DEVELOPMENT OF A DECISION SUPPORT MODEL FOR POST-OPERATIVE MANAGEMENT OF PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY: A PILOT STUDY FOR MODEL DERIVATION AND FACE VALIDATION

By

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A CAPSTONE PROJECT

Presented to the Department of Medical Informatics & Clinical Epidemiology
and the Oregon Health & Science University
School of Medicine
in partial fulfillment of
the requirements for the degree of

Master of Biomedical Informatics

December 2016

School of Medicine

Oregon Health & Science University

CERTIFICATE OF APPROVAL

This is to certify that the Capstone Project of

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has been approved

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Acknowledgements

First and foremost, I thank God for the blessing of being able to pursue this degree and for opening new doors in my professional development. Additionally, without the support of my wife Lori and sons Zach, Ephrem and Bo, I would have never been able to accomplish all of this. I thank that faculty of the OHSU Department of Medical Informatics and Clinical Epidemiology. They have inspired me to stretch myself and their expertise and commitment to learning has been infectious. Specifically, I thank my advisor Dr. Karen Eden for her guidance and support through this capstone process. I thank Therapeutic Associates Inc. for encouraging me to pursue this degree, for financial support, and for giving me opportunities and latitude to put what I learned in this program into practice for the company. Finally, I thank my fellow students in the program. The cooperative learning has been exceptional and I have learned a great deal from all of the interactions.

Abstract

As reimbursement for healthcare procedures changes to a bundled payment model, providers will need to alter the way they handle patient care. Specifically, managing populations of patients and stratifying patients into groups requiring varying levels of care will be increasingly important. The purpose of this study was to create, and preliminarily validate, a clinical decision support (CDS) model for the post-operative management of patients following total knee arthroplasty (TKA).

This study began with a review of the current literature related to factors associated with poor post-operative outcomes and medical complications following TKA. An initial model was created, which was validated and refined through qualitative interviews. Interviewees included two orthopedic surgeons, a rheumatologist who acts as a medical director of an insurance payer, and a primary care physician.

A preliminary model was created using only post-operative factors that divided patients into three classifications. These classifications included low, medium, and high touch groups related to the amount of additional oversight required due to elevated risk of either poor post-operative outcomes or medical complications. Low-touch patients require only the standard post-operative care. Medium-touch patients require additional monitoring to ensure patients are making appropriate post-operative progress. High-touch patients require additional medical management to address medical comorbidities and monitor for early signs of complications.

The preliminary model was altered following the interviews. Most notably, pre-operative factors were added to identify patients who should be medically optimized prior to attempting surgery. Additionally, a second level of pre-operative factors was added for surgeons to engage the patient in focused shared decision making. This was based upon an identified risk of poor post-operative prognosis due to the presence of modifiable medical risk factors. In general, the interviewees agreed the list of factors were appropriate and comprehensive. The ordering of factor was modified and a few factors slightly modified with added detail following the interviews.

The surgeons felt the model is simple enough to utilize in their practices, but they also felt that the added cost and administrative burden needed to gather the required information for the model, was not justified at this time. They felt that as bundled payment enters the surgeon reimbursement model in the near future, the need for tools such as this model would increase. Additionally, the surgeons did not agree if the model was best administered on paper, or if an electronic application would be a better option.

While the physicians felt the model is potentially useful, more development is warranted. Further work should focus on developing screening questionnaires that can efficiently gather the requisite information for the model, and implementation strategies to ensure use of the model can be introduced into practices with minimal added cost and effort for practices. Even with the most precise decision support model, it is these last two factors that will maximize uptake of the tool by practitioners.

List of Commonly Used Acronyms

BMI – Body Mass Index

CAD – Coronary Artery Disease

CCJR – Comprehensive Care for Joint Replacement

CDS – Clinical Decision Support

CMS – Centers for Medicare & Medicaid Services

CVA - Cerebrovascular Accident

DVT – Deep Vein Thrombosis

EHR – Electronic Health Record

KOOS – Knee injury and Osteoarthritis Outcome Score

MI – Myocardial Infarction

OR – Odds Ratio

PRO – Patient Reported Outcomes

TE – Thromboembolisim

THA – Total Hip Arthroplasty

TKA – Total Knee Arthroplasty

WOMAC – Western Ontario and McMaster Universities Arthritis Index

Introduction

It is undeniable that the speed of health care decision making is increasing, due to the need for clinicians to make decisions on patient care, reimbursement, regulatory requirements, and more, all while seeing an increasing volume of patients for less time, and less frequently. Because the use of electronic health records (EHRs) is now nearly ubiquitous in healthcare, the use of clinical decision support (CDS) imbedded within the EHR presents a promising solution to help positively influence workflows that promote wise-action by the clinician.(1) This paper presents a CDS model for stratified management of patients undergoing total knee arthroplasty (TKA), based upon the current best evidence and validated through stakeholder interviews.

Decision models such as these are important as regulatory pressures and mandates from insurance payers place an increased emphasis on maximizing quality and reducing negative events like hospital readmissions and post-operative complications. Add to this the increasing trend of moving financial risk for caring for patients onto providers, and a situation is emerging where population health management by frontline providers is increasing in prevalence. Clinical providers need tools to get information, required for sound management of populations with the right level of direct patient interaction, at the point of care. Too much unnecessary direct interaction with patients causes inefficiencies, while too little contact causes increased risk for adverse events. Providers need tools to understand what amount of direct interaction a given patient may require for an optimal outcome at the lowest cost, while minimizing the risk of adverse events.

The application of best evidence into CDS systems can be coupled with clinical decision making algorithms, in order to give scientifically based recommendations, complete with projected costs and probabilities of success for given decisions. Further, computerized CDS systems can assist in managing large populations and perform syndromic surveillance with fewer human resources required.(2) This paper serves as an important first step to develop one such CDS model for managing populations of individuals undergoing TKA procedures for use by both surgeons and general practitioners. Additionally, this initial rule was vetted via interviews with key stakeholders, to establish preliminary face validity.

Impact of Total Knee Arthroplasty (TKA) on the US Economy

TKA procedures are occurring at an increasing rate in the US, with 719,000 procedures performed in 2010 alone.(3) Additionally, it is projected that by 2030 the number of TKA procedures will increase by 673% up to 3.48 million procedures per year, with the cost of managing total hip arthroplasty (THA) and TKA patients exceeding $50 billion annually. (4, 5) By comparison, the cost for both primary lower extremity (hip and knee) total joint replacement surgeries and revision surgeries was only $5 billion in the US in 2006.(5) Because of the burden total joint replacement procedures will increasingly place on the US healthcare system, various stakeholders are looking for ways to slow the rising costs. One such solution that has shown preliminary benefits is the use of bundled payment reimbursement strategies, where clinicians are incentivized to increase efficiency, while at the same time controlling quality, in an attempt to prevent readmissions. (6) Regardless of the reimbursement structures, it is clear that tools to help providers manage populations, in an attempt to improve outcomes, are needed.

One of the benefits of the recent initiation of bundled joint replacement (BJR) models is the identification of a stratified pathway most non-complicated patient cases follow, pre-surgery through post-surgical management.(7) Figure 1 represents the course of care for a patient from 30 days pre surgery through 90 days post-surgery. This work flow has served as the baseline for quality improvement and efficiency improvement projects. One background study defined the cost of managing an uncomplicated TKA patient to one major academic medical center to manage the entire BJR ranging between $9,816 and $13,319 per episode depending on the implant used.(7) Of this cost, $733 came from pre-operative and $1,642 came from post-operative management. It must be reiterated that these costs were from only one academic medical center and will be different for different regions and varying hospital types. However, this information is necessary to allow providers to negotiate reasonable bundled reimbursement rates, and can be used as a model for other regions. The model derived through this study seeks to add CDS at steps 1-5 from figure 1, to help reduce the costs incurred from adverse events experienced in the post-hospital phase of care.

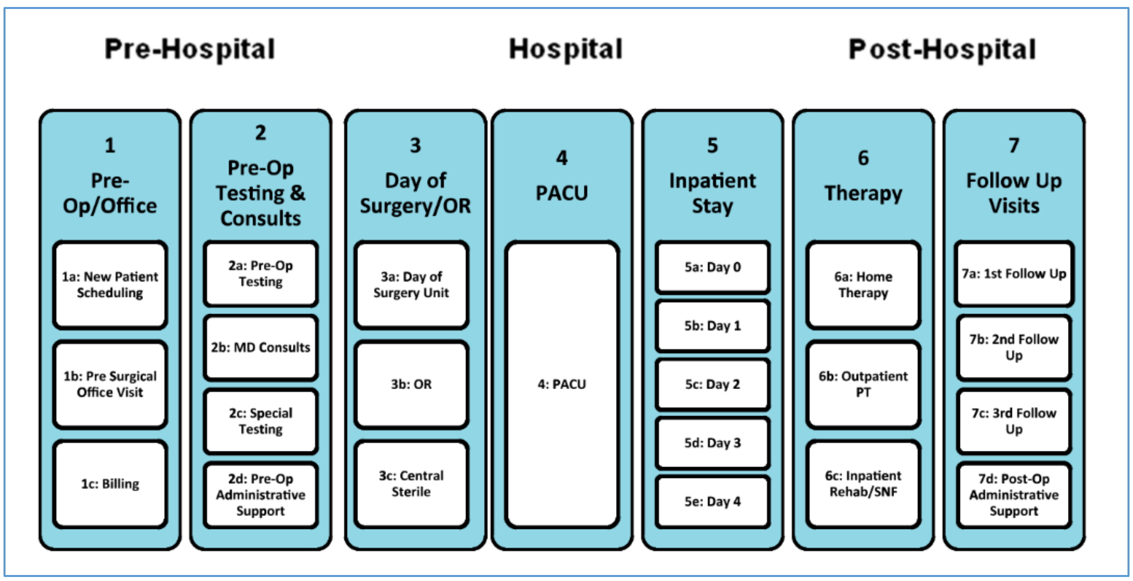

Figure 1: Management stages for patients with TKA (From DiGioia et.al.)

Methods

Literature Review

I performed a review of the literature prior to the initiation of the qualitative study portion of the project. Using Medline as the primary database, I performed the initial literature review between April and September 2016. Additionally, I utilized the Cumulative Index to Nursing and Allied Health Literature (CINAHL) to search the allied health literature. Search terms initially included concepts of total joint replacement complications, post-operative management of TKA, and regulatory issues related to TKA management. I expanded the subsequent searches based upon the returned results and content of the reviewed studies. The first criterion of study fit was article titles, followed by a review of the abstract. I then reviewed those articles with abstracts fitting the topic criteria, in full text. The literature review was not meant to be exhaustive, nor a formal systematic review, but rather sought to be adequately broad and deep to provide a basis for the initial CDS model design understanding the model would be later refined.

Initial Decision Model Derivation

I derived the model from themes emerging out of the review of the literature. I did not intend the model to be predictive, but rather informative. Specifically, the model was meant to help clinicians identify patient specific and surgical factors, related to an increased risk of either poor surgical outcomes or post-operative medical complications. Additionally, the objective of the model was to classify patients into either low, medium or high touch cohorts.

I defined a low-touch cohort as a group of patients that requires no additional oversight than usual care, based upon a low risk of poor outcomes or complications. Second, I defined a medium-touch group as a cohort of patients requiring some additional oversight or detailed management since they were at a higher risk of poor post-operative outcomes. Finally, I defined the high-touch cohort as patients needing an additional level of direct oversight given their high risk for post-operative complications. It was beyond the scope of this project to further subgroup patients by specific complications. I left the initial management level of each cohort purposely vague, in order to allow for further refinement from the outcome of the stakeholder interview analysis.

Qualitative Study

The qualitative study portion of the project consisted of semi-structured, in person and phone interviews with key stakeholders involved in the management of patients undergoing

TKA. I utilized a stratified sample of two orthopedic surgeons, one internal medicine physician, and one insurance payer medical director for interviews.

The study received Institutional Review Board (IRB) exemption from the Oregon Health and Science University IRB prior to recruitment for the interviews. I created a field guide (Appendix A) to structure the interviews. The interviews were semi-structured in nature, utilizing a grounded theory approach, and as such were modified based upon the responses of the interviewees and the results of previous interviews. I audio recorded the interviews and took field jottings during each interview. On the same day of the interview, I transcribed these field jottings into formal field notes. Additionally, within 48 hours of the interview, I transcribed the audio recordings.

Interview transcriptions were coded and combined with field notes using the qualitative research software QDA Miner Lite application (Motreal, QC Canada). I used this application to define and systematically track themes. I used these themes, in addition to direct recommendations and critiques from the interviews, to refine the decision model.

Model Refinement

The initial model was refined based upon themes discovered from the interviews. Feedback related to tool utility and validity influenced the refinement. An iterative approach was used where recommendations from one interviewee was tested in subsequent interviews.

Results

Review of the Literature

Post-operative Complications

Complications following knee surgery occur following a myriad of procedures. The American College of Surgeons began the National Surgical Quality Improvement Program (ACS-

NSQUIP) to study quality improvement strategies following orthopedic surgical procedures. Through the use of a unifying patient registry, NSQUIP found that TKA had the second highest incidence of post-surgical complications (following only hip fracture repair) of all orthopedic procedures.(8) TKA accounted for 18% of the adverse events and 6% of the excess hospital-stay days, among all of the procedures studied. Based upon the results of this analysis and the number of TKA procedures performed annually, the ACS suggested quality studies for TKA procedures to help lower the adverse event rate and lower the excess hospital-stay days, are needed. In attempting to identify areas for quality improvement, the cost of surgical complications, variations in procedures, and patient comorbidities, among other things must also be factored into the quality improvement equations.

TKA Management and Risk Factor Overview

Influence of surgical procedure on post-operative outcomes

Depending on patient condition-specific and other health factors, and patient and surgeon preference, patients can undergo either a full joint or hemi-arthroplasty. Patients undergoing hemi-arthroplasty procedures have significantly shorter length of hospitalization and lower 30-day readmission rates than patients undergoing total joint procedures.(9) In this study, TKA patients had 30-day readmission rates nearly twice that of hemi-arthroplasty patients.

Beyond the choice of full versus hemi arthroplasty, the choice of the implant influences complication rates as well. While the overall incidence of post-operative complications does not differ between total and uni-compartmental knee replacement, the incidence of deep vein thrombosis is higher for total knee replacement (1.50% vs. 0.5%).(10) Additionally the use of computer-guided surgeries is increasing, due to the claim of better outcomes and lower complication rates. One systematic review showed superior implant alignment for computer-guided minimally invasive procedures compared to other minimally invasive procedures.(11) However, this study pointed out that there has not been shown to be any better post-operative outcomes for the computer-guided procedures and no long-term studies have been published.

Not surprisingly, the proficiency of the surgeon and facility influence post-operative prognosis. One study in Nordic countries found that hospitals performing > 100 TKAs per year had a significantly reduced post-operative revision rate at 2, 5, 10 and 15 years than those hospitals performing < 100 procedure per year.(12) Unfortunately, no studies exist relating 30 or 90-day readmission rate to hospital TKA procedure volume. Relative to physician's experience level, one systematic review found that patients of physicians performing a low volume of TKA procedures had higher rates of post-operative infections, thromboembolism, and worse functional outcomes than patients of physicians performing a high number of procedures.(13)

Patient-specific risk factors for poor post-operative outcomes

Beyond the non-complicated patient managed by the process in figure 1, and in addition to the influence of the surgical procedure, a multitude of patient-specific risk factors have been identified that place a patient at an elevated risk for post-surgical complications, or simply poorer post-operative outcomes. Of these factors, those studied the most include obesity, depression, diabetes, impaired renal function, age, smoking status, chronic narcotic use, race, and socioeconomic status. Additionally, a task force of the Patient Reported Outcomes Summit (a meeting of various stakeholders in the management of TKA patients) recommended adding back pain, pain in the non-operative leg, and general health-risk status.(14)

Of the recently studied risk factors, three were predictive of delayed functional recovery and increased length of hospital stay.(15) Specifically higher age (OR 1.08), female sex (OR 2.05), and elevated BMI (OR 1.13) all predicted delayed functional recovery and increased length of hospital stay. Not surprisingly, significantly elevated BMI (>35) is associated with higher post-surgical complications (including infection, return to OR, and increased hospital length of stay) compared to patients with BMI within normal ranges (BMI < 30).(16)

Diabetes and impaired kidney function are also intuitively associated with poorer post-surgical outcomes. In patients undergoing TKA, receiving pre-surgical renal dialysis is predictive of inpatient mortality (OR 3.31), and post-surgical complications (OR 1.86). Diabetes was shown to be related to persistent pain (OR 8.0) 1-2 years after surgery.(17) Relative to more immediate complications, diabetes also increases the risk of joint infection (OR 2.3).(18)

Of the factors that are not intuitively associated with poorer post-surgical outcomes, the patient's race does have an influence, although marginal.(19) Black patients were found to have significantly higher post-surgical pain and lower quality of life scores than white patients, but the clinical significance of this difference was minimal. Additionally, economically disadvantaged individuals (defined as those with an annual income < $13,000 per year) had significantly poorer post-operative functional outcomes than other patients.(20) However, this group was found to have a significantly higher proportion of black and Hispanic individuals compared to the non-economically disadvantaged group, indicating race may have played a role in the difference, which is supported by the study cited above.

Depression is another non-intuitive risk factor for poor post-surgical outcomes. However, it has been reported that approximately 12% of TKA patients have documented depression or anxiety.(21) These patients have significantly higher hospital charges, but do not have longer lengths of stay than patients without anxiety disorders or depression. Additionally, depression has been shown to be related to a greater risk of post-operative psychosis (OR 1.74), anemia (OR 1.14), infection (OR 1.33), and pulmonary embolism (OR 1.20).(22) Interestingly, this same study showed that depression was related to lower gastrointestinal (OR 0.80) and cardiac (OR 0.93) complications. Despite these elevated post-surgical risks for depressed patients, improvements (pre vs. post-surgery) in physical function and overall patient satisfaction are similar for depressed and non-depressed patients.(22) Additionally, depressed patients in another study obtained greater quality of life improvements in some domains at one year, than non-depressed patients, despite the elevated complication risks seen in the previous study.(23) However, pre-operative pain catastrophizing (as measured by a pain catastrophizing scale of ≥ 16) had significantly poorer quality of life outcomes than patients without elevated pain catastrophization (OR 2.67).(24)

Higher pre-surgical quality of life (as measured by the EuroQol) is negatively associated with patients reporting less than clinically meaningful changes in pain stiffness and function (as measured by the Western Ontario and McMasters University Arthritis Index [WOMAC]) (OR 0.21 – 0.3). However, patients with higher pre-surgical function (as measured by the WOMAC) were more likely to report less than clinically meaningful post-operative patient satisfaction with pain, stiffness and function improvements (OR 1.05-1.06).(25) Additionally and not surprisingly, longer hospital length of stay was positively associated with patients reporting less than clinically meaningful changes in pain, stiffness, and function (OR 1.12 -1.29).(25)

One tool has been developed that predicts a TKA patient's discharge status to home vs. rehabilitation facility based upon seven questions, with >70% accuracy.(26) This tool includes questions on age, gender, ambulatory status, use of walking aides, community support, and choice to return home after surgery. A higher score is related to discharge to home (OR 2.32).(27) However, it must be noted that patient's desire to return home after surgery was actually more predictive of actual discharge to home (OR 9.79), indicating the tool has limited utility. Several other tools to predict discharge status, hospital length of stay, risk for post-surgical status, and mortality have been derived. However either these tools were found to have low predictive ability or have not been externally validated, and thus their wide-spread use as CDS should be questioned.(28)

With nearly 50% of patients discharged home after major surgery taking opioid medications, the risk of long term dependence is great.(29) A major finding in patients with poor post-surgical outcomes is reliance on opioid medications six months following surgery. One study described a model able to predict patients at risk of continued opioid use six months after TKA.(30) This study found that only 8.2% of patients never taking opioids prior to surgery were still taking them six months following surgery. This is compared to 53.3% of patients taking opioids prior to surgery, were still taking opioids six months after surgery. Of the patients taking opioids prior to surgery, and regardless of the level of degeneration present, those taking > 60 mg morphine equivalents prior to surgery had an 80% chance of continuing use six months after surgery. There was a slight reduction in the odds of persistent opioid use if the patient reported greater overall decrease in general body pain (OR 0.72), but a reduction in knee pain did not relate to decreased prevalence of chronic opioid use. Thus, patients taking opioids (especially higher amounts) should be monitored more closely.

<u>General measures of function following TKA</u>

In addition to tools that predict post-operative outcomes, more widely-used tools have been developed and validated that simply measure patients' functional status and quality of life. These tools can be used in studies of treatment effectiveness as they have established psychometrics, and thus can be used to measure pre to post-surgical improvements. These measures include the Knee Society Knee Scoring System (KSS) , Oxford Knee Score, the Knee Osteoarthritis Outcomes Score (KOOS), and the WOMAC.(31, 32) The KSS consists of a pre-operative and a post-operative instrument that is comprised of patient demographic information, physician objective measures, and patient centric questions including pain, expectations, function, and satisfaction domains.(33) It is recommended that the KSS be administered pre-operatively and then at one month and three months post-surgery.(34) The KSS was shown to be reliable, have good construct and concurrent (compared to the KOOS and SF-12) validity, as well as good internal consistency (Cronbach's α = 0.90 for the pre-operative questionnaire and 0.95 for the post-operative questionnaire).(35)

The Oxford Knee Score was created specifically to measure function in patients following TKA. It has 12 questions related to pain and function.(36) Specifically the questions relate to pain and knee function in the four weeks preceding completion of the survey. The questionnaire has good internal consistency (Cronbach's α = 0.85), test-retest reliability (ICC 0.92), construct and concurrent validity (compared to the SF-36), and is responsive to change.(36) The previous study recommended collecting the score at pre-surgery, six and 12 months post-surgery.

The KOOS is a self-reported quality of life measure consisting of activities of daily living (ADL), knee related quality of life, and recreation/sport subscales.(37) Additionally, for the more active population, there is a physical function short form that combines components of the ADL and recreation/sport subscales.(38) The tool is shown to have good test retest reliability (ICC 0.75 for ADL, 0.86 for knee related quality of life, and 0.81 for recreation/sport), good construct and concurrent validity (compared to the SF-36), and is responsive to change.(37) This study also proposed collecting the KOOS pre-surgery and three, six and 12 months post-surgery. The minimal detectable change (MDC) ranges from 5-12 points depending on the subscale used.(39) Specifically, in post-TKA patients the concurrent validity is weaker in the recreation/sport subscale than the other subscales, indicating the constructs measured in the KOOS recreation/sport subscales may be slightly different than those measured by other sport/recreation quality of life measures to which the KOOS was compared.(40, 41)

The WOMAC was developed in 1982 and has undergone multiple revisions over the years.(42) It measures function in patients with knee OA and contains pain, stiffness and physical function subscales. There is also a short form consisting of seven of the physical function subscale questions that has also been validated.(43) The full WOMAC has a reported minimal clinical important Change of 15 points.(44) In this study patients were asked to complete the WOMAC pre-surgery, 6 months and 24 months post-surgery.

Additional cut points have been established for the WOMAC and include: (a) pain or function change at least 50% or an absolute improvement of 20 points of function, or at least 2 of the following: (a) at least 20% improvement in pain and an absolute change of 10 points, (b) at least 20% change in function and an absolute change of 10 points, and (c) at least 20% global assessment of change and 10 points of absolute change.(45) These values are meaningful when using the WOMAC in clinical efficacy trials. Additionally, a clinical predication rule has been established that can be used to identify patients at a high risk of poor functional outcomes (As defined by patients in the lowest WOMAC score quintile at 6 months) 6 months after TKA (F).(46) 5 questions on the WOMAC showed an ability to identify these high risk patients with good validity (sensitivity 82.1%, specificity 71.7%) and + likelihood ratio 2.90 and – likelihood ratio 0.25.

There has been more clinical research on and use of the WOMAC in clinical trials than the other measures. This makes it potentially a preferred tool for measuring function in patients with knee OA.(32) However, the KOOS is geared towards a more active population than the other measures and used in both surgical and non-surgical populations. The Oxford Knee Score was specifically developed for patients undergoing TKA. Additionally, the WOMAC score can be derived from the KOOS score based upon concurrent validation work.(47)

Impact of post-surgical complications and recommended prevention strategies

Joint infection has been reported in between 0.7and 1.0% and superficial infection in 2.9% of TKA patients.(48-50). These infections result in approximately 4 days longer hospital stay and 1.52 times the hospital cost than non-infected joints.(49) Additionally, approximately 25% of these infections go undetected in the inpatient setting.(50) Factors related to an elevated risk of perioperative infection include rheumatoid arthritis (OR 2.99), elevated BMI (OR 1.50), poor preoperative health as measured by the American Society of Anesthesiologists (ASA) risk score (ASA-3 OR = 3.89, ASA-4 OR = 13.97), and greater preoperative dysfunction as measured by the KSS pain score (OR 3.60).(50) Use of prophylactic suppression antibiotics post-surgery has been shown to increase the 5-year survivability from 41.1% to 68.5% (HR 0.63).(51)

In addition to perioperative infection, postoperative pulmonary complications (PPC) can also occur. These complications include respiratory failure, pneumonia, pleural effusion, atelectasis, pneumothorax, and aspiration pneumonitis. PPCs constitute the primary reason for ICU admissions following arthroplasty surgeries.(52) These complications have been reported in 45.9% of patients following TKA.(53) Smoking prior to surgery was strongly associated with post-operative PPCs (OR 5.99).(53) The same article showed that post-operative hypoxemia was strongly associated with PPCs (OR 6.0), and post-operative blood transfusion was associated with pleural effusion (OR 2.6).

A major complication following TKA is the development of a pulmonary embolus (PE), which has been reported to occur within 30 days post-surgery in 0.5% and 90 day post-surgery in 1.24% of patients undergoing TKA or THA.(54) Four factors have been identified as predictive of developing a PE following TKA.(54) These include anemia (HR 0.7), female gender (HR 1.2), BMI > 30 (HR 1.8), and age > 70 (HR 1.7). Additionally, patients undergoing TKA are more likely to develop a PE within 90 days post-surgery than patients undergoing THA (HR 2.6). From these factors, the authors of the previous study developed a scoring system that places an individual at either a high, medium or low risk of developing a PE and has been validated on a cohort of >22,000 patients for 90 days post-surgery.

The development of a thromboembolism (TE) or deep vein thrombosis (DVT) following surgery is indirectly related to PE. While a TE/DVT may result in a PE, it may remain benign or relate to a myocardial infarction (MI) or other vascular complications including a stroke or cerebrovascular accident (CVA). TE/DVT has been reported to occur in 0.8% of patients undergoing TKA.(55, 56) Some patient specific risk factors have been shown to be predictive of developing a TE/DVT. In patients with no known history of TE/DVT age >65 years (OR 1.7), female gender (male gender OR 0.5), and Deyo-Charlson Comorbidity Index (OR 1.2) were related with an elevated 90-day post-operative TE/DVT event.(57) In patients with a known history of TE/DVT, only an elevated Deyo-Charlson Comorbidity Index was associated with an elevated 90-day post–operative TE/DVT risk (OR 1.2).

The development of cardiac complications following a TKA is often related to TE/DVT. As with TE/DVT, the 90-day risk of developing cardiac complications following a TKA is 0.8%.(56, 57) In patients with previous cardiac disease, age > 65 years (OR 4.4) and poor health as rated by ASA ≥ 3 (OR 3.0) was related with an elevated 90-day post-operative cardiac complication rate. In patients with no known previous cardiac disease, only the elevated ASA related to an elevated 90-day risk (OR 3.2). A separate study found that specific previous cardiac events including arrhythmias (OR 2.6), or previous MI, coronary artery disease, valvular disease, or congestive heart failure (OR 1.6), were related to an elevated risk of a cardiac complication during the surgical inpatient stay.(58)

Another related complication includes suffering a stroke following surgery. aAs noted above, the stroke/CVA may be related to a concurrent TE/DVT, or may be hemorrhagic. One study found a 30-day post-operative stroke rate or 0.2% for TKA and THA patients, with no significant difference in the incidence rate between the two procedures.(59) The one year mortality rate for these patients suffering a stroke/CVA was 25%. Many of the factors predictive of a post-operative stroke/CVA were related to prior heart disease. These included prior MI (OR 3.47), prior coronary artery bypass graft (CABG) (OR 4.27), coronary artery disease (CAD) (OR 4.9), history of CVA (OR 6.67) or stroke (OR 7.57), valvular disease or arrhythmia (OR 4.3), and non-coronary cardiac disease (OR 4.0). Additional patient factors included multiple comorbidities as measured by the Deyo-Charlson Index (OR 3.57), and age > 75 yrs (OR 1.14). Surgical factors, predictive of a post-operative CVA included general vs local anesthesia (OR 4.95), urgent surgery (OR 5.89), heart arrhythmia during surgery (OR 6.75), and post-operative blood transfusion (OR 1.47).(59)

Additionally, Perioperative fractures can occur after TKA, with femoral supracondylar fractures occurring most frequently and reported with an incidence between 0.3% to 2.5% of TKA patients.(60) The majority of these fractures occur as the result of trauma from falls, but certain factors have been cited as predisposing individuals to perioperative fractures. These risk-factors include patients with vascular compromise, osteoporosis, joint ankylosis, previous revision TKA, prolonged steroid use, rheumatoid arthritis, advanced age, female gender and neurological compromise.(61). No specific odds ratios have been given in the literature for these risk factors. It must also be noted that many of these risk factors are correlated with an elevated risk of falling which is the primary cause of a fracture following TKA. In addition to supracondylar fractures, proximal tibial fractures occur at a rate of 0.5 – 1.7%.(61) Additionally, depending on the study cited, patellar fractures can occur with an incidence of 0.2 – 21% when the patellar surface is resurfaced along with the TKA, and 0.05% when the patella is not resurfaced.

Specific Rehabilitation Following TKA

There is limited research giving guidance to physicians as to the proper discharge disposition for patients. Rehabilitation is common following TKA despite conflicting reports of the long term efficacy.(62-64) while there is general consensus that post-operative rehabilitation improves short term outcomes, disagreement exists with respect to long-term effects. Additionally, there is little to no guidance as to whether a specific form of rehabilitation (inpatient, outpatient, or home-based) shows different levels of outcomes.   Some studies suggest that home based therapy yields similar results to clinic based therapy.(65) However, there is weak evidence that inpatient and outpatient therapies are preferred for certain patient groups.(66)

Despite anecdotal evidence that, due to increased attention, formal interaction with rehabilitation professionals can improve function and decrease complications, no studies have explored this topic formally. One study did show that when patients were matched for age, sex and ASA scores, patients discharged to skilled nursing facilities had significantly higher readmission rates than patients discharged home.(67) A separate study also showed that beginning in home therapy the day after discharge, in addition to preoperative education and exercise, resulted in shorter length of stay, skilled nursing facility discharge dispositions, and improved function than patients not receiving this accelerated rehabilitation.(68) Unfortunately, this study did not examine the effect of early home care in isolation.

Regulatory Case for Managing Post-Surgical Complication

The days of the pure, fee-for-service reimbursement model for healthcare are numbered.(69) Risk sharing models of reimbursement where payer and provider share in the risks of patient care through reimbursement negotiations are on the rise. In these models, providers are held accountable for the cost and quality of the care delivered via the structure of a bundled payment of reimbursement.(70) The fact the nearly 5% of patients undergoing TKA have a hospital readmission within 30 days, calls into question the quality of the care prior to discharge.(71) Bundled payment models hold the providers accountable for poor post-operative outcomes.

The Department of Health and Human Services (HHS) has implemented a pilot program specific to THA and TKA known as the Comprehensive Care for Joint Replacement (CCJR model) to study a bundled payment model of reimbursement for these procedures. This model fits with the HHS initiative of having at least 30% of Medicare fee-for service payments come from alternative payment models by 2016 and 50% by 2018.(72) In this model, hospitals are paid a bundle to cover a discounted portion of all care related for TKA for 90-days following surgery. Hospitals are held to specific quality standards but also receive no additional reimbursement should a patient require re-hospitalization within that 90-day window. The ability of the hospital to recoup the discounted fee is based upon hospital and provider quality rankings, 90-day readmission rates, complication rates, and patient satisfaction. Additionally, an extra 0.03% of fees can be recouped if hospitals voluntarily report patient reported outcomes measures, such as the KOOS, among other measures. Appendix C outlines the voluntary patient reported outcome CCJR quality reporting standards.

All outpatient, imaging and prescription costs are paid not by Medicare, but from the hospital out of the bundle paid by Medicare. In this model, the hospital performing the surgery holds accountability for the total patient care, as opposed to the traditional fee-for service model where the payer is financially accountable for that care. This model makes population surveillance post-surgery very important for surgeons and hospital systems.

Initial Model Design

Based on the literature review, I created an initial CDS model to guide the management of patients undergoing TKA (Figure 2). This model included seven factors leading to a designation of medium-touch, and 18 factors leading to a designation of high-touch. Whether a patient did or did not meet the criteria for medium touch had no bearing on whether he/she had the follow-up screen performed for determination of a high-touch classification. If a patient did not have any of the factors leading to medium touch, but did have one or more of the factors in the follow-up screen, he/she was designated high-touch. Only if a patient had none of the initial, and no follow up screen factors, was he/she designated low-touch. Socioeconomic status and race were left off of the factors predicting poor post-surgical outcomes in the initial model, due to the sensitive nature of these factors and limited mention in the literature, but were tested in the qualitative portion of the study for possible inclusion in the final model.

It was acknowledged from the literature that, based upon the reported odds ratios, some factors were more predictive of a poor outcome or a medical complication than other factors. However, since the purpose of this model was not to be prescriptive, the factors were left unweighted. The choice to keep these factors unweighted was validated through specific interview questions

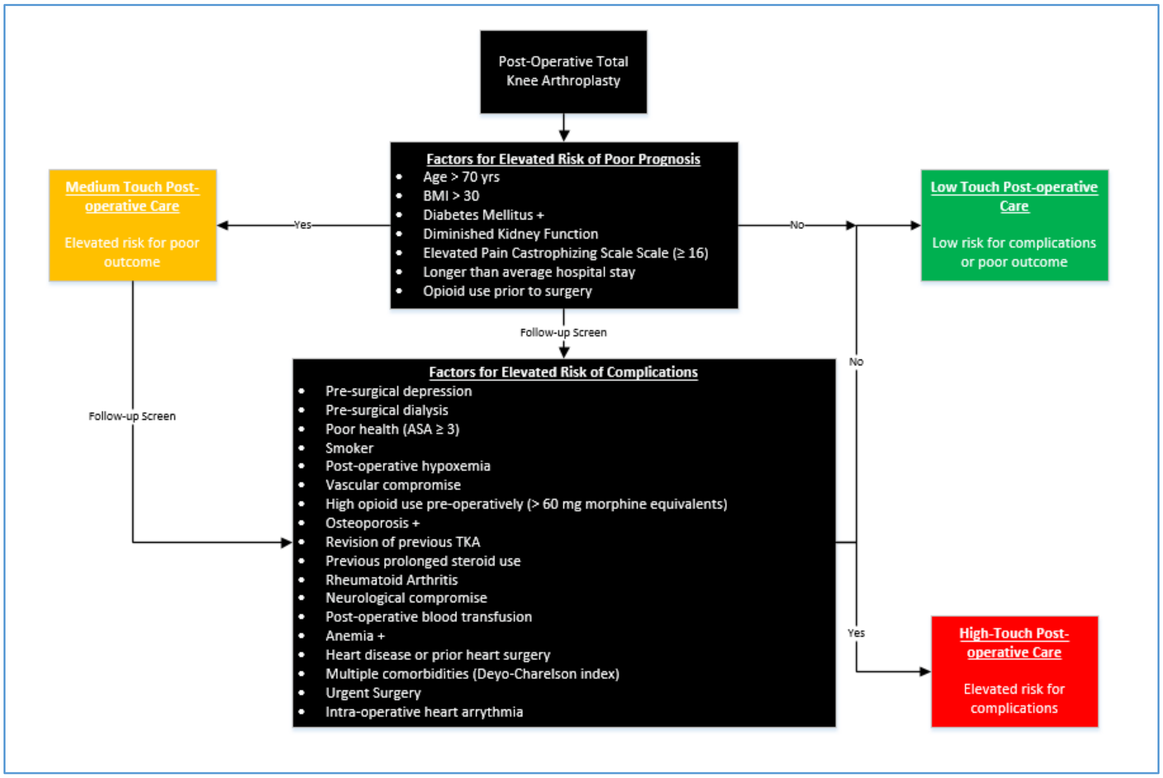

Figure 2: Initial Decision Model

Once the decision model was created, it became evident that it offered no specific guidance as to what factors related to which potential negative outcomes. For this reason, the factors are listed in Appendix 2, under the complication to which they relate, and are ordered from highest to lowest odds ratio. While not specifically part of the initial CDS model, the factor specific weighting had the potential of providing more condition specific decision support to providers. Because of this fact, the factor breakdown and related odds ratios were also presented to interviewees for validation and determination if they should be included in the final model.

Qualitative Study Results

Interviewee Characteristics

Four interviews were performed over one month, from early-October to mid-November 2016. The first interviewee (MD1) is a retired rheumatologist with 35 years of clinical practice. In addition to his role as a rheumatologist, he possess a Master's of Public Health degree and served as Medical Director of a Medicare replacement insurance provider for five years. Additionally, he consults extensively on clinical quality improvement and value. The second interviewee (MD2) is an orthopedic surgeon, specializing in TKA and THA in private practice for ten years. He performs approximately 600 TKA procedures per year. He operates at a hospital currently in a CCJR pilot. The first model modification was made after this interview.

The third interviewee (MD3) is also an orthopedic surgeon in private practice with 15 years of experience, exclusively performing THA and TKAs in private practice. He performs approximately 500 TKA procedures per year. The final physician (MD4) practices in internal medicine with fifteen years of experience. He refers many of his patients for surgical consults for TKA and THA, but has no current experience with bundled payment models.

Results from Qualitative Analysis

<u>Model Validation</u>

From the payer's perspective, there is little need for a model like this in the bundled payment arrangement. MD1 said it best when he said of bundles shifting responsibility, "However that is what the bundle does in that the payer says, 'Hey we are going to pay you 'X' and you figure out the best way to take care of all of those risk factors yourself'". MD2 described this arrangement in his current CCJR participation this way, "[CMS] is not really trying to change care delivery with CCJR. They are just trying to save money."

Both payer and provider interviewees agreed that one of the issues of a bundled payment system is that sicker patients for whom surgery is potentially indicated, will not be offered surgery because of the increased risk of added expense to manage them. They all agreed, that to prevent this, bundles must be risk-stratified. This risk stratification negotiating, that would precede any bundled payment arrangement, could use the factors in this model as discussion points. After price negotiation, the payer could care less if the tool was used by providers, because the risk of dealing with complications is shifted to the provider. However, the payer is still responsible for ensuring quality, in order to prevent under-utilization on the part of a provider seeking to retain an additional portion of the bundle, but not delivering a quality outcome.

Model Utility

MD2, MD3, and MD4 are all practicing clinicians, and were asked how they foresaw using such a tool in their practices. They agreed that an individual in the practice would need to be assigned the task of collecting all of the surveys and conveying that synthesized information to the physician. MD3 pointed out that the patients could not reliably complete all of the necessary information without assistance from the clinic staff. However, MD2 made the point that the added cost of that individual has no financial return for the practice, and as such would be a low priority, until these measures are mandated or bundled payment models more widely implemented.

When asked if an electronic version of the CDS tool would be more beneficial than paper, MD2 felt that paper is likely better. He did not feel the EHR provides much added benefit to his current practice. However, this physician admittedly did not use much of his current EHR's functionality. By contrast, MD3 felt the model needed to be integrated into the EHR. Unlike MD2, he currently uses his EHR intimately in his practice including some CDS. All of the interviewees agreed that it would be a challenge to engage patients with this process, since they are already inundated with paperwork in their visits, and thus an electronic interface for the patient could be helpful.

Model Urgency

Both orthopedic surgeons knew a great deal about the CCJR, but only MD2 is currently involved in CCJR reimbursement systems. However, reimbursement for physician services currently lies outside of the bundled payment model. Thus, urgency for adoption of a model like this is low for surgeons. However, all interviewees agreed that in the next five to ten years, physician services will likely be pulled into these bundles, so surgeons will need to find ways to more efficiently manage patients. It is likely not until then that the cost of hiring someone in their practices to administer the CDS process will be justified.

As mentioned earlier, all of the physicians also agreed that as the bundled payment systems come to physicians, there will be impetus to “cherry pick” patients by refusing to perform surgery on high risk patients. Because of this, only those patients with the best chance of a complication free recovery, would be offered surgery. They all echoed that TKA is an elective procedure, and as such is not mandated, nor medically necessary. Additionally MD2 shared that any bundled payment restrictions will likely be “gamed”. He used the example of the current 90 day, all charge bundle for the CCJR. If a non-urgent procedure needs to be performed on a patient, it would be easy to simply push that out until day 91 and receive full reimbursement. Both surgeons stressed the need to do what is right for the patient, but also voiced frustration at the reimbursement models and arbitrary restrictions on timelines.

Both orthopedic surgeons voiced difficulties with communicating medical concerns between the surgeon and primary care provider (PCP). MD3 voiced specific concern that PCPs could not handle all of the necessary pre-surgical care in a bundled model, because they are not trained in perioperative screening of patients. He recommended having specific clearinghouses of specially trained physicians who would perform the medical screening and medical optimization intervention. He felt these either needed to be anesthesiologists or specially trained general practitioners. He also felt these physicians needed to either be affiliated with or at least closely aligned with the surgeons, due to the communication needs for managing these higher risk patients. MD4 described a pre-operative clinic in his integrated delivery system that does just this. These physicians are solely tasked with ensuring patients are appropriate for surgery. MD3 and MD4 agreed that such a specialty practice would be more difficult for private practice surgeons to affiliate with than surgeons in large integrated delivery systems.

Model Adjustment Recommendations

The biggest theme that came from all four interviews was that many of the factors listed in the high-touch criteria are actually seen as factors often precluding surgery by orthopedists. This theme was noted from the first two interviews with MD1 and MD2. Nine factors were identified by MD2 as factors leading to identification of poor surgical candidates. Appendix D presents the final model and will be described further in the next section. These nine factors (seen in the Factors for Poor Surgical Candidate box) were validated for use as pre-surgical screening factors through interviews with MD3 and MD4.

MDs 1,2 and 3 agreed these factors were appropriate for pre-surgical screening, and better suited there than in a post-surgical screening. MD4 agreed he typically screens for these factors prior to referral to the surgeon, but admitted that he misses these diagnoses on occasion, which often results in the patient being referred back to him for medical management prior to surgery. Much conversation revolved around the current broken referral system where primary care providers refer patients for surgery, who medically should not be having elective surgery. The surgeons felt that they lack sound criterion to refuse surgery, and they must send the patient back to the primary care provider for further medical management. Rather, they felt they make arbitrary cutoffs. HbA1c, BMI, mental health factors, and smoking were all given as factors with poorly defined cut-off criteria. All interviewees felt tools including these pre-surgical screening factors would assist in this inter-specialty communication.

MD1 and MD2 expressed a need for shared decision making with the patients when the high potential for a poor post-surgical outcome was identified prior to surgery. MD2 identified five factors (seen in Appendix D in the Factors Potentially Precluding Surgery box) that he felt warranted conversation with the patient prior to surgery, coupled with education of the patient on the risks of poor outcomes, and surgical alternatives. Specifically, it was felt that patients with these factors often need more information in order to make an informed decision about the appropriateness of surgery. This assertion was validated in the interviews with MD3 and MD4. This is not to say that shared decision making should not be used with all patients prior to surgery, but rather that patients with these specific factors must have additional education and screening because of the specific risk factors identified.

Of additional note is the fact that all four interviewees stressed the significant impact patients' impaired communication ability had on post-operative outcomes.   They noted that race, socioeconomic status and educational level are all related. However, clinicians often have difficulty considering these factors due to societal influences. MD2 lent clarity when he said, "It is politically charged stuff, so nobody wants to deal with it because they don't want to be called the racist or whatever. But it really comes down to a communication issue". The other interviewees echoed this sentiment and validated that the focus on communication challenges, whatever the cause, are heavily related to poor post-surgical outcomes and should be included in the model. MD3 did point out that language deficit was a slightly less problematic issue if appropriate interpreters were available, but if a proper interpreter was not present, could influence post-operative prognosis.

Despite none of the interview questions directly relating to screening tools, MD1, MD2, and MD3 all spent considerable time talking about the need for screening tools for patients as a method for identifying the presence of the model factors. MD1 pointed out that often the presence of medical comorbidities are undiagnosed, or at least not reported to a surgeon. Both MD1 and 2 discussed the need for preliminary, simple screeners that raise an initial level of suspicion, and then a follow up, more in depth screening can be undertaken. MD1 felt these screeners could be used to assign appropriate pre-and post-surgical medical management. Both MD1 and MD2 agreed that any screeners provided to the patient, need to be of minimal length, simple, and preferably in an electronic format to encourage compliance. MD2 felt that realistically this could potentially top 40 questions, which he felt may be too many for the average patient. MD2 focused heavily on the patient reported outcomes (PRO) in his interview.

While MD2's reimbursement is not affected by the CCJR pilot, he does receive an incentive on his surgical fee for collecting PROs, both pre-surgery and 6 months following surgery (Outlined in Appendix C). By contrast, MD3 thought his practice collected PROs but could not say for certain. MD3 is not affiliated with any PRO incentive payment program. MD2 felt strongly that patient reported factors and PROs would be a major component of implementing the studied decision model. For this reason, the factors in Appendix C should be included in the final model to remind surgeons to collect these measures at the appropriate time.

Model Refinement

Following the interviews, the final model was altered considerably from the original form, and is listed in Appendix D. Most notably, it added a pre-surgical screen. All interviewees agreed that, while serious medical complications affect post-operative outcomes, they also agreed that waiting to manage them until after surgery, is too late. MD2 put it well when he said, "…I think if you need to change your post-operative management of many of these [factors for elevated risk of complication], you ought to have changed your preoperative management. You need to optimize the patient before thinking about surgery." The initial creation of the model was based upon post-operative management exclusively. However, it became clear through the interviews that these factors would rarely need to be managed post-operatively, because the surgeons would not have operated in the first place.

Additionally, as indicated in the qualitative analysis results above, five factors were pulled out to indicate an individual should be counseled directly on the risk of poor prognosis following surgery. Both surgeons agreed these factors would not preclude surgery, but the individual should have a more formal shared decision making and counseling session with the physician. If the physician and patient agree surgery is not a good current option, the patient should be referred for specific management of the identified factor, and surgery possibly considered at a later date. If the physician and patient agree that surgery is appropriate, the patient should be placed into the medium touch group for closer monitoring post-operatively, and potentially utilizing other healthcare providers, likely counselors or social workers, especially if mental health, depression, or anxiety issues are identified.

The impact of depression, anxiety, and mental health issues were under-appreciated in the initial model design, based solely on the literature review. Both surgeons spent considerable time discussing the negative impacts of these conditions on post-operative management. Additionally, both surgeons felt they did not have clear criteria from the literature to identify cutoff scores on screeners that they could use to identify high-risk patients. Additionally, according to MD3, physicians referring patients to surgeons for TKA rarely screen patients for these issues prior to referral. Thus, this model could be used by both surgeons and general practitioners. MD4 confirmed that currently he rarely screens for depression and anxiety prior to surgical referrals.

Other minor changes to the model included combining rheumatoid arthritis and any inflammatory arthropathy into a single factor, and moving that factor to the medium touch factors vs. the high touch group. Ostroporosis was removed from the model, since both orthopedists agreed these individuals should not be managed any differently following TKA. They do treat them differently for THA where the post-operative risk of fracture is much higher. Finally, MD3 also recommended adding poor home social support to the group at an elevated risk of poor post-surgical prognosis.

The majority of these changes to the model were made following the first two interviews with MD1 and MD2, and the alterations validated through interviews with MD3 and MD4. Both of the orthopedic surgeons agreed that adding the odds ratios and eventually an algorithm to predict a post-operative prognosis score had potential value. However, they both agreed the first step would need to be the broad classifications, and further testing of the efficacy of that classification system would be needed before moving to a predictive model. This is due to the complexity of creating such a model, surgeons not currently being accustomed to working in these sort of predictive models, and little urgency to begin using these models until the bundled payments are more regularly used by payers.

Discussion

Much of the information gleaned from the literature to create the initial model was echoed by the interviewees. Few additional risk factors were added by the interviewees despite direct questioning, indicating the original model was fairly exhaustive. However, it was clear that none of the interviewees had given formal thought to CDS tools to manage populations of TKA patients. Most physicians, and surgeons especially, currently work in the traditional single-patient focused approach to post-operative management.

Based upon the considerable time interviewees spent discussing it, anxiety and depression are major influencers of post-operative prognosis for clinicians, yet not much literature spoke to these factors. This fits with the frustrations of the surgeons that no good screening tools exist that help them accurately identify these risky patients pre-operatively. Further work on this model should emphasize this area of screening, since it has such tremendous value for the clinicians. MD2 made it clear that he would use the model extensively if it did nothing else but help him to identify these patients early, and either pull in additional mental health resources, or give him tools to communicate and help persuade these individuals to avoid surgery until their mental health issues were appropriately addressed.

Despite the physicians feeling that simple preliminary and more in depth secondary screeners need to be created to gather the needed factors in this model, it was beyond the scope of this study to create these screening tools. Future research must identify the simplest first line screeners to identify areas of further exploration, and then the specific screeners for given risk-factors identified. The problem will come in the sheer length of these tools, especially when two or three are administered concurrently. For this reason, overlap between the various screening tools should be eliminated and a new, compound tool will likely be more engaging for the patient than multiple condition specific screening tools.

Both surgeons agreed that orthopedic surgeons are not versed at managing populations of patients. They handle their patients individually, and based on the current fee-for-service reimbursement model, have no impetus to change. MDs 2, 3, and 4 indicated that surgeons in integrated delivery systems will be better prepared to deal with population health strategies, due to their inclusion into larger systems. Both surgeons agreed that simple tools like this model will be beneficial in helping them make the transition, but also agreed that this transition is still futuristic. There is currently not enough urgency for the surgeons to make this move, without a shift in reimbursement strategies.

Conclusion

The final model serves as a good first step in the development of a clinical decision support tool for managing patients following TKA. Future work in this area should involve developing workflows to engage the primary care physicians in the decision making process, improving communication loops between the orthopedists, primary care physicians and perioperative specialists, and patient questionnaire development.

All interviewees agreed that as the payment model shifts, new models of patient referral and provider communication will need to emerge. Additionally, clinical decision making processes will need to be altered with this shift in reimbursement. Starting now to refine these processes and creating tools for providers, before the mandate comes, will allow practitioners to weather the transition more efficiently.

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Appendix A: Field Interview Guide

- A grounded-theory approach will be utilized. Because of this design, questions may be altered slightly based upon the responses to the initial questions.
- Additionally, up to 2 additional interviews may be scheduled based upon expert nomination, stemming from the initial interviews
- Interview process
    1. Send interviewee copy of the model 2 weeks prior to interview
    2. On-site Introductions
    3. Provide Interviewee with Study Information Sheet describing the aims and process of the study.
    4. Ask for consent to audio record the interview
    5. Initiate recording of the interview
    6. Identify the interviewee and obtain verbal consent on the recording
    7. Take field jottings as required for detailed information or to guide future questions
- Initial Interview Questions
    1. Based upon your review of the proposed model, what is your general impression of the completeness of the model?
    2. Do you feel any significant post-surgical factors, worthy of surveillance or monitoring should be added or deleted from the model?
    3. What, if anything, does this model ad to your current post-operative management of TKA patients?
    4. Describe any similar decision support tools you use in your clinical practice
    5. What processes do you currently employ to manage populations of post-surgical patients (electronic or other systems)?
    6. Is the model presented in a clear manner that is conducive to use in clinical practice.
    7. What other recommendations do you have to improve the utility of the tool in your practice?
- Question modification
    1. Based upon the responses of the interviewee and themes presented, ask additional questions as necessary
    2. Ask clarifying questions as required
- Interview conclusion
    1. Thank interviewee for his/her time
    2. Describe the study timeline and the plan for disseminating the study results

Appendix B: Complication Factors

Infection

Poor health (ASA $\geq$ 3) (OR 3.89 for 3 and 13.97 for 4)
High pre-operative dysfunction (low KSS pain score) (OR 3.60)
Rheumatoid Arthritis (OR 2.99)
BMI > 30 (OR 1.50)
No Pre-operative antibiotic-use (HR 0.63)

Pulmonary Complications

Post-operative acute hypoxemia (OR 6.0)
Smoker (OR 5.99)
Post-operative blood transfusion (OR 2.6)

Pulmonary Embolus

BMI > 30 (OR 1.8)
Age > 70 (OR 1.7)
Female (OR 1.2)
Anemia (HR 0.7)

Thromboembolisim/DVT

Multiple comorbidities (measured by Deyo Charlson Index $\geq$ 3) (OR 1.2)
Age > 65 - If no previous TE/DVT (OR 1.7)
Female gender - if no previous TE/DVT (Male gender OR 0.5)

Cardiac event

Poor health (ASA $\geq$ 3) (OR 3.0)
Previous cardiac event (OR 1.6)
Age > 65 - if previous cardiac disease (OR 4.4)

Stroke/CVA

intra-operative heart arrhythmia (OR 6.75)
Prior CVA (OR 6.67)
Urgent surgery (OR 5.89)
General anesthesia (OR 4.95 vs. local anesthesia)
Prior MI/CABG/CAD (OR 3.47-4.9)
Heart valve disease (OR 4.3)
non-coronary cardiac disease(OR 4.0)
multiple comorbidities (OR 3.57)
Post-operative blood transfusion (OR 1.47)
Age > 75 years (OR 1.14)

Fracture(No specific OR given)

Vascular compromise

Osteoporosis

Joint ankylosis

Revision TKA

Prolonged steroid use

Rheumatoid arthritis +

Age > 70

Female

Neurological compromise

Patellar resurfacing

Appendix C: CCJR Quality Patient Reported Outcome Requirements

	Collection Timing	
Measure	**Pre-Operative**	**Post-Operative**
Date of Birth	0 - 90 days pre	270-365 post
Race	0-90 days pre	n/a
PROMIS Global Measure	0-90 days pre	270-365 post
VR -12	0-90 days pre	270-365 post
KOOS	0-90 days pre	270-365 post
BMI	0-90 days pre	n/a
Use of narcotics chronically (> 90 days)	0-90 days pre	n/a
Total Painful Joint Count	0-90 days pre	n/a
Quantified Spinal Pain	0-90 days pre	n/a
Single Item Health Literacy Screening Questionnaire	0-90 days pre	n/a

Table 1: CCJR Quality Reporting Outcomes - Produced from the CCJR rule(72)

Appendix D: Final Decision Model

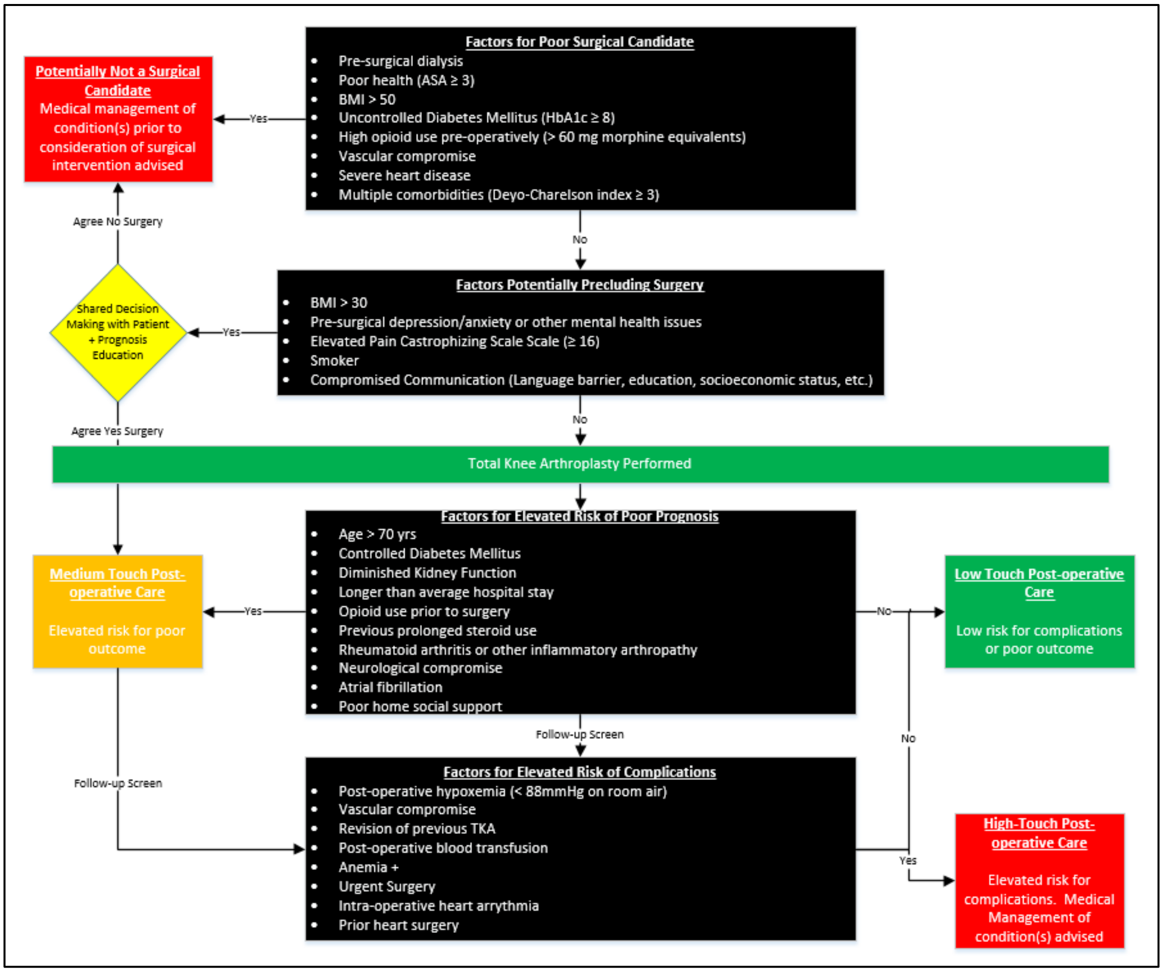

Figure 3: Final Decision Model