



MN Community Measurement Total Knee Replacement Impact and Recommendation Document June 2010

<p>Degree of Impact</p> <p>Relevance to Consumers, Employers and Payers</p>	<p>Annually there are over 500,000 total knee replacement (TKR) procedures performed in the US. It is projected that by 2030 the volume of this procedure will increase to over 3.48 million per year due to the aging baby-boomers, increased obesity and indications for TKR that extend to both younger as well as older patients.¹ From 2000 to 2006, the Medicare TKR rate overall in the United States increased 58%, from 5.5 to 8.7 per 1000² and TKR revisions currently represent 8.2% of all Medicare dollars spent.³ It is estimated that annual hospital charges for TKR will approach 40.8 billion dollars annually by 2015.⁴</p> <p>For the Minnesota Medicare population in 2006, 9,856 patients underwent a primary hip or knee replacement procedure (DRG 544) and 1,174 patients had a hip or knee revision (DRG 545). Nationally, for DRG 544 the average charge per hospitalization was \$38,447 with an average payment of \$11,916.⁵</p>
<p>Degree of Improvability</p>	<p>Based on existing research, total knee replacement is a safe and cost effective treatment for alleviating pain and restoring physical function in patients who do not respond to non-surgical therapies. A recent study demonstrated that TKR is cost effective for older adults across all patient risk groups and appeared more costly and less effective in low-volume centers than in high-volume centers⁶</p> <p>There are few contraindications to this surgery as it is currently used, despite variations in patient health status and characteristics, type of prosthesis used, orthopedic surgeon and surgical facilities. Advancements in TKR technology have enhanced the design and fit of knee implants resulting in improved short and long term outcomes.⁷</p> <p>Complications are relatively low for this population. In a large study of Medicare patients who had a primary TKR (n = 124,986), complication rates tracked 90 days following the procedure were as follows:⁸</p> <ul style="list-style-type: none"> • 0.7% death • 0.8% acute myocardial infarction • 0.8% pulmonary embolus • 0.4% wound infection • 0.9% readmission • 1.4% pneumonia requiring hospitalization • 1.3% manipulation under anesthesia <p>A recent study of Medicare TKR patients (n=69,993) the two year incidence of infection was 1.6% and between 2 and 10 years the incidence was 0.46%.⁹</p> <p>The incidence of revision is commonly used as a measure of prosthesis failure, but is not a viable option for direct data submission because of the length of time to capture this event. Revision rate at 10 years is 10% and at 20 years is 20%.⁷</p> <p>Reporting a flat rate of the number of revisions done by a medical group is not indicative of treatment failure as there may not be a relationship between the provider who placed the original joint and the provider who performed the revision. Risk factors for revision are age younger than 55 at the time of TKR, male gender, diagnosis of osteoarthritis, obesity and the</p>

	<p>presence of co-morbid conditions.¹⁰</p> <p>There is a high level of satisfaction with this procedure. In a multi-center study involving 32 states and over 7,700 patients, 95% report that they are satisfied with their procedure.¹¹</p>
<p>Degree of Inclusiveness</p>	<p>Approximately 12 percent of adults older than 60 have symptoms of knee osteoarthritis⁶ and 94% of patients undergoing a primary TKR do so because of osteoarthritis.</p> <p>There are few absolute contra-indications to TKR other than active local or systemic infection and other medical conditions that substantially increase the risk of serious perioperative complications or death.⁷</p> <p>Because it is an elective procedure, patients have a lower Charlson Comorbidity Index (CCI), for primary TKR the score distribution was 64% at 0, 23% at 1 and 13% at 2 or greater.⁸ This procedure is not limited by age, gender or race; however it does occur more frequently for whites and females. Blacks and individuals with low income undergo this procedure less frequently and have higher rates of adverse outcomes. Obesity is not a contraindication to this procedure; however this comorbidity can lead to an increased risk of delayed wound healing or perioperative infection.</p> <p>A study by Mayo clinic (n = 4701) found moderate-severe activity limitation was reported by 20.7% at 2-years post TKR and identified risk factors to be BMI > 30, female gender and increased co-morbidity index.¹²</p> <p>Obesity as measured by BMI could be collected as a means to risk-adjust the population.</p>
<p>Fit with National, Regional, and Local Priorities</p> <p>Indications for Total Knee Replacement</p>	<p>The National Priorities Partnership (NQF) lists TKR as a targeted procedure on its list of potentially unwarranted procedures¹³ as does ConsumerWatch.org.</p> <p>The National Institutes of Health (NIH) convened a consensus development conference in 2003 and made recommendations/ conclusions in the following areas.</p> <ul style="list-style-type: none"> • appropriate candidates for the procedure * • short term outcomes by functional status and overall health related quality of life • influence of surgeon case volume, technique and choice of prosthesis • periop interventions of pre-op education, antibiotic prophylactic antibiotics, aggressive pain management, risk assessment, and management of medical conditions • insufficient data to provide recommendation in the following areas: anticoagulation for pulmonary emboli, periop rehab strategies, methods to reduce post-op anemia, postop physical activity and site of post acute care <p>* NIH defined: “Candidates for elective TKR have radiographic evidence of joint damage, moderate to severe persistent pain that is not adequately relieved by an extended course of non-surgical management and clinically significant functional limitation resulting in diminished quality of life”</p> <p>Indications fall into three categories:</p> <ul style="list-style-type: none"> • Pain • Disability/ Handicap • Extent of local joint damage <p>Clinical guidelines for TKR are sorely lacking.</p> <p>The American Academy of Orthopedic Surgery (AAOS) has guidelines for only seven clinical conditions; one of the conditions is osteoarthritis of the knee and guideline was “explicitly</p>

	<p>developed to include only treatments less invasive than knee replacement (arthroplasty).”</p> <p>The International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine (ISAKOS) have no guidelines for any condition.</p> <p>There are no ICSI guidelines for the TKR procedure; guidelines for the diagnosis of degenerative joint disease of the knee prior to referral to a specialist and order sets for musculoskeletal conditions have been retired. ICSI Basket of Care subcommittee for TKR experts confirms that there are no national guidelines, especially for the intra-operative phase of care.</p> <p>Some recent studies attempt to further define indications for the TKR procedure. One examined outcomes in relation to three criteria for indication of procedure (age \geq 61, WOMAC score \leq 50% of full mark and radiographic OA score \geq 4.5) found that increasing age was associated with poorer postoperative outcomes and lower preoperative WOMAC score were associated with patient dissatisfaction. Radiographic severity had no association with postoperative outcomes.¹⁴ Another study whose goal was to create a formula for indications based on patients that had TKA versus a non-surgical approach found that women had more TKAs than men (P = 0.002), and the TKA and non-TKA groups differed in terms of self-care ability (P < 0.001). There were no significant differences in age or body mass index between the two groups. The relevant factors in the reflective formula were age, sex, self-care ability, joint space narrowing, and osteophytes in the medial compartment.¹⁵</p>
<p>Performance Variation</p>	<p>Is really an unknown.</p> <p>Past experience with reporting prophylactic antibiotic compliance and adverse events has not yielded opportunities for improvement or identified provider variation; with groups hitting targets in the high nineties.¹⁶</p> <p>According to the NIH consensus development program “one of the clearest associations with better outcomes appears to be procedure volume of the individual surgeon and the procedure volume of the hospital.” Medicare data indicate that the highest complication rate is observed among surgeons who perform 12 or fewer operations per year and complication rates decrease when the number of procedures per year increases. Patients operated upon by low-volume surgeons in low-volume hospitals were twice as likely to have a poor WOMAC functional status score as patients operated upon by higher volume surgeons and in higher volume hospitals¹⁷</p>
<p>Existing Measures at a National and Local Level</p>	<p>Search of existing measures at the national level reveals many process measures that reflect the standard of care, are relatively easy to achieve and do not provide outcome information.</p> <p>Count of types of measures:</p> <ul style="list-style-type: none"> 1 - functional status is assessed for osteoarthritis patients 3 - prophylactic antibiotic use 2- venous thromboembolism prophylaxis 2- volume of procedure measures 2- surgical site infection 1- functional status outcome 90 days post TKR 1-readmission for procedure or complication within 90 days post TKR 2- referral of patients with severe OA or RA of the hip or knee to an orthopedic surgeon <p>Outcome Measures</p> <p>NQMC:004688 Surgical site infection: percentage of superficial incisional surgical site infections (SSIs) in knee prosthesis procedures performed, during the 6 month time period. Australian Council on Healthcare Standards.</p>

	<p>NQMC:004689 Surgical site infection: percentage of deep incisional surgical site infections (SSIs) in knee prosthesis procedures performed, during the 6 month time period. Australian Council on Healthcare Standards.</p> <p>ICSI Basket of Care: Average change in individual patient functional status, as measured by the Oxford Knee Score at both pre-op and 90 days post procedure</p> <p>Avoidance of complications: Percent of patients who were not readmitted to a hospital and who did not receive any inpatient or outpatient procedures for a complication related to the surgical site within 90 days of the total knee replacement.</p> <p>Process Measures</p> <p>NQF # 0050 Osteoarthritis: functional and pain assessment (AMA)</p> <p>NQF # 0527 Prophylactic antibiotic received within 1 hour prior to surgical incision (CMS)</p> <p>NQF # 0528 Prophylactic antibiotic selection for surgical patients (CMS)</p> <p>NQF # 0529 Prophylactic antibiotics discontinued within 24 hours after surgery end time (CMS)</p> <p>NQF # 0218 Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery End Time (CMS)</p> <p>NQF # 0217 Surgery Patients with Recommended Venous Thromboembolism (VTE) Prophylaxis Ordered (CMS)</p> <p>NQMC:002854 Frequency of selected procedures: summary of utilization of seventeen frequently performed procedures. National Committee for Quality Assurance.</p> <p>NQMC:002745 Knee replacement surgery: age-standardized rate of unilateral or bilateral knee replacement surgery performed on patients in acute care hospitals or same-day surgery facilities, per 100,000 population age 20 years and over. Canadian Institute for Health Information.</p> <p>NQMC:002166 Osteoarthritis: percentage of patients with severe symptomatic osteoarthritis of the knee or hip who have failed to respond to nonpharmacologic and pharmacologic therapy who are referred to an orthopedic surgeon. Arthritis Foundation</p> <p>NQMC:002193 Rheumatoid arthritis: percentage of patients with rheumatoid arthritis who have severe pain of the hips or knees, which significantly limits activities despite non-pharmacologic and pharmacologic interventions for whom referral to an orthopedic surgeon is offered unless contraindication to surgery is documented. Arthritis Foundation</p>
<p>Enhance the patient/ provider relationship</p> <p>Functional Status Tool</p>	<p>Using a patient assessment tool, in this case for functional status pre and post intervention, can serve many purposes. Not only as an assessment of current status, a patient self administered tool can provide a point of reference for measurement of outcomes and engage the patient in their progress. A pre-op functional status score could be a “back door” attempt at addressing appropriateness of procedure.</p> <p>Current VA Clinical Trial for Standard versus Otismed MRI Generated Cutting Guides <u>does</u> include functional status scores as the primary outcome of the study. They are not prescriptive as to the type of tool and allow the Oxford, WOMAC and the Knee Society Scores which are measured at 4 weeks, 3 months, six months, 1 year and 2 years.</p> <p>ICSI BoC workgroup experts selected the Oxford Knee Score for measuring functional status after a thorough evaluation of all available tools. This patient self questionnaire was easy to</p>

	answer, easy to score, non-proprietary and readily available (free internet tool that provides score)
Considerations for Recommendation Feasibility (resources, barriers, culture)	<p>Things to consider in thinking about measurement for this population:</p> <ul style="list-style-type: none"> • Lack of guidelines, especially that support indications for procedure • Numerous types of prostheses available and associated surgical techniques • No agreement on a functional status tool • No current use in practice of a functional status tool <p>Potential measures may include:</p> <ul style="list-style-type: none"> • pre-operative and postoperative functional status- score change (Oxford Knee Score); would consider a six month or three month score, but not out beyond 1 year. • attempt to measure/ quantify indications (pain, disability, joint damage) • return to OR for manipulation within 90 days • postoperative alignment? (VA Trial also capturing leg alignment based on long leg CT) • overall TKR procedure volume by clinic site or medical group

1 American Association of Orthopedic Surgeons 2006 Annual Meeting Presentation Future Caseload Kurtz SM .

2 Racial Disparities in Total Knee Replacement Among Medicare Enrollees 2000—2006 MMWR 2/20/2009

3 Economic Burden of Total Hip and Knee Arthroplasty in Medicare Enrollees Ong et al 2006

4 Kaiser-Permanente March 2007, Future Clinical & Economic Impact of Revision Total Hip & Knee Revision Kurtz, Ong JBJS 2007

5 Inpatient Hospital Payment Information for Value-Driven Health Care Top 31 DRGs Aug 2008 www.cms.gov

6 Total Knee Replacement Appears Cost-Effective In Older Adults Arch Internal Med June 2009

7 NIH Consensus Development Program Conference on Total Knee Replacement- 2003

8 Epidemiology of Total Knee Replacement in the United States Medicare Population JBJS 2005

9 Prosthetic Joint Infection Risk after TKA in the Medicare Population Kurtz, SM Clin Orthop Relate Res August 2009

10 National Guideline Clearinghouse www.guideline.gov Feb 2004

11 American Association of Orthopaedic Surgeons 2010 Annual Meeting Presentation C. Ayers

12 Predictors of moderate–severe functional limitation after primary TKA at 2 and 5 Yrs Mayo Clinic AORSI May 2009

13 National Priorities Partnerships and Goals November 2008

14 Key Factors in Determining Surgical Timing of TKA -Age, Radiographic and Symptom Severity Chang, CB J Orthoped Tramadol Jan 2010

15 Creation of a reflecting formula to determine a patient's indication for undergoing total TKA Chan WP J Orthop Sci. Jan 2010

16 MN BCBSM Recognizing Excellence program for Orthopedics

17 Association of Hospital and Surgeon Procedure Volume with Patient Centered Outcomes Katz et al Arthritis Rheum Feb 2007