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SPECIAL ARTICLE

Clinical Practice Guidelines: Incorporating Input From a Patient Panel

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Objective. **To describe the integral role of a Patient Panel in the development of the 2017 American College of Rheumatology (ACR)/American Association of Hip and Knee Surgeons (AAHKS) clinical practice guideline.**

Methods. **We convened a Panel of 11 patients with rheumatoid arthritis and juvenile idiopathic arthritis, all of whom had undergone 1 or more arthroplasties, to review the evidence and provide guidance on recommendations for the 2017 ACR/AAHKS guideline to address the perioperative management of antirheumatic medication in patients with rheumatic diseases undergoing elective total hip or total knee arthroplasty. The guideline used the Grading of Recommendations Assessment, Development, and Evaluation methodology that acknowledges the critical role of patient values and preferences when the quality of the evidence base is low or when there are important trade-offs between benefits and harms. The Patient Panel considered the relative importance of complications including perioperative infection versus rheumatic disease flare and voted on the recommendations. Before the Voting Panel's own discussion of the recommendations, they reviewed a summary of the Patient Panel's discussion, including their perioperative experience, the relative importance they placed on infections versus flares in the perioperative period, and their votes on the recommendations.**

Results. **The Patient Panel placed higher importance on avoiding an infection than a disease flare despite the far greater frequency of flares than infections. The decisions of the Voting Panel were concordant with those of the Patient Panel. For the 7 recommendations that both Panels voted on, the Panels agreed on the direction as well as the strength of recommendation (which was conditional for all recommendations).**

Conclusion. **The Voting Panel considered the importance that the patients placed on risk of infection. The Patient Panel's values informed the direction and strength of the recommendations in the final 2017 ACR/AAHKS guideline.**

INTRODUCTION

Patients and physicians may have different perspectives on medical outcomes and what may constitute a reasonable risk to achieve those outcomes (1–3). In light of these differences, the Institute of Medicine recommends the inclusion of patients in guideline development projects to help ensure adequate consideration of patients' perspectives (4). A small number of patients on a panel may, however, be unrepresentative and a method to ensure representative patient input for a guideline development project remains unresolved (5). Options to incorporate patients' values and preferences might include focus groups or systematic reviews of formal studies of patients' values and preferences that can also inform Guideline Panels on what is important to patients.

Patients have contributed their perspectives to multiple projects to develop treatment recommendations and guidelines. Previous work has further demonstrated that when presented with high-quality evidence, panels composed entirely of patients may reach similar conclusions as do panels of physicians (5). Patients' values and preferences are particularly important when the evidence quality is not

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Significance & Innovations

- This guideline demonstrates the clear benefit of patient input informing the strength and direction of the recommendations.
- Patient values and preferences can play a critical role when the quality of the evidence base is low or when there are important trade-offs between benefits and harms.
- The patients' recommendations were guided by their strong and unanimous preference for minimizing risk of infections over minimizing risk of disease flares.
- Formally determining patient values and preferences led to patient-centric recommendations that were ultimately congruent for both Patient and Voting Panels.

high or when trade-offs between benefits and harms are closely balanced (6). Recommendations in these situations may be characterized as value and preference sensitive (7–10). In this setting, the patients' perspective may have a particularly strong influence on the direction and strength of the recommendations.

The American College of Rheumatology (ACR) and the American Association of Hip and Knee Surgeons (AAHKS) proposed the development of a guideline for the perioperative management of antirheumatic medication in patients with rheumatic diseases undergoing elective total hip arthroplasty (THA) or total knee arthroplasty (TKA) (11). No guideline has been published since the introduction of many of the current antirheumatic medications, and practice patterns vary widely. Observations that patients with rheumatic diseases were at higher risk for adverse events, including infection, after THA and TKA compared to patients with osteoarthritis (odds ratios/risk ratios for infection of 1.8–4.8) (12) and that most patients with rheumatic diseases undergoing THA and TKA were receiving potent immunosuppressant antirheumatic medications at the time of surgery, suggested that perioperative medication management decisions might contribute to the frequency of adverse outcomes. The aim of the guideline was to help minimize adverse events including perioperative infections and disease flares. The topics addressed by the guideline included: 1) Should antirheumatic medications be withheld prior to elective THA/TKA? 2) If they are withheld, when should they be stopped? 3) If withheld, when should they be restarted after surgery? 4) In patients receiving glucocorticoids, what dose should be administered at the time of surgery?

For the guideline, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was used as specified in the ACR guideline development process (available at www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines). Using this method, the clinically relevant questions are formatted into PICO (population/intervention/comparator/outcomes) questions that identify the specific elements of the relevant clinical question and that inform a systematic literature review (13,14). The Guideline Panel reviews the relevant evidence to assess the balance between the potential benefit of the intervention (withholding medication may decrease infection) and the potential for harm (withholding medication may increase flares of disease) prior to developing practice recommendations.

GRADE, an internationally recognized method, rates the strength of the recommendation as either strong or conditional based largely on the quality of the available evidence informing the recommendations, but also on the presumed variability of patient values and preferences. A strong recommendation indicates that all or almost all informed patients would select that treatment option. A conditional recommendation indicates that the evidence base is not robust, the balance of benefit and harm is not as certain, and the optimal clinical decision requires the consideration of individual patient values and preferences. Conditional recommendations are warranted when the majority (defined as >50%) of informed patients would choose to follow a conditional recommendation, but others would not (8,15,16).

For this guideline, the crucial trade-off was between perioperative infections (ranging in severity from nonserious to serious) and the risk of disease flares, which are common when medications are discontinued. An ACR/AAHKS Panel supported by ACR staff and consisting of 6 orthopedists, 5 rheumatologists, an infectious disease expert, a systemic lupus erythematosus (SLE) expert, 2 patient representatives with rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIA), 2 rheumatology methodologists, and an additional expert in GRADE methodology voted on the final recommendations. Our aim is to report on the significant contribution of the Patient Panel, which was convened for the perioperative medication management guideline, and to describe a successful model for increased integration of the patients' perspective in guideline development.

METHODS

Patient Panel. Patients with RA who had undergone THA or TKA were identified and recruited through the Arthritis Foundation and the Global Healthy Living Foundation. The participants completed the Collaborative Institutional Training Initiative Human Subjects Protection Training and 2 modules from the Cochrane Collaboration, "Understanding Evidence Based Healthcare" and "Serving on a Clinical Practice Guideline," during 8 hours of research and guideline methodology webinars prior to the meeting. A face-to-face meeting of the Patient Panel was convened on July 10, 2016, the day prior to the ACR/AAHKS Voting Panel meeting. At this first meeting of the Patient Panel, participants were provided with the background material and scope of the guideline project. The Patient Panel meeting was facilitated by the ACR Co-Principal Investigator (SMG), an ACR staff member with previous experience leading Patient Panels (ASM), the ACR Co-Literature Review Panel leader (JAS), and was supported by ACR staff (MT).

Scope of the project. The patients were informed of the rationale and the scope of the project, and the assumptions of the project were presented. They were informed that the

goal was to provide guidance for perioperative antirheumatic medication management even when evidence was sparse, to provide guidance for clinicians and patients, to optimize THA and TKA outcomes, and to minimize adverse outcomes. Routine preoperative medical assessment and adverse events of concern, including venous thromboembolism or cardiac events, were not within the scope of this guideline and were covered by other guidelines (17,18). Medications and diseases were initially to be considered separately, but limitations in the available literature led us to group them together, except for questions pertaining to SLE.

This guideline addresses only those perioperative events that could be attributable to the disease-specific antirheumatic therapy. Although outcomes that included hip dislocation and 90-day hospital readmission were sought in the literature, literature was sparse and these complications could not be directly linked to the medication management decisions. Therefore, the outcomes of interest were limited to infections (including nonserious and serious infections involving either the surgical site or a remote site) versus flares of rheumatic disease.

The values and preferences of the patients were elicited to give weight to the balance between benefits and harms. The patients were specifically queried on the relative importance of infections, infrequent events possibly linked to continued immunosuppressant disease-modifying antirheumatic drug and biologic agent therapy, compared to the importance of flares of disease that occur frequently after THA and TKA and may be linked to withholding the medications. The Patient Panel was encouraged to consider their personal experiences relevant to the questions and judge the importance of the outcomes accordingly.

RESULTS

Moving from evidence to recommendations. The Patient Panel consisted of 11 adults with RA or JIA, all of whom had undergone THA or TKA (range of 1 to 8 joints replaced per patient). Only 1 patient reported experiencing a prosthetic joint infection. The mean age of participants was 47 years (range 23–71 years) and the mean disease duration was 26 years (range 8–42 years). Of these patients, 10 were female and 1 was of a minority race/ethnicity.

The Patient Panel reviewed the evidence synthesized by the guideline Literature Review Panel as each PICO question was discussed (the same information that the ACR/AAHKS Voting Panel considered the following day) (Table 1). The patients addressed the PICO questions that informed the guideline project, reviewed and discussed the data, and formally voted anonymously on the drafted recommendations that were formulated from the PICO questions. The methods used were the same between the Patient and Voting Panels (Figure 1). When consensus was not reached, there was further clarifying discussion and the votes were repeated until an 80% or higher consensus was achieved. Because this meeting was held the day prior to the meeting of the Voting Panel, the Patient Panel had no knowledge of the ACR/AAHKS Voting Panel's decisions.

Table 1. Overview of PICO (population/intervention/comparator/outcomes) questions

Populations

Adult patients with rheumatoid arthritis, juvenile idiopathic arthritis, spondyloarthritis, psoriatic arthritis, ankylosing spondylitis, or systemic lupus erythematosus undergoing elective total hip and total knee replacement

Interventions

1. Stop or continue medications?
2. If withheld, when should they be stopped?
3. When to restart medications that were stopped?
4. How to dose glucocorticoids at the time of surgery?

Comparator

1. Stop or continue medications?
2. Withhold for shorter vs. longer periods before the surgery?
3. Restart medications early vs. late?
4. Give usual vs. high dose ("stress dose") glucocorticoids?

Outcomes

Disease flare, infection, serious (deep) surgical site infections, superficial surgical site infections, minor non–surgical site infections (e.g., urinary tract infection), serious non–surgical site infections (e.g., pneumonia, bacteremia/sepsis), death, cytopenias in systemic lupus erythematosus, acute kidney injury (cyclosporine), need for revision surgery, readmission within 90 days, long-term arthroplasty outcome

Patient values, preferences, and recommendations. The Patient Panel uniformly attached far greater weight to the possibility of infections if medications were continued despite the greater likelihood of a flare if the medications were stopped. Specifically, the difference was at least 10–20:1, although the Patient Panel was unable to precisely quantify the difference.

The Patient Panel facilitators questioned the patients at length to better understand this preference. The patients felt that flares represented a "known risk" that they could control and that in particular can usually be treated. In contrast to the predictability of flares, the patients perceived that there is no "average" infection—only very bad ones, with a risk of much worse outcomes than flares (e.g., permanent loss of prosthesis, extremity amputation, prolonged hospitalization, dependence and disability, and death).

The patients viewed enduring the perioperative period as a "job" in which their task was to focus on the eventual positive outcomes of better mobility and less pain, and "dealing with a flare was simply part of the hard work." One patient said, "I always assume I will be in a flare when I enter surgery and for a while when I come out, but I'm afraid of infection." Others agreed, "I always expect to flare." They considered the burden of infection to be much larger than the burden of flares, as their lives were already set up to deal with flares. Although flares were perceived as difficult, patients were aware that an infection could postpone recovery and/or introduce other health issues, which they felt was unacceptable because it would delay achieving the positive outcomes they sought. One patient noted that, "you can die from an infection, but you won't die from a flare," and that, "infections usually mess up [her] life for months on end ...

RA, SpA including AS and PsA, JIA, or SLE: Continue the current dose of methotrexate, leflunomide, hydroxychloroquine, and/or sulfasalazine (nonbiologic DMARDs) for patients undergoing elective THA or TKA.		
Rationale: Both patients and physicians were comfortable with the summary of evidence presented for the infection risk profile of these medications.	ACR/AAHKS Voting Panel Continue Unanimous	Patient Panel Continue Unanimous
RA, SpA including AS and PsA, JIA, or SLE: Withhold all current biologic agents prior to surgery in patients undergoing elective THA or TKA, and plan the surgery at the end of the dosing cycle for that specific medication.		
Rationale: While both patients and physicians agreed that all biologic agents should be withheld prior to surgery and agreed that the surgery should be timed to the end of the dosing cycle to minimize persistent immunosuppression, the patients stressed individualizing the recommendations for each patient. The patients were comfortable with the indirect/ low-quality evidence presented, while the 1 discordant vote among the expert panel was due to low-quality evidence. The patients were reluctant to vote on the clinical scenario related to patients with SLE, as there were no patients with SLE on the Patient Panel.	ACR/AAHKS Voting Panel Withhold 92%	Patient Panel Withhold Unanimous
RA, SpA including AS and PsA, or JIA: Withhold tofacitinib for at least 7 days prior to surgery in patients undergoing THA or TKA.		
Rationale: Both Panels agreed with withholding tofacitinib due to the risk of infection	ACR/AAHKS Voting Panel Withhold Unanimous	Patient Panel Withhold Unanimous
Severe SLE: Continue the current dose of mycophenolate mofetil, azathioprine, cyclosporine, or tacrolimus through the surgical period in all patients undergoing THA or TKA.		
Rationale: The patients were hesitant to vote on this clinical scenario related to patients with SLE, as there were no SLE patients on the Patient Panel, and voted based on their understanding of severe vs. not-severe SLE.	ACR/AAHKS Voting Panel Continue Unanimous	Patient Panel Continue Unanimous
SLE (not severe): Withhold the current dose of mycophenolate mofetil, azathioprine, cyclosporine, or tacrolimus 1 week prior to surgery in all patients undergoing THA or TKA.		
Rationale: The patients were hesitant to vote on this clinical scenario related to patients with SLE, as there were no SLE patients on the Patient Panel, and voted based on their understanding of severe vs. not-severe SLE.	ACR/AAHKS Voting Panel Withhold Unanimous	Patient Panel Withhold Unanimous
RA, SpA including AS and PsA, JIA, or SLE: Restart biologic therapy in patients for whom biologic therapy was withheld prior to undergoing THA and TKA once the wound shows evidence of healing (typically ~14 days), all sutures/staples are out, there is no significant swelling, erythema, or drainage, and there is no clinical evidence of non–surgical site infections, rather than shorter or longer periods of withholding.		
	ACR/AAHKS Voting Panel Unanimous	Patient Panel Unanimous
RA, SpA including AS and PsA, or SLE: Continue the current daily dose of glucocorticoids in patients who are receiving glucocorticoids for their rheumatic condition and undergoing THA or TKA, rather than administering perioperative supra-physiologic glucocorticoid doses (so-called "stress dosing").		
Rationale: The Patient Panel was concerned about the inadvertent loss of protection from flares that the stress dosing might have conferred.	ACR/AAHKS Voting Panel Unanimous	Patient Panel Unanimous

Figure 1. Summary of recommendations and ACR/AAHKS Panel and Patient Panel votes. RA = rheumatoid arthritis; SpA = spondyloarthritis; AS = ankylosing spondylitis; PsA = psoriatic arthritis; JIA = juvenile idiopathic arthritis; SLE = systemic lupus erythematosus; DMARDs = disease-modifying antirheumatic drugs; THA = total hip arthroplasty; TKA = total knee arthroplasty; ACR = American College of Rheumatology; AAHKS = American Association of Hip and Knee Surgeons.

as months of antibiotics and other things related to infections messes up a patient's life." Moreover, while they felt they could manage flares at home, the consequences of infections (including the frequent occurrence of associated flares) would likely require prolonged hospitalization and a stay in a rehabilitation center.

DISCUSSION

For this guideline, which was limited by the absence of high-quality evidence for any of the common perioperative clinical scenarios, the values and preferences of the Patient Panel provided clear direction to the ACR/AAHKS Voting Panel and contributed to the rigor of guideline development. The uniformity of the patients' views and the consensus of the entire Patient Panel added power to their views.

The strengths of our study include the organization of a Patient Panel, all of whom had prior experience with joint replacement. Although the validity of the patients' values and preferences reflects, in part, the depth of their knowledge of the relevant outcomes, selecting a panel of patients who had experience with THA or TKA contributed to their ability to weigh outcomes and vote decisively on interventions in patients like them undergoing THA or TKA. The Patient Panel's input was obtained prior to the Guideline Panel's deliberations, and informed the Voting Panel's decisions. There was a strong consensus among the patients. The voting by the Patient Panel and the formal Guideline Panel were independent, and considered the same clinical situations. The high concordance of both the voting and the recommendations between the 2 Panels was most impressive.

Our study had several limitations. The Patient Panel was chosen by 2 patient advocacy organizations to be representative of patients with rheumatic conditions. However, it is possible that despite our effort to have an adequate representation of men, minority races/ethnicities, and patients with lower income/socioeconomic status, this Panel may not be representative of all patients in the US. In particular, the panelists were hesitant to make recommendations for patients with SLE because there were no patients with SLE on the Patient Panel. Patient experience ranged from 1 to 8 joint replacements, which may have influenced their values and preferences and their perception of risks and benefits. However, each patient on the Panel had had at least 1 joint replacement, and therefore the Panel had substantial experience with the perioperative period and antirheumatic medication use during that period.

Although patients have previously reached concordant votes with Physician Panels and have developed recommendations based on similar evidence as expert Voting Panels, patients have previously withheld votes when the evidence was not high quality (5). In this project, patients voted on all the recommendations despite the lack of high-quality evidence, guided by their strong preference for minimizing the risk of infection over risk of flares. As there were no patients with SLE in this group, the Patient Panel expressed discomfort making assumptions about the values and preferences of patients with SLE, but voted based on their understanding of severe SLE contrasted with SLE that was not severe. This suggests that patients were comfortable with their experience contributing to an evidence base that would shape practice guidelines, similar in fashion to the consideration of experience taken by Expert/Physician Panels.

Although physician and patient values and preferences may differ and at times be opposed, patient values and preferences typically shape and inform physician advice. In this study, we have demonstrated the importance of formally determining the values and preferences of the patients, leading to patient-centric recommendations that were ultimately congruent for both groups, and which may facilitate implementation (19–21). However, it should be noted that we do not know whether the Voting Panel would have made the same recommendation without the input of the Patient Panel.

There is no consensus among guideline developers on how best to incorporate patient values and preferences into guidelines. The ACR has previously involved 1 to 2 patients as members of guideline Voting Panels, but has received feedback that these patients do not always feel empowered to speak up in that setting, nor do they feel that their perspectives and experiences are uniquely valued. Moreover, the values of these 1 or 2 individuals may not be representative of the wider community. Therefore, the ACR piloted the idea and logistics of including a separate Patient Panel in a guideline project, but has previously asked patients to provide input on recommendations only when the evidence is high quality. For this ACR/AAHKS guideline we went a step further, asking the patients to consider and vote on *all* preliminarily drafted recommendations, even though all of the evidence was indirect or of moderate to low quality.

In summary, in this project, the patients' preferences were elicited prior to the decisions of the ACR/AAHKS Voting Panel, and presented to the Voting Panel to consider as the final recommendations were determined. Although the optimal method for incorporating patients' preferences into clinical practice guidelines has not been determined, this guideline demonstrated the clear benefit of patient input in the presence of a relatively weak evidence base in shaping the strength and direction of the decisions made by a Physician Voting Panel. The findings of this project support the formal incorporation of information elicited from separately convened Patient Panels into clinical practice guidelines.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Goodman had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Goodman, Miller, Guyatt, Yates, Springer, Singh.

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