperative and postoperative data by the National Surgical Quality Improvement Program (NSQIP) of the Veterans Affairs Medical Centers were analyzed. All patients from 1996 to 2003 in the NSQIP database who underwent TKA or THA were identified via CPT codes. NSQIP defined, 30-day, postoperative outcomes were analyzed. Data were compared using bivariable analysis, as well as limited multivariable logistic regression. RESULTS: A total of 41,633 arthroplasties (24,029 TKA, 2077 redo-TKA, 13,494 THA, 2033 redo-THA) were identified in the NSQIP database. A total of 34 (0.08%) lower extremity arterial injuries were recognized (0.08% TKA, 0.19% redo-TKA, 0.04% THA, 0.20% redo-THA). Eighteen injuries were repaired on the same day of surgery (seven intraop, 11 postop), eight between postoperative days 1 and 5, and 8 between days 6 and 30. Only two patients underwent lower extremity amputation (overall limb loss rate of 5.9% of patients who had arterial injury). Statistically significant predictors of lower extremity arterial injury identified on logistic regression analysis included redo procedure (odds ratio [OR] 2.7, 95% confidence interval [CI] 1.2-6.0, P = .013) and African American race (OR 2.5, 95% CI 1.2-5.3, P = .02). CONCLUSION: Lower extremity arterial injury was exceedingly rare after total knee or total hip arthroplasty. There is an increased incidence in African American patients and those undergoing redo arthroplasty. Among patients who sustain vascular injury, excellent limb salvage rates can be achieved with close postoperative surveillance to achieve early detection and repair of injuries.

Bolognesi MP, Marchant MH Jr, et al. The impact of diabetes on perioperative patient outcomes after total hip and total knee arthroplasty in the United States. *The Journal of Arthroplasty*. 2008; 23(6 Suppl 1): 92-98.

The purpose of this study was to determine whether patients with diabetes mellitus (DM) have a higher likelihood of immediate, inpatient complications following primary and revision total hip (THA) and total knee arthroplasty (TKA) than patients without DM. From 1988 to 2003, the Nationwide Inpatient Sample identified 751340 primary or revision THA or TKA patients. 64262 (8.55%) had DM. Comparisons of specific outcome measures between diabetic and nondiabetic cohorts were performed using bivariate and multivariate analyses with logistic regression modeling. Diabetic patients had fewer routine discharges and higher inflation-adjusted hospital charges for all procedures. Although complications were not uniformly increased, diabetic patients had significantly increased odds of pneumonia, stroke, and transfusion (P < .001) after primary arthroplasty. This analysis of a large patient database indicates clinically relevant information for patients and surgeons, suggesting that patients undergoing THA and TKA demonstrate more complications and utilize more resources if they have the comorbidity of DM level II evidence.

Bozic KJ, Kurtz SM, et al. The epidemiology of revision total knee arthroplasty in the United States. *Clinical Orthopaedics and Related Research*. 2010; 468(1): 45-51.

Understanding the cause of failure and type of revision total knee arthroplasty (TKA) procedures performed in the United States is essential in guiding research, implant design, and clinical decision making in TKA. We assessed the causes of failure and specific types of revision TKA procedures performed in the United States using newly implemented ICD-9-CM diagnosis and procedure codes related to revision TKA data from the Nationwide Inpatient Sample (NIS) database. Clinical, demographic, and economic data were reviewed and analyzed from 60,355 revision TKA procedures performed in the United States between October 1, 2005 and December 31, 2006. The most common causes of revision TKA were infection (25.2%) and implant loosening (16.1%), and the most common type of revision TKA procedure reported was all component revision (35.2%). Revision TKA procedures were most commonly performed in large, urban, nonteaching hospitals in Medicare patients ages 65 to 74. The average length of hospital stay (LOS) for all revision TKA procedures was

5.1 days, and the average total charges were $49,360. However, average LOS, average charges, and procedure frequencies varied considerably by census region, hospital type, and procedure performed. LEVEL OF EVIDENCE: Level II, economic and decision analysis. See Guidelines for Authors for a complete description of levels of evidence.

Hervey SL, Purves HR, et al. Provider Volume of Total Knee Arthroplasties and Patient Outcomes in the HCUP-Nationwide Inpatient Sample. *J Bone Joint Surg Am.* 2003; 85-A(9): 1775-1783.

BACKGROUND: The relationship between volume and outcome of total knee arthroplasties has never been evaluated in a nationally representative sample, to our knowledge. We hypothesized that surgeons and hospitals with higher patient volumes would have better outcomes, as defined by lower mortality rates, shorter hospital stays, and lower postoperative complication rates. METHODS: The 1997 Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample, Release 6, provided discharge abstracts of patients undergoing total knee arthroplasty from a national stratified probability sample. Logistic and multiple regression models were used to estimate the adjusted association of surgeon or hospital volume with rates of in-hospital mortality, pulmonary thromboembolism, deep venous thrombosis in the lower extremity, and postoperative wound infection as well as length of hospital stay. Estimates were calculated for a target population of 277,550 patients. Models were adjusted for comorbidity, age, gender, race, household income, and procedure (primary or revision arthroplasty). RESULTS: The patients were mostly white (70.2%) and female (62.7%), with a mean age of 68.9 years. The overall in-hospital mortality rate for the target population was 0.2%, and the average length of stay was 4.6 days for the primary total knee arthroplasties and 4.9 days for the revision procedures. Surgeon volumes of at least fifteen procedures per year and hospital volumes of at least eighty-five per year were significantly and linearly associated with lower mortality rates (odds ratio = 0.56 [0.24 to 1.31] for surgeon volume of > or = 60). No other association demonstrated a significant and directionally consistent linear trend for improved outcomes. CONCLUSION: Patients treated by providers with lower caseload volumes had higher rates of mortality following total knee arthroplasty in 1997. Proposing volume standards could decrease patient mortality following this procedure.

Koval KJ, Zhou W, et al. Complications after ankle fracture in elderly patients. *Foot & Ankle International / American Orthopaedic Foot and Ankle Society [and] Swiss Foot and Ankle Society*. 2007; 28(12): 1249-1255.

BACKGROUND: Controversy exists regarding the risks and benefits of ankle fracture treatment in elderly patients. The purpose of this study was to use the United States Medicare database to determine the complication rate for ankle fractures in elderly patients treated operatively and to compare it to fractures treated nonoperatively. METHODS: We used the National Medicare Claims History System to study all enrollees who sustained ankle fractures between 1998 and 2001. A total of 33,704 patients were identified and their outcomes at numerous time points were evaluated. These outcomes included mortality, rate of repeat hospitalization, rate of medical and operative complications, and the rate of additional surgery. The predictor variables were either nonoperative or operative intervention. Covariates included patient age, gender, race, medical comorbidity status, and fracture type. RESULTS: Patients treated nonoperatively had significantly higher mortality (p < 0.05) than those treated operatively at all time periods except for 30 days. However, patients treated operatively had significantly higher rehospitalization rates (p < 0.05) at all time periods studied. The medical and operative complication rates at all time periods were less than or equal to 2% for patients who had either operative or nonoperative treatment. In the group that had operative management, a relatively small number of patients had additional procedures. Eleven

percent had removal of hardware. Less than 1% of all patients had revision of the internal fixation, arthroplasty, arthrodesis, or amputation. CONCLUSION: In properly selected cases, the complication rates of both operatively and nonoperatively treated elderly patients are low.

Manley M, Ong K, et al. Total knee arthroplasty survivorship in the United States Medicare population: effect of hospital and surgeon procedure volume. *The Journal of Arthroplasty*. 2009; 24(7): 1061-1067.
Greater short-term complication risks after total knee arthroplasty (TKA) have been associated with lower hospital and surgeon procedure volume, but the relationship between procedure volume and implant survival is unclear. We examined the association between hospital and surgeon volume and TKA survivorship in the elderly population using 1997 to 2004 Medicare data. Kaplan-Meier method and Cox regression were used to determine implant survivorship and hazard ratios associated with procedure volume at 0.5, 2, 5, and 8 years. The TKA patients in lowest-volume hospitals (1-25 procedures) had a higher risk of revision at 5 and 8 years compared with those operated on in highest-volume hospitals (>200 procedures) (adjusted odds ratio: 1.57 and 1.52, respectively). Surgeon volume was not significantly correlated with implant survivorship. Our findings suggest that TKA patients at low-volume hospitals have a greater revision risk at medium-term follow-up, but not in the short term.

Ong KL, Lau E, et al. Effect of procedure duration on total hip arthroplasty and total knee arthroplasty survivorship in the United States Medicare population. *The Journal of Arthroplasty*. 2008; 23(6 Suppl 1): 127-132.
The effect of procedure duration on joint arthroplasty survivorship in the USA is unknown. We examined the association between procedure duration with primary total hip arthroplasty and total knee arthroplasty survivorship at 8 years in the Medicare population using 1997 to 2004 Medicare claims data. Procedure duration was determined using anesthesia time as a proxy. Kaplan-Meier analysis and Cox regression were used to determine implant survivorship at 8 years and hazard ratios associated with procedure duration. Total knee arthroplasty implant survival was significantly associated with procedure duration (P = .001), in contrast to total hip arthroplasty (P = .127). Total knee arthroplasty procedures shorter than 90 minutes, between 150 and 180 minutes, and more than 240 minutes had significantly higher revision rates than those lasting 120 to 150 minutes. Total hip arthroplasty procedures lasting more than 240 minutes also had a significantly higher revision risk than those lasting 120 to 150 minutes. Our findings support the general belief that longer procedures are associated with the greater probability of complications.

Rastogi A, Mohr BA, et al. Prometheus payment model: application to hip and knee replacement surgery. *Clinical Orthopaedics and Related Research*. 2009; 467(10): 2587-2597.
The Prometheus Payment Model offers a potential solution to the failings of the current fee-for-service system and various forms of capitation. At the core of the Prometheus model are evidence-informed case rates (ECRs), which include a bundle of typical services that are informed by evidence and/or expert opinion as well as empirical data analysis, payment based on the severity of patients, and allowances for potentially avoidable complications (PACs) and other provider-specific variations in payer costs. We outline the methods and findings of the hip and knee arthroplasty ECRs with an emphasis on PACs. Of the 2076 commercially insured patients undergoing hip arthroplasty in our study, PAC costs totaled $7.8 million (14% of total costs; n = 699 index PAC stays). Similarly, PAC costs were $12.7 million (14% of total costs; n = 897 index PAC stays) for 3403 patients undergoing knee arthroplasty. By holding the providers clinically and financially responsible for PACs, and by segmenting and quantifying the type of PACs generated during and after the procedure, the

Prometheus model creates an opportunity for providers to focus on the reduction of PACs, including readmissions, making the data actionable and turn the waste related to PAC costs into potential savings.

SooHoo NF, Zingmond DS, et al. Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty. *J Bone Joint Surg Am.* 2007; 89(10): 2143-2149.

BACKGROUND: The role of ankle arthroplasty in the treatment of ankle arthritis is controversial. Ankle fusion is commonly performed, but there is ongoing concern about functional limitations and arthritis in the adjacent subtalar joint following ankle arthrodesis. The use of ankle arthroplasty as an alternative to ankle fusion is expanding, but reported results have been limited to those in case series. The purpose of this study was to compare the reoperation rates following ankle arthrodesis and ankle replacement on the basis of observational, population-based data from all inpatient admissions in California over a ten-year period. Our hypothesis was that patients treated with ankle replacement would have a lower risk of undergoing subtalar fusion but a higher overall risk of undergoing major revision surgery. METHODS: We used California's hospital discharge database to identify patients who had undergone ankle replacement or ankle arthrodesis as inpatients in the years 1995 through 2004. Short-term outcomes, including rates of major revision surgery, pulmonary embolism, amputation, and infection, were examined. Long-term outcomes that were analyzed included the rates of major revision surgery and subtalar joint fusion. Logistic and proportional hazard regression models were used to estimate the impact of the choice of ankle replacement or ankle fusion on the rates of adverse outcomes, with adjustment for patient factors including age and comorbidity. RESULTS: A total of 4705 ankle fusions and 480 ankle replacements were performed during the ten-year study period. Patients who had undergone ankle replacement had an increased risk of device-related infection and of having a major revision procedure. The rates of major revision surgery after ankle replacement were 9% at one year and 23% at five years compared with 5% and 11% following ankle arthrodesis. Patients treated with ankle arthrodesis had a higher rate of subtalar fusion at five years postoperatively (2.8%) than did those treated with ankle replacement (0.7%). Regression analysis confirmed a significant increase in the risk of major revision surgery (hazard ratio, 1.93 [95% confidence interval, 1.50 to 2.49]; p < 0.001) but a decreased risk of subtalar fusion (hazard ratio, 0.28 [95% confidence interval, 0.09 to 0.87]; p = 0.03) in patients treated with ankle replacement compared with those treated with ankle fusion. CONCLUSIONS: This study confirms that, compared with ankle fusion, ankle replacement is associated with a higher risk of complications but also potential advantages in terms of a decreased risk of the patient requiring subtalar joint fusion. Additional controlled trials are needed to clarify the appropriate indications for ankle arthrodesis and ankle replacement.

Zhan C, Kaczmarek R, et al. Incidence and short-term outcomes of primary and revision hip replacement in the United States. *J Bone Joint Surg Am*. 2007; 89(3): 526-533.

BACKGROUND: The purpose of this study was to use 2003 nationwide United States data to determine the incidences of primary total hip replacement, partial hip replacement, and revision hip replacement and to assess the short-term patient outcomes and factors associated with the outcomes. METHODS: We screened more than eight million hospital discharge abstracts from the 2003 Healthcare Cost and Utilization Project Nationwide Inpatient Sample and approximately nine million discharge abstracts from five state inpatient databases. Patients who had undergone total, partial, or revision hip replacement were identified with use of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes. In-hospital mortality, perioperative complications, readmissions, and the association between these outcomes and certain

patient and hospital variables were analyzed. RESULTS: Approximately 200,000 total hip replacements, 100,000 partial hip replacements, and 36,000 revision hip replacements were performed in the United States in 2003. Approximately 60% of the patients were sixty-five years of age or older and at least 75% had one or more comorbid diseases. The in-hospital mortality rates associated with these three procedures were 0.33%, 3.04%, and 0.84%, respectively. The perioperative complication rates associated with the three procedures were 0.68%, 1.36%, and 1.08%, respectively, for deep vein thrombosis or pulmonary embolism; 0.28%, 1.88%, and 1.27% for decubitus ulcer; and 0.05%, 0.06%, and 0.25% for postoperative infection. The rates of readmission, for any cause, within thirty days were 4.91%, 12.15%, and 8.48%, respectively, and the rates of readmissions, within thirty days, that resulted in a surgical procedure on the affected hip were 0.79%, 0.91%, and 1.53%. The rates of readmission, for any cause, within ninety days were 8.94%, 21.14%, and 15.72%, and the rates of readmissions, within ninety days, that resulted in a surgical procedure on the affected hip were 2.15%, 1.61%, and 3.99%. Advanced age and comorbid diseases were associated with worse outcomes, while private insurance coverage and planned admissions were associated with better outcomes. No consistent association between outcomes and hospital characteristics, such as hip procedure volume, was identified. CONCLUSIONS: Total hip replacement, partial hip replacement, and revision hip replacement are associated with different rates of postoperative complications and readmissions. Advanced age, comorbidities, and nonelective admissions are associated with inferior outcomes.

B. APPENDIX B: LIST OF CITATIONS SELECTED FOR FULL-TEXT REVIEW BUT NOT INCLUDED, BY REASONS FOR EXCLUSION

1. Full Text Studies Excluded Due to Not Being Arthroplasty (n=11)

Keating 1997 (42): Keating JF, Orfaly R, O'Brien PJ. Knee pain after tibial nailing. *J Orthop Trauma*. 1997 Jan; 11(1): 10-3.

Khuri 1997 (43): Khuri SF, Daley J, Henderson W, Hur K, Gibbs JO, Barbour G, et al. Risk adjustment of the postoperative mortality rate for the comparative assessment of the quality of surgical care: results of the National Veterans Affairs Surgical Risk Study. *J Am Coll Surg*. 1997 Oct; 185(4): 315-27.

Kurtz 2008 (44): Kurtz SM, Lau E, Schmier J, Ong KL, Zhao K, Parvizi J. Infection burden for hip and knee arthroplasty in the United States. *J Arthroplasty*. 2008 Oct; 23(7): 984-91.

Lagaay 2008 (45): Lagaay PM, Hamilton GA, Ford LA, Williams ME, Rush SM, Schuberth JM. Rates of revision surgery using Chevron-Austin osteotomy, Lapidus arthrodesis, and closing base wedge osteotomy for correction of hallux valgus deformity. *The Journal of Foot and Ankle Surgery*. 2008; 47(4): 267-72.

Lu 2009 (46): Lu X, Hagen TP, Vaughan-Sarrazin MS, Cram P. The impact of physician-owned specialty orthopaedic hospitals on surgical volume and case complexity in competing hospitals. *Clin Orthop Relat Res*. 2009 Oct; 467(10): 2577-86.

Lu 2010 (47): Lu X, Hagen TP, Vaughan-Sarrazin MS, Cram P. The impact of new hospital orthopaedic surgery programs on total joint arthroplasty utilization. *J Bone Joint Surg Am*. 2010 Jun; 92(6): 1353-61.

Rashiq 2006 (48): Rashiq S, Finegan BA. The effect of spinal anesthesia on blood transfusion rate in total joint arthroplasty. *Can J Surg*. 2006 Dec; 49(6): 391-6.

SooHoo 2006 (49): SooHoo NF, Lieberman JR, Ko CY, Zingmond DS. Factors predicting complication rates following total knee replacement. *J Bone Joint Surg Am*. 2006 Mar; 88(3): 480-5.

SooHoo 2006 (50): Soohoo NF, Zingmond DS, Lieberman JR, Ko CY. Primary total knee arthroplasty in California 1991 to 2001: does hospital volume affect outcomes? *J Arthroplasty*. 2006 Feb; 21(2): 199-205.

SooHoo 2006 (51): Soohoo NF, Zingmond DS, Lieberman JR, Ko CY. Optimal timeframe for reporting short-term complication rates after total knee arthroplasty. *J Arthroplasty*. 2006 Aug; 21(5): 705-11.

SooHoo (52): SooHoo NF, Farng E, Zingmond DS. Incidence of pulmonary embolism following surgical treatment of metatarsal fractures. *Foot and Ankle International*. 2010 Jul; 31(7): 600-3.

2. Full Text Studies Excluded Due to Not Being Registry (n=7)

Bozic 2005 (53): Bozic KJ, Durbhakula S, Berry DJ, Naessens JM, Rappaport K, Cisternas M, et al. Differences in patient and procedure characteristics and hospital resource use in primary and revision total joint arthroplasty: a multicenter study. *The Journal of Arthroplasty*. 2005; 20(7 Suppl 3): 17-25.

Deshmukh 2005 (54): Deshmukh AV, Koris M, Zurakowski D, Thornhill TS. Total shoulder arthroplasty: long-term survivorship, functional outcome, and quality of life. *Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al]*. 2005; 14(5): 471-9.

Gioe 2003 (55): Gioe TJ, Killeen KK, Hoeffel DP, Bert JM, Comfort TK, Scheltema K, et al. Analysis of unicompartmental knee arthroplasty in a community-based implant registry. *Clinical Orthopaedics and Related Research*. 2003; 416: 111-9.

Gioe 2004 (56): Gioe TJ, Killeen KK, Grimm K, Mehle S, Scheltema K. Why are total knee replacements revised?: analysis of early revision in a community knee implant registry. *Clin Orthop Relat Res*. 2004 Nov; 428: 100-6.

Lyman 2009 (57): Lyman S, Dunn WR, Spock C, Bach PB, Mandl LA, Marx RG. Validity of same-side reoperation after total hip and knee arthroplasty using administrative databases. *The Journal of Knee Surgery*. 2009; 22(1): 17-20.

Singh 2010 (58): Singh JA, Ayub S. Accuracy of VA Databases for Diagnoses of Knee Replacement and Hip Replacement. *Osteoarthritis Cartilage*. 2010 Dec; 18(12): 1639-42.

Wright 2004 (59): Wright RJ, Sledge CB, Poss R, Ewald FC, Walsh ME, Lingard EA. Patient-reported outcome and survivorship after Kinemax total knee arthroplasty. *J Bone Joint Surg Am*. 2004 Nov; 86-A(11): 2464-70.

3. Full Text Study Excluded Due to Being Editorial (n=1)

Khuri 1995 (60): Khuri SF, Daley J, Henderson W, Barbour G, Lowry P, Irvin G, et al. The National Veterans Administration Surgical Risk Study: risk adjustment for the comparative assessment of the quality of surgical care. *J Am Coll Surg*. 1995 May; 180(5): 519-31.

4. Previously Included Studies Excluded Due to Being Duplicate (n=3)

Kurtz 2009 (28): Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. *Clinical Orthopaedics and Related Research*. 2009; 467(10): 2606-12.

Soohoo 2007 (19): SooHoo NF, Zingmond DS, Ko CY. Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty. *J Bone Joint Surg Am*. 2007; 89(10): 2143-9.

Bozic 2010 (13): Bozic KJ, Kurtz SM, Lau E, Ong K, Chiu V, Vail TP, et al. The epidemiology of revision total knee arthroplasty in the United States. *Clinical Orthopaedics and Related Research*. 2010; 468(1): 45-51.

C. APPENDIX C: LIST AND DEFINITIONS OF ICD OR PROCEDURAL CODES INCLUDED IN VALIDATED ALGORITHMS

Study	Type of Code	Code	Description
Coyte (6)	Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures plus one of the following three ICD-9-CM codes	93.41 AND	TKA- primary or revision
Coyte (6)	ICD-9-CM	996.4 Or 996.6 Or 996.7	Mechanical complication of internal orthopaedic device, implant and graft Infection and inflammatory reaction due to internal prosthetic device, implant and graft Other complications of internal prosthetic device, implant and graft
Heck (7)	ICD-9-CM	81.41	All TKA before October 1, 1989
Heck (7)	ICD-9-CM	81.54	Primary TKA after October 1, 1989
Heck (7)	ICD-9-CM	81.55	Revision TKA after October 1, 1989
Heck (7)	ICD-9-CM	996.xx	In addition to having the 81.55 code, some claims also included one of several 996 "complication diagnosis codes (no details provided which ones)[a]
Katz (8)	CPT	27134 or 27137 or 27138 AND One code for revision [a]	Revision of total hip arthroplasty; both components, with or without autograft or allograft (27134) Revision of total hip arthroplasty, acetabular component only Revision of total hip arthroplasty, femoral component only Removal of internal fixation device, mechanical & other complications/infection due to internal prosthetic device, implant or graft, removal of prosthesis/internal fixation device, revision of hip replacement, or CPT procedure codes for removal of implant.
Mahomed (9)	CPT-4	27130	Primary THA
Mahomed (9)	CPT-4	27134	Revision THA
Mahomed (9)	CPT-4	27137	Revision THA
Mahomed (9)	CPT-4	27138	Revision THA
Mahomed (9)	ICD-9-CM	81.51	Primary THA

[a]Katz 2001 (8)**:** The following codes were required in addition to the first code (as listed in the table) if the patient was not in the hospital on the day of the first code: removal of internal fixation device, mechanical & other complications/infection due to internal prosthetic device, implant or graft: V54.0, 996.4, 996.6, 996.60, 996.66, 996.67, 996.7, 996.70, 996.77, 996.78; removal of prosthesis/internal fixation device: 78.6, 78.60, 78.65, 80.0, 80.00, 80.05; revision of hip replacement (partial, total): 81.53; CPT procedure codes for removal of implant: 20680, 27090, 27091. These details were provided in an appendix with the original article.

Exclusions for Katz 2001 and Mahomed 2003 Studies:

- Conversion of previous hip surgery to THR: All patients with CPT code 27132 during the index admission, in a transfer IN, or within 2 days of the index surgical claim are excluded.

- Acetabuloplasty; resection femoral head (Girdlestone procedure): All patients with CPT code 27122 during the index admission, in a transfer IN, or within 2 days of the index surgical claim are excluded.

- Infection of pelvic region and thigh: All patients with a code for Arthropathy associated with infections; Osteomyelitis, periostitis and other infections involving bone; or hip arthrotomy for infection with drainage, during the index admission, or in a transfer IN are excluded from the revision cohort. The excluding codes are: ICD-9-CM diagnoses 711.05, 711.65, 711.95, 730.0, 730.00, 730.05, 730.1, 730.10, 730.15, 730.2, 730.20, 730.25, 730.9, 730.90, and 730.95.

- CPT 27030 Arthrotomy, hip, for infection, with drainage.

- Pathological Fractures: A candidate case may also be excluded if there is a mention of metastatic cancer or bone cancer on the index admission or in a transfer. The excluding codes are:

    ICD-9-CM diagnoses:

    - 170.x Malignant neoplasm of bone and articular cartilage

    - 170.6 Malignant neoplasm of pelvic bones, sacrum & coccyx

    - 170.7 Malignant neoplasm of long bones of lower limb

    - 170.9 site unspecified

    - 195.3 pelvis

    - 195.5 lower limb

    - 198.x Secondary malignant neoplasm, other spec. sites

    - 198.5 Secondary malignant neoplasm of bone and bone marrow

    - 199.0 Disseminated malignant neoplasm

    - 733.1 Pathologic fracture

    - 733.14 Pathologic fracture of neck of femur

    CPT codes: 27075-9 Radical resection for tumor or infection, pelvis or hip

D. APPENDIX D: ADDITIONAL 21 STUDIES WITH UNVALIDATED ALGORITHMS

These studies are in addition to the 10 studies with unvalidated algorithms described in Table 5.

1. Original Search Articles (16 Non-Validated Algorithms)

Citation	Study Population and Time Period	Description of Outcome Studied	Algorithm
Aynardi 2009 (21)	7478 THA patients in the Social Security Death Index, Centers for Disease Control and Prevention National Death Index, and State Departments of Vital Statistics database files from Jan 2000 to July 2006.	Mortality	ICD-10 codes
Bozic 2009 (22)	51,345 patients undergoing THA were identified by the NIS database from Oct 2005 to Dec 2006.	Risk factors of revision surgery	ICD-9-CM codes
Cram 2007 (23)	51,788 THA and 99,765 TKA patients in the MEDPAR-Part A database from 1999 to 2003.	Complications after surgery	ICD-9-CM codes
Hawker 1998 (24)	487 TKA patients in the MEDPAR database from 1985 to 1989.	Complications after surgery	ICD-9-CM codes
Hudson 1998 (25)	264 THA patients in the Health Care Financing Administration Part A Medicare Provider Analysis and Review database from Oct 1, 1984 to Sept 30, 1986.	Revision rate	ICD-9-CM codes
Kurtz 2007 (26)	238,500 THA and 434,800 TKA patients in the NIS database from 1990 to 2003.	Revision rate	ICD-9-CM codes
Kurtz 2007 (27)	28,055 THA and 56,673 TKA patients in the Medicare database from 1990 to 2003.	Revision rate	ICD-9-CM codes, CPT-4 codes
Kurtz 2009 (28)	267,100 THA and 571,000 TKA patients in the NIS database from 1993 to 2006.	Revision rate	ICD-9-CM codes
Kurtz 2009 (29)	160,410 THA and 295,750 TKA patients in the NIS database from 1990 to 2004.	Revision rate	ICD-9-CM codes
Kurtz 2010 (30)	69,633 TKA patients in the Medicare database from 1997 to 2006.	Infection risk	ICD-9-CM codes, CPT-4 codes
Losina 2004 (31)	1149 THA patients in the Medicare database in 1995.	Revision rate	ICD-9-CM codes, CPT-4 codes
Losina 2004 (32)	57,488 THA patients in the Medicare Part-A database from 1995-1996.	Revision rate	ICD-9-CM

Lyman 2005 (33)	1307 total shoulder arthroplasty patients in the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) database from 1996 to 1999.	Revision rate	ICD-9-CM
Mahomed 2005 (34)	136,712 TKA patients from the Medicare Part-A or Part-B database in 2000.	Risk factors of surgery	ICD-9-CM codes, CPT-4 codes
Manley 2008 (35)	23,145 THA patients in the Medicare National claims history database from 1997 to 2004.	Revision rate	ICD-9-CM codes, CPT-4 codes
Ong 2006 (36)	THA and TKA patients in the Medicare Part-A or Part-B database from 1997-2003.	Revision rate	ICD-9-CM codes, CPT-4 codes

2. Updated Search Articles (2 Non-Validated Algorithms)

Citation	Study Population and Time Period	Description of Outcome Studied	Algorithm
Kreder 1999 (37)	40 THA and 18 TKA patients had undergone conversion from fusion surgery and were identified by the Canadian Institute for Health Information (CIHI) and Ontario Health Insurance Plan (OHIP) database from 1993 to 1996.	Complications after surgery	ICD-9-CM codes, CIHI codes
Paterson 2010 (38)	20,290 THA and 27,217 TKA patients were identified by the Canadian Institute for Health Information (CIHI) and Ontario Health Insurance databases from April 2000 to March 2004.	Revision rate	ICD-9-CM codes, CCP (Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures) codes, ICD-10 codes, and CCI (Canadian Classification of Health Interventions) codes

3. E-mailed Articles (3 Non-Validated Algorithms)

Citation	Study Population and Time Period	Description of Outcome Studied	Algorithm
Bozic 2010 (39)	The 2005 to 2007 Medicare inpatient claim files were used to perform a matched cohort analysis in three separate cohorts of 57,047 THA patients based on type of implant bearing.	Rates of revision and complications	ICD-9-CM codes
Hagen 2010 (40)	483,970 patients undergoing THA and 873,125 patients undergoing TKA were identified by the Medicare database from 2001 to 2005.	Complications and revisions after primary surgery	ICD-9-CM codes
SooHoo 2010 (41)	138,399 patients in the California's Office of Statewide Health Planning and Development (OSHPD) database undergoing primary THA from 1995 to 2005.	Complications after primary surgery	ICD-9-CM codes

E. APPENDIX E. SUMMARY OF VALIDITY STATISTICS FOR THE FIVE STUDIES WITH VALIDATED ALGORITHMS

	Coyte 1999 (6)	Heck 1998 (7)	Katz 2001 (8)	Mahomed 2003 (9)	Katz 2010
Method of Validation	Ontario Health Insurance physician fee service claims	Compare algorithm with gold standard of specific revision code	Medical record review of random sample	Medical record review of random sample	Medical record review for attributing revision to primary by laterality[b]
Type of implant	TKA	TKA	THA	THA	THA
Sensitivity	77.7%	87.2%	NR	NR	NR
Specificity	97.6%	99.0%	NR	NR	NR
PPV	32%	NR	92%[a]	91%[a]	71%
NPV	0.2%	NR	NR	NR	NR

[a]For primary THA, PPV were 99% for both these studies: PPV (NPV), positive (or negative) predictive value; NR, not reported; THA, total hip arthroplasty; TKA, total knee arthroplasty.
[b]Medical record review was performed to assess the assumption that revision THA performed in the decade after an index primary THA in Medicare database can be attributed to the primary THA without the knowledge of laterality (which is missing in administrative databases).