

**AMERICAN ACADEMY OF ORTHOPAEDIC
SURGEONS**

**INTRODUCTORY INFORMATION
FOR**

WORK GROUP MEMBERS

PARTICIPATING IN GUIDELINE DEVELOPMENT

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I. INTRODUCTION

Dear AAOS Work Group Volunteer,

Welcome and Thank-you for volunteering to participate in the AAOS guideline development process as a work group member. AAOS appreciates your time and effort and we hope this process will be rewarding and informative.

AAOS strongly believes that evidence-based medicine is part of our future and we are indeed fortunate to have dedicated volunteers who are committed to the process of developing guidelines based on the most current and best available evidence. The results will most certainly improve the quality of healthcare.

Please also note that this document is constantly evolving. New revisions will supersede all other revisions. Once you have participated in the process and completed a guideline, it is likely the introductory packet given to you at the beginning of this process will be obsolete.

CONFLICT OF INTEREST

AAOS guideline work group members are held to a high standard of disclosure concerning conflicts of interest. In fact, they are held to the same standard that the AAOS Board of Directors is held to. The form you will be required to fill out once upgraded to a work group member is more detailed than the current form you are currently required to use. A very limited number of AAOS staff will have access to the detailed information you provide while the majority of other individuals may see only if a potential conflict of interest exists. Moving the disclosure program online has streamlined the process and improved transparency throughout the Academy. If you have additional questions concerning the information collected, how this information will be used, retention of the information and privacy, please visit the site. Once you are in the system, you will be automatically notified for updates and will only need to fill this information out once every six months.

You are required to disclose both verbally and in writing your conflicts of interest prior to beginning work on the guideline. You may disclose in writing via the AAOS website in member services at http://www3.aaos.org/education/disclosure/disclose_intro.cfm now but again, once the work group is officially formed, the level of your disclosure will be upgraded. You will be asked to verbally disclose any new conflicts of interest on the first teleconference or at the introductory recommendation meeting for the guideline.

Mandatory disclosure applies to all participants in guideline development. If you are not a member of AAOS, you will still be required to disclose your conflicts of interest. If you have a customer identification number and password established these numbers can be used to login, access the system and disclose the necessary information.

If you do not have a customer identification number and password, you may contact AAOS Member services and they will be created for you. As always if you have any problems with disclosure, you may contact the AAOS Guidelines Manager for assistance.

The criteria for disclosure are copied below for your information:
In December 2006, the AAOS Board of Directors adopted, upon the recommendation of the Council on Research, Quality Assessment and Technology, requirements for financial conflicts of interest for the AAOS Guidelines Work group members. The Board also adopted these requirements for itself. These requirements provide as follows:

*A **conflict of interest** exists when there is a current or past financial relationship with a business entity (e.g., drug or implant manufacturer) AND the use of the product(s) manufactured by this business entity may be directly affected by the guideline recommendations.*

“Financial relationships” include:

- 1. Research sponsored by the manufacturing company (For disclosure, list all grants, dates and dollar amounts).*
- 2. Ownership of shares or stock options (For disclosure, list amount and if held by you or family members). Mutual fund holdings are exempt from this rule.*
- 3. Seat on Board of Directors or Advisory Board (For disclosure, list stipend paid for board membership)*
- 4. Speaker fees (For disclosure, list frequency of speaking and total amounts received).*
- 5. Royalty payments (e.g., from patents or consultative agreements, etc.)*
- 6. Consulting agreements.*

II. WORK GROUPS

APPOINTMENT OF THE WORK GROUP CHAIRPERSON

The work group Chairperson is appointed by the AAOS Guidelines and Technology Oversight Committee (GTOC) at their biannual meetings. The Work group Chair must have taken the AAOS educational course on evidence based practice (http://www3.aaos.org/research/eawonline/eaw_ppt.cfm) or an equivalent training course.

Once the work group chair has accepted the invitation to participate in the process, he/she will need to select a vice chair and a work group. This process takes several weeks and all work group members must be approved by the Oversight Chairs, the Chair of the Council on Research Quality Assessment and Technology and the AAOS medical Director.

The next step in the process is to attend the introductory meeting. During this introductory meeting the rigorous AAOS guideline development process is explained in detail.

- This meeting date will need to be confirmed based on the availability and schedules of the Oversight Committee Chairs and the Director of Research.
- This date will be a Saturday or Sunday so members who will not travel for meetings on the weekend will not want to participate.
- If meetings are held in January or February, consideration should be given to holding the meeting in a geographical area without inclement winter weather.

Attendance at the introductory meeting is mandatory for all guideline work group members participating in the process. Participation on the work group is contingent on the panel members' ability to attend the date that is coordinated with the Work Group Chair, the vice chair, the Committee Chairs and the AAOS Director of Research.

Once the potential list of panel members is approved by the Committee Chairs, the work group chair and vice chair should make the initial contact with work group members with a personal invitation to participate in the development process as well as attend the meetings. Participation is contingent on the members' availability to attend the introductory meeting and to make a reasonable commitment to attend the final recommendation meeting that will occur approximately eight months to one year following the introductory meeting in most cases. Once members have agreed to participate on the work group and attend the meetings, formal invitations (welcome) will be sent by AAOS staff and the introductory meeting will be arranged.

The work group chairperson, in conjunction with the GTOC Chairperson and AAOS staff, guides the development process based on sound evidence-based methodology. Evidence-based methodology is a rigorous process and well defined. ***We ask the work group chair and work group members not to supersede this process by beginning with an exchange of articles or other literature. This may/could introduce significant bias.***

We respectfully ask that no work begin until the work group chairperson, GTOC Chairperson, Evidence-Based Practice Chairperson, AAOS Director of Research and CPG Manager convene an introductory conference call to discuss the rigorous AAOS development process.

The work group chairperson also convenes conference calls, makes the work group assignments and oversees the final material compiled for the guideline document. The work group chair will coordinate with staff to ensure the final product is moved forward through the approval process. The work group chair may also be invited to attend the Guideline and Technology Oversight Committee Meeting and the Evidence Based Practice Committee Meeting to garner support and approval from the membership for the guideline.

THE REQUIREMENTS OF THE WORK GROUP VICE-CHAIR

The vice chairperson's main responsibilities will occur following completion of the guideline. In addition to being the content expert, the vice chair will be responsible for helping to disseminate the finished product. In this capacity, the vice chair will be responsible for writing articles in JBJS, JAOS and *AAOS Now* announcing completion of the guideline and introducing the highlights of the guideline to the membership. The vice chair will also be responsible for answering inquiries by the reviewers, public commentators and membership as the guideline moves through the approval process.

REQUIREMENTS OF THE WORK GROUP MEMBERS

TIME COMMITMENT

Work group members are expected to have some training in evidence-based medicine. This training will be provided at the first meeting. Hence, this meeting is very important and all work group members are required to attend. In addition, work group members should have taken AAOS' evidence analysis course. This course is available on the AAOS website at https://www4.aaos.org/timssweb/timssnet/login/tnt_login.cfm?appl_code=EAW).

The first meeting will be devoted to establishing the scope of a guideline and compiling a list of inclusion criteria that will be applied to the literature. The scope of the guideline will be accomplished by constructing preliminary recommendations (see Step 1A below). The inclusion criteria are generally a standard set of criteria that are edited to clarify the specific guideline topic.

Work group members are expected to review the literature search strategies and provide appropriate input. Similarly, members are expected to review the list of articles that will be included in the guideline, and note whether any articles that met the inclusion/exclusion criteria were missed. Generally, two conference calls will be scheduled to address these issues.

Please Note: Members are expected to attend the introductory meeting, a majority of the scheduled conference calls and the last recommendation meeting in order to vote/approve the final guideline document developed.

If a member does not attend the Introductory Meeting, he/she cannot participate on the workgroup. In addition, the last recommendation meeting and a majority of the conference calls must be attended or the final document will not be sent to him/her for approval. It will be up to the discretion of the work group chairperson, vice chairperson, Guidelines Technology and Oversight Committee Chair and Vice Chair persons, Evidence-based Practice Committee Chair and/or the Chair of the Council on Research, Quality Assessment, and Technology and the AAOS Medical Director to determine if that member's name will appear as an author in the document. The member will generally receive the final document and be invited to provide input during the peer review process if they participated in a portion of the process.

It should also be noted that the work group members serve at the discretion of the work group chairperson and the Committee Chairs. The work group chairperson, vice chairperson and Guideline Technology and Oversight Chairperson may consider the removal of any work group member who does not contribute to or appropriately participate in the guideline development process. Work group members may be terminated for reasons including, but not limited to failure to disclose conflict of interest, failure to work as a team member, inability or failure to complete assignments and/or nonparticipation. In addition, The American Academy of Orthopedic Surgeons has established policies promoting a productive work environment and rejecting discrimination, harassment and sexual harassment of any kind. Violation of these policies may cause dismissal of the work group member.¹

The amount of time required by a work group member during the next phase of guideline development is limited. During this time, the Guideline Unit is abstracting data, conducting analyses, and preparing the Guideline Evidence Report upon which the guideline will be based.

Once the Evidence Report is prepared, a "Recommendation Meeting." will be held.

RECOMMENDATION MEETINGS

The "Recommendation Meeting" serves three purposes; (1) provide a forum for AAOS Guideline Unit to present the evidence and their analyses to the work group, (2) refining recommendations, and (3) for voting on the recommendations. During this meeting, the work group will discuss the supporting evidence or lack thereof, review the assigned level of evidence for each included article, refine recommendations accordingly, and assign a grade of recommendation for each guideline recommendation.

All work group members should make attending the final recommendation meeting a high priority in their schedules. The recommendation meeting requires a two-day commitment plus your travel time. Voting on the recommendations will take place at this

last work group meeting so if the work group member disagrees with either the recommendation or grade assigned to it, this is his/her opportunity to discuss that dissention.

Please Note: If the member is not present at the meeting, his/her input cannot be considered. Individual members who cannot attend the recommendation meeting will not be allowed to delay guideline progress. At the discretion of the work group chair, vice chair and AAOS Guidelines Oversight Chair, the guideline will move through the approval process in the absence of input from members who do not attend this meeting.

Voting on guideline recommendations will be conducted using secret ballot. Each member of the guideline work group either agrees (“yes”) or disagrees (“no”) with a guideline recommendation. Work group members are blinded to the responses of other members. Agreement must be unanimous in order for a recommendation to pass. If voting is not unanimous, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved following three voting rounds, no recommendation is adopted.

Either during or immediately following the last work group meeting, members will be asked to write rationales to accompany each guideline recommendation. (Voting on guideline recommendations will be conducted using secret ballot. Each member of the guideline work group either agrees (“yes”) or disagrees (“no”) with a guideline recommendation. Work group members are blinded to the responses of other members. Agreement must be unanimous in order for a recommendation to pass. If voting is not unanimous, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved following three voting rounds, no recommendation is adopted.

Step 10: Writing the Rationales). Generally, the rationales should be completed within two weeks of the last meeting if not completed at the final meeting and submitted to AAOS staff for editing and collating. The work group chair and vice-chair will be asked to review all member input and associated edits prior to the compiled document being sent to the work group for review.

In the event that a work group member cannot attend the final meeting, the Chairperson of the Guidelines Technology and Oversight Committee or the GTOC representative present at the final meeting shall serve as an alternate and have all voting privileges. At the discretion of the work group chair and GTOC Chair, if more than one alternate is required, the work group chair, with the approval of the GTOC Chairperson may choose to appoint a second alternate or move forward with the available members of the work group who attend the recommendation meeting.

PLEASE NOTE: Once the final recommendations are discussed, voted on, accepted and approved at the final recommendation meeting they cannot be changed by the work group. They will be edited by AAOS staff if they do not conform to the

standardized guideline language used in all AAOS guidelines. The expectation is that the wording derived at the final meeting should conform to the standardized language adopted by the AAOS.

Members who do not attend the recommendation meeting will forfeit their opportunity to contribute to the development of the final recommendations. The final document will not be sent to them for review and it will be at the discretion of the work group chair (as discussed above) as to whether or not that member's name will be included in the document as a contributor. Members whose names are retained on the document, but do not attend the final recommendation meeting will be included in the peer review process of the document and may provide input at that time.

DOCUMENT SUPPORT INFORMATION/ DISSEMINATION TO THE WORK GROUP

Because the Evidence Report that supports a guideline is quite long, copies cannot be e-mailed to members (most mailboxes are too small to accommodate even the zipped versions of this information), and paper copies cannot be routinely sent. The Evidence Report will typically be sent via CDs.

Large documents for review will also be posted on SharePoint. The link to SharePoint is <http://teamwork.aaos.org/rsa/> "group" abbreviation. Your login is Academy\ "last name" and your password is aaosgls. If you have already used the Academy SharePoint site your password will be the password assigned for the first site you were signed on to the portal with. If you cannot remember this password, it can be reset.

WORK GROUP RESTRICTIONS

As stated above, in most cases, it is expected that the work group will be diverse, consisting of multi-specialty participation. Work group members who help construct a guideline for AAOS may not act as an advisory panel reviewer on the same guideline for another specialty society.

In addition, please know in advance, that when the guideline is updated in approximately five years, a maximum of two of the original work group members will be invited to participate on the work group panel convened to update the guideline. Generally, the Vice Chair will be invited to chair the updating committee and he/she will have the option of retaining one member of the original work group.² This restriction promotes transparency, enhances reproducibility and minimizes bias. If the results of a guideline are reproducible, any work group should be able to examine the evidence and reach similar if not identical conclusions, as long as the evidence has not significantly changed.

We also ask that members of a guideline work group not publically advertise their participation on the panel until the AAOS Board of Directors has approved the final draft. We request anonymity for several reasons. The participation of well known "thought leaders" on a guideline development work group can elicit bias in the peer review and public commentary process. These members are often well known and highly published and their very participation in the process may influence the reviews both "in favor of"

and “not in favor of” the guideline. Hence, we blind the identity of a work group for all drafts to the reviewers. In addition, industry and the media may pursue members who participate on work groups that develop guidelines on a particularly controversial guideline topic. Further, draft documents are subject to change and those interested in the content of a specific guideline need to have the final BOD approved document before evaluating the contents. If there are questions concerning dissemination of AAOS guidelines, please consult the AAOS Evidence-based Medicine Coordinator or the AAOS Clinical Practice Guideline Manager.

THE GUIDELINE UNIT

The Guideline Unit is responsible for preparing the Evidence Report upon which a guideline is based. This report is a systematic review of the evidence that addresses each preliminary recommendation. The Guideline Unit consists of four research analysts and the CPG Unit Manager. Occasionally, independent contractors and/or others within the Department of Research and Scientific Affairs may assist the unit. The research analysts responsible for the work on each guideline will attend the guideline Recommendation Meeting to answer questions and present the Evidence Report. In addition, the CPG Unit manager is available to answer all questions and will be present on all conference calls during the guideline development process.

III. PROCESSES

STEP 1: FRAME THE GUIDELINE'S SCOPE

The first step in developing a clinical practice guideline is framing its scope. Guideline developers are faced with the challenge of wanting to include everything of clinical interest in a guideline and the need for timely publication of that guideline. This balance is at the forefront of framing a guideline's scope. Here are some things to consider when thinking about what a guideline should and should not address:

1. Guidelines that include information from about 100 published articles will require 6-8 months to complete (not including review, which adds an additional seven months to development). The more articles that are included, the longer it will take to complete the guideline.
2. In general, it is best to consider diagnosis and treatment in two separate guidelines, not in a single guideline.
3. Stay away from framing questions about the natural history of a disease. This information can be covered in the introduction to the guideline.
4. We have adopted "first principles" of analysis to assist you in defining a guideline's scope (See below)

First Principles of Evidence-Based Analysis

Below are our "first principles" of evidence-based analysis:

- Obtaining a careful history and physical underlies good clinical practice. The process of obtaining a history and physical supplies the information for the formation of diagnostic and treatment questions fundamental to the practice of Evidence-based Medicine. **(The implication is that we will not conduct systematic reviews to validate recommendations for a history and physical).**
- Treatments should improve on the natural history of a disorder, which in many cases is recovery without treatment. **(The implication is that we will include only controlled trials when evaluating conditions that improve without treatment).**
- Patient-oriented outcomes take precedence over intermediate/surrogate outcomes.
- Validated outcomes measures take precedence over non-validated outcomes measures.
- **Retrospective case series studies are excluded.**
- The level of evidence for an underpowered study is inconclusive unless that study is used in a de novo meta analysis by the guideline unit.

STEP 1A: PREPARE PRELIMINARY RECOMMENDATIONS

We will begin framing a guideline's scope by asking each of the work group members to construct preliminary guideline recommendations (also called mock guideline statements). A preliminary recommendation takes the form: [What] should be done in [whom], [when], [where] and [how often].

Here is an example of a properly framed preliminary guideline recommendation: Hip and knee surgery patients at standard risk of both PE and major bleeding should receive aspirin 325 mg 2x/day (reduce to 81 mg 1x/day if gastrointestinal symptoms develop), starting the day of surgery, for 6 weeks.

NOTE: The recommendations prepared at this stage are not final recommendations. The drugs, doses, and frequency at which they are used may change upon review of the evidence. At this point, we are using what you write as a placeholder.

STEP 1B: VOTE ON WHICH RECOMMENDATIONS SHOULD BE INCLUDED

When the Guideline Unit has received all of your preliminary recommendations, we will collate them and the work group members will discuss whether any of the preliminary recommendations should be excluded. Please remember to consider the guideline's scope and projected timeline when you consider each preliminary recommendation.

When we arrive at the final set of preliminary recommendations, we will sometimes ask each member of the work group to rank each recommendation from most to least important. AAOS staff will compute an average rank for each preliminary recommendation. This average ranking will often determine the order of our work.

STEP 1C: SPECIFYING ARTICLE INCLUSION/EXCLUSION CRITERIA

Next, we will ask you to assist in framing criteria for determining which articles should be included and which articles should be excluded from consideration. Obviously, some of these criteria will be based on relevance. Other criteria may be based on the dates during which a study was conducted (some studies may be so old that their results are unlikely to reflect current best practice). Typically, inclusion criteria should also consider study design. For example, if the natural course of disease is such that patients improve without an intervention, then there is little point in including uncontrolled studies. Only controlled studies should be included.

Please note that we will never include all available evidence. Wherever appropriate, we will search for and include the best available evidence. Hence, if Level II evidence is available, we will not search for or include Level III evidence or lower unless there is very little Level II evidence, and a great deal of Level III evidence.]

We will never include the following types of information:

- 1. Animal studies, cadaveric studies, in vitro studies or biomechanical studies*
- 2. Meeting abstracts, case reports or reviews*

3. *Studies of <10 patients in any arm*
4. *Studies published in a foreign language*
5. *Studies that do not report patient-oriented outcomes*
6. *Retrospective case series studies*
7. *The level of evidence for an underpowered study is inconclusive unless that study is used in a de novo meta-analysis by the guideline unit.*

STEP 2: SEARCHING FOR STUDIES

STEP 2A: CONSTRUCTING THE SEARCH STRATEGIES

The AAOS medical librarian will be responsible for constructing search strategies. He/she will ask you for assistance in developing the searches by requesting relevant terms from you. Typically, we will search for literature in PubMed, EMBASE, the Cochrane Library, and the ACP Journal Club. On occasion, additional sources may be used.

STEP 2B: REVIEWING THE SEARCH RESULTS

When the searches are complete, we will ask you to review them to see if there are any relevant articles that they did not identify. We will generally hold a teleconference to be certain members have a clear understanding of the literature base that has been identified. Because these searches are designed to find as much relevant information as possible, they will also contain many irrelevant articles. In fact, over half of the articles in these searches are likely to be irrelevant. If there are too many articles missed by our searches, we will modify our search strategies.

STEP 3: DETERMINING WHETHER ARTICLES MEET THE INCLUSION CRITERIA

AAOS staff will determine whether articles meet the inclusion criteria. When they have finished this task, we will send you a list of the articles that were included and a list of the excluded articles and the reason(s) for excluding them. You will almost never receive this material all at once. Typically, you will receive it at logical break points, such as when all of the articles for a certain preliminary recommendation have been evaluated.

After examining this information, please feel free to ask AAOS staff to revisit inclusions or exclusions, and to submit any additional articles to AAOS staff for consideration for inclusion.

STEP 4: EXTRACTING DATA

AAOS staff will extract the relevant information from each article and enter it into a database. This process will take a long time, and during this time, we will probably not have many conference calls. Once this work is complete, you will know that we are

nearing the end of the development of the guideline. Your work load will dramatically increase at this time.

STEP 5: EVALUATING AND ANALYZING THE DATA

AAOS Staff will assign a Level of Evidence to each study, but we will ask you to review these levels. AAOS staff will also conduct meta-analyses (if the data permit) and/or draw any graphs that will help you interpret the data.

STEP 6: EVIDENCE REVIEW

AAOS Staff will present the results of their analyses to work group members at a face-to-face meeting, the final work group or the recommendation meeting. This meeting will generally be scheduled following the introductory meeting and after the initial literature search has been completed. The Guidelines Unit will have a better idea of the scope of the guideline based on the literature and will be able to better estimate the time needed to complete a topic. We will try to schedule it as far in advance as possible so that you will have every opportunity to coordinate your schedules to participate in the final meeting.

STEP 7: ASSIGNING A GRADE OF RECOMMENDATION

After you have seen the data, you may choose to revise your preliminary guideline recommendations. You will also need to assign a grade to each recommendation. This grade should reflect how confident you are in the recommendation. If the recommendation is unlikely to change when new information becomes available, you would assign a relatively high grade to a recommendation. However, if new information could change the recommendation with relative ease, you would assign a low grade to the recommendation.

To assist you in assigning a grade to the recommendation, AAOS staff will provide you with the following information *for each outcome of interest*:

Name of Intervention(s):

Name of outcome:

Evidence tables

Meta-analyses (when conducted)

Level of Evidence (which accounts for quality of evidence)

Strength of Evidence (which accounts for the quality, consistency, and amount of available evidence)

Preliminary Grade of Recommendation

You will then be asked to modify the preliminary Grade of recommendation prepared by AAOS staff. This is a five step process that requires you to consider:

1. Trade-offs

- Is there a net benefit? If the intervention clearly does more good than harm, you will probably wish to keep the original grade of recommendation intact. However, in rare cases (e.g., a low cost intervention with virtually no associated harms), you may wish to upgrade the recommendation.

- Are there important trade offs involved with using the intervention? If there are important trade-offs between benefits and harms, you may wish to downgrade the preliminary grade of recommendation.
 - Uncertain trade off: If it is not clear whether the intervention does more good than harm, you may wish to downgrade the recommendation or make no recommendation at all.
 - Is there no net benefit? If the intervention clearly does not do more good than harm, you may wish to recommend against using the intervention.
2. Strength of evidence: This is a combination of the quality, quantity and consistency of evidence. For example, the strength of evidence provided by a single well-designed RCT is lower than the strength of evidence provided by many RCTs, all of which found the same result.
 3. Applicability of evidence: You may wish to downgrade the preliminary grade of recommendation if, for example, the effectiveness of the interventions is affected by proximity to a hospital or the availability of necessary expertise. Accordingly, the effects of that intervention that are seen in actual clinical practice may be very different from those observed in the research setting.
 4. Uncertainty of baseline risk? If a treatment has significant harms but also provides great benefits, you may be less likely to use it if you don't know the baseline risk for adverse events for the population of interest. Therefore, you may wish to downgrade the preliminary grade of recommendation.
 5. Costs: In some cases, you may wish to consider the incremental costs of an intervention. However, AAOS staff does not routinely search for or provide cost information to Work group members during guideline development.

We will provide you with a form to assist you in grading the recommendation. The form appears in Appendix: Form for Assigning Grade of Recommendation (Interventions).

STEP 8: WRITING THE RECOMMENDATIONS

At this point, you will re-write your preliminary recommendations. The wording of these recommendations is dictated by their grade. Please use the following wording:

We **recommend** Treatment X: (for strong recommendations)

We **suggest** Treatment X: (for moderate recommendations)

Treatment X is an **option**: (for weak recommendations)

It is the consensus of this workgroup: (for recommendations where no evidence is available to support the recommendation and the workgroup believes it is absolutely necessary to address the topic based on the harms and/or benefits associated with the recommendation.)

We cannot recommend for or against: (for inconclusive or conflicting evidence)

STEP 9: VOTING ON THE RECOMMENDATIONS

Votes on the recommendations will be held during the final recommendation (face-to-face) meeting of the work group. The grade of recommendation will be bundled into this vote, so if a work group member disagrees with either the recommendation or grade of recommendation based on the evidence reviewed, (s)he should vote to not accept the recommendation.

Voting on guideline recommendations will be conducted using secret ballot. Each member of the guideline work group either agrees (“yes”) or disagrees (“no”) with a guideline recommendation. Work group members are blinded to the responses of other members. Agreement must be unanimous in order for a recommendation to pass. If voting is not unanimous, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved following three voting rounds, no recommendation is adopted.

STEP 10: WRITING THE RATIONALES

A rationale will accompany each guideline recommendation. The rationale should make extensive reference to the systematic review, and discuss each of the critical benefits and harms that you identified in Step 7. Please also explain any weaknesses in the data. If you modified the preliminary grade of recommendation in Step 7, please provide the reason(s) for this.

Examples of rationales will be provided at the Final Recommendation Meeting.

IV. REVIEW OF CLINICAL PRACTICE GUIDELINES

PURPOSE

This document describes potential review processes for AAOS' clinical practice guidelines. This review has two purposes. First, it will enhance the quality of our guidelines. Guidelines are commonly peer reviewed, and whether such review is conducted is commonly used as a measure of a guideline's quality (cf. the AGREE instrument at <http://www.agreecollaboration.org/instrument/>). The second purpose of review is to afford interested parties who are not directly involved in the development of our guidelines the opportunity to comment on them before they are released.

This document also describes processes for guidelines approval.

TYPES OF REVIEW

As implied in the preceding section, there will be two types of review, peer review, and commentary.

PEER REVIEW

Peer Review will begin when the draft guideline is complete and ready for review, generally within one month of the final recommendation meeting. Peer reviewers will be comprised of:

1. The Evidence-Based Practice Committee (EBPC)
2. The Guidelines Technology and Oversight Committee (GTOC)
3. Members of outside specialty organizations nominated by the work group.
4. The chair of the Medical Liability Committee or his/her designee.
5. In applicable guidelines, the chair of the Worker's Compensation Committee will also receive a copy of the confidential draft for peer review.

Outside specialty organizations will be invited to provide peer reviewers for each guideline and will consist of experts in that guideline's topic area. These experts will be chosen by professional societies other than AAOS. Preferably, members chosen by the outside specialty organizations to provide peer review will have training and/or experience in evidence-based medicine. There will be 10-15 members from a variety of outside specialty organizations invited to provide peer review for each guideline.

Peer reviewers will receive the entire guideline and all of its supporting documentation, including the evidence report. However, these reviewers will be allowed the option to reviewing only that portion of a guideline in which they are expert. Because peer reviewers will receive several hundred pages of material to review, they will be given one month to review the document. This time frame will depend on the guideline topic, amount of supporting documentation, and the schedule for Board of Directors meetings. Reviews must be written. Verbal reviews will not be accepted.

The Guidelines Unit in the Department of Research and Scientific Affairs at AAOS will document the disposition of all non-editorial comments from each reviewer, obtain the

Work group chair or vice-chairperson's approval for these comments, and will send each reviewer the approved documentation for his/her comments.

Peer review may result in modification of a guideline. However, there is no obligation to change a guideline in response to all reviewers' comments. For example, comments that are not backed by evidence (e.g., "In my experience.....") will not result in modification of a guideline.

There will be approximately 42 peer reviewers for each guideline (12 EBPC members, 15 GTOC members, and 15 Advisory Panel members). Documenting the disposition of their comments and gaining the Work group chair or vice-chairperson's approval of this documentation will require approximately one month.

PUBLIC COMMENTARY

Public Commentary will begin when documentation about the disposition of reviewer comments has been sent to peer reviewers. Generally, thirty days will be allowed for public commentary; again this is dependent on the guideline topic, amount of documentation and the schedule for Board of Directors' meetings. Commentators will consist of:

1. Members of the AAOS Board of Directors (BOD)
2. Members of the Council on Research, Quality Assessment, and Technology (CORQAT)
3. Members of the Board of Councilors (BOC)
4. Members of the Board of Specialty Societies (BOS)

Commentators will receive the guideline and evidence report if they request it when polled for interest.

There will be up to 185 commentators (16 BOD members, 21 CORQAT members, 100 BOC Members, and 48 BOC members and officers) for each guideline. Each commentator who returns a review within 30 days will receive a "thank you" letter and, if their review engendered a change in the guideline, documentation of that change. The work group chair will approve any letters documenting a change. Preparing the appropriate documentation will require approximately one to two months.

GUIDELINE APPROVAL

The approval process for any given guideline will begin when peer review and public commentary are completed. There will be four AAOS bodies will be involved in the approval process:

1. The Evidence-Based Practice Committee
2. The Guidelines and Technology Oversight Committee
3. The Council on Research, Quality Assessment, and Technology
4. The Board of Directors

Each person serving on one these bodies will receive the guideline, evidence report, peer review documentation letters, and any public commentator “thank you” letter that documents a guideline change that resulted from a commentator’s review.

Approval will proceed in the order shown in the above bullet points, and a guideline will not proceed from one body until the previous one has approved it.

Should any of these bodies not approve a guideline, that guideline’s work group could be reconvened, the work group could be reconvened with the possible addition of one or two new member additions, or a totally new work group could be convened. You should also be aware that the Oversight Chairs representing the AAOS oversight bodies may decide at any time, based on varying circumstances, to discontinue work on any given guideline. This includes if time and budget constraints dictate a change in priorities, if the work group cannot or will not follow the AAOS methodology or if other circumstances dictate unforeseen rescheduling. The Guidelines and Technology Oversight Committee will be responsible for determining the make-up of a reconvened guideline work group, for appointing any additional members and for determining the disposition of any guideline and work group.

The guideline will be updated in approximately five years. (See the AAOS procedure for updating existing AAOS guidelines).

V. APPENDIX: FORM FOR ASSIGNING GRADE OF RECOMMENDATION (INTERVENTIONS)³

ASSIGNING A GRADE OF RECOMMENDATION

(Please complete this form for each guideline recommendation)

GUIDELINE RECOMMENDATION _____

PRELIMINARY GRADE OF

RECOMMENDATION: _____

STEP 1: LIST BENEFITS AND HARMS

- a) Please list the benefits (as demonstrated by the systematic review) of the intervention

- b) Please list the harms (as demonstrated by the systematic review) of the intervention

- c) Please list the benefits for which the systematic review is not definitive

- d) Please list the harms for which the systematic review is not definitive

STEP 2 IDENTIFY CRITICAL OUTCOMES

Please circle the above outcomes that are critical for determining whether the intervention is beneficial *and* whether it is harmful

- a) Are data about critical outcomes lacking to such a degree that you would lower the preliminary grade of the recommendation?
Yes No

b) What is the resulting grade of recommendation?

STEP 3: EVALUATE APPLICABILITY OF THE EVIDENCE

a) Is the applicability of the evidence for any of the critical outcomes so low that substantially worse results are likely to be obtained in actual clinical practice?

Yes No

b) Please list the critical outcomes backed by evidence of doubtful applicability:

c) Should the grade of recommendation be lowered because of low applicability?

Yes No

d) What is the resulting grade of recommendation?

STEP 4: BALANCE BENEFITS AND HARMS

a) Are there trade-offs between benefits and harms that alter the grade of recommendation obtained in STEP 3?

Yes No

b) What is the resulting grade of recommendation?

STEP 5 CONSIDER COSTS

a) Are there cost considerations that cause you to modify the grade of recommendation obtained in STEP 6?

Yes No

b) What is the resulting grade of recommendation?

NOTE: Because we are not performing a formal cost analyses, you should only consider costs if their impact is substantial.

VI. APPENDIX: WORK GROUP MEMBER CHECKLIST

As stated previously, the work group chairperson, in conjunction with the GTOC Chairperson and AAOS staff, guides the development process of the guideline. The following items provide a checklist of items to complete for the work group.

Initial Step:

1. Attend the Introductory Meeting
2. Tasks the work group will complete at the Introductory Meeting:
 - The work group will create a list of preliminary recommendations; this list will be limited to fifteen recommendations per guideline.
 - External guidelines and/or recommendations are not included as evidence in AAOS guidelines because developers' processes are different from the AAOS process. The bibliographies will be reviewed for additional literature to review for inclusion.
 - External systematic reviews are not included as evidence in AAOS guidelines because developers' inclusion criteria vary. The authors' conclusions will be acknowledged in the evidence report following all AAOS *de novo* analyses.
 - The work group will approve the list of inclusion criteria for the literature.
 - The inclusion criteria may include dates as related to specific development of techniques or change in practice.
 - The work group will assist the Medical Librarian construct and review the list of search criteria for primary studies

Next Steps:

3. The work group chair or individual work group members may be contacted intermittently as these searches progress and "in process" questions arise.
4. The work group will review the list of included and excluded articles. A teleconference will be held to discuss the literature base of included articles and resolve any differences of opinion as to articles that are excluded.
5. Even though the work group will be given the opportunity to review and suggest additions to the list of included articles, all articles suggested for inclusion must meet the a priori criteria established prior to the search in order to be included.

Final Steps:

6. The work group will attend the Final Recommendation Meeting.
7. The work group will write the supporting rationales for the final recommendations within seven to fourteen days of the final recommendation meeting if not completed at the meeting.
8. The work group chair will support these deadlines in order to support the AAOS BOD Directives.
9. The work group chair will write the pertinent introductory sections in the guideline template.

Note: This section of the guideline may require additional references to support the appropriate sections on incidence, prevalence, burden of disease, etiology and risk factors.

10. The work group chairperson will review and edit the final guideline with the support of the CPG Manager.
11. The assembled document will then be sent to the work group for review.
12. The work group chair and vice-chair person will work with the AAOS CPG manager to edit and incorporate the member's rationales and will indicate when the final draft of the document is ready to be submitted for peer review.
13. Both the work group chair and vice chair will help to clarify, answer and approve all peer reviewer non-editorial comments.
14. The work group chairperson will approve the final guideline document and submit the draft to the GTOC, EBPC, CORQAT and the BOD for approval.
15. The work group chairperson will assist the vice-chairperson in addressing member and manufacturer comments about completed guidelines.
16. The work group chair person may also be asked to assist in conducting a webinar on the guideline.

Dissemination of the Guideline will include some if not all of the following:

Dissemination efforts vary by guideline; the vice chair will be responsible for these dissemination efforts if they are included in the AAOS marketing strategy:

- Helping to produce an AAOS press release introducing the guideline to the membership.
- Developing an AAOS Webinar based on the guideline
- Developing an Online Module available on Orthopaedic Knowledge Online
- Participation in a Radio Media Tour
- Participation in a Media Briefing

Other dissemination efforts, that the work group vice chair may be asked to help coordinate include:

- Submission of the guideline to the National Guideline Clearinghouse
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- Distribution of the Guideline at the AAOS Annual Meeting in various venues including Academy Row and Committee Scientific Exhibits
- Distribution of the Guideline by other medical specialty societies
- Distribution of the Guideline at AAOS CME courses
- Distribution of the Guideline through the AAOS Resource Center
- Helping to get the guideline recommendations included in self assessment/ABOS exam questions, OITE questions and for those recommendations based on high levels of evidence, helping to develop possible pay for performance measures.

Reference List

- (1) American Academy of Orthopaedic Surgeons. American Academy of Orthopaedic Surgeons Personnel Policy Manual. 11-1-2005. 2-10-2009.
Ref Type: Unpublished Work
- (2) Sniderman AD, Furberg CD. Why Guideline-Making Requires Reform. *JAMA* 2009 January 28;301(4):429-31.
- (3) GRADE Working Group. Grading quality of evidence and strength of recommendations. *BMJ* 2004 June 19;328.