Evidence Report

Chapter 1. Introduction

Throughout this report the term total knee arthroplasty will be used in lieu of total knee replacement because the abbreviation of the latter term may be confused with total knee revision.

At present, approximately 43 million individuals suffer from arthritis. Because this condition becomes increasingly prevalent with advancing age,[1, 2] given the population projections, the Centers for Disease Control estimate that by 2030 over 41 million persons aged 65 and older will have arthritis or chronic joint symptoms.[3] In particular, arthritis of the knee and accompanying joint symptoms result in considerable morbidity, loss of functional status, independence, and quality of life. The high prevalence of arthritis in the population is reflected in the high cost of treatment, which has been estimated at $95 billion per year.[4] These figures do not include the additional costs due to lost job productivity. Treatment options are primarily designed to relieve pain and improve functional status.

Standardized instruments have been developed in order to assess the severity of the symptoms and evaluate outcomes related to treatment. For example, Callahan et al., defined a generic global knee score (GKS) as "an instrument that measured patient outcomes in the domains of pain, function, and range of motion and combined these domains in a summary scale."[5] Widely used scales include the Hospital for Special Surgery score (HSS),[6] Knee Society (KS) score,[7] and Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index.[8] (Copies of these scales are shown in Appendix A.) These scales typically cover aspects of pain and function (usually emphasizing walking). The HSS and KS are completed by clinicians; the WOMAC and SF-36 are designed to be completed by patients. They are intended to provide a score of 0 to 100, where a higher score implies a better outcome. For at least the HSS and KS scores, less than 60 is considered poor pain and function status; 60-69 represents fair pain and function status; 70-84 is considered good; 85-100 is considered excellent pain and function status.

Treatment options include physical therapy, analgesic and/or anti-inflammatory medications, and surgical therapy. The primary surgical treatment for patients is replacement of the native knee joint with a prosthesis (Total Knee Arthroplasty—TKA). A wide variety of prostheses and surgical techniques have been utilized but all are considered under the category of TKA. Total knee arthroplasty is one of the most common orthopaedic procedures performed. In 2001 171,335 primary knee replacements and 16,895 revisions were performed.[9] Medicare paid approximately $3.2 billion in 2000 for hip and knee joint replacements. Because these procedures are elective and expensive and because the prevalence of arthritis is expected to grow substantially as the population ages, these procedures are likely to come under increasing scrutiny. By 2030, it is estimated that there will be an 85 percent increase in TKA.[10] With this growth in mind, as well as the uncertainty related to the indications for, and outcomes associated with TKA, the Minnesota EPC was asked to conduct a systematic review of the literature to address four specific questions:

1. What are the current indications for, and outcomes from, primary total knee replacement?
2. How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short-term and long-term outcomes of primary total knee replacement?

3. Are there important perioperative interventions that influence outcomes?
4. What are the indications, approaches, and outcomes for revision total knee replacement?
5. What factors explain disparities in the utilization of total knee replacement in different populations?
6. What are the directions for future research?

The Total Knee Replacement evidence report will help inform the deliberations of the Consensus Conference Panel.

Previous reports suggest that TKA improve functional status, relieve pain, and result in relatively low perioperative morbidity. A systematic review and meta-analysis of 130 studies evaluating 154 cohorts published in 1994 by Callahan and colleagues evaluated patient outcomes following tricompartmental total knee replacement. They noted that global rating scale scores improved by 100% for the typical patient and that 89% of patients reported good or excellent outcomes after a mean followup of 4.1 years. The weighted mean complication rate was 18.1% and the mean mortality rate per year of followup was 1.5%. The overall rate of revision during 4.1 years was 3.8%.[5]

However, based on conclusions from consensus panels or surveys of health care providers, there is considerable disagreement about the indications for the procedure (Tables 1 and 2); that is, which patients are most likely to benefit from TKA and, conversely, in which patients is TKA contraindicated or of low value. For example, there is substantial variation in opinion about the indications for surgery, among orthopaedic surgeons[11-13] or between orthopaedists and rheumatologists and family physicians,[14-16] The level of agreement for primary TKA indications is significantly higher among orthopaedists than among family physicians or among rheumatologists.[14] Efforts at achieving consensus have yielded mixed results. One study found some level of agreement among a consensus panel comprised of specialty and primary care physicians, an epidemiologist, and physiotherapist around criteria such as the patient's pain at rest, severity of functional impairment, problems with caregiving, and perceived likely improvement in function.[17] Another panel composed of varied specialties found a lack of evidence on which to base decisions, especially the lack of comparison with other forms of treatment including nonsurgical intervention strategies. However, they did propose three "useful variables for surgical decision making": 1) severity of joint damage as determined by pain at night, severity of pain and function; 2) other patient-related variables (eg, patient motivation and social impact of problems); and 3) the health care system and living environment (patient's socioeconomic status, availability of surgeons).[18]

Table 1 summarizes the studies that have examined physicians' beliefs about indications and contraindications for TKAs. Based on a survey of all orthopaedic surgeons in Ontario, Canada (n=325) surgeons' enthusiasm for performing TKAs was correlated with the rate of these procedures and the dominant modifiable determinant of regional variation utilization.[15] In order to understand reasons for variation in utilization TKA, Tierney et al surveyed orthopedists in Indiana (n = 280). Analysis was limited to 188 respondents who had cared for at least one patient with osteoarthritis of the knee in the prior two weeks. Persistent weight-bearing pain was the only factor positively affecting the decision to perform knee replacement (agreed to by at least 95% respondents). Interestingly, surgeons who reported more knee replacements in the prior year had significantly higher estimates of pain relief and functional improvement following surgery, and lower estimates of prosthesis infection and failure rates. However, measured factors only

explained 24% of the variation in self-reported knee replacement performance. The authors recommended that other factors such as access to orthopaedic surgeons performing TKA, decision making of referring physicians, and patient perceptions about knee replacement should be evaluated.[11]

Table 2 summarizes studies that sought areas of consensus about the indications for knee replacement surgery. As such, it is not evidence of effectiveness. Rather, it shows the areas of agreement for either referral to an orthopaedic surgeon or proceeding with TKA (defined as 90 percent or better consensus) across such studies. Pain is the overridingly consistent element. A larger number of contraindications were noted at least twice: peripheral vascular disease, alcohol or drug abuse, mental disorders, and local skin infection. The largest group of variables, however, (the area where less than 60 percent consensus was reached) included age greater than 80 years, nursing home residents, severe hip osteoarthritis, weak quadriceps, joint instability, obesity, septic knee arthritis, patients demanding a TKA, and painful feet. The level of agreement from study to study may be influenced by the techniques used to obtain consensus.