

Robert Bree Collaborative

Overview of Products

The Bree Collaborative has developed two products for total knee and total hip replacement (TKR/THR) surgeries:

1. *Warranty – adopted at July 18th, 2013 Bree meeting*

The Warranty defines complications and time-frames after surgery during which those complications should be attributed to the original surgery. The purpose of the Warranty is to track clinical and financial accountability for the extra care needed to diagnose, manage, and resolve those complications.

2. *Bundle – adopted at November 21st, 2013 Bree meeting*

The Bundle defines expected components of pre-operative, intra-operative, and post-operative care needed for successful TKR/THR surgery. The Bundle includes both clinical components and quality standards.

a. Clinical components:

- Documentation of disability due to osteoarthritis despite conservative therapy
- Documentation of fitness for surgery
- Repair of the osteoarthritic joint
- Post-operative care and return to function

b. Quality standards:

- Appropriateness
- Evidence-based surgery
- Rapid return to function
- Patient care experience
- Patient safety

The warranty is a stand-alone product that does not include quality standards other than accountability for complications. The bundle includes both clinical components and quality standards. The Bree Collaborative recommends that the elements of the bundle not be separated since each component is necessary to ensure the appropriateness, safety, and quality of joint replacement surgery.

Providers are responsible for gathering all of the necessary documentation to demonstrate that bundle conditions and quality standards have been met. An appeal process should be in place for cases in which a provider recommends proceeding with TKR/THR surgery for a patient who does not meet the appropriateness standards.

The Bree Collaborative will review the warranty and bundle every three years and update as needed.

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Bundle: Clinical Components for Total Knee or Total Hip Replacement Surgery

I. DISABILITY DUE TO OSTEOARTHRITIS DESPITE CONSERVATIVE THERAPY

Prior to surgery, candidates for joint replacement therapy should have clearly documented disability and evidence of osteoarthritis according to standardized radiographic criteria. Unless highly disabling osteoarthritis is evident at the time the patient first seeks medical attention, a trial of conservative therapy is appropriate.

A) Document disability

1. Document disability according to Knee Osteoarthritis Outcome Score (KOOS) or Hip Osteoarthritis Outcome Score (HOOS).
2. Document self-reported productivity loss related to usual activity (absenteeism and presenteeism).

B) Document osteoarthritis

1. Review standard x-ray of the affected joint and interpret according to Kellgren-Lawrence scale. Total joint replacement therapy generally requires a grade of 3 or 4.

C) Document conservative therapy for at least three months unless symptoms are severe and x-ray findings show advanced osteoarthritis

1. The length of time and intensity of conservative therapy will vary by patient-specific factors such as severity of symptoms and ability to engage actively in treatments such as physical therapy. The Bree Collaborative recommends patient-customized conservative treatments for at least three months, focusing on improving functionality and helping patients adapt to persisting functional limitations.
2. Trial of one or more of the following physical measures:
 - Strengthening exercises
 - Activity modification
 - Assistive devices
 - Bracing if judged appropriate
 - Weight loss, if indicated
3. Trial of one or more of the following medications:
 - Acetaminophen
 - Oral non-steroidal anti-inflammatory drugs
 - Topical non-steroidal anti-inflammatory drugs
 - Intra-articular injection of corticosteroids

D) Document failure of conservative therapy

1. Document lack of improvement in pain and/or function as indicated by re-measurement of HOOS/KOOS scores.
2. Document x-ray findings supporting need for surgery:
 - Grade 3 or 4 on Kellgren-Lawrence scale, if not previously documented

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- Avascular necrosis of subchondral bone with or without collapse
- Angular deformity of limb with threatened stress fracture
- 3. Document informed decision making *after* maximal effort and benefit of conservative treatment.

II. FITNESS FOR SURGERY

Prior to surgery, candidates for joint replacement therapy should meet minimal standards to ensure their safety and commitment to participate actively in return to function. If a provider chooses to proceed with TKR/THR surgery on a patient who does not meet these standards, then informed consent, individual review, and preauthorization are required.

A) Document requirements related to patient safety

1. Patient should meet the following minimum requirements prior to surgery:
 - Body Mass Index less than 40
 - Hemoglobin A1c less than 8% in patients with diabetes
 - Adequate peripheral circulation to ensure healing
 - Adequate nutritional status to ensure healing
 - Sufficient liver function to ensure healing
 - Control of opioid dependency, if present
 - Avoidance of smoking for at least four weeks pre-operatively
 - Absence of an active, life-limiting condition that would likely cause death before recovery from surgery
 - Absence of severe disability from a condition unrelated to osteoarthritis that would severely limit the benefits of surgery
 - Absence of dementia that would interfere with recovery – performing TKR/THR surgery for a patient with such dementia requires preauthorization, informed consent of a person with Durable Power of Attorney, and a contract with the patient's care provider

B) Document patient engagement

1. Patient must participate in Shared Decision-making with WA State-approved Decision Aid.
3. Patient must designate a personal Care Partner.¹
4. Patient and Care Partner must actively participate in the following:
 - Surgical consultation
 - Pre-operative evaluation
 - Joint replacement class and/or required surgical and anesthesia educational programs
 - In-hospital care
 - Post-operative care teaching

¹ In addition to friends, neighbors, and family members, individuals who have already had knee or hip replacement surgery have been effective Care Partners in existing programs.

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- Patient's home care and exercise program
- 5. Patient must participate in end of life planning, including completion of an Advance Directive and designation of Durable Power of Attorney.

C) Document optimal preparation for surgery

1. Perform pre-operative history, physical, and screening lab tests based on review of systems:
 - Evaluate for cardiac and pulmonary fitness
 - Obtain basic lab profile, plasma glucose, prothrombin time, complete blood count, urinalysis with culture, if indicated
 - Culture nasal passages to identify staphylococcal carrier state
 - Ensure A1c 8% or less in patients with diabetes
 - Perform x-rays of knee or hip, if not performed within previous 12 months
 - Screen for predictors of delirium
2. Obtain relevant consultations:
 - Evaluate for good dental hygiene with dental consultation as necessary
 - Refer to Anesthesia for pre-operative assessment
 - Consult Physical Therapy to instruct in strengthening of upper and lower extremities
 - Request additional consults as necessary
3. Collect patient-reported measures:
 - General health questionnaire: Patient Reported Outcomes Measurement Information System-10 (PROMIS-10)
 - HOOS/KOOS survey

III. REPAIR OF THE OSTEOARTHRITIC JOINT

An experienced surgical team should use evidence-based practices to avoid complications related to implanted hardware; prevent infection, venous thrombosis, and blood loss; manage pain while avoiding side effects; and manage pre-existing medical problems carefully.

A) General standards for a surgical team performing TKR/THR surgery

1. The surgeon must perform at least 50 joint replacements a year.
2. Members of the surgical team must have documented credentials, training and experience. The roster of the surgical team should be consistent.
3. Elective joint arthroplasty must be scheduled to begin before 5:00 pm.
4. Facilities in which surgery is performed should have policies that align with the American College of Surgeons Statement on Health Care Industry Representatives in the Operating Room.

B) Elements of optimal surgical process

1. Optimize pain management and anesthesia:

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- Use multimodal pain management format to minimize sedation and encourage early ambulation
 - Minimize use of opioids
 - Assess and manage other anesthesia-related risk factors such as sleep apnea and pulmonary hypertension
2. Avoid infection:
 - Require application of chlorhexidine skin prep by patient at bedtime and morning prior to surgery
 - Use surgical hoods or laminar flow technique with closed or limited access to operating room
 - Administer appropriate peri-operative course of antibiotics according to Centers for Medicare and Medicaid Services (CMS) guidelines set forth in the Surgical Care Improvement Project
 - Restrict use of urinary catheter to less than 48 hours
 3. Avoid bleeding and low blood pressure:
 - Administer standardized protocols using appropriate medications to limit blood loss
 - Use standardized IV fluid protocols including those implemented by RNs post-operatively with appropriate supervision and monitoring
 4. Avoid deep venous thrombosis and embolism according to CMS guidelines set forth in the Surgical Care Improvement Project.
 5. Avoid hyperglycemia:
 - Use standardized protocol to maintain optimal glucose control

C) Selection of the surgical implant

1. Providers must select an implant that has a <5% failure rate at ten years.²
2. To track outcomes, all implants must be registered with a national joint registry such as the American Joint Replacement Registry.
3. Informed consent should include the experience level of the surgeon with the device.

IV. POST-OPERATIVE CARE AND RETURN TO FUNCTION

A standard process should be in place to support the goals of avoiding post-surgical complications, ensuring rapid return to function, optimizing hospital length of stay, and avoiding unnecessary readmissions.

A) Standard process for post-operative care

² This performance standard is supported by evidence from both the Australian Orthopedic Association National Joint Replacement Registry and the National Joint Registry for England and Wales. The 2012 reports are available online: <https://aoanjrr.dmac.adelaide.edu.au/annual-reports-2012> and http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR_9th_Annual_Report_2012.pdf, respectively.

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1. Utilize a rapid recovery track to mobilize patients on the day of surgery:
 - Provide accelerated physical therapy and mobilization if regional pain control is acceptable
 - Provide a patient-oriented visual cue to record progress on functional milestones required for discharge
 - Instruct patients in home exercise, use of walking aids and precautions
 - Instruct “care partner” to assist with home exercise regimen
2. Patients that meet Medicare standards for placement in a skilled nursing facility will have their post-operative nursing and rehabilitative needs addressed.
3. Hospitalists or appropriate medical consultants will be available for consultation to assist with complex or unstable medical problems in the post-operative period.

B) Use standardized hospital discharge process aligned with Washington State Hospital Association (WSHA) toolkit

1. Arrange follow up with care team according to WSHA toolkit.
2. Evaluate social and resource barriers based on WSHA toolkit.
3. Reconcile medications.
4. Provide patient and family/caregiver education with plan of care:
 - Signs or symptoms that warrant follow up with provider
 - Guidelines for emergency care and alternatives to emergency care
 - Contact information for orthopedist and primary care provider
5. Ensure post-discharge phone call to patient by care team to check progress, with timing of call aligned with WSHA toolkit.

C) Arrange home health services

1. Provide the patient and Care Partner with information about home exercises that should be done three times daily.
2. Arrange additional home health services as necessary.

D) Schedule follow up appointments

1. Schedule return visits as appropriate.
2. Measure patient-reported functional outcomes with KOOS/HOOS instrument.
3. If opioid use exceeds six weeks, develop a formal plan for opioid management.

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GUIDANCE ABOUT BUNDLE PAYMENT CONTRACTING AND DISTRIBUTION OF PAYMENT

The method of bundle payment contracting will need to be developed as part of the discussion and negotiations between the purchaser, provider, and payer. Therefore, this section provides only general comments rather than recommend any specific models.

The time windows for this bundle will be determined in the contracting process and include all four clinical components of the bundle. The recommended time window for the bundle extends to 90-days post-operatively. Pre-operatively, the time window should include sufficient time to deliver the care necessary to meet the appropriateness standards.

Retrospective and prospective payment models can both be effective in different situations. A retrospective model may be most suitable when a number of providers or provider groups are contributing to the delivery of the bundle. A prospective model may be most suitable for situations in which 1) a budget is determined for a single provider entity delivering the entire bundle or specified components and 2) benefit design issues can be addressed.

Many entities will need to come together to operationalize TKR/THR bundle services, including the hospital, surgeon, anesthesia, and other supporting services. The Bree Collaborative is not specifying any particular process for distributing the bundle payment across those parties, but encourages the adoption of cost and reimbursement strategies that equitably allocate resources and payments.

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Bundle: Quality Standards for Total Knee or Total Hip Replacement Surgery

The provider group performing surgery must maintain or participate in a registry of all patients having first-time, single-joint total knee or total hip replacement surgery for osteoarthritis (TKR/THR patients), excluding patients with joint replacement for fracture, cancer, or inflammatory arthritis. This registry will be updated quarterly and be available for reporting to current or prospective purchasers and their health plan. It will be made available to quality organizations such as the Puget Sound Health Alliance and the Foundation for Health Care Quality.

During the first year of the bundled contract, providers will be expected to install methods to measure appropriateness, evidence-based surgery, return to function, and the patient care experience according to the standards noted below. Reporting of results will be expected to begin the second year of the contract. The only exception to this reporting requirement is that the measures of patient safety and affordability noted in section 5 below will begin the first year of the contract.

See **Appendix** for more detailed information on quality standard numerators and denominators.

1. Standards for appropriateness

These standards are intended to document patient engagement in medical decision-making and measurement of disability prior to surgery. Report:

- a. Proportion of TKR/THR patients (as defined above) receiving formal shared decision-making decision aids pre-operatively
- b. Proportion of TKR/THR patients with documented patient-reported measures of quality of life and musculoskeletal function prior to surgery – the Knee Osteoarthritis Outcome Score (KOOS), Hip Osteoarthritis Outcome Score (HOOS), or PROMIS-10 Global Health tools may be used
- c. Results of measures from 1b, specifically including responses to Quality of Life (Q1-Q4) and Pain (P1 and P4-5) scores for KOOS and HOOS and questions regarding everyday physical activities (Question 7) and pain (Question 10) on the PROMIS-10 survey

2. Standards for evidence-based surgery

These standards are intended to document adherence to evidence-based best practices related to the peri-operative process. Report the proportion of TKR/THR patients that have received all of the following in the peri-operative period:

- a. Measures to manage pain using multimodal anesthesia
- b. Measures to reduce risk of venous thromboembolism and pulmonary embolism
- c. Measures to reduce blood loss such as administration of tranexamic acid
- d. Measures to reduce infection such as administration of prophylactic antibiotics

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- e. Measures to maintain optimal blood sugar control

3. Standards for ensuring rapid return to function

These standards are intended to optimize mobilization following surgery and measure patient recovery. Report:

- a. Proportion of TKR/THR patients with documented physical therapy within 24 hours of surgery
- b. Proportion of TKR/THR patients for which there are documented patient-reported measures of quality of life and musculoskeletal function six months following surgery – the same measures should be used as in standard 1b
- c. Results of measures from 2b, specifically including responses to the questions identified in standard 1c

4. Standards for the patient care experience

These standards are intended to measure patient-centered care. Report:

- a. Proportion of TKR/THR patients surveyed using HCAHPS
- b. Results of measures from 4a, specifically including responses to Q6 and Q22 if HCAHPS is used

5. Standards for patient safety and affordability

These standards are intended to measure success in avoiding complications and reducing readmissions. Report:

- a. 30-day all-cause readmission rate for TKR/THR patients
- b. 30-day readmission rate for TKR/THR patients with any of the nine complications included under the terms of the warranty

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Appendix: Detailed Quality Standards

For all of the following, THR/TKR patients refers to first-time, single-joint total knee or total hip replacement surgery for osteoarthritis, excluding patients with joint replacement for fracture, cancer, or inflammatory arthritis.

Please note that three of the quality measures refer to specific results or scores and therefore have no numerator or denominator.

	Numerator	Denominator
1: Standards for appropriateness		
a	Number of TKR/THR patients receiving formal shared decision-making decision aids pre-operatively.	Total number of TKR/THR patients.
b	Number of TKR/THR patients with documented patient-reported measures of quality of life and musculoskeletal function prior to surgery (Knee Osteoarthritis Outcome Score (KOOS), Hip Osteoarthritis Outcome Score (HOOS), or PROMIS-10 Global Health tools may be used.	Total number of TKR/THR patients.
c	Results of measures from 1b, specifically including responses Quality of Life (Q2 and Q4) and Pain (P1, and P4-5) scores for KOOS and HOOS and questions regarding everyday physical activities (Question 7) and pain (Question 10) on the PROMIS-10 survey.	
2: Standards for evidence-based surgery		
a	Number of TKR/THR patients receiving measures to manage pain while speeding recovery in a multimodal format in the peri-operative period.	Total number of TKR/THR patients.
b	Number of TKR/THR patients receiving measures to reduce risk of venous thromboembolism and pulmonary embolism in the peri-operative period.	Total number of TKR/THR patients.
c	Number of TKR/THR patients receiving measures to reduce blood loss such as administration of tranexamic acid in the peri-operative period.	Total number of TKR/THR patients.
d	Number of TKR/THR patients receiving measures to reduce infection such as administration of prophylactic antibiotics in the peri-operative period.	Total number of TKR/THR patients.
e	Number of TKR/THR patients receiving measures to maintain optimal blood sugar control in the peri-operative period.	Total number of TKR/THR patients.
3: Standards for ensuring rapid return to function		
a	Number of TKR/THR patients with documented physical therapy within 24 hours of surgery.	Total number of TKR/THR patients.
b	Number of TKR/THR patients with documented patient-reported measures of quality of life and musculoskeletal function six months following surgery (same as used as in standard 1b).	Total number of TKR/THR patients.
c	Results of measures from 2b, specifically including responses to the questions identified in standard 1c (Quality of Life (Q2 and Q4) and Pain (P1, and P4-5) scores for KOOS and HOOS and questions regarding everyday physical activities (Question 7) and pain (Question 10) on the PROMIS-10 survey).	
4: Standards for the patient care experience		
a	Number of TKR/THR patients surveyed using HCAHPS.	Total number of TKR/THR patients.
b	Results of measures from 4a, specifically responses to Q6 and Q22 if HCAHPS is used.	

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5: Standards for patient safety and affordability		
a	Number of TKR/THR patients readmitted to the hospital within 30 days of discharge, all causes.	Total number of TKR/THR patients.
b	Number of TKR/THR patients readmitted to the hospital within 30 days of discharge for any of the nine complications included under the terms of the warranty.	Total number of TKR/THR patients.