Response to Public Comments on the Project Plan for the 2023 American College of Rheumatology (ACR) and American Association of Hip and Knee Surgeons (AAHKS) Guideline: Indications for Total Hip and Knee Replacement

October 2021

We have reviewed the comments and appreciate the concerns and suggestions raised. They can be grouped under 3 major topics: 1) team composition; 2) definition of our study population; 3) use of non-FDA approved therapies. Several points require clarification, and they are reflected in edits made to the project plan.

1. **Team composition:**
   a. The ACR and the American Association of Hip and Knee Surgeons both participated in team formation. Our team includes balanced volunteer representatives from both rheumatology and surgery, as well as patient representatives. Patient representatives on the voting panel will be part of a larger patient panel, to allow patients to express their views in a setting that is not dominated by physicians while also ensuring that these views are then adequately represented in the discussions where decisions about the guideline recommendations will be made. Our intention is to obtain patient input by including representatives on our MD concentrated panel as well as holding a panel exclusively for patients.

   b. While other projects have focused on the value of specific non-surgical and non-pharmacologic therapy across the spectrum of arthritis, the focus of this project is any justification for delay in elective total hip or knee replacement surgery when symptoms, deformity, and radiographs are severe enough to justify surgery. As such, we have not included physical therapists, occupational therapists, or pharmacists on the panel.

2. **Population of interest:**
   a. Our overarching intention is to address what value exists for delaying of arthroplasty when it is indicated. This intention includes an important assumption that pre-operative optimization of reversible risks is appropriate.

   b. We have edited the project plan for clarity, as our aim is not to determine appropriateness or indications for arthroplasty. For the purposes of this clinical practice guideline, our defined population are **patients who have been indicated for arthroplasty through a shared decision-making process with their physician and surgeon and have completed trials of appropriate conservative therapy such as physical therapy, NSAIDs, and/or intra-articular glucocorticoid injections**. Our defined population has radiographically moderate to advanced osteoarthritis of the hip or knee and moderate to severe pain or loss of function.

   c. The research questions include:
      i. Is the continuation of various conservative therapies, when possibly not effective in relieving pain or restoring function, of any value when pain is severe, function poor, and radiographs demonstrate moderate to severe disease?

ii. Do delays in proceeding to arthroplasty allowing for optimization of patients with reversible risks reduce complications and/or improve outcomes?

3. **Use of non-approved therapies:**
   Because they are aimed at a U.S. primary target audience, ACR guidelines do not include therapies that have not been approved by the FDA for use in the United States. However, this project addresses delays imposed before proceeding to arthroplasty by external agencies/payers. Those agencies/payers routinely do not require or cover non-FDA approved therapies.