Letters to the Editor

AAOS Osteoarthritis Guideline: Transparency and Credibility

To the Editor:

We read the commentary \(^1\) and editorial \(^2\) recently published in *Arthroscopy* with interest and concern: interest in the lack of understanding of the American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guideline (CPG) development process and concern over the misrepresentation of evidence-based medicine (EBM) and the Academy’s CPG development process.

The Academy’s CPG process meets all of the Institute of Medicine’s CPG standards, \(^3\) which include (1) establishing transparency, (2) managing conflicts of interest, (3) guideline development group composition, (4) CPG system review intersection, (5) establishing foundations for evidence and rating strength of evidence, (6) articulating recommendations, (7) external review, and (8) updating. The Osteoarthritis of the Knee (second edition) Work Group was multidisciplinary, with representatives from primary care, rheumatology, physical therapy, and orthopaedic subspecialty societies, as well as Academy fellows. The Academy’s CPG process uses the highest level of evidence available, which is sometimes called a “best evidence analysis.” The evidence is graded for quality (prospective, power, group assignment, blinding, group comparability, treatment investigator bias) and applicability (participants, intervention and expertise, compliance and adherence, analysis). Finally, the CPG goes through an extensive peer-review process.

Bannuru et al. \(^1\) report that “one of the tenets of EBM is the incorporation of expert opinion” and go on to assert that “[a]rmed with this understanding, physicians can critically evaluate EBM analyses to provide important expert-opinion filters to such programs.” This assertion is not accurate. The levels of evidence are delineated by Wright et al. \(^5\) Level I therapeutic evidence consists of high-quality randomized clinical trials (RCTs) and systematic reviews of Level I RCTs. Expert opinion is Level V Evidence and is considered in the development of CPGs only with issues of risk or harm and when higher levels of evidence are not available. The EBM process does not “filter” Level I Evidence when the evidence is inconvenient or the evidence does not support an expert’s opinion or current practice patterns. It is a tenet of EBM that a myriad of factors, including clinician experience, patient preferences and values, and comorbid conditions, will affect the complex clinical decision-making process for individual patients. Incorporating clinical judgment in situations in which interventions do not have a strong evidence base and there is a minimal potential for harm, is not the same thing as including expert opinion in place of research when developing recommendations. Evidence trumps opinion.

Bannuru et al. \(^1\) cite a recent meta-analysis by Rutjes et al. \(^6\) published in the *Annals of Internal Medicine* to indict the AAOS CPG process for excluding a number of research articles. Although Rutjes et al. did review 89 articles related to viscosupplementation, they divided these studies into smaller subgroups relating to specific outcomes (i.e., knee pain, physical function, or safety) and conforming to specific inclusion criteria for sub-analysis. Rutjes et al. included just 18 large trials with blinded outcome assessment in their meta-analysis, which is just 4 more than the 14 studies that supported the AAOS systematic review. \(^7\) One difference between the inclusion criteria of these 2 reviews is that Rutjes et al. included unpublished trials whereas AAOS methodology relies on studies published in peer-reviewed publications.

In addition, we are perplexed as to why Bannuru et al. \(^1\) cite Rutjes et al. \(^6\) as a credible meta-analysis and not the AAOS OA Knee CPG \(^7\) because the conclusions are similar. Rutjes et al. found that “the 95% CI did not overlap the minimal clinically important difference” and state, “We conclude that the benefit of viscosupplementation on pain and function in patients with symptomatic osteoarthritis of the knee is minimal or nonexistent. Because of increased risks for serious adverse events and local adverse events, the administration of these preparations should be discouraged.” These findings from the meta-analysis of Rutjes et al. are consistent with the AAOS recommendation that “[w]e cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.” \(^7\)

Similarly, the Centre for Clinical Practice at the National Institute for Health and Clinical Excellence (NICE) published the following recommendation \(^8\): “Intra-articular hyaluronan injections are not recommended for the treatment of osteoarthritis.”

Bannuru et al. \(^1\) suggested that the “negative shift” from the 2008 “inconclusive” recommendation for viscosupplementation was based on changes in methodology, not evidence. First, we disagree with the use of the term “negative”; evidence is neutral. Second,
although the AAOS has always considered clinical significance as the highest standard and one that should be used when the appropriate conditions are met, it is true that clinical significance could not be calculated in the 2008 AAOS OAK CPG because it relied on secondary research from the Agency for Healthcare Research and Quality (AHRQ). In fact, the update of this guideline was moved up in the queue at the request of stakeholders who advocated for the AAOS to conduct its own meta-analysis relying on primary research studies as in other AAOS guidelines. Finally, we would like to point out that 7 RCTs on viscosupplementation were published after the 2008 OAK CPG and are included in the 2013 OAK CPG,9-15 which represents a significant amount of new evidence.

Clinical significance is different than statistical significance. The minimum clinically important improvement (MCII) reflects the smallest clinical change that is important to patients and recognizes that there are some treatment-related statistically significant improvements that are too small to be relevant. Statistical significance (typically $P < .05$) can be achieved by “overpowering” a study (increasing the subgroup sizes). The criticism of MCII made by Bannuru et al.1 rely on outdated references from 1998 and 2002.16,17 Important advances have been made in subsequent years, and the Academy’s CPG process uses the MCII to normalize the mean difference and standard error to perform meta-analyses.18-20 The commentary by Lubowitz et al.2 that accompanied the critique of Bannuru et al. suggested that “the AAOS should seek the counsel of independent experts to review the AAOS CPG methods and alternatives.” In fact, methodologists experienced in EBM were consulted in response to a critique regarding the use of MCII that was previously brought to our attention during the public commentary phase of the guideline development process. This consultation verified that the application of MCII in this guideline was correct and on firm footing. At the suggestion of our consultants, the AAOS also calculated and reported clinical significance in minimum important difference (MID) units, and we obtained the same results as with the MCII. Our guideline reports both the MCII and MID.7,19,20

In their commentary, Lubowitz et al.2 stated that the guideline recommendations “highlighted the profound impact that unfavorable recommendations may have on multiple stakeholders.” One purpose of the AAOS CPGs is to provide stakeholders with unbiased, high-quality evidence about the effectiveness of treatments based on the best available data. Conclusions that a treatment does not provide meaningful effects for most patients above and beyond placebo comprise a valuable outcome of the process—even if the data contrast with clinical experience.

The veracity and transparency of the AAOS CPG development process is unparalleled. The AAOS is committed to multiple quality- and evidence-based programs that look to improve care for our patients and improve practice for our members. The changing health care landscape mandates introspective analysis of the care we provide to patients. The integrity and character of the AAOS are demonstrated when we can critically review these practices in an unbiased manner. Within the health policy arena, the unbiased approach of the AAOS significantly enhances our positions on those treatments that are effective. As such, this work is critical to both the advocacy and quality missions of the AAOS, and it will continue.

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References


Authors’ Reply

Drs. Jacobs, Jevsevar, Brown, and Cummins have responded to our article, “Did the American Academy of Orthopaedic Surgeons Osteoarthritis Guidelines Miss the Mark?,” with a letter defending the CPG process. We welcome this debate because their letter is an important illustration that the best way to assess the orthopaedic literature to provide guidance to surgeons, patients, and other interested parties is not settled. Just because a process comports well with Institute of Medicine guidelines does not mean it is applicable or relevant to every setting in medicine. It certainly does not mean that the process is beyond legitimate criticism despite such comportment. We have studied the CPG methodology for over 4 years and think it could be improved significantly. We have made recommendations to the Academy in meetings and in writing as to how this might be accomplished. Our article was an integral part of that effort. We will let readers of the Journal decide the value of our efforts.

Our goal in publishing the article was to educate orthopaedic surgeons on aspects of the CPG process so that they can critically examine these documents and provide meaningful input in their localities as these guidelines begin to affect the way they make treatment recommendations to their patients. Orthopaedic surgeons are the musculoskeletal disease experts and are in the best