

2023 American College of Rheumatology (ACR) and American Association of Hip and Knee Surgeons (AAHKS) Guideline: Indications for Total Hip and Knee Replacement

Public Comments

The 2023 American College of Rheumatology (ACR) and American Association of Hip and Knee Surgeons (AAHKS) Guideline: Indications for Total Hip and Knee Replacement public comment was posted on the ACR website August 26, 2021. The announcement was e-mailed to the Practice Guidelines Subcommittee, Quality of Care Committee and ACR Board of Directors, and was included in multiple ACR publications and on ACR social media platforms. Eight (8) responses were received via the online form. The public comment period closed on September 25, 2021.

RESPONSES RECEIVED ONLINE:

- **Name:** Jason Kim
- **Institution:** Arthritis Foundation
- **Position:** Vice President
- **Disclosure (optional):** Nothing to disclose

Comment:

*Please explain rationale for voting panel numbers, particularly only 2 patient representatives? Does this mean that 1 patient will represent THR and the other TKR?

*The team seems to heavily lean toward northeastern, particularly New York, representation. Would the community not be better served with more geographic diversity?

*Please consider adding a military/VA perspective to your group.

*Device manufacturers do not seem to be evenly represented on the Voting Panel; only one person from DePuy.

*Although "stem cell" or regenerative medicine procedures are not FDA approved, patients do consider those procedures prior to make decisions on TJR. Consideration of those procedures do lead to patients receiving such procedures or delay of their decision to TJR. Please address as a Workgroup question and hopefully make an appropriate statement in the guidelines.

*Although CBD is not FDA approved, patients consider taking CBD as an alternative to NSAIDs and other analgesics. Please address as a Workgroup question and hopefully make an appropriate statement in the guidelines.

*As a complement to the PT question, please consider exercise or physical activity as an impact to an TJR decision.

- **Name:** Christine Stamatou
- **Institution:** Northwell Health, Division of Rheumatology
- **Position:** Nurse Practitioner
- **Disclosure (optional):** Nothing to disclose

Comment:

While i feel the PICO questions are on target and your plans for project are appropriate, i have significant concerns regarding the questions related to surgical interventions vs. non surgical without the consultation of the Physical Therapy team. It seems to me there should be at least one professional physical therapist, and possibly a clinical pharmacist on this team. Please consider this

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request and feel free to reach out to the ARP team if you need help finding a representative from PT / and or Pharm discipline.

- **Name:** Michael Ward
- **Institution:** None
- **Position:** None
- **Disclosure (optional):** I am writing in my personal capacity and not as a representative of NIH or the federal government.

Comment:

The topic of this proposal is important and the results will be of great interest to payers and patients, but I am concerned that use of treatment recommendations/guidelines is not the correct approach for this topic. The essential issue of "indications" for an intervention is the selection of the appropriate patient for the procedure. That is, matching a patient to an intervention that will best treat him or her. This should be addressed using methods specifically designed to assess appropriateness, such as the RAND/UCLA method. The proposed approach largely focuses on examining the effectiveness of arthroplasty versus conservative treatment (particularly picos 1-6), which will not answer the question of appropriateness or "indications."

To established "indications for surgery," the intervention ("I" in the PICO) is a given (i.e. arthroplasty), and there is no relevant "C". Rather, the most relevant aspect is the "P" patient or population. It seems that the entity that must be tested is variation in the patients for whom arthroplasty is being considered as a treatment option. For example, what level of pain, and for how long? What degree of functional limitation, and in what context of demands (job, leisure, etc)? The P should vary among the PICOs, rather than the "C" comparator. Picos 7-11 address this more closely, but the issue requires more nuance than has been expressed. A smoker with moderate symptoms may be considered for smoking cessation treatment or arthroplasty differently than one with very severe symptoms.

Given the effectiveness of arthroplasty, the results of picos 1-6 are likely a foregone conclusion, which has the potential to lead to inappropriate recommendations. It is not a question of whether physical therapy is better or worse than arthroplasty, rather a question of when physical therapy is indicated (and for whom) and when arthroplasty is indicated. This is a question of patient selection, timing, and clinical judgment. It does not seem as though the picos will lead to this answer, but rather will result in a misleading set of recommendations that arthroplasty dominates all types of conservative treatment and none of these treatments should be used.

Parenthetically, Pico 14 is not constructed appropriately. Consider "In a patient with unicompartamental OA who also has comorbidities, what is the relative impact of unicondylar versus total joint arthroplasty on outcomes?"

- **Name:** Kori Dewing
- **Institution:** University of Washington
- **Position:** Teaching Associate, School of Medicine, Affiliate Assistant Professor, School of Nursing, Rheumatology Nurse Practitioner

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- **Disclosure (optional):** Nothing to disclose

Comment:

Important project that will benefit us all. Curious why there are no rehab professionals included in your team given the scope of the project. Including rehab recommendations further strengthens adequate reimbursement for these essential services, especially for this population. Please consider adding, at the minimum, a physical therapist to your working group.

- **Name:** Carole Dodge
- **Institution:** University of Michigan
- **Position:** Occupational Therapist
- **Disclosure (optional):** Nothing to disclose

Comment:

I strongly feel that this group must include rehabilitation professionals as some of the PICO questions require additional expertise of a physical therapist. Would also consider having representation from a board certified surgeon to add their perspective as well. If rheumatology is truly a team, which I believe it is then having input of the other teammates involved in joint replacement is crucial to have an end product that has merit.

- **Name:** Karina Torralba
- **Institution:** Loma Linda University Health
- **Position:** Chief, Division of Rheumatology
- **Disclosure (optional):** Nothing to disclose

Comment:

Line 46-47 and Lines 167- onwards.

The questions related to conservative/non-surgical management are not as comprehensive as I think they should be. They don't cover the following areas, which I think are vital for both associations to comment on and not ignore. Many providers are already resorting to these things, and it would be a major criticism of any guidelines if any of these items are not considered or even mentioned in the final publication:

- Stem cell treatment
- Platelet rich plasma injection
- Radiofrequency ablation
- Synovectomy - I still get patients who are getting synovectomies
- Geniculate artery embolization
- Percutaneous neurolysis nerve ablation
- Thermal neurolysis

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It would also be nice to get a comment on the following invasive component, in addition to line 210/#14: doing a Unicompartmental joint replacement - vs tricompartmental/complete TKA.

- **Name:** Hassan Ghomrawi
- **Institution:** Northwestern University
- **Position:** Associate Professor of Surgery, Rheumatology, and Pediatrics
- **Disclosure (optional):** Editorial Board member: Clinical Orthopedics and Related Research
Grant funding: NIAMS

Comment:

Co-Signers: Hassan Ghomrawi, PhD MPH*

Patrician Franklin, MD, MPH, MBA*

Rowland Chang, MD, MPH*

Daniel Riddle, PT, PhD**

*Northwestern University, **Virginia Commonwealth University

We read with great interest the call for public comment issued by the American College of Rheumatology and American Association of Hip and Knee Surgeons to develop guidelines around the indication for total hip and knee replacement. As stated in their proposal, the aims of this collaboration are to:

1. Define the indications for conservative treatment in patients with moderate to severe osteoarthritis or osteonecrosis.
2. Define indications for total hip and knee replacement in patients with moderate to severe osteoarthritis or osteonecrosis.
3. Develop recommendations regarding the timing of hip or knee arthroplasty for patients with specific medical co-morbidities.

We certainly agree that this is an important topic, and with the aims. Our recently published paper in JBJS clearly indicates that a significant number of patients either undergo total knee replacement (TKR) too early or too late.¹ In our study of 8,000 patients with or at risk of knee osteoarthritis followed over time, a quarter of patients who underwent knee replacement did that pre-maturely, and approximately 90% of patients who would benefit from the surgery were delaying it. While our study is the first to quantify premature and delayed use, there is significant other evidence showing large variability in TKR patients' preoperative functional status and radiographic severity of OA, among those having surgery.²⁻⁴

Our work builds on the concept of appropriateness of surgical care, and the use of appropriateness (also sometimes referred to as appropriate use) criteria. Appropriateness criteria (AC) are evidence-based and provide valid metrics to assess the timely/appropriate uses of surgical procedures.⁵ Although a number of ACs have been developed to assess timeliness/ appropriateness of TKR, the Escobar AC stands out as arguably the most rigorously developed consensus panel-based AC.⁶ A Modified Delphi technique and a panel of Spanish experts from different fields of musculoskeletal care were formed to develop the Escobar AC in 2003.⁷ Six factors were used to classify TKR surgery as appropriate, uncertain or inappropriate. In 2014, Riddle and colleagues modified the original Escobar AC in important ways to

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incorporate new evidence and more closely align the system to US clinical practice.^{8,9} Riddle and his colleagues validated the modified Escobar AC using outcomes data. They classified the preoperative status of 167 participants who underwent TKR into inappropriate, inconclusive and appropriate, and examined improvement from preoperatively to 1-year postoperatively. They found that the inappropriate group on average, improved by 2.3 WOMAC Function points from pre-surgery to one year following surgery, whereas appropriate and inconclusive groups improved by an average of 19.8 WOMAC Function points at one year post-surgery.⁸ More recently, Karunaratne and colleagues showed that there is substantial agreement between these criteria recommendations and surgeon decisions.¹⁰ These findings reinforce the value of the modified Escobar AC as an important tool in determining indications for, and timing of TKR.

As a follow-up to our JBJS study, we are currently investigating the association between geographic social determinants of health and timing of TKR (1R01AR078342-01; PI: Ghomrawi). We believe these may be important factors affecting the timing of TKR.

While the AC remain pivotal to accurately assess timing, as the committee develops proposed guidelines, we wonder whether the "indications" for TKR should be expanded beyond the pre-op profile of a patient (minimum pathology for surgery such as OA grade or mal-alignment) to also include the potential for best post-operative outcomes. These are different concepts, and may affect indications (and timing) differently. For example, an obese patient can have advanced OA symptoms with x-ray changes consistent with advanced OA. Using pre-op knee pathology and symptoms, TKR may be indicated. Using post-op infection criteria, she may be at higher risk of sub-optimal outcomes, tempering the indication. Last, using national patient-reported outcome data, obese patients may achieve comparable pain relief as non-obese patients and the ultimate outcome may justify TKR.¹¹ In summary, considering which pre- and post-operative criteria will be used to define indications will be important.

Finally, we caution that the evidence base to guide TKR and THR indications may be limited by the scope of the existing literature. To our knowledge, few randomized controlled trials of TKR or THR surgery as compared to alternative treatments have been conducted to document the incremental value of surgery in sub-groups of knee and hip OA patients. For example, one RCT of TKR and physical therapy for knee OA documents that TKR is associated with improved pain relief as compared to physical therapy.¹² While this trial can inform indications for TKR in patients with a comparable knee OA profile, sparse evidence exists to document the relative benefits of TKR and THR.

Recommendations for your consideration:

Literature review:

1. Document the strength of evidence to support each indication, including whether RCTs exist to support a recommendation.
2. Document whether heterogeneity of TKR/THR effect among patient sub-groups was considered in each publication, and using which outcome variables (e.g., adverse events, revision, patient-reported outcome measures).

Panel determination:

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1. Consider including expertise in appropriateness criteria interpretation on the panel.
2. Document criteria for consideration, including whether indications are based on patient symptoms and knee/hip pathology or if potential post-operative outcomes (e.g., adverse events, pain relief) influence the indication.

References:

1. Ghomrawi HMK, Mushlin AI, Kang R, et al. Examining Timeliness of Total Knee Replacement Among Patients with Knee Osteoarthritis in the U.S.: Results from the OAI and MOST Longitudinal Cohorts. *J Bone Joint Surg Am*. 2020.
2. Ackerman IN, Dieppe PA, March LM, et al. Variation in age and physical status prior to total knee and hip replacement surgery: a comparison of centers in Australia and Europe. *Arthritis and rheumatism*. 2009;61(2):166-173.
3. Cobos R, Latorre A, Aizpuru F, et al. Variability of indication criteria in knee and hip replacement: an observational study. *BMC Musculoskelet Disord*. 2010;11:249.
4. Dieppe P, Judge A, Williams S, et al. Variations in the pre-operative status of patients coming to primary hip replacement for osteoarthritis in European orthopaedic centres. *BMC Musculoskelet Disord*. 2009;10:19.
5. Lawson EH, Gibbons MM, Ko CY, Shekelle PG. The appropriateness method has acceptable reliability and validity for assessing overuse and underuse of surgical procedures. *J Clin Epidemiol*. 2012;65(11):1133-1143.
6. Quintana JM, Escobar A, Arostegui I, et al. Health-related quality of life and appropriateness of knee or hip joint replacement. *Arch Intern Med*. 2006;166(2):220-226.
7. Escobar A, Quintana JM, Arostegui I, et al. Development of explicit criteria for total knee replacement. *Int J Technol Assess Health Care*. 2003;19(1):57-70.
8. Riddle DL, Perera RA, Jiranek WA, Dumenci L. Using surgical appropriateness criteria to examine outcomes of total knee arthroplasty in a United States sample. *Arthritis care & research*. 2014.
9. Riddle DL, Jiranek WA, Hayes CW. Use of a validated algorithm to judge the appropriateness of total knee arthroplasty in the United States: a multicenter longitudinal cohort study. *Arthritis & rheumatology*. 2014;66(8):2134-2143.
10. Karunaratne S, Harris IA, Trevena L, Horsley M, Solomon M. Observing the use of knee arthroplasty appropriateness tools in clinical practice: do appropriateness criteria tools predict surgeon decision-making? *Osteoarthritis Cartilage*. 2021;29(9):1275-1281.
11. Li W, Ayers DC, Lewis CG, Bowen TR, Allison JJ, Franklin PD. Functional Gain and Pain Relief After Total Joint Replacement According to Obesity Status. *J Bone Joint Surg Am*. 2017 Jul 19;99(14):1183-1189. doi: 10.2106/JBJS.16.00960. PMID: 28719557; PMCID: PMC5508191.
12. Søren T. Skou, P.T., Ph.D., Ewa M. Roos, P.T., Ph.D., Mogens B. Laursen, M.D., Ph.D., Michael S. Rathleff, P.T., Ph.D., Lars Arendt-Nielsen, Ph.D., D.M.Sc., Ole Simonsen, M.D., D.M.Sc., and Sten Rasmussen, M.D., Ph.D. A Randomized, Controlled Trial of Total Knee Replacement. *N Engl J Med* 2015; 373:1597-1606. DOI: 10.1056/NEJMoa1505467