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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences
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PREDICTORS OF APPROPRIATE REFERRAL TO TOTAL KNEE ARTHROPLASTY: A VALIDATION STUDY

(Thesis format: Monograph)

by

Samuel Joseph Malian

Graduate Program in Health and Rehabilitation Sciences

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
London, Ontario, Canada

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Abstract

Approximately 45% of referrals from primary care physicians to arthroplasty surgeons are inappropriate. Currently, Canadians are waiting over three months for consultation with an arthroplasty surgeon. Reducing the proportion of inappropriate referrals will reduce the wait time to first consultation with an arthroplasty surgeon. This study's objective was to validate a model that identified patient-reported predictors of appropriate referrals to arthroplasty. We screened 258 patients attending their first consultation with an arthroplasty surgeon. Participants completed the questionnaires prior to their appointment and the surgeon detailed each consultation outcome on a standardized form. We constructed our validation model using the same variables as the original model. We showed that the original model was valid by demonstrating that the parameters, the fit, and the discriminative abilities of both models were similar. Future research should examine the effectiveness of patient-reported radiological results as a predictor of appropriate referral to total knee arthroplasty.

Keywords

Keywords: predictors, osteoarthritis, total knee arthroplasty, wait time, referral, validation, appropriateness

Co-Authorship Statement

Dr. Dianne Bryant, Dr. Steven MacDonald, Dr. J. Robert Giffin, and Ms. Laura Churchill helped me develop this validation study. We worked together to develop the incoming patient questionnaire used in this study. They previously created the surgical consultation form for Ms. Churchill's Master's Thesis. Participant recruitment and the subsequent data collection, entry, and analysis were solely my responsibility. I wrote the original copy of the manuscript and Dr. Bryant and Dr. MacDonald provided me with suggestions and observations regarding the final copy.

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Chapter 1

1 Introduction

Osteoarthritis (OA) is a progressive disease that causes the decomposition of cartilage, tissue, and bone within joints such as the knees. OA is the most common form of arthritis in Canada and it is estimated that more than 4.4 million Canadians are currently living with the disease[1]. Joint replacement, in particular total knee arthroplasty (TKA), represents the most frequent surgical treatment for patients with severe end-stage knee OA[2]. However, according to a 2014 report, the median wait time from general practitioner referral to orthopaedic surgery is approximately 42 weeks. This is the longest wait time among all specialties[3]. The Wait Time Alliance (WTA) developed an evidence-based benchmark to describe the maximum amount of time patients should wait for a knee replacement consultation. This benchmark was approximately three months[4]. Currently, Canadians experience a median wait time of 18.9 weeks from general practitioner referral to consultation with an orthopaedic specialist[3]. Therefore, patients in Canada are waiting over a month longer than recommended to see an orthopaedic specialist.

Previous literature has demonstrated that a large proportion of patients referred to TKA are inappropriate candidates. For instance, McHugh, Campbell, and Luker (2011) evaluated the characteristics of patients referred for their initial TKA or total hip arthroplasty (THA) consultation and found that 67% of the patients referred for knee OA did not receive a TKA within 12 months. Some of the reasons for not receiving TKA were: not desiring TKA, need to try conservative treatments, does not require any surgical or non-surgical interventions, referred for arthroscopy, requires further monitoring or investigating, too young, and co-morbidity[5]. Similarly, Klett, Frankovich, Dervin, and Stacey (2012) reported that almost half (47%) of the patients referred to their surgical screening clinic were inappropriate TKA candidates and referred them back to their general practitioner. This outcome, along with the lack of conservative treatments used prior to TKA consultation, suggest that there is a need for patient and physician education regarding OA[6]. A previous study from this centre[7]revealed a large proportion of inappropriate referrals to TKA (45%) and suggested that there is need for further physician education and training regarding patient referral to TKA and the management of non-surgical patients.

Given the high rate of inappropriate referrals to TKA, it may be beneficial to examine predictors of appropriately referred patients. Previous literature has examined: predictors of TKA[2,8,9]; predictors of time to total joint arthroplasty (TJA) [10]; and predictors of rapid progression towards TKA[11]. To our knowledge, only the work of Churchill et al. (2015) has examined predictors of appropriate referral to TKA. Specifically, they constructed a statistical prediction model (based on patient-reported factors) that classified patients as appropriate or inappropriate referrals to TKA[7]. Furthermore, Churchill et al. (2015) recommended that their model required validation and that a validated model would facilitate the development of a guided-referral system, as well as educational tools, for physicians and patients. Therefore, the goal of this study was to validate the prediction model constructed by Churchill et al. (2015).

Chapter 2

2 Literature Review

2.1 Knee OA

OA is a progressive joint disease resulting in the deterioration of articular cartilage in synovial joints (i.e. hands, feet, knees, hips, and spine). Cartilage loss in these joints is associated with osteophyte formation, subchondral bone scleorsis, thickening of the joint capsule, increased laxity of ligaments, inflammation of the synovium, and weakened bridging muscles[12,13]. OA can affect any of the three compartments of the knee (medial, lateral, or tibiofemoral) and is often characterized by joint pain, stiffness, swelling, limited mobility, crepitus, and tenderness[14]. Knee OA is categorized as being either primary or secondary. Primary knee OA is idiopathic, while secondary knee OA has a number of potential etiologies, including: traumatic knee injury, previous knee surgery, congenital defect, varus or valgus alignment, aseptic osteonecrosis, metabolic disorders, and endocrine disorders[15].

2.2 Incidence and Prevalence of Knee OA

There is a limited amount of data regarding the incidence of knee OA because of issues associated with defining the disease, as well as, determining its onset[12]. However, according to research conducted by Oliveria, Felson, Reed, Cirillo, and Walker (1995) the incidence rates of symptomatic radiographic knee OA in individuals aged 20 years and older is 240 per 100 000 person years, while hand OA and hip OA is 100 per 100 000 person years and 88 per 100 000 person years, respectively[16].

In terms of prevalence, OA affects 1 in every 8 Canadians (approximately 13%). In the next 30 years, the number of Canadians with OA is expected to increase to 10 million, with approximately 500 000 Canadians experiencing moderate to severe disability caused by OA. Furthermore, nearly 30% of Canadians in the labour force will experience problems working because of OA[1]. Research conducted by Murphy, Schwartz, and Helmick (2008) found that the risk of an individual developing symptomatic knee OA by the age of 85 years is almost 1 in 2. This risk increases in persons with previous knee injuries and is nearly 66% for obese individuals[17]. Meanwhile, the risk of developing symptomatic hip OA by the age of 85 years is 25%[18].

2.3 Diagnosis

The Subcommittee on Classification Criteria for OA, which is a subcommittee of the Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association, developed criteria for classifying idiopathic knee OA. In a classification that includes a clinical assessment and laboratory tests, patients must have knee pain and at least five of nine outcomes: age greater than 50 years old; morning stiffness less than 30 minutes in duration; crepitus; tenderness of the body margins of the knee joint; bony enlargement; no palpable warmth; erythrocyte sedimentation rate (ESR) less than 40 mm/hour; rheumatoid factor (RF) titer less than 1:40; and synovial fluid indicative of OA. In a classification that includes a clinical assessment and radiographic tests, patients must have knee pain, osteophytes, and at least one of three outcomes: age greater than 50 years old; morning stiffness less than 30 minutes in duration; and crepitus. Finally, in a classification that only includes a clinical assessment, patients must have knee pain and at least three of six outcomes: age greater than 50 years old; morning stiffness less than 30 minutes in duration; crepitus; tenderness of the body margins of the knee joint; bony enlargement; and no palpable warmth[19]. The European League Against Rheumatism (EULAR) has come up with recommendations for diagnosing knee OA based on research evidence and expert opinion. EULAR proposes that an accurate diagnosis can be made clinically without the use of imaging if three symptoms (knee pain, temporary morning stiffness, functional limitation) and three signs (crepitus, restricted movement, bony enlargement) are present on examination[20]. The American College of Rheumatology (ACR) and the United Kingdom National Institute for Health and Clinical Excellence (NICE) echo EULAR's recommendations to diagnose OA based on patient symptoms and examination results[21]. Imaging is rarely needed to confirm the diagnosis of knee OA, however, it may be useful for evaluating the severity and the progression of the disease. Imaging can also be used to exclude other diseases (i.e. Paget's disease, avascular osteonecrosis, stress fractures, complex regional pain syndrome, inflammatory arthropathies) when there is any ambiguity[22]. Furthermore, the value of imaging to diagnose OA is diminished by the fact that some patients with radiographic evidence of OA do not report having any symptoms[23].

2.4 Treatment

2.4.1 Conservative Treatment

Patients with knee OA should exhaust all conservative treatment options before exploring surgical interventions, TKA[24]. Effective conservative treatment of knee OA requires a combination of both pharmacologic and non-pharmacologic therapy[20]. The ACR (2012) has come up with several recommendations for both of these conservative treatment options. The ACR conditionally recommends that patients with knee OA should try one of the following pharmacological agents: acetaminophen, oral or topical non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, or intraarticular corticosteroid injections. The ACR also recommends against the use of nutritional supplements (i.e. glucosamine, chondroitin sulfate) or topical capsaicin in the initial treatment of knee OA because the existing literature that they reviewed did not support the effectiveness of these treatments. Furthermore, there is a limited amount of supplements that have been assessed and approved by the Food and Drug Administration (FDA) for the treatment of knee OA. In terms of non-pharmacologic therapy, the ACR strongly recommends that patients with knee OA participate in aerobic, resistance, and aquatic exercises. Furthermore, patients that are overweight are strongly recommended to lose weight. The ACR conditionally recommends the following non-pharmacologic treatment options: psychosocial interventions, manual therapy coupled with supervised exercises, medially directed patellar taping, medially wedged insoles for lateral compartment OA, laterally wedged subtalar strapped insoles for medial compartment OA, walking aids, thermal agents, and tai chi programs[25].

The Osteoarthritis Research Society International (OARSI) recently released updated guidelines for non-surgical treatment of knee OA. Thirteen experts from a variety of medical disciplines and a patient representative composed their Osteoarthritis Guidelines Development Group (OAGDG). According to this group, appropriate conservative treatment options for all individuals with knee OA include: land-based exercises, aquatic-based exercises, weight management, strength training, intra-articular corticosteroid injections, biomechanical interventions, and self-management and education. To accommodate individuals with differing health profiles and degrees of OA, recommendations were also made for four clinical sub-phenotypes: knee OA without co-morbidities, knee OA with co-morbidities, multi-joint OA without co-morbidity, and multi-joint OA with co-morbidities. Along with the treatment options appropriate for all individuals, patients with knee OA and without co-morbidities were also recommended to try: topical NSAIDs, a walking cane, selective and non-selective NSAIDs, capsaicin, duloxetine, and acetaminophen. These guidelines differ from previous OARSI, ACR, and EULAR guidelines in that it exclusively focuses on the treatment of knee OA[26].

2.4.2 Surgical Treatment

Individuals experiencing pain and limited function in activities of daily living (ADL) should be referred for consultation to an orthopaedic surgeon after exhausting conservative treatment options[27]. In a review conducted by Englund, Roemer, Hayashi, Crema, and Guermazi (2012), the authors noted that patients are at a higher risk of developing knee OA if they have traumatic or degenerative changes to their menisci. Arthroscopic surgery may provide relief to these patients, especially if they are experiencing mechanical or physical limitations in their knees. Although this procedure may alleviate symptoms in the short-term, it should be viewed cautiously given that it may contribute to the long-term development of knee OA[28]. According to Kirkley et al. (2008), arthroscopic debridement provides no additional benefit to physical and medical therapy in patients suffering from moderate to severe knee OA. Similarly, Moseley et al. (2002) found that, in comparison to placebo surgeries, neither arthroscopic debridement nor lavage resulted in improved outcomes in the treatment of knee OA[29]. High tibial osteotomy (HTO) may inhibit OA progression and provide pain relief in patients that are not yet candidates for total joint arthroplasty (TJA)[27]. The goal of HTO is to realign the axis of the knee so that the majority of forces through the knee joint affect the non-arthritic compartment. This procedure is generally reserved for younger patients that have varus or valgus malalignment and corresponding unicompartmental knee OA[30]. Similarly, unicompartmental knee arthroplasty (UKA) is used to treat unicompartmental knee OA[14]. The purpose of knee arthroplasty, whether it is a UKA or a total knee arthroplasty (TKA), is to replace damaged articular surfaces with prostheses[30].

TKA is generally reserved for individuals with severe OA and replaces all three of the compartments of the medial and lateral femorotibial joint (FTJ) and the patellofemoral joint (PFJ) [31,32]. TKA offers significant improvement in pain, function, and quality of life measures[31]. Specifically, Bachmeier et al. (2001) found that patients who undergo TKA report better outcomes on the Western Ontario and McMaster Osteoarthritis Index (WOMAC) and the Medical Outcomes Study SF-36 Health Survey (MOS SF-36). In regards to the WOMAC, these patients see a reduction in pain and stiffness and an improvement in physical functioning. The MOS SF-36 shows an improvement in vitality and social functioning in TKA patients, along with improvements in pain, physical function, and physical role function[33]. Long, Bryce, Hollenbeak, Benner, and Scott (2014) have demonstrated that TKA provides positive long-term outcomes for patients with severe end-stage knee OA[34].

2.5 Predictors of TKA

A limited number of studies have identified predictors that are common among patients undergoing TKA. Hawker et al. (2006) study identified several predictors of time to TJA via questionnaire in both an urban and rural region in Ontario. This study evaluated individuals 55 years and older in one rural (high TJA rate) and one urban region (low TJA rate) of Ontario. Of the 28 451 individuals contacted, 2128 were included in the analysis. The primary outcome measure was the occurrence of TJA, determined by the hospital discharge abstract database. Willingness of the patient to consider the procedure was the strongest predictor (hazard ratio (HR) = 4.92, $p < 0.001$), along with higher baseline WOMAC scores (HR = 1.22 per 10 unit increase, $p < 0.001$), increased age (compared to the reference age • 62 years (HR = 1.00), the HR increased to: 1.57 for 63 – 68 years, $p < 0.05$; 1.46 for 69 – 74 years, $p < 0.05$; and 1.51 for 75 – 81 years, $p < 0.05$), and superior health (HR = 1.14 per 10 unit increase in SF-36 general health subscale score, $p < 0.001$). Furthermore, when willingness to consider TJA was removed from the model, education level became a significant predictor of TJA. As noted by the authors, these outcomes emphasize the robust relationship between education and willingness and highlight the need for population education concerning OA[10].

Conaghan et al. (2010) study identified clinical and radiographic predictors of TKA. This three-year prospective study followed up with a cohort of painful knee OA from a EULAR-sponsored multicentre study. The cohort consisted of participants from seven European countries (Belgium, France, Germany, Italy, Spain, Switzerland, and the United Kingdom) and inclusion criteria included: age of 18 years or older, primary knee OA, Kellgren and Lawrence (K&L) grade 1-4, symptoms lasting more than six months, Steinbrocker functional capacity score of 1-3, and pain intensity during physical activity in the past two days • 30 mm on a visual analog scale out of 100 mm. Patients were excluded if they had: secondary knee OA, inflammatory arthritis, pseudogout, or previous surgery on the study knee in the past year. Of the 600 original participants, 531 were analyzed for this study. The rate of TKA in this cohort was evaluated using a survival analysis based on the Kaplan-Meier estimator. Results of the multivariate analysis revealed the following predictors of TKA: K&L grade (grade • III vs. < III, HR = 4.08 (95% CI 2.34 to 7.12), p < 0.0001), ultrasonographic (US) knee effusion depth (• 4 mm vs. < 4 mm) (HR = 2.63 (95% CI 1.70 to 4.06), p < 0.0001), knee pain intensity (• 60 mm vs. < 60 mm) (HR = 1.81 (95% CI 1.15 to 2.83), p = 0.01), and disease duration (• 5 years vs. < 5 years) (HR = 1.63 (95% CI 1.08 to 2.47), p = 0.02). This study underscores the utility and importance of radiographic evidence and clinical symptoms in predicting future TKA. Furthermore, it appears to one of the first studies to identify US knee effusion as a predictor of TKA[8].

Research conducted by Riddle, Kong, and Jiranek (2012), which sought to identify predictors of rapid progression towards TKA within three years of baseline, also identified knee effusion as a predictor of TKA. This research builds upon a previous two-year study conducted by Riddle, Kong, and Jiranek (2009) [35], which used data from the Osteoarthritis Initiative (OAI) to identify radiographic disease severity and physical/mental functional deficits as predictors of TKA. The OAI is a cohort study consisting of individuals with or at risk of OA. Riddle et al. (2012) added 3892 participants to the original 778 participants from the preliminary study and included data from both knees in all participants. Exclusion criteria were: presence of rheumatoid arthritis (RA), previous bilateral TKA, bilateral end-stage knee OA, pregnant, inability to provide blood samples, the use of ambulatory aids for more than 50% movements (excluding canes), any co-morbidities, geographically isolated from clinic's location, already included in a double-blind randomized controlled trial (RCT), men that weigh > 130 kg and women that weigh > 114 kg (because of magnetic resonance imaging (MRI) weight restrictions), and inability to give informed consent. Alternating logistic regression models were used to analyze the data and revealed several previously identified predictors, including: considering TKA for either knee in the next three years, radiographic OA grade, severity of knee pain, global rating score for the effect of knee pain and OA on daily life, use of medication, treated by an arthritis physician, and age. Riddle et al. (2012) also found predictors that have not been previously reported, including: self-reported past surgery (non-arthroplasty) (relative risk (RR) = 2.04 (95% CI 1.33 to 3.13), p = 0.001), clinically diagnosed knee effusion (RR = 1.58 (95% CI 1.04 to 2.40), p = 0.03), pain with active knee flexion (RR = 1.58 (95% CI 1.04 to 2.39), p = 0.03), weak quadriceps muscles (RR = 0.79 (95% CI 0.65 to 0.96), p = 0.02), and knee flexion contractures (RR = 1.06 (95% CI 1.02 to 1.11), p = 0.007). The authors also noted that for every incremental increase in radiographic knee OA grade, the risk for TKA more than doubled (RR = 2.09 (95% CI 1.63 to 2.69), p < 0.0001). However, even with this increased risk, 88% of the cohort that had end-stage knee OA at baseline did not undergo TKA during the follow-up. This study was limited by the small number of TKAs that occurred (n=128) and by its short three-year follow-up[11].

Similarly, Zeni, Axe, and Snyder-Mackler (2010) used logistic regression models to identify predictors of TKA. The University of Delaware Physical Therapy Clinic provided functional data for 120 individuals with end-stage knee OA. They defined end-stage knee OA as having a K&L score • 3 in more than one knee compartment and complaints of pain during ADLs. A physical therapist conducted the functional examination (Delaware Osteoarthritis Profile) on the study participants. This examination evaluated knee range of motion (ROM), self-reported functional ability, functional mobility, quadriceps strength, ability to climb stairs, and anthropometric measurements, such as height and weight. The Knee Outcome Survey - Activities of Daily Living Subscale (KOS – ADLS) was used to evaluate self-reported functional ability, while the Timed Up and Go (TUG) test and the Stair Climbing Task (SCT) were used to evaluate functional mobility and stair climbing, respectively. Their first model, which includes

KOS – ADLS, TUG, SCT, quadriceps strength, age, and ROM during knee extension, significantly predicts TKA (p • 0.001, R^2 = 0.412). Their second model was created using backward logistic regression. The purpose of this second model was to see if fewer variables could be used to predict TKA. This model consisted of only KOS – ADLS, age, and ROM during knee extension. It also significantly predicted whether an individual would undergo a TKA (p • 0.001, R^2 = 0.403). The authors, however, noted that both of these models were more effective at predicting individuals that did not undergo TKA (model 1 = 91% correctly predicted; model 2 = 86% correctly predicted), as opposed to those who underwent TKA (model 1 = 59%; model 2 = 62%). This suggests that other predictors not included in this study may affect a patient's decision to undergo TKA. Receiver operating characteristic (ROC) curves used to establish meaningful useful cut-offs for the variables in the model were also more effective at predicting which patients did not undergo TKA (no TKA: age • 60, 75% correctly predicted; ROM during knee extension • 0, 77% correctly predicted; KOS – ADLS > 50, 77% correctly predicted). Furthermore, Zeni et al. (2010) propose that physicians and healthcare practitioners should be aware of possible predictors (i.e. knee ROM) that can be modified to reduce the risk of TKA for individuals with severe knee OA[2].

A prospective cohort study, by Liu et al. (2014) investigated predictors of undergoing TKA in patients with end-stage knee within six months of baseline data collection. The cohort consisted of 240 Japanese women with painful medial knee OA and a K&L grade of 4. Patients with a history of TKA in either knee were excluded. Patients were followed for six months after baseline as they completed a therapeutic exercise program. The following measures were evaluated at baseline: standing, extended, antero-posterior, and lateral radiographs; the Japanese Knee Osteoarthritis Measure (JKOM), which is a patient-reported survey that evaluates pain and stiffness, ADLs, social activities, general health conditions; and the visual analog scale (VAS) for pain. Of the 240 enrolled, 17 were lost to follow-up and 8 were excluded because of missing data[36]. JKOM has been proven to have adequate validity and reliability in comparison to both the WOMAC and the MOS SF-36[37]. RR values were obtained by using the area under curve (AUC) for ROC curves. Failure to reject the null hypothesis occurred for AUC scores < 0.70. Results of the analysis revealed the JKOM total score (AUC = 0.71, 95% CI 0.64 to 0.79) and VAS pain (AUC = 0.70, 95% CI 0.62 to 0.77) to be predictive of patients undergoing TKA within six months of baseline. The RR for JKOM at its cut-off point (65) was 2.20 (CI 95% 1.33 to 3.63, $p < 0.01$), while the RR for VAS pain at its cut-off point (78) was 2.24 (CI 95% 1.32 to 3.82, $p < 0.01$). Furthermore, the ADL subscale of JKOM reported an AUC score of 0.72 (95% CI 0.65 to 0.80) and a RR of 1.95 (95% CI 1.18 to 3.22) at its cut-off point (17), suggesting that it may be an important predictor of patients undergoing TKA. A major limitation of this study is that the cohort is extremely exclusive (Japanese women with K&L grade 4 knee OA). Thus, the applicability of these results to the general population is significantly hindered[36]. Although there is a modest amount of research evaluating predictors of future TKA, currently there appears to be a lack of agreement among physicians regarding the appropriate TKA candidate[38].

2.6 Wait Times for TKA Consultation

The wait time continuum for a patient begins when they first have signs/symptoms of a medical affliction. Since this is often difficult to report or quantify, the earliest reported time on the wait time continuum is when patients schedule an appointment with their general practitioner[39]. In their 2014 report card, the Fraser Institute reported that the median wait time from general practitioner referral to orthopaedic surgery is the longest among all specialties (42.2 weeks) and has increased by 2.6 weeks since 2013. Overall, the wait time from general practitioner referral to the beginning of treatment in all specialties has increased by 96% since 1993 (9.3 weeks to 18.2 weeks)[3]. In the 2010 National Physician Survey, only 23.7% of family physicians/general practitioners across Canada rated patient access to orthopaedic care as excellent (7%) or very good (16.7%), while 54.2% of these physicians rated this access as fair (21.7%) or poor (32.5%)[40]. Furthermore, the majority of focus tends to be given to the wait time from when a patient sees a specialist to when they receive a treatment (i.e. TKA). Modest attention has been given to the wait times for specialist referral often referred to as “wait one”[41,42].

In partnership with the Saskatchewan Medical Association, the Saskatchewan Ministry of Health has implemented an initiative to measure wait one. The province used a new billing code that evaluates the time from when a patient is referred to see a specialist (from primary care) to when they are seen and billed by the specialist. Along with allowing patients and providers to see the approximate wait times for all specialists in the province; this initiative will help to calculate the total time that patients wait to receive specialty care[43].

Currently, most of the data that has been collected concerning wait one implies that it is as long as the wait times to receive treatments or procedures[41]. According to a 2013 survey conducted in eleven Commonwealth countries, Canada had the highest percentage of patients (29%) that had to wait two months or more for an appointment with a specialist. The survey was administered to adults' age 18 years and older in each of the following countries: (United States, n = 2002; United Kingdom n = 1000; Switzerland, n = 1500; Sweden, n = 2400; Norway, n = 1000; New Zealand, n = 1000; Netherjennalands, n = 1000; Germany, n = 1125; France, n = 1406; Canada, n = 5412; and Australia, n = 2200) [44]. In Canada, the median wait time from general practitioner referral to consult with an orthopaedic specialist is 18.9 weeks (compared to 8.1 weeks in 1993). In Ontario, this wait time is 13.3 weeks and is the fourth shortest among all Canadian provinces (Manitoba = 5 weeks, Saskatchewan = 12 weeks, Quebec = 13 weeks) [3].

The 2004 Health Accord was signed by the First Ministers of Canada to help Canadians receive timely access to quality healthcare. Specifically, the First Ministers sought to reduce wait times and improve the management of this issue in significant areas such as cancer, heart, diagnostic imaging, sight restoration, and joint replacements. The Wait Times Reduction Fund was established to help all jurisdictions decrease wait times in Canada. The purpose of the Fund was to: support the training and development of healthcare professionals; improve backlogs; increase the building capacity for regional centres of excellence; and enhance the tools and programs designed to help improve wait times. Furthermore, Health Ministers in the Municipal, Provincial, and Federal governments were tasked to develop benchmarks for wait times and also set multi-year goals to achieve them[45]. The WTA, which was developed after the 2004 Health Accord, used this opportunity to develop evidence-based benchmarks in the five key areas mentioned in the Accord. Since then, the WTA has revised these benchmarks based on new evidence and data, and also expanded the benchmarks to include other specialty areas. However, the WTA does acknowledge that there is a need, across Canada, for a standardized approach for reporting wait time benchmarks[46]. These benchmarks are not standards but rather represent the maximum amount of time a patient should have to wait to receive a treatment or procedure. Waiting beyond these benchmarks can have negative consequences on a patient's health[47]. Currently, the wait time benchmark for knee and hip replacement consultation is approximately 90 days or three months[4].

Fyie, Frank, Noseworthy, Christiansen, and Marshall (2014) examined referral processes and their effect on the wait time from when patients are referred to orthopaedic surgeons from their general practitioner. Patients were referred to either TKA or THA. This study used a mixed methods approach at three clinics in Alberta, Canada. Each clinic was located in a different setting: urban, mid-sized, and rural. The approach consisted of: an interview with an administrator at each site to identify specific processes by which a referral is carried out and also to identify the performance measures that are important to these processes; review of 218 patient charts (urban clinic or clinic 1, n =127; rural clinic or clinic 2, n = 41; clinic in mid-sized city or clinic 3, n = 50) using a standardized data extraction template; and direct observation of a nurse and medical office administrator for one week at each clinic to record data concerning the quality of the referral and the specific tasks performed during the referral process. Accessibility (health care is received in the proper setting at an acceptable time and distance) and appropriateness (health care is fitting to a patient's needs and is determined by standardized or evidence-based practices) were used to assess the referral processes at each clinic[48,49]. Referral processing was similar at all three clinics: referral is received, referral is entered into the electronic medical records, the patient is triaged, and a surgeon or musculoskeletal specialist sees the patient. The requirements for consultation differed between the clinics, however all three clinics had similar protocols for handling incomplete or inappropriate referrals. Incomplete referrals were pended until the necessary patient information was received, while inappropriate referrals resulted in general practitioners receiving a rejection notice. The mean wait times from general practitioner referral to the initial consultation with the surgeon or specialist was 97 days at clinic 1 (standard deviation (SD) = 56), 51 days at clinic 2 (SD = 45), and 139 days at clinic 3 (SD = 86). At clinics 1 and 3, patients had the opportunity to select their surgeon or see the next available surgeon (clinic 2 only had one surgeon). Wait times for patients who selected their surgeon were 11% (n = 10 business days) and 36% (n = 47 business days) longer than patients that opted for the next available surgeon, at clinics 1 and 3 respectively. Waiting for the referral to be accepted (i.e. involuntary waiting) accounts for 11% of total wait time[48]. Approximately 40% – 80% of the total time patients wait for TKA or THA takes place from general practitioner referral to initial consultation with surgeon or specialist. Researchers were not able to capture information concerning incomplete referrals at clinic 3 due to software limitations. Patients with incomplete referrals had their wait time from general practitioner referral to initial consultation with surgeon or specialist extended by 36% and 13%, at clinics 1 and 2 respectively. Finally, the musculoskeletal specialists found that 35 patients at clinic 1 and 13 patients at clinic 3 did not require surgery. A major limitation of this study was that there were no records of the denied referrals, which could have been useful for identifying predictors or indicators of an inappropriate referral. The authors suggest that improved referrals processes that are standardized between clinics could significantly enhance patient access to specialty care[48]. Since inappropriate referrals may contribute to longer wait times for patients, future research should perhaps focus on this relationship.

Research conducted by Snider, MacDonald, and Pototschnik (2005) looked at patient perspectives regarding wait times for total joint replacement and for initial consultation with the surgeon. Surveys were mailed retrospectively to patients that have received a TKA or THA at two orthopaedic practices in Ontario. One practice was located in a rural location (Stratford, Ontario) and the other was located in an urban location (London, Ontario). Overall, 260 surveys were mailed to eligible patients and 202 surveys were returned (115 from the urban clinic; 87 from the rural clinic). Patients were excluded from the study if: they did not return the survey, they did not complete the survey in full, or if their chart information could not be found or accessed. Survey items asked the patients about: their perspectives regarding the wait times for the initial consultation and for the surgery (TKA or THA), the level of acceptability regarding the wait times to surgery, the extent to which wait times affect their health, and what they thought would be an appropriate wait time. The charts of patients that returned the surveys were examined to determine the actual wait times for initial consultation and for surgery. Following chart review, the investigators found that the mean wait times for the initial consultation were significantly shorter ($p < 0.001$) in the rural practice (1.10 months, SD = 0.53) compared to the urban practice (3.40 months, SD = 1.34). Over half the patients in both the rural (53%) and the urban (59%) practices had to wait over 9 months for the surgery. In terms of patients' perspectives regarding wait times, they significantly overestimated ($p < 0.001$) the wait for initial consultation by almost three weeks (patients' perceived wait = 3.55 months, SD = 3.19; actual wait = 2.64, SD = 1.57). Half of all of the patients found the wait time for surgery to be inappropriate or unacceptable. Almost half of all of the patients (47%) thought that the wait times were detrimental to their health. The investigators suggested that the perceived wait times for initial consultation may have been overestimated because the survey was completed approximately one to two years after their consultation. Patients may not have had these consultations dates documented and thus their memory or recall may have been inaccurate. This study demonstrates that increased wait times are being perceived by patients to be unacceptable and harmful to their health[50].

Research conducted by Fortin et al. (1999), suggested that patients that wait too long to receive a TKA or THA may have a lower functional status than those that receive the procedures earlier. The investigators surveyed surgical candidates for TKA or THA at the Brigham and Women's Hospital (BWH) in Boston and at the Montreal General Hospital (MGH). Patients were excluded from the study if they had other inflammatory diseases in the joint undergoing surgery or if they could not read and comprehend English or French. Participating patients completed a preoperative questionnaire that contained: a sociodemographic form, a form evaluating pain and function, the MOS SF-36, and the WOMAC. Follow-up questionnaires were completed at three and at six months. The WOMAC pain and physical function score and the MOS SF-36 physical function score were identified a priori as important postoperative outcomes for these procedures. Therefore, the differences within and between the centers in these scores was evaluated preoperatively and six months postoperatively. Patients were divided into two groups based on their preoperative physical function score on the WOMAC. Multiple linear regressions were calculated to predict pain and function at six months postoperatively. At BWH, 177 of 257 eligible patients consented to participate in the study; of these 177 patients, 138 of them returned the questionnaire. Meanwhile, 91 of 130 eligible patients at MGH consented to participate; of these 91 patients, 84 of them returned the questionnaire. Patients from MGH had lower preoperative physical function scores and experienced more pain, while patients at BWH were more educated, had more cemented knee prostheses, and had fewer co-morbidities. The investigators acknowledged that the differences in health care systems in the United States and Canada could account for the different preoperative statuses of the patients, as the publicly funded Canadian system is traditionally more conservative concerning elective procedures. Although patients in both groups (low and high baseline physical function scores) improved postoperatively, the low function preoperative group did not reach the same level of physical function or reduced pain as the high function preoperative group. For instance, at six months postoperative in patients that underwent TKA, the high function group had better WOMAC pain (mean = 2.1, SD = 2.5), WOMAC function (mean = 9.5, SD = 8.3), and MOS SF-36 physical function (mean = 63.0, SD = 25.0) scores compared to the low function group (WOMAC pain: mean = 5.9, SD = 4.7; WOMAC function: mean = 23.0, SD = 16.6; MOS SF-36 physical function: mean = 47.0, SD = 26.8). Results of the multiple linear regressions revealed that the best predictors for scores on WOMAC pain, WOMAC physical function, and MOS SF-36 physical function at six months postoperatively in TKR patients were their respective baseline scores (WOMAC pain, $R^2 = 0.25$; WOMAC function, $R^2 = 0.36$; and MOS SF-36 physical function, $R^2 = 0.21$). The investigators recognize that their study was limited by: the use of only two centres, the lack of long term follow-up for functional outcomes, and the inability to collect postoperative information for patients that dropped out of the study. Nevertheless, this study demonstrates the potential negative postoperative consequences of waiting too long to undergo TKR or THR[51].

2.7 Appropriateness of TKA Referral

The literature is limited concerning which patients are appropriately referred to an orthopaedic surgeon for TKA by their general practitioner. Hudak et al. (2008), sought to understand the process by which physicians determine patient eligibility or appropriateness for TJA by conducting several interviews with general practitioners (n = 18), rheumatologists (n = 15), and orthopaedic surgeons (n = 17) from across Ontario. The physicians were organized into six specialty-specific focus groups, two for each specialty, and then engaged in discussion with the help of a health research moderator. The moderator began discussions with each group by posing the following question, “What do you consider when deciding to refer a patient for TJA/to perform TJA surgery for a patient?” Follow-up questions were then asked regarding the impact of patient characteristics, such as age, weight, and co-morbidity, on the physicians’ decisions. These focus group discussions revealed that when evaluating patient eligibility for TJA, health care system constraints (extensive waiting lists and backlogs; lack of home care and support postoperatively; surgeon access to operating rooms and other resources) often significantly impacted and influenced the decision-making process. Furthermore, a new term called “medical brokering” emerged from these discussions. It referred to the strategies used by these physicians to prioritize patients, while also working and collaborating with other physicians in a constrained health care system. Instead of identifying appropriate candidates for TJA and referring/booking them for surgery, brokering often forces general practitioners, rheumatologists, and orthopaedic surgeons to identify the “best” candidates on a case-by-case basis. The result of this brokering is variability in the criteria and decision-making processes used by referring physicians and surgeons to identify surgical candidates. The investigators concluded that until research is implemented addressing wait times, TJA delivery cannot sustain the growing demand[52].

Ang, Thomas, and Kroenke (2007) examined the effectiveness of primary care physicians (PCPs) at making treatment decisions (i.e. surgical versus non-surgical) for patients with OA. Specifically, the investigators were interested in PCPs’ ability to appropriately refer patients to TJA. PCPs attending one of six continuing medical education (CME) primary care programs in Indianapolis, Indiana, were asked to complete a survey that consisted of ten clinical vignettes. The vignettes were based on common primary care scenarios and five orthopaedic surgeons, five internists, and five rheumatologists reviewed their validity. PCPs received a score from zero to ten based on the number of correct responses they had to the vignettes. The RAND appropriateness measure, which offers guidelines for handling a multitude of clinical scenarios[53], determined which responses were correct for each vignette. The survey also collected the PCPs demographic information and queried their opinion regarding the effectiveness of TJAs. One hundred and forty-nine PCPs, of a possible 245 (60.9%), fully completed the survey. The mean number of correct responses to the vignettes was 6.5 (±1.5) and the majority of the respondents (83%) underestimated the effectiveness of TJA. The investigators suggested that the low mean score might have been the result of PCPs not utilizing or exploring enough conservative approaches to the treatment of OA. The investigators propose that future research should focus on educating both the PCPs and the patients regarding the treatment and management of OA. Furthermore, research should evaluate the effect of patients having direct access to specialty care as opposed to having to be referred by their PCP[54].

McHugh et al. (2011) conducted a longitudinal study that aimed to identify the differences among OA patients referred for their initial TJA consultation. The authors also examined the predictors of having a TJA, as well as, the differences among patients that are put on the TJA waiting list. Data was collected at baseline, 3 months, 6 months, and 12 months via postal questionnaire from a regional orthopaedic centre in North West England. Ten orthopaedic surgeons provided the data regarding patients' study eligibility: over the age of 18, diagnosed with OA, appropriate TJA candidate. Of the 431 eligible patients, 257 consented to participate. Less than half of the consented patients had knee OA (47.9%), while the remaining had hip OA (52.1%). The WOMAC was used to measure pain, stiffness, and physical function, while VAS pain was also evaluated. Health related quality of life was evaluated using MOS SF-36 and the severity of joint OA and the surgical outcome were measured using the Oxford Knee Score and the Oxford Hip Score. Results of the analysis revealed that VAS pain ($p = 0.003$), WOMAC pain ($p = 0.034$), WOMAC stiffness ($p = 0.050$), WOMAC physical function (0.044), SF-36 physical function ($p = 0.002$), SF-36 role limitation (physical) ($p = 0.016$) and Oxford Knee Scores ($p = 0.018$) were significantly worse in patients that underwent TKA. Following forward stepwise logistic regression, only SF-36 physical was selected as a significant predictor of TKA (OR = 0.96 (CI 95% 0.94 to 0.99), $p = 0.002$). Furthermore, only 33% of patients with knee OA underwent TKA within 12 months of baseline. The outcomes for the remaining 67% of patients that did not undergo TKA were: not desiring TKA, did not need treatment or surgical intervention, need to try conservative treatment (i.e. injection, physiotherapy, exercise, weight management), need to monitor knee OA, age (i.e. too young), appropriate but did not receive TKA during follow-up, co-morbidity, further investigation required, and scheduled for arthroscopy. Considering that a large proportion of the knee OA cohort did not receive a TKA during the follow-up period, the authors suggest that enhanced management and assessment strategies need to be developed between primary and tertiary care to improve quality of care. A potential limitation of this study was that the ten orthopaedic surgeons might have had different criteria for selecting appropriate TKA candidates[5]. Therefore, improved standardization is required among healthcare providers to identify which patients are appropriate TKA candidates.

A published abstract by Harrison, Cooke, Hopman, Brean, and Hope (2014), examined the effectiveness of a triage tool that was used to assess TKA candidacy in patients with knee OA. The triage tool was based on patient self-report disability measures and standardized knee radiograph scores. This prospective study assessed 173 patients with knee pain that were referred for an initial consultation with an orthopaedic surgeon. Participating patients completed several self-report disablity measures including: SF-12, WOMAC, Tegner and Lysholm questionnaires, Functional Comorbidity Index, and Inflammatory Disorder Questionnaire. An Advanced Practice Physiotherapist (APP) then evaluated patients using an OA referral questionnaire called the Western Canada Waitlist Priority Referral Score (WCWL-PRS). Qualified evaluators scored and assessed patients' knee radiographs. The orthopaedic surgeons determined patients' candidacy for surgery. Forty-six patients were classified as inappropriate for TKA, while 127 patients were classified as appropriate candidates. A step-wise logistic regression analysis revealed that age, WOMAC score, and radiographic score could correctly predict patients' appropriateness for TKA. Specifically, older patients with higher WOMAC and radiographic scores were more likely to be considered appropriate for TKA.[55]

In their 2013 report card, the WTA described the efforts made by Bone and Joint Canada and the Canadian Orthopaedic Association (COA) to instill patient-centered models in the delivery of orthopaedic care. They credit their inspiration to the fast-food industry, where the timing and coordination of several small steps are essential to the delivery of the customers' orders. These models of care focus on minor changes and improved communication at the fundamental level. The result is an improvement in the effectiveness and delivery of healthcare. A model of care currently practiced by orthopaedic centres in all ten provinces of Canada is the total joint assessment clinic, which triages patients prior to their initial consultation with the surgeon. Since approximately 30% of referred patients are inappropriate candidates for surgery, physiotherapists and other healthcare professionals working in the assessment clinic can refer or direct these patients to other non-operative treatment modalities. The result of this model is a more efficient referral process that leads to reduced costs, improved patient satisfaction, and potentially decreased time spent by patients in hospitals. It is important to note, however, that these models are not uniform across all centres[56].

Newfoundland and Labrador implemented a strategy in 2012 in an attempt to reduce wait times for knee and hip replacements. Their first goal was to reduce wait one through the implementation of an Interdisciplinary Central Intake and Assessment Clinic, which triages surgical candidates based on their readiness for surgery (i.e. ready for surgery or requires additional medical intervention or diagnostic tests prior to surgery). Patients that are not ready for surgery have their additional tests or services arranged by this clinic. This results in fewer delays and a more effective referral process. Provincial health officials believe that this approach can be adapted to include all orthopaedic referrals (i.e. referred patients that are not appropriate surgical candidates). The Department of Health and Community Services in Newfoundland and Labrador also sought to establish provincial policies and standards in the reporting of wait one times for TKA and THR. Finally, in partnership with the Newfoundland and Labrador Medical Association and the Office of Professional Development at Memorial University's medical school, the Department of Health and Community Services is working to improve the training and education of general practitioners in their assessment and treatment of patients with minor orthopaedic afflictions. If these patients are treated prior to specialty care by their family physician or general practitioner than the number of orthopaedic referrals may decrease and lead to shorter wait times for appropriate surgical candidates[57].

Aiken, Harrison, Atkinson, and Hope (2008) found that conservative treatments are significantly underutilized in patients referred to TKA. The objective of their research was to examine the level of agreement between a physiotherapist and a surgeon in determining patients' eligibility and priority for TKA and THR. All patients, referred to a tertiary care centre in Kingston, Ontario for TJA, were seen by both the physiotherapist and the surgeon to determine their eligibility for surgery. The urgency for surgery in eligible candidates was decided using the Western Canada Waitlist Hip and Knee Priority Criteria Tool (WCWL-HKPT). Patients also completed the WOMAC before they were evaluated. Both healthcare practitioners also provided recommendations for patients, including: OA education, further testing, specialist referral, conservative treatments, and surgery. Of the 40 subjects enrolled in the study, 21 were referred for their knee, 16 were referred for their hip, one was referred for knee and hip, and two patients did not have usable data. The physiotherapist and the surgeon had 100% agreement regarding eligibility for surgery and found that only 34% (n = 13) of the patients did not require surgery. In terms of priority, the healthcare practitioners agreed on 64% (n = 16) of the patients. Patient WOMAC scores (only 23 fully completed) were compared with the WCWL-HKPT scores completed by both the physiotherapist and the surgeon. Patients' perceptions of their disease severity and their priority rating were more similar to the surgeon's opinions (agreed on 18 of 23 cases, 78%) than the physiotherapist's opinions (agreed on 12 of 23 cases, 52%). Furthermore, the physiotherapist recommended conservative treatments or further education for nearly all of the patients (37 of 38 patients, 97%), while the surgeon only suggested that for 6 of the 38 patients (16%). The model of care used in this study demonstrates the utility of physiotherapists in the referral process and suggests that the number inappropriate TKA consultations (i.e. patients that are not booked for surgery) could potentially be reduced through patient screening[58].

Klett et al. (2012) conducted a descriptive study to examine the effectiveness of a surgical screening clinic for knee OA patients referred to TKA. The authors also investigated management options for these patients prior to referral. Four physicians work at the surgical screening clinic, which is located at a large Canadian teaching hospital. Surgical eligibility was determined using the WOMAC and the WCWL - HKPT, which included the National Institutes of Health criteria for TKA. Of the 327 eligible patients, approximately half (n = 172, 52.6%) were referred to the orthopaedic surgeon, while the remaining 155 (47.4%) were referred back to their general practitioner. Of the 172 patients referred to the surgeon, 131 (76.2%) underwent TKA. Prior to referral, knee OA patients reported trying the following conservative treatments: analgesia, NSAIDs, cortisone, viscosupplementation, physiotherapy, bracing, glucosamine, weight loss and other (walking aids, acupuncture, massage, exercise, wheel chair, physiatrist). Patients referred to the surgeon, were most likely to have attempted three or more conservative treatments ($p = 0.01$), tried injections ($p < 0.001$), met the surgical eligibility ($p < 0.001$), and have high WOMAC ($p < 0.001$) and HKPT ($p < 0.001$) scores. Patients referred to the screening clinic by sports medicine physicians were more likely to have tried a greater number of conservative treatments and were more likely to be referred to the surgeon. In summary, this study demonstrated the utility of the screening clinic, as the number of surgical consultations decreased by approximately 50%, and also revealed the lack of conservative treatments used prior to referral. These outcomes demonstrate the need for general practitioners to receive continuing education regarding OA[6]. It is important to note, however, that these screening clinics are also susceptible to long wait times and limited resources. Thus, it is may be more efficient to focus on patient and physician education to avoid going through these additional and sometimes unnecessary steps (i.e. screening clinics) in patient care.

2.8 Summary

The prevalence of Canadians living with OA is expected to double within the next few decades. Consequently, there will be an increased demand for surgical and non-surgical or conservative treatment interventions. Generally, a physician or healthcare practitioner clinically diagnoses knee OA. Imaging assessments can confirm the presence of knee OA and provide supplemental information regarding the disease severity. Conservative treatment of knee OA usually involves some combination of pharmacological and non-pharmacological therapies, while surgical treatment options include: arthroscopy, HTO (for younger patients with varus or valgus malalignment that are experiencing early signs of knee OA), and TKA (for patients with severe knee OA).

A major obstacle for patients requiring treatment for knee OA is the wait time for an initial consultation with an orthopaedic specialist. Depending upon where a patient is living, these wait times can be significantly long and result in patients not receiving necessary care at the appropriate time. More often than not a significant proportion of patients are inappropriately referred to orthopaedic specialists by their general practitioner. Specifically, these patients are not yet appropriate candidates for TKA (i.e.

they do not advanced OA; they have not tried enough conservative treatment). Thus, there is a need for more physician and patient education regarding conservative treatment options for knee OA, especially if these non-surgical interventions can improve a patient's disease state. Recently, research has evaluated predictors that are common among patients undergoing TKA. Understanding what constitutes an appropriate TKA candidate can considerably improve the quality of referrals to orthopaedic specialists. Furthermore, standardized models of care that specify appropriate timing of referral and appropriate surgical candidates could significantly help to alleviate this wait time dilemma.

Chapter 3

3 Objectives

The primary objective of this study was to validate a statistical model that identifies patient-reported predictors of appropriate referral to a TKA surgeon.

Chapter 4

4 Methodology

This prospective cohort study took place in London, Ontario at the Rorabeck Bourne Joint Replacement Clinic. This clinic serves seven orthopaedic surgeons specializing in TKR and THR and is located in the London Health Sciences Centre's (LHSC) University Hospital. Participating patients completed a short questionnaire (see Appendix C) in the waiting room prior to their consultation. Following consultation, the surgeon completed a form (see Appendix D) that described the outcome of the visit. The Health Sciences Research Ethics Board at the University of Western Ontario granted approval for this study (see Appendix A).

4.1 Patient eligibility criteria

We screened patients referred for initial consultation with an orthopaedic surgeon for the treatment of their knee OA. We excluded patients who were not mentally competent; could not speak English; were not a new referral to the clinic; or had previously undergone a TKA.

4.2 Patient recruitment

Recruitment for this study began on November 24th, 2014 and finished on February 23rd, 2015. The study coordinator identified all new eligible patients prior to their appointment. Patients were greeted in the clinic waiting room and invited to complete the questionnaire prior to meeting with the surgeon. A letter of information was provided (see Appendix B). Consent to participate was considered explicit upon patients beginning the questionnaire. Following completion of the questionnaire, the study coordinator entered the data into a secure online data management system (Empower Health Research, Inc; empowerhealthresearch.ca).

4.3 Outcomes

4.3.1 Incoming patient questionnaire

The questionnaire provided to the patients was composed of eight items. Surgeon expertise and the results of the study by Churchill et al. (2014) guided the selection and order of these items within the questionnaire. All of the included items were patient-reported to ensure that the results of this validation study were applicable to the overall goal of the research program, which is to develop an online guided-referral system for clinicians and patients. The first two items on the questionnaire asked patients about basic demographic information (age and sex). Patient sex was only collected for descriptive purposes. Patients were then asked about their willingness to undergo TKA[10]. If unwilling, patients were asked to provide a reason(s) including, I am a caregiver; I don't have anyone to care for me; I am afraid of making my condition worse; I believe there are still other options available for me; and other (there was a text-box to specify this response).

Patients were also asked a global rating of knee pain question, "considering all ways knee pain and arthritis affects you, how are you doing today?" This question was rated on a Likert-type scale between 0 – 10 (0 = very good; 10 = very poor)[11]. A global pain score was used instead of other pain measures (i.e. WOMAC pain score) because of the perceived clinical utility of asking a single question[7].

Next, patients were asked a Patient Acceptable Symptom State (PASS) question. Specifically, this question asked patients if they would be satisfied with the state of their knee OA if it remained the same over the next couple of months. This question has response options of yes or no. Previous research has shown that patients with knee OA, who answer "yes" to the PASS question, have scores less than approximately 32 mm (0 – 100 mm) on both the pain visual analog scale (VAS) and the patient global assessment VAS. Furthermore, patients that answer "yes" to PASS have WOMAC function scores that are less than approximately 31 (0 – 100)[59].

Subsequently, patients were asked to indicate whether they had undergone any radiological tests for their study knee within the past year (i.e. X-ray, MRI, MRI (arthrogram), CT scan, ultrasound, or other). X-rays completed on the day of the appointment at University Hospital were not considered. Given that efficiency may be related to the number of required points-of-contact, we wondered whether patients were aware of the results of their radiological tests and could therefore provide this information to the web-based system thereby avoiding the need to also interface with a clinician. Therefore, one new item we added asked patients to specify the results of radiological tests: mild/moderate OA, severe OA, or unknown.

Finally, we asked patients to indicate whether they had received any of the following treatments for their knee OA: physical therapy, massage therapy, chiropractic therapy, acupuncture therapy, or injections. We asked patients that received injections to indicate if they received corticosteroid and/or non-steroid injections.

4.3.2 Surgical consultation form

Following consultation with consenting patients, attending surgeons were asked to complete a form that detailed the outcome of the consultation. Specifically, these forms tracked: the date of the consultation, the date of the referral, the name of the referring doctor, and the name of the orthopaedic surgeon that saw the patient. Furthermore, this form tracked if patients received x-rays by their referring physician. If x-rays were done, surgeons were asked if they were the appropriate or preferred views.

The surgeon was also asked whether the patient was appropriate for TKA. If patients were appropriate, surgeons were asked to triage the patient as a late referral, timely referral or early referral. If the surgeon felt that the patient should have been referred sooner the patient was classified as a late referral. Reasons for classifying the patient as a late referral included, advanced OA and symptoms for a long duration.

If the surgeon rated the patient as a timely referral the surgeon was then asked whether the patient was booked for TKA. If the patient was not booked for surgery, surgeons were asked to provide an explanation (patient did not want TKA, patient had too many co-morbidities, or other). The surgeon rated the patient as an early referral if they felt that the referral was premature: OA was not sufficiently advanced, patient age, patient occupation, patient expectations, insufficient symptoms, lack of sufficient conservative treatment, patient is more appropriate for a sports orthopaedic surgeon or other specialist.

If the surgeon felt the patient was inappropriately referred, surgeons were asked to describe why these patients should not have been referred using one or more of the following reasons: there was not advanced OA, patient age, patient occupation, patient expectations, misdiagnosis, insufficient symptoms, lack of sufficient conservative treatment, patient is more appropriate for sports or other.

4.4 Sample size calculation

The sample size needed for this validation study was estimated using the following formula from Peduzzi, Concato, Feinstein, and Holford (1995): $N = (10 \times k)/p$, where k represented the number of independent predictors and p was the proportion of inappropriate referrals found by Churchill et al. (2015) in a previous internal study ($p = 0.45$). Given that we included 7 independent predictors, we required approximately 160 patients. We recruited 204 patients to ensure that the study was sufficiently powered.

4.5 Statistical analysis

We used the following steps to validate the predictors of appropriate referral to TKA, as identified by Churchill et al. (2015):

1. We used SPSS Statistics software, version 22, to construct a logistic regression model using the enter method of selection[60] with the following identified predictors: age, willingness to undergo TKA, global rating of pain, PASS question, and tried injections. The dependent variable in their analysis was appropriateness of the referral (appropriate versus inappropriate). Using the same criteria as Churchill et al. (2015) we classified patients as appropriate referrals if they were booked for TKA or if they were a late referral as indicated by the surgeon on the surgical consultation form. All other classifications on this form were considered inappropriate referrals[7].

2. We calculated the tolerance, the Studentized residual, the leverage, and the dbeta for the validation model.

3. We compared the adjusted ORs in the validation model with the adjusted ORs in the original model. We also compared the sensitivity, the specificity, the Hosmer and Lemeshow goodness-of-fit, and the Nagelkerke R^2 values between the two models. Furthermore, we used the output from the 2 x 2 classification tables of the observed and predicted outcomes (i.e. appropriate versus inappropriate) to compare the overall percentage of correctly predicted outcomes between the two models. Note that Churchill et al. (2015) split their sample into a training group (n = 203) and a test group (n = 203) for their analysis. We used Churchill et al. (2015) full sample size (n = 406) for all analyses involving the original model.

4. We then used the syntax of the original logistic regression model to develop predicted probabilities of outcomes for the validation dataset. We measured the agreement between these probabilities with the observed outcomes from the validation dataset using Cohen's kappa[61]. We also, calculated the overall percentage of correctly predicted outcomes, the sensitivity, and the specificity.

5. Furthermore, we computed the predicted probability of each model. We used these probabilities to construct ROC-AUC for each model, where predicted probability was our test variable and the dependent variable was our state variable. We stated that an AUC score was valid if it was within 0.05 of the original model[62].

6. Finally, we constructed three additional logistic regression models with the same set of predictors and two new items that were not included in the Churchill et al. (2015) model: tried allied health and self-reported results of radiological tests. The self-reported results of radiological tests item was dichotomized into patients that reported severe OA and those that did not. We performed these additional analyses to determine whether we could improve the original model. Two of these models contained the original predictors and one of the new items, while the third model contained the original predictors with both of the new items. Along with examining the diagnostics of each of these new models (the tolerance statistic, the Studentized residual, the leverage, and the dbeta), we examined the Hosmer and Lemeshow goodness-of-fit, and the Nagelkere R^2 values for these new models. We also evaluated their overall percentage of correctly predicted outcomes, their sensitivity, and their specificity.

Chapter 5

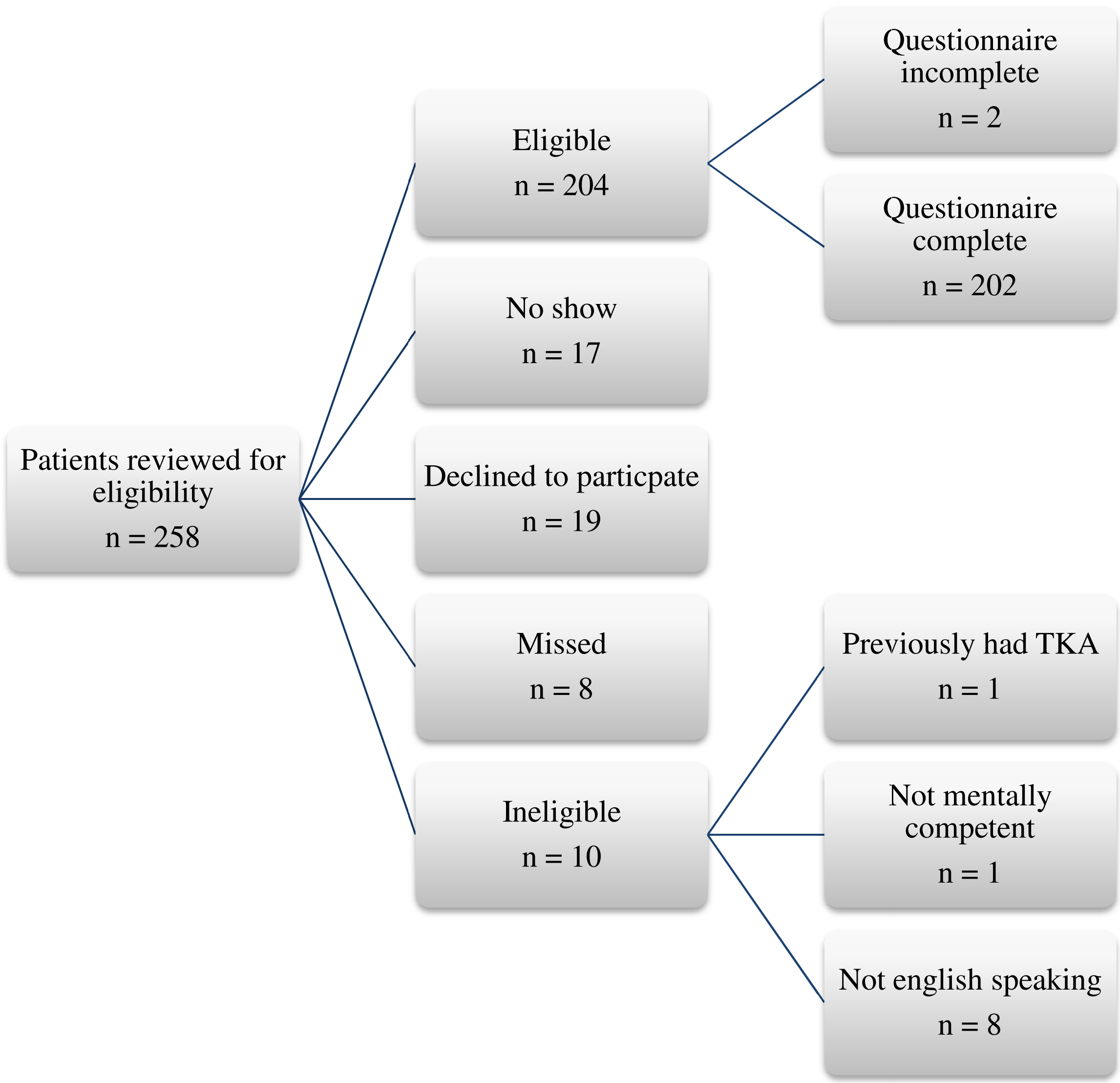
5 Results

Two hundred and fifty-eight patients were screened for eligibility. Two hundred and four patients were eligible to participate and 202 of these completed the questionnaire in its entirety. Nineteen patients declined to participate, 17 patients did not show up for their appointment at the clinic, eight potential patients were missed for recruitment, and ten patients were ineligible to participate. Patients were considered ineligible, if they: could not speak English (n = 8), were not mentally competent (n = 1), or previously had a TKA (n = 1) (see Figure 1). The average age of the 202 patients that completed the questionnaire was 64 (11) years. Of these 202 patients, 118 were female (see Table 1).

Table 1: Participant demographics

Characteristics	Eligible and completed questionnaire (n = 202)	Eligible and started questionnaire (n = 2)	Declined to participate (n = 19)	Ineligible (n = 10)
Age at consultation (mean, SD)	64 (11) years	59 (1) years	71 (9)	65 (12)
Gender (number female, % female)	118 (58.4%)	1 (50%)	11 (57.8%)	7 (70%)

Figure 1: Participant movement



5.1 Appropriateness

Eighty-four patients were classified as inappropriate referrals (41.6%). Table 2 provides a breakdown of the reasons why patients were classified as inappropriate referrals. It is important to note that some patients had multiple reasons for being inappropriate referrals (i.e. the patient had insufficient symptoms and also a lack of advanced OA). The "other" reasons why patients were inappropriate referrals included: referred to a surgeon closer to their home (n = 1); requires MRI to evaluate trochlea changes (n = 1); needs to be referred for their toe (n = 1); requires lab results to test for infection (n = 1); and requires spinal surgery (n = 1). Of the 118 appropriate referrals (58.4%), only two patients were classified as late referrals. Both of these patients had advanced arthritis with symptoms for at least one and a half years.

Table 2: Inappropriate referrals

Patient does not want a knee replacement (priority 2)	33
Lack of advanced OA	17
Too young	2
Insufficient symptoms	15
Not enough conservative treatment	21
More appropriate for a sports orthopaedic surgeon or other specialist.	8
Misdiagnosis	4
Other	5

5.2 Model diagnostics

The tolerance statistic calculated for each predictor was greater than 0.2 (see Table 3), indicating that collinearity was not a problem in the validation model. None of the Studentized residuals calculated in our model yielded a score less than negative three or greater than positive three, thus, it appears that all of the cases in our model were adequately fit. All of the dbeta values were less than one indicating that individual cases did not influence the regression coefficients more than they should have[63]. Menard (2002) specified that leverage values should be examined if they were "several times" greater than the expected value. The expected leverage value ((k + 1)/n) [63] was 0.030. There were only three cases with large leverage values relative to the expected value (case one = 0.14, case two = 0.14, case three = 0.12). Upon closer examination, these cases were kept in the model because they had dbeta values that were less than one[63].

Table 3: Model collinearity

Predictor	Tolerance
Age	0.96
Willingness to Undergo TKA	0.91
Global Rating of Pain	0.82
PASS	0.83
Tried Injections	0.92

5.3 Odds ratios

The ORs for the predictors in the validation model were comparable to those in the original model (see Table 4 and 5). Similar to the original model, the validation model reported the highest OR for willingness to undergo TKA. Patients that were willing to undergo TKA were almost four times more likely to be classified as appropriate referrals by the surgeon. Patients that answered ‘yes’ to the PASS question were about 50% less likely to be considered appropriate referrals. Patients that tried injections were about one and a half times more likely to be classified appropriate referrals. Finally, for each incremental increase on the global rating of pain scale, patients were approximately 40% more likely to be classified as an appropriate referral.

In the original model, the sensitivity was 0.83 and the specificity was 0.56. In the validation model, the sensitivity was 0.84 and the specificity was 0.52. The Hosmer and Lemeshow goodness-of-fit and the Nagelkerke R^2 values for both models are presented in Table 6. Each model had a non-significant Hosmer and Lemeshow statistic indicating that they both had a good model fit. However, the Nagelkerke R^2 values in both models appear to show a weak relationship between the predictors and the dependent variable.

Using a cut point of 0.50 for predicting appropriateness, both models correctly predicted approximately 70% of the outcomes (Original Model = 71.2%; Validation Model = 70.8%).

Table 4: Original model

Predictor	Odds Ratio	95% Confidence Interval	P-Value
Age	1.04	1.01, 1.06	<0.01
Willingness to Undergo TKA	5.37	2.55, 11.31	<0.01
Global Rating of Pain	1.23	1.11, 1.36	<0.01
PASS	0.38	0.22, 0.65	<0.01
Tried Injections	1.70	1.07, 2.67	0.02

Table 5: Validation model

Predictor	Odds Ratio	95% Confidence Interval	P-Value
Age	1.04	1.00, 1.07	0.03
Willingness to Undergo TKA	3.88	1.62, 9.28	<0.01
Global Rating of Pain	1.39	1.16, 1.65	<0.01
PASS	0.46	0.23, 0.95	0.04
Tried Injections	1.57	0.81, 3.04	0.19

Table 6: Hosmer and Lemeshow and Nagelkerke R^2 values

Model	Hosmer and Lemeshow χ^2_{8df} *(p-value)*	Nagelkerke R^2 *(range = 0 – 1)*
Original	9.87 (0.27)	0.30
Validation	11.34 (0.18)	0.35
Validation + Tried Allied Health	11.31 (0.19)	0.35
Validation + Self-Reported Results of Radiological Tests	11.66 (0.17)	0.36
Validation + Tried Allied Health + Self-Reported Results of Radiological Tests	10.68 (0.22)	0.36

5.4 Agreement

There was fair agreement (Cohen's kappa = 0.34, p =< 0.001) between the observed outcomes in the validation dataset and their predicted outcomes from the original model's syntax[64]. The sensitivity and specificity for these observed and predicted outcomes were 0.88 and 0.44, respectively. Furthermore, the overall percentage of correctly predicted outcomes was 70%.

5.5 ROC – AUC

The ROC curves constructed for the original model and the validation model are presented in Figure 2 and Figure 3, respectively. The AUC for the original model was 0.78 (95% CI 0.74 – 0.83, p =< 0.001) and the AUC for the validation model was 0.81 (95% CI 0.75 – 0.87, p =<0.001). This difference in AUC values, which is less than 0.05, validates the original model[62].

Figure 2: ROC curve - original model

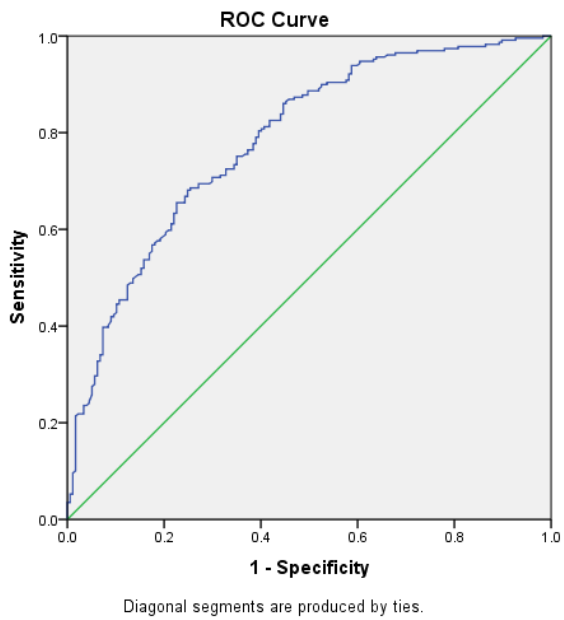
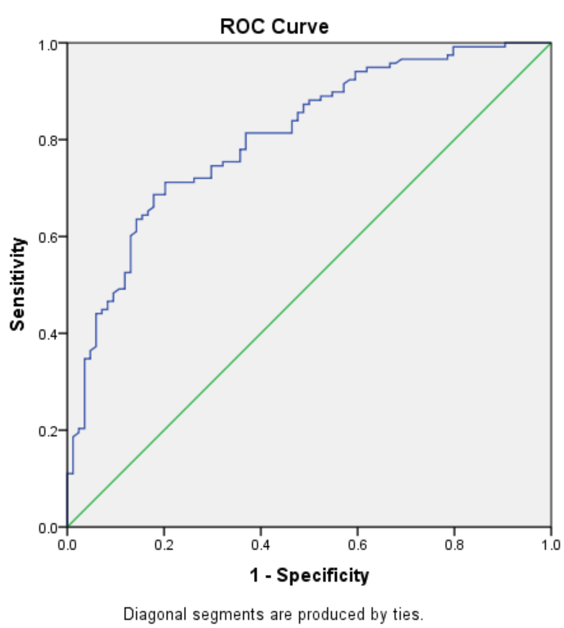


Figure 3: ROC curve - validation model



5.6 New models

One hundred and nineteen patients reported that they had tried allied health (i.e. physical therapy, massage therapy, chiropractic therapy, or acupuncture therapy). The first new model included the original predictors and the tried allied health item (see Table 7). This new item was not significant (p => 0.20) and did not confound the other predictors in the model. Collinearity between predictors, the model fit and the Nagelkerke R^2 statistic were not affected by the addition of this item (see Table 6). None of the Studentized residuals were less than negative three or greater than positive three and all of the dbeta values were less than one. There were three cases with large leverage values relative to the expected value. The overall percentage of correctly predicted outcomes from this model was 70.8%. The sensitivity and specificity were 0.84 and 0.52, respectively.

One hundred and twenty-eight patients did not know the results of previous radiological tests. Of the 74 who knew the results of their radiological tests, 45 claimed that the results indicated severe OA. The second model included the original predictors and the self-reported results of radiological tests item (see Table 8). This new item was significant (p =< 0.20) and its OR indicated that patients who self-reported that previous radiological tests noted severe OA were approximately twice as likely to be appropriate referrals. However, the addition of this new item resulted in tried injections becoming a non-significant predictor (p => 0.20). Collinearity between predictors, the model fit and the Nagelkerke R^2 statistic were not affected by the addition of this item (see Table 6). None of the Studentized residuals were less than negative three or greater than positive three and all of the dbeta values were less than one. There were three cases with large leverage values relative to the expected value. The overall percentage of correctly predicted outcomes from this model was 71.8%. The sensitivity and specificity were 0.84 and 0.55, respectively.

The third and final new model included the original predictors, the tried allied health item, and the self-reported results of radiological tests item (see Table 9). The tried allied health and the tried injections items were not significant (p => 0.20) in this model, while the rest of the original predictors and the self-reported results of the radiological tests item were significant (p =< 0.20). Once again, collinearity between predictors, the model fit and the Nagelkerke R^2 were not considerably affected by the addition of these new items (see Table 6). None of the Studentized residuals were less than negative three or greater than positive three and all of the dbeta values were less than one. There were three cases with large leverage values relative to the expected value. The overall percentage of correctly predicted outcomes from this model was 71.8%. The sensitivity and specificity were 0.84 and 0.55, respectively.

Table 7: Validation + tried allied health

Predictor	Odds Ratio	95% Confidence Interval	P-Value	Tolerance
Age	1.04	1.00, 1.07	0.03	0.95
Willingness to Undergo TKA	3.89	1.62, 9.34	0.00	0.91
Global Rating of Pain	1.39	1.16, 1.65	0.00	0.82
PASS	0.46	0.23, 0.95	0.04	0.83
Tried Injections	1.57	0.80, 3.07	0.19	0.92
Tried Allied Health	0.97	0.50, 1.90	0.94	0.98

Table 8: Validation model + self-reported results of radiological tests

Predictor	Odds Ratio	95% Confidence Interval	P-Value	Tolerance
Age	1.04	1.01, 1.07	0.02	0.94
Willingness to	3.95	1.64, 9.50	0.00	0.91

Undergo TKA				
Global Rating of Pain	1.36	1.14, 1.62	0.00	0.81
PASS	0.52	0.25, 1.07	0.07	0.80
Tried Injections	1.50	0.77, 2.94	0.24	0.92
Self-Reported Results of Radiological Tests	2.08	0.84, 5.16	0.12	0.90

Table 9: Validation model + tried allied health + self-reported results of radiological tests

Predictor	Odds Ratio	95% Confidence Interval	P-Value	Tolerance
Age	1.04	1.01, 1.07	0.02	0.94
Willingness to Undergo TKA	3.96	1.64, 9.58	0.00	0.91
Global Rating of Pain	1.36	1.14, 1.62	0.00	0.81
PASS	0.52	0.25, 1.07	0.07	0.80
Tried Injections	1.51	0.77, 2.96	0.23	0.91
Tried Allied Health	0.95	0.48, 1.87	0.88	0.97

Self-Reported Results of Radiological Tests	2.08	0.84, 5.18	0.11	0.89

Chapter 6

6 Discussion

The purpose of this study was to validate a statistical model, constructed by Churchill et al. (2015) that identified five patient-reported predictors of appropriate referral to TKA surgeons. The rate of inappropriate referrals in the validation study (41.6%) was slightly less than the rate found by Churchill et al. (2015) in the original study (44.8%). Validation model diagnostics did not reveal any miscoded data or flaws to model design. We found that all of the identified predictors from the original model were significant in our validation model. Furthermore, the parameters (i.e. odds ratios) and the fit (i.e. Hosmer and Lemeshow and Nagelkerke R^2 estimates) were similar between the two models.

We also felt that it was important to evaluate the discriminative abilities of the two models by comparing their respective ROC-AUC values. Discrimination refers to a model's ability to differentiate individuals with and without the outcome of interest[65]. More specifically, the AUC refers to the probability that the model will assign a higher probability of the outcome to a randomly selected individual with the outcome than a randomly selected individual without the outcome[66]. Others have used an AUC within 0.05 between original and validation model to declare the models similar[62]. We found a difference of 0.03 between our two models further strengthening the support of the original model; both models have comparable discriminative abilities and they are both similarly calibrated or fitted.

The agreement between the predicted outcome (appropriate referral or not) produced by the original model and the observed outcomes in the validation dataset, is low. At first glance, this would appear to reduce the certainty about the model. However, the overall percentage of correctly predicted outcomes for these observed and predicted outcomes was relatively high (70%); an apparent contradiction with our low kappa value. In fact, Feinstein and Cicchetti (1990) [67] described a paradox that occurs when there are imbalances in the marginal totals within the 2 x 2 classification tables used to construct the Kappa statistic. These authors recommend reporting the individual values for positive and negative agreement, along with the kappa value, to improve the understanding of the results[68]. Positive and negative agreement is analogous to sensitivity and specificity[68]. The original model's predictions demonstrate a high sensitivity, 0.88, and a low specificity, 0.44, with the observed outcomes in the validation dataset. Churchill et al. (2015) acknowledged the importance of greater sensitivity (i.e. the chances that an appropriate referral is classified as such) for these prediction models; we would rather risk accepting patients that are inappropriate referrals than risk rejecting patients that are appropriate referrals. Diagnostic tests (or discriminative models) with a high sensitivity are excellent at ruling out the disease (truly an inappropriate referral) if you have a negative test result (model predicts that the referral is inappropriate).

Hosmer and Lemeshow (2004) argue that pseudo R^2 estimates (i.e. Nagelkerke R^2) should not be included when presenting the results of a fitted and completed logistic regression model. This pseudo R^2 statistic is an approximation of the coefficient of determination (R^2) and its values tend to be low, which is troublesome for readers that are used to evaluating larger R^2 values in linear regression[69,70]. However, Hosmer and Lemeshow (2004) suggest that pseudo R^2 estimates may be useful early in the logistic regression model building process to compare preliminary models. Therefore, we thought it was appropriate to include Nagelkerke R^2 estimates for each of the models we analyzed and compared. All of our R^2 estimates were <0.40, which essentially indicated that less than 40% of the variance in each models' dependent variable was explained by the predictors[69].

Similar to Churchill et al. (2015), our study was limited by the highly specific clinic and cohort that we worked with. Since, the majority of the patients referred to this clinic are consulted primarily for joint replacement, either THA or TKA, it may be difficult to apply this model to a practice that sees a wider variety of orthopaedic injuries or afflictions. Future research should evaluate the effectiveness of this type of prediction model in other orthopaedic clinics and settings.

Furthermore, at this time we are uncertain about the applicability of this model outside this catchment area. It is possible that a population with greater cultural and socioeconomic variability will interpret the patient-reported questions differently and since these questions are used to construct the independent variables this may add variability to each predictor changing the relative contribution to the model across different regions. It is also possible that surgeons classify appropriateness of referral differently, which could be explained by practice preference and experience.

In practice, this model will help to improve the time patients wait for first consult ("wait one") by enhancing patient and physician education regarding TKA appropriateness. Its possible that increasing the proportion of appropriate referrals will increase the length of time patients wait for surgery ("wait two"). Nevertheless, if patients entering wait two have better preoperative health because they have exhausted all the necessary conservative treatment options and experienced a shorter wait one, then they should also have better postoperative outcomes[51].

In an attempt to improve the original model, we added two new variables (tried allied health and self-reported results of radiological tests). The tried allied health variable was not a significant predictor when included in the model, however it may be beneficial to modify its response options to reflect specific interventions rather than professions. Specifically, it may have been more suitable to ask patients about specific conservative modalities (i.e. land-based exercises, aquatic-based exercises, strength training, etc.) [26] that have been recommended in the literature. Patients' self-reported results of radiological tests was a significant predictor and in fact, produced the second strongest contribution when included. Although the addition of patient-reported radiographic severity resulted in the tried injections variable to become non-significant, it did slightly improve the specificity, the Nagelkerke R^2 values, and the percentage of correctly predicted outcomes for the entire model. This is a crucial finding to the development of the guided referral system because it may help reduce the number of points-of-contact in the referral process; specifically remove the need to require input from both the patient and their family physician. Finally, given that the accuracy or overall percentage of correctly predicted outcomes for this model is moderate, we suggest that future research should examine and evaluate additional predictors of appropriate referral to TKA.

As previously stated by Churchill et al. 2015, the validation of the original model reinforces its clinical utility and applicability to a primary care setting. Specifically, this model will assist with the development of a guided-referral system and educational tools that can be used in practice by general practitioners and patients with knee OA.

Chapter 7

7 Conclusion

We are able to correctly predict 70% of incoming referrals as either appropriate or inappropriate using patient-reported responses to five questions in an arthroplasty clinic in London, Ontario. Future work should look at expanding the applicability of this model to other regions and spectrums of practice.

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hpad-V-tXPSeqAM70rq_Zi9N5tGjM5IMOb64fBbdD0aggUYxyCxCEZGYNRoKWDcEJoqYVWIo0yLZMQuJGxSa2NTKSYVdKhmjgGpZmxJilc2D0kW2ghpEghFUwfEQoi0zFkkABWrUKkhXvMSpBWS1Qv7ZDz5VXKR89l7urZBGXqEA12yKVftnxUq3fkzAuco9KQsyUeTIaVTFGHXODKrjHyeO2RJ6TlYlxYc31OyeZ0PDNnFYz5Al8U7Ww. doi: 10.1177/001316446002000104.

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Appendices

Appendix A: Ethics approval form

Western Research

Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Robert Giffin
File Number: 103374
Review Level: Delegated
Approved Local Adult Participants: 1000
Approved Local Minor Participants: 0
Protocol Title: Predicting outcome of surgical consultation for TKA and HTO
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: April 15, 2013 **Expiry Date:** September 30, 2013
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Instruments	Form for orthopaedic surgeon to fill out after surgical consultation for HTO with study participants.	
Instruments	Form for orthopaedic surgeon to fill out after surgical consultation for TKA with study participants	
Western University Protocol		2012/12/30
Instruments	Revised forms for the online survey	2013/01/30
Revised Letter of Information & Consent	Revised LOI FKSMC clean	2013/04/14
Revised Letter of Information & Consent	Revised LOI LHSC clean	2013/04/14
Amendment	Response to REB Comments	2013/04/09

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the

Ethics Officer to Contact for Further Information

Janice Sutherland [illegible]	[illegible]	Shantel Walcott [illegible]

This is an official document. Please retain the original in your files.

Western University, Research, Support Services Bldg., Rm. 5150
London, ON Canada N6A 3K7 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/services/ethics

Appendix B: Letter of information

London Health Sciences Centre

Caring for You. Innovating for the World.®

Title of Research: Predicting outcome of surgical consultation for TKA and HTO

Principal Investigators:
Dr. Robert Giffin
Dr. Steven MacDonald
Co-investigators:
Dr. Douglas Naudie
Dr. James McAuley
Dr. James Howard 5
Dr. Richard McCalden
Dr. Brent Lanting
Dr. Ted Vasarhelyi

The purpose of this letter is to provide you with the information you require to make an informed decision about participating in this research.

You are being invited to participate in a study to investigate the predictors of the need for surgery. We are asking you to take part because you have been referred for a surgical consultation for total knee arthroplasty (TKA).

If you agree to participate, you will be asked to complete an online survey detailing information about yourself and your knee problem such as: demographics, willingness to undergo surgery, arthritis health, medication information, and various knee-related self report measures. The online survey is expected to take 5 minutes of your time. 1000 patients are expected to participate in this study. Completion of survey indicates consent to participate.

<u>Compensation:</u>
There are no costs to participating in this study.

<u>Risks:</u>
There are no known risks to your participation in this study. Participation is voluntary. You may refuse to participate, refuse to answer any questions or discontinue the survey at any time with no effect on your future care. Should you choose to discontinue the survey, we will keep the data you have contributed to that point. If you choose not to participate, you will receive the usual care provided by your current health care provider at LHSC.

<u>Benefits:</u> There are no known benefits to your for participating in this study; however, participation may benefit society as the ability to offer appointments and surgery to patents in need of surgery in a timely manner can improve access to surgeries, like TKA and HTO that are in high demand.

Version date: 10/10/14 Initials_______ 1 of 2

Confidentiality:
All information collected will be kept in strict confidence. Upon agreeing to participate in this study, you will be assigned a unique number that will be used for all your information and data collection. Data that is collected will be username and password protected and stored on a server located in Montreal, Quebec. The company that houses the database is a professional company with extremely high standards of physical and virtual security (Netelligent). It is important to understand that despite these protections, there continues to be the risk of unintentional release of information. The study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

If you have any questions about your surgery, please contact your orthopaedic surgeon. If you have any questions about this research, please contact the research assistant Samuel Mulian at or the principal investigator Dr. Robert Giffin

If you have any questions about your rights as a study participant, please contact Dr. David Hill, Scientific Director, Lawson Health Research institute at

Completion of the questionnaire indicates your consent to participate.

☐Yes I would like to participate and begin the online survey.

☐Yes, I would like to receive a copy of the study results once the study has been published.

Sincerely,
Dr. Steven MacDonald, MD, FRCSC
Dr. Robert Giffin, MD, FRCSC
Dr. Douglas Naudie, MD, FRCSC
Dr. James McAuley, MD, FRCSC
Dr. James Howard, MD, MSc, FRCSC
Dr. Richard McCalden, MD, FRCSC
Dr. Brent Lanting, MD, FRCSC
Dr. Edward Vasarhelyi, MD, FRCSC
Laura Churchill, MSc Candidate

Appendix C: Incoming patient questionnaire

IPC - Incoming Patient Characteristics

New Consultation

1. What is your age today (in years)? ______________________

2. What is your sex? ○ Male ○ Female

3. Willingness to undergo TKA

4. Global rating of knee pain

5. PASS question

6. Radiological Tests - Please indicate which tests you have undergone on your study knee in the past year. DO NOT INCLUDE XRAYS DONE TODAY FOR THIS APPOINTMENT

☐ X-ray

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

☐ MRI

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

☐ MRI (arthrogram)

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

☐ CT scan

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

☐ Ultrasound

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

☐ Other ____________________

What were the results? ○ Mild/Moderate Osteoarthritis ○ Severe Osteoarthritis ○ Unknown

7. Have you tried any of the following allied health options?

☐ Physical Therapy

☐ Massage Therapy

☐ Chiropractic Therapy

☐ Acupuncture

☐ Other ____________________

8. Have you ever had an injection into your study knee? ○ Yes ○ No

What type of injection(s) have you received? (Check all that apply)

☐ Corticosteroid

☐ Non-steroid

Appendix D: Surgical consultation form

IPC - Incoming Patient Characteristics

Surgical Consultation Form

Date of Visit: ☐☐☐☐-☐☐-☐☐
YYYY MM DD

Date of Referral: ☐☐☐☐-☐☐-☐☐
YYYY MM DD

PID ____________________

Name of referring clinician: ____________________ Please specify:
____

Name of completing surgeon: ____________

1. Did this patient have x-rays done that were ordered by the referring physician?
○ Yes ○ No ○ Unknown

If yes, did the series of x-rays include the preferred views (i.e. appropriate weight-bearing films)? ○ Yes ○ No ○ Unknown

Outcome of consultation:

2. Based on looking at the patients radiograph is this patient appropriate for TKA?

A) ○ Yes, this patient is **appropriate**, I would triage them in the following way:

○ Priority-rating 1: The surgical consult for this patient should have occurred **sooner**

Please provide reasons:
☐ Patient's arthritis has been advanced for a long time with symptoms
☐ Other: ____________________

○ Priority-rating 2: The surgical consult for this patient was at the **appropriate** time

Is this patient being booked for surgery?

- ◯ Yes
- ◯ No — Please explain
  - ☐ Patient not desiring of surgical intervention
  - ☐ Too many Comorbidities
  - ☐ Other: (explain) ______________________

○ Priority-rating 3: The surgical consult for this patient could have **waited**

- ☐ Lack of advanced arthritis
- ☐ Patient age
- ☐ Patient occupation
- ☐ Patient expectations
- ☐ Insufficient symptoms
- ☐ Patient has not had sufficient conservative management (e.g. PT, injection, etc)
- ☐ Patient is perhaps more appropriate for sports
  - ○ Yes ○ No Are you referring this patient to sports (e.g. for an HTO or scope)?
- ☐ Other: (explain) ____________________

B) ○ No, this patient should **not have been referred for arthroplasty at this time**

Why?

- ☐ Lack of advanced arthritis
- ☐ Patient age
- ☐ Patient occupation
- ☐ Patient expectations
- ☐ Misdiagnosis (alternative cause for patientâ€™s symptoms i.e. back pain)
- ☐ Insufficient symptoms
- ☐ Patient has not had sufficient conservative management (e.g. PT, injection, etc)
- ☐ Patient is perhaps more appropriate for sports
  - ○ Yes ○ No Are you referring this patient to sports (e.g. for an HTO or scope)?
- ☐ Other: (explain) ____________________

Curriculum Vitae

Name:	Samuel Joseph Malian
Post-secondary Education and Degrees:	University of Windsor Windsor, Ontario, Canada 2008-2012 B.H.K. (Conferred "With Great Distinction").
Honours and Awards:	President's Honour Roll – University of Windsor 2008-2009, 2009-2010, 2010-2011, 2011-2012 Renewable Entrance Scholarship – University of Windsor 2008-2009, 2009-2010, 2010-2011, 2011-2012 Canadian Interuniversity Sport (CIS) Academic All-Canadian - University of Windsor – 2008-2009, 2009-2010, 2010-2011, 2011-2012 William Hunter Jr. Memorial Scholarship – University of Windsor 2010, 2011 Michael W. Ayris Memorial Award – University of Windsor 2012 Province of Ontario Graduate Scholarship 2013-2014, 2014-2015 (Declined) Canadian Institutes of Health Research (CIHR) Canada Graduate Scholarship – Masters 2014-2015
Related Work Experience:	Research Assistant – Children's Hospital of Michigan - Retrospective data collection from the hospital's electronic medical records. September 2012 – April 2013 Research Assistant – Western University – Recruit patients for a hip arthroscopy registry. January 2014 – February 2015 Research Assistant – Western University – Help test the functional outcomes of patients receiving a total hip

arthroplasty from either a direct anterior or a direct lateral approach.
May 2014 – February 2015

Conferences: Arora R, Saraiya S, Thomas RL, Malian S, Kannikeswaran N. Post tonsillectomy hemorrhage: Who needs intervention? This abstract was presented at the 2013 Society for Ear, Nose, and Throat Advances in Children (SENTAC) meeting in Long Beach, California.

Publications: Churchill L, Malian S, Chesworth BM, Bryant D, MacDonald SJ, Giffin JR. A large proportion of patients referred for total knee Replacements are inappropriate: A prospective cohort study. 2015. Submitted for publication to *Clinical Orthopaedics and Related Research*.