

Task Force for Outside Guideline Review

Establishing a formal process for AAOS endorsement of external organization clinical practice guidelines

I. Introduction:

The American Academy of Orthopaedic Surgeons (AAOS) has been developing evidence-based clinical practice guidelines (CPGs) to improve patient care (CPGs are defined as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances⁽¹⁾). The Academy has received recognition for these efforts, and consequently has received requests by other medical specialty societies to review and possibly endorse their guidelines. The AAOS Task Force (TF) for Outside Guideline Review was assembled to determine whether the AAOS should endorse CPGs prepared by others, and if so, to develop a process for endorsement. Inasmuch as the task force determined that the AAOS should endorse external CPGs, the present document is devoted to describing the processes for doing so.

The protocol described in the present document is based upon two premises, first, that the AAOS' process for reviewing external CPGs should be transparent and second, that the AAOS will not endorse CPGs that are of lower quality than the AAOS' evidence-based CPGs. The AAOS' evidence-based CPGs are developed using processes designed to combat bias, enhance transparency, and promote reproducibility. Specifically, the AAOS' evidence-based CPGs are developed from systematic reviews of the relevant literature. Systematic reviews employ rigorous methods for selecting published clinical studies, impartially appraising research findings with well-defined rules of evidence analysis, and offering a balanced summary of the research results⁽²⁾. CPGs based on systematic reviews are prepared very differently from those based on consensus methods. CPGs prepared by consensus methods may incorporate evidence, but do not systematically identify or evaluate it. Often, such CPGs incorporate information as a method of supporting the authors' preconceived ideas. Such CPGs are not methodologically sound.

II. Tools Referenced to Develop Review Process for External Clinical Practice Guideline Endorsement:

The criteria for CPG endorsement that are described here have been adapted from existing instruments that were developed to evaluate the quality of CPGs and systematic reviews. These instruments include the AGREE instrument,⁽³⁾ the AMSTAR instrument,⁽⁴⁾ the Cancer Care Ontario Program in Evidence-Based Care Practitioner Feedback instrument as adapted by the American Society of Clinical Oncology,⁽⁵⁾ and the requirements for CPG submission to the National Guideline Clearinghouse⁽⁶⁾.

AGREE is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of CPGs by establishing a shared framework for CPG development, reporting and assessment. The collaboration has the participation of a core of European countries: Denmark, Finland, France, Germany, Italy, the Netherlands, Spain, Switzerland and the United Kingdom as well as Canada, New Zealand and the USA. The purpose of the AGREE Instrument is to provide a framework for assessing the quality of clinical practice guidelines. It provides an assessment of the predicted validity of a CPG that is the likelihood that it will achieve its intended outcome. It does not assess the impact of a guideline on patients' outcomes⁽³⁾.

The measurement tool AMSTAR was developed to assess the methodological quality of systematic reviews. It was designed using sound psychometric principles, and consists of 11 items with good face and content validity⁽⁴⁾.

The third instrument we rely on allows for incorporating clinical expertise into the guideline endorsement process. It originally derives from the Cancer Care Ontario Program in Evidence-Based Care, which developed an instrument to measure clinicians' assessment of CPGs in oncology. This instrument was further evaluated and refined using psychometric principles such as, factor analysis and multilevel modeling techniques⁽⁷⁾. The American Society of Clinical Oncology (ASCO) adapted the instrument and used it to review the recommendations from external CPGs seeking endorsement⁽⁵⁾. The adapted form excludes questions that are either not pertinent to CPG endorsement, or are already asked by the AGREE or the AMSTAR tools. The AAOS will be using the adapted form as well.

Finally, The National Guideline Clearinghouse™ (NGC) is a comprehensive database of evidence-based clinical practice guidelines and related documents. The NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), and was originally created by AHRQ in partnership with the American Medical Association and the American Association of Health Plans (now America's Health Insurance Plans [AHIP]). The NGC's mission is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use⁽⁶⁾.

III. Review Process for External Clinical Practice Guideline Endorsement

The task force recommends a six step process for reviewing external CPGs seeking AAOS endorsement. These steps are described below.

STEP 1: Submitting and Selecting an External Clinical Practice Guideline for AAOS Endorsement

An external organization seeking AAOS endorsement for its CPG must first submit its request to one of the following: A member of the AAOS Board of Directors, the Chair of the AAOS Advocacy Committee, the Chair of the AAOS Council on Research, Quality Assessment, and Technology, or the Chair of the AAOS Education Committee. These individuals will contact the AAOS Evidence Based Medicine Coordinator to begin the review process for external CPG endorsement. He/she will notify the Chair of the Guidelines and Technology Oversight Committee (GTOC) that a request for endorsement has been submitted.

The GTOC will be responsible for determining which external CPGs will be reviewed based on their current method for selecting topics for AAOS guideline development. This process employs the topic prioritization matrix shown in Appendix A. The GTOC will use this matrix to prioritize external CPG submissions twice a year at its semi-annual meetings.

STEP 2: Assembling External Guideline Review Team (EGR team)

An external guideline review (EGR) team will be assembled for each external CPG the GTOC has prioritized for review. The formation of the team will be based on the current method used to assemble a workgroup for AAOS evidence-based CPG development. Briefly, the Chairpersons from GTOC and the Evidence Based Practice Committee (EBPC) will nominate a member to chair the team. Once the Chair of the team is selected he/she will select the members of the team. A team will consist of one chair and five members.

STEP 3: Staff Performs the Initial Criteria Review

Two AAOS staff members, who will work blinded from each other, will evaluate the external CPG to determine whether it meets all the initial criteria. To meet these criteria, the external CPG must receive a 'yes' for all the questions in Appendix B. During the initial criteria review the staff may contact the developer for more information about the CPG.

If the external CPG does not meet the initial criteria, staff will notify the EGR team, which will audit the decision. If they are in agreement, the chair of the team will notify the GTOC Chair who in turn will notify the point of contact, and the external organization, that the external guideline will not be endorsed by the AAOS. The completed tool in Appendix B and the external CPG will be kept on file at AAOS headquarters.

STEP 4: Staff Reviews Methodology Used to Produce External Clinical Practice Guideline-

If an external CPG meets all the criteria in step 3, the external CPG will receive a more detailed methodological review. Two AAOS staff members, working blinded from each other, will review the methodology used to produce the external CPG using the tool in Appendix C. The external CPG must receive a ‘yes’ for all the questions asked by the tool in Appendix C, in order to proceed with the endorsement process. As before, staff may contact the CPG developer for more information.

If the external CPG does not meet the methodology criteria, the appropriate notification procedure described in step 3 will be followed. The completed tools shown in Appendix B, Appendix C, and the external CPG will be kept on file at AAOS headquarters.

STEP 5: Team Reviews Recommendations

After the successful completion of the tools in Appendix B and Appendix C, each EGR team member will review the external CPG recommendations using the tool in Appendix D. Based on the overall results from the tool in Appendix D, the team will determine whether to endorse the external CPG.

The team as a whole will decide whether to endorse the external CPG by using the Nominal Group Technique (NGT). This technique is also used by the AAOS’ workgroups when voting on evidence-based CPG recommendations⁽⁸⁾. Briefly each member of the team ranks his or her agreement with the external CPG on a scale ranging from 1 to 9 (where 1 is “extremely inappropriate” and 9 is “extremely appropriate”). Consensus is obtained if the number of individuals who do not rate a measure as 7, 8, or 9 is statistically non-significant (as determined using the binomial distribution). Because the number of team members who are allowed to dissent with the external CPG depends on statistical significance, the number of permissible dissenters varies with the size of the team. The number of permissible dissenters for several team sizes is given in the table below:

<i>Team Size</i>	<i>Number of Permissible Dissenters</i>
≤ 3	<i>Not allowed. Statistical significance cannot be obtained</i>
4-5	0
6-8	1
9	1 or 2

The NGT is conducted by first having members vote on a given external CPG without discussion. If the number of dissenters is “permissible”, the external CPG is adopted without further discussion. If the number of dissenters not permissible, 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 after three voting rounds, the external CPG is not adopted.

In the event that the external CPG does not meet the endorsement criteria, the appropriate notification procedures described in step 3 will be employed. The completed tools in Appendix B, Appendix C, Appendix D, and the external CPG will be kept on file at AAOS headquarters.

STEP 6: Approval

Subsequent to approval of an external CPG by an EGR team, the external CPG will be subject to processes similar to those used to approve an AAOS evidence-based CPG. As such, four AAOS bodies will be involved in the approval process. The external CPG is not endorsable if one AAOS body does not approve. The four AAOS bodies involved in the process include:

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 of these bodies will receive the external CPG and a report from the EGR team containing results from the three measuring tools. The external CPG will not proceed to the next group until the previous group has completed their approval process. Voting on endorsing the external CPG will follow the regular voting methods as established by each AAOS body.

In the event that the external CPG does not meet the approval process, the appropriate notification procedure described in step 3 will be followed, and all AAOS bodies involved will be notified. The completed tools in Appendix B, Appendix C, Appendix D, and the external CPG will be kept on file at AAOS headquarters.

Reference List

- (1) Institute of Medicine. *Clinical Practice Guidelines: Directions for a New Program*. 38. 1990. Washington, DC, National Academy Press.
- (2) Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med* 1997 Aug 1;127(3):210-6.
- (3) The AGREE Collaboration. *Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument*. 2008.
- (4) Shea B, Grimshaw J, Wells G, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology* 2007;7(1):10.
- (5) Basch EM, Somerfield MR, Beer TM, Carducci MA, Higano CS, Hussain MH, et al. American Society of Clinical Oncology endorsement of the Cancer Care Ontario Practice Guideline on nonhormonal therapy for men with metastatic hormone-refractory (castration-resistant) prostate cancer. *J Clin Oncol* 2007 Nov 20;25(33):5313-8.
- (6) National Guideline Clearinghouse (NGC). 2008.
- (7) Brouwers MC, Graham ID, Hanna SE, Cameron DA, Browman GP. Clinicians' assessments of practice guidelines in oncology: the CAPGO survey. *Int J Technol Assess Health Care* 2004;20(4):421-6.
- (8) Murphy MK et al. Consensus development methods, and their use in clinical guideline development. *Health Technology Assessment* 1998; 2(3).

Appendix A: Topic Prioritization Matrix

	High Disease Burden?	High Cost?	Practice Variation?	Sufficient Research Findings?	Public or Political Demand?	Feasible?	No Existing Guidelines?	Is this guideline significant to AAOS?
<i>(Enter Topic of External Guideline seeking AAOS Endorsement)</i>								

Instructions for Completion:

For each field corresponding to each possible guideline topic, answer each of the column-header questions according to the following scale:

Strongly Disagree **Neutral** **Strongly Agree**
1 **2** **3** **4** **5**

The column headers in the table above address the following questions:

1. Does the health problem in question carry a high individual or population burden of morbidity, mortality, or disability?
2. Does the health problem and/or its diagnosis and/or treatment carry a high unit or aggregate cost?
3. Are there substantial variations in the diagnosis and/or treatment of the health problem?
4. Are there sufficient research findings available upon which to base the external clinical practice guideline?
5. Is there substantial public or political demand for this external clinical practice guideline (please consider pay for performance measures when answering this question)?
6. In reviewing this external clinical practice guideline feasible with current AAOS resources?

7. Is there an absence of existing clinical practice guidelines on this topic? If not, will a newly developed guideline have a meaningful impact on clinical decision-making/clinical outcomes and/or reduce practice variation.
8. Will this external clinical practice guideline be of significant benefit to AAOS members?

Priority will be given to topics that lend themselves to performance measure construction and to topics that are backed by sufficient evidence (both in terms of quantity and quality) to allow for at least some of the guideline's recommendations to be evidence-based.

Appendix B: Initial Criteria Review of External Guideline

1. Is the guideline based on systematically reviewed evidence? ^{2,5}	<u>Yes</u>	<u>No</u>	<u>Unclear</u>	<u>Comments</u>
2. Is this guideline less than 5 years old? ⁴	<u>Yes</u>	<u>No</u>	<u>Unclear</u>	<u>Comments</u>
3. Is there a description of the funding source used for the development of the CPG? ^{1,5}	<u>Yes</u>	<u>No</u>	<u>Unclear</u>	<u>Comments</u>
4. Is there a statement of conflict of interest? 1, 2, 5	<u>Yes</u>	<u>No</u>	<u>Unclear</u>	<u>Comments</u>
5. Has the external organization submitted a complete copy of the guideline including supporting evidence tables? ^{2,5}	<u>Yes</u>	<u>No</u>	<u>Unclear</u>	<u>Comments</u>

- (1) The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. www.agreecollaboration.org
- (2) Shea et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 2007 Feb; 7(10). www.biomedcentral.com/1471-2288/7/10
- (3) Basch et al. American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Nonhormonal Therapy for Men with Metastatic Hormone-Refractory (castration-resistant) Prostate Cancer. Journal of Clinical Oncology 2007 Nov; 25(35). Retrieved on Nov. 1, 2007. <http://jco.ascopubs.org/cgi/content/full/25/33/5313>
- (4) National Guideline Clearinghouse requirement- <http://www.ngc.org/>
- (5) AAOS procedure

Appendix C: Reviewing the Method Used to Produce an External Clinical Practice Guideline

1. Was a systematic method used to search for peer reviewed literature? ^{1, 2, 5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>
2. Is there a description of the inclusion/exclusion criteria for evidence? ^{1, 2, 5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>
3. Is the scientific quality of the included studies/evidence assessed and documented? ^{2, 5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>
4. Is a grade assigned to the recommendations based on the scientific quality of the included studies? ^{2, 5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>

- (1) The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. www.agreecollaboration.org
- (2) Shea et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 2007 Feb; 7(10). www.biomedcentral.com/1471-2288/7/10
- (3) Basch et al. American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Nonhormonal Therapy for Men with Metastatic Hormone-Refractory (castration-resistant) Prostate Cancer. Journal of Clinical Oncology 2007 Nov; 25(35). Retrieved on Nov. 1, 2007. <http://jco.ascopubs.org/cgi/content/full/25/33/5313>
- (4) National Guideline Clearinghouse requirement- <http://www.ngc.org/>
- (5) AAOS procedure

5. Are the health benefits being considered in formulating the recommendations? ^{1,5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>
6. Are the side effects and risks being considered in formulating the recommendations? ^{1,5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>
7. Is there documentation/proof of an external review of the guidelines by experts? ^{1, 2, 5}	<u>YES</u>	<u>NO</u>	<u>Unclear</u>	<u>Comments</u>

- (1) The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. www.agreecollaboration.org
- (2) Shea et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 2007 Feb; 7(10). www.biomedcentral.com/1471-2288/7/10
- (3) Basch et al. American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Nonhormonal Therapy for Men with Metastatic Hormone-Refractory (castration-resistant) Prostate Cancer. Journal of Clinical Oncology 2007 Nov; 25(35). Retrieved on Nov. 1, 2007. <http://jco.ascopubs.org/cgi/content/full/25/33/5313>
- (4) National Guideline Clearinghouse requirement- <http://www.ngc.org/>
- (5) AAOS procedure

Appendix D:

Review of External Guideline Recommendations

Please use this table to inform your final vote

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Unsure	Comments
The results of the studies described in this guideline are interpreted according to my understanding of the data.							
The recommendations in this report are clear.							
I agree with the recommendations as stated in the guideline.							
The recommendations are suitable for the patients for whom they are intended.							
The recommendations are too rigid to apply to individual patients.							
When applied, the recommendations will produce more benefits than harm for patients.							

Final Vote: Please rank your agreement with the guideline on a scale ranging from 1 to 9 (where 1 is “extremely inappropriate” and 9 is “extremely appropriate”). For further details please see Step 5.

The external CPG should be endorsed by the AAOS	
---	--

*This form was adapted from the Cancer Care Ontario Program in Evidence-Based Care Practitioner Feedback instrument by the American Society of Clinical Oncology, Basch et al 2007.