

AAOS Appropriate Use Criteria Update Methodology

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OVERVIEW

The American Academy of Orthopaedic Surgeons (AAOS) develops Appropriate Use Criteria (AUC) to determine the appropriateness of select orthopaedic procedures. An “appropriate” procedure is one for which the expected health benefits exceed the expected negative consequences by a sufficiently wide margin.¹ Evidence-based information in conjunction with the clinical expertise of physicians from multiple medical specialties is used to develop AAOS AUC in order to improve patient care and obtain the best outcomes while considering the subtleties and distinctions necessary in making clinical decisions.

Evidence-based medicine methods often illustrate the lack of evidence that is detailed enough to apply to the full range of patients seen in everyday clinical practice. Despite this, physicians must make decisions based on clinical indications about when to use a procedure. Accordingly, the AAOS uses the RAND/UCLA Appropriateness Method (RAM)¹ to combine available scientific literature with the collective judgment of experts to yield statements about the appropriateness of performing a procedure. To that end, AAOS conducts a systematic review of the available literature regarding a procedure (i.e. an AAOS Clinical Practice Guideline) and a panel of physicians applies their clinical expertise to compile a list of clinical scenarios. Then an expert panel, comprised of representatives from multiple medical specialties, determines appropriateness of clinical indications by rating a clinical scenario (i.e. a group of clinical indications) ‘appropriate’, ‘may be appropriate’, or ‘rarely appropriate’.

TOPIC SELECTION

AAOS selects topics using the suggestions provided by RAM. They are:

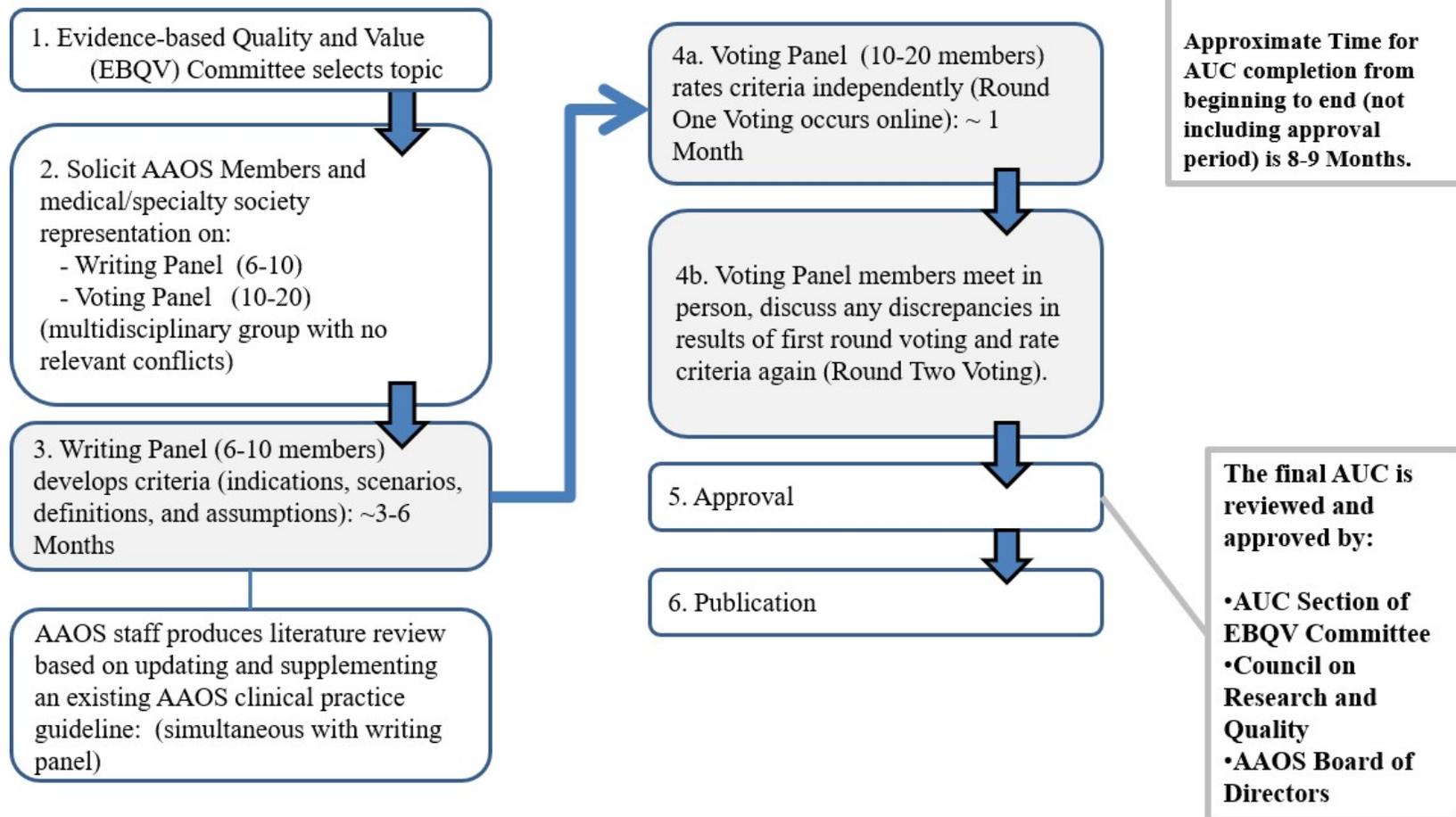
- **The procedure is associated with a substantial amount of morbidity and/or mortality.** AUCs consider procedures with these outcomes to ensure quality patient care and avoid inappropriate use.
- **The procedure consumes significant resources.** Resources quantifying total cost for procedures in a given time frame determine high cost procedures.
- **The procedure has wide geographical variations in use.** Resources quantifying the number of procedures performed (by location) determine high practice variation patterns for a procedure in the United States.
- **The procedure is widely and frequently performed.** Resources quantifying the number of procedures performed in a given time frame determine wide and frequent use of a procedure.

AUC topics derive from AAOS Clinical Practice Guidelines that establish the effectiveness of various procedures for a given disease, disorder, or condition. AUCs address the patients that these procedures are appropriate for, given the nuances of everyday clinical practice. As such, AUC topics focus on procedures supported by evidence-based information. AUCs do not consider ineffective procedures identified by AAOS Clinical Practice Guidelines (recommendations against use).

The Appropriate Use Criteria Section of the AAOS Evidence-Based Quality and Value Committee (henceforth referred to as the EBQV Committee) determines potential topics to address with an AUC. The EBQV Committee makes the final determination of AUC topics.

AUC PROCESS FLOWCHART

Development of AAOS Appropriate Use Criteria (AUCs)



METHOD OF DEVELOPMENT

This section describes the methods adapted from the RAND/UCLA Appropriateness Method (RAM). A brief overview of the AAOS process is:

- a) Writing Panel develops a list of clinical indications.
 - a. Combine indications to form a matrix of clinical scenarios
 - b. Develop definitions of indications (i.e. classifications)
 - c. Develop assumptions for clinical scenarios
- b) AAOS Evidence-Based Medicine Unit compiles an updated literature review (and associated analyses) to be provided to voting panel during rating process.
- c) Voting Panel determines appropriateness of scenarios by rating scenarios (i.e. criteria) as ‘appropriate’, ‘may be appropriate’, or ‘rarely appropriate’.
- d) Approval Process
- e) Publication (dissemination, implementation, and revision)

CONFLICTS OF INTEREST

All panel members must complete the AAOS disclosure process. Writing panel members are allowed to have relevant conflicts of interest. **All** voting panel members must be free from relevant financial conflicts for the AUC topic of interest.

The writing panel and voting panel operate independently of each other. An individual physician can serve on only one of the panels involved in the production of a single AUC.

The Appropriate Use Criteria Section Leader, along with the Evidence-Based Medicine Unit Manager, is responsible for assigning the distribution of orthopaedic specialists, general orthopaedic surgeons, and non-orthopaedic physicians in each of the panels listed below. Generally, a majority (>50%) of topic specialists that routinely perform the procedure comprise the Writing Panel. The Voting Panel will not have a majority (<50%) of topic specialists that routinely perform the procedure.

AUC MODERATOR

The AUC Moderator provides clinical and methodological oversight as a non-voting participant on the writing panel calls and in-person voting panel meeting in Rosemont, IL. During the in-person meeting, the moderator will be responsible for leading the voting panelists’ discussion regarding the voting panel’s first round ratings, focusing on those patient scenarios that resulted in disagreement amongst the group.

Time Commitments

The AUC moderator will be required to lead a one day in-person voting panel meeting in Rosemont, IL. The moderator should also participate on a majority of the writing panel calls ($\geq 60\%$).

WRITING PANEL AND DEVELOPMENT OF CRITERIA

The Writing Panel is a group of 6-10 clinicians who are specialists in the selected topic. This panel is primarily responsible for creating the content for AUCs. As such, these panel members

are often thought of as procedural experts for the selected procedure. Solicitation of Writing Panel members is through specialty societies most closely associated with the selected procedure. The Appropriate Use Criteria Section Leader is responsible for selecting the specialty society/societies represented on the Writing Panel and solicitation of the specialty society/societies.

The Writing Panel convenes for 6-10 teleconferences and communicates via e-mail to:

- Discuss methods described in this document
- Select clinical indications
- Write definitions and assumptions
- Approve scenario matrix and literature review

SELECTING CLINICAL INDICATIONS

The Writing Panel begins development of criteria by identifying clinical indications typical of patients commonly presenting in clinical practice for the selected procedure. The indications are most often parameters observable by the clinician including symptoms or results of diagnostic tests. Additionally, the Writing Panel can consider “human factor” (e.g. activity level) or demographic variables. Indications identified in clinical trials (derived from patient selection criteria) included in AAOS Clinical Practice Guidelines serve as a starting point for the Writing Panel and ensure a link between criteria and the evidence base for the selected procedure. The Writing Panel considers this initial list and other indications based on their clinical expertise to select the most clinically relevant indications. The Writing Panel determines the major/key clinical decision-making indications in order to organize the scenarios into “chapters”.

AAOS staff organizes the indications into a matrix of clinical scenarios that address all combinations of the indication classifications and categorizes patients in terms of variables evident during the clinical decision-making process. The Writing Panel ensures that scenarios:

- Include a broad spectrum of patients that may be eligible for selected procedure (comprehensive)
- Classify patients into a unique scenario (mutually exclusive)
- Consistently classify similar patients into the same scenario (reliable, valid indicators)
- Reflect actual clinical practice (remove scenarios that never occur in clinical practice)

CREATING DEFINITIONS AND ASSUMPTIONS

The Writing Panel writes concise and explicit definitions for the indications in order to explain the classifications used in constructing the clinical scenarios. This standardization helps ensure that physicians’ definition of a clinical indication (e.g. fracture type, “high” risk) is consistent among those reading the clinical scenario matrix or the final criteria. Definitions draw explicit boundaries when possible and are based on standard medical practice or existing literature.

The main goal of assumptions is to focus scenarios so that they apply to the average patient presenting to an average physician at an average facility. The list of general assumptions also provides more consistent interpretation of a scenario.

The assumptions differ from definitions in that they identify circumstances that exist outside of the control of the clinical decision-making process. Examples of assumptions are:

- Conduct of diagnostic exams is accurate (e.g. x-rays, labs)
- Mitigating factors do not complicate clinical scenarios (e.g. do not resuscitate, non-compliance)
- Existing published literature regarding the effectiveness of treatment [*accuracy of diagnosis*] is accurate
- Procedural skill level of physicians is adequate
- Those intrinsic to the methods such as:
 - The role of cost considerations in rating appropriateness
 - Validity of the definition of appropriateness

The Writing Panel constructs definitions and assumptions to afford readers a common starting point in interpreting the clinical scenarios. The list of definitions and assumptions accompanies the clinical scenario matrix in all stages of the development of this AUC and appears in the final publication of the AUC.

CHECKLIST DEVELOPMENT

The writing panel has the option to develop checklists for use in clinical practice. During the voting panel process, the voting panel members will rate the importance of each of the listed checklist items for the topic under study using the following 9-point importance scale. The items rated as “not important will be excluded from the checklist. Those items rated “May be Important” will be discussed at the in-person voting panel meeting regarding their inclusion or removal.

Rating	Explanation
7-9	Important Item is important to include within the checklist
4-6	May be Important: Item may be important to include in the checklist (evidence or efficacy is limited for the checklist item)
1-3	Not Important: Item is not important to include in the checklist

APPROVAL ACTIVITIES OF WRITING PANEL

The Writing Panel must approve the final scenario matrix to be used by the Voting Panel.

LITERATURE REVIEW

Concurrent with the development of the criteria by the Writing Panel, the AAOS Evidence-Based Medicine Unit undertakes a literature review based on the results of the clinical practice guideline related to the selected topic. This literature review considers the relevant articles from the clinical practice guideline. The literature review informs the decisions relevant to the indications identified by the Writing Panel when articles are available and necessary. The literature review also considers lower quality evidence when the best available evidence (i.e. the

evidence used in AAOS Clinical Practice Guidelines) does not contain information relevant to the clinical scenarios.

AAOS staff “maps” the findings of the literature review to the criteria developed by the Writing Panel by referencing the relevant article(s) that the literature review identifies (or figures/tables developed by AAOS staff based on the relevant article(s)).

The Writing Panel can suggest additional articles for consideration in the literature review or suggest removal of an article that does not correctly address the clinical scenario it is associated with. The addition or deletion of articles to/from the literature review is at the discretion of the entire Writing Panel (all panel members must agree that the article is relevant/not relevant to the clinical scenario). No article previously included in an AAOS Clinical Practice Guideline related to the selected topic can be removed from the literature review.

VOTING PANEL AND DETERMINING APPROPRIATENESS

VOTING PANEL

The Voting Panel is a multidisciplinary group of 10-20 clinicians on the selected topic. If there are members on the panel who have expertise in selected areas pertaining to only a few of the clinical scenarios, they will be asked to recuse themselves from voting on any clinical areas outside their expertise. This panel is primarily responsible for rating the scenarios that comprise AUCs. Solicitation of Voting Panel members is through medical societies (not restricted to orthopaedics) that have a relevant interest in the selected topic or commonly treat/interact with patients that receive the procedure. The Appropriate Use Criteria Section Leader, along with the AUC Unit manager, is responsible for selecting the medical societies represented on the Voting Panel and also solicit involvement of the medical societies.

The Voting Panel uses a modified Delphi procedure to determine appropriateness ratings. The Voting Panel participates in two rounds of voting while considering evidence-based information provided in the literature review. While cost is often a relevant consideration, panelists focus their appropriateness ratings on the effectiveness of the selected procedure. After the first round of voting is complete, the members of the Voting Panel participate in an in-person discussion regarding the scenarios/treatments which resulted in disagreement (i.e. the panel members’ ratings were distributed on both the “rarely appropriate” and “appropriate” spectrums of the rating scale). This meeting will be held in Rosemont, IL. Hotel, meals, and airfare will be paid for by AAOS. A member of the Appropriate Use Criteria Section moderates the in-person Voting Panel meeting that occurs after the first round of voting is complete. This moderator does not vote on the scenarios. The moderator’s main purpose is to focus the Voting Panel’s discussion of criteria and ensure the methods of development are rigorously followed. In the event that a voting panel member is unable to complete his or her charges between the first and second rounds of voting, that panel member’s first round ratings will be removed from the final results.

RATING APPROPRIATENESS

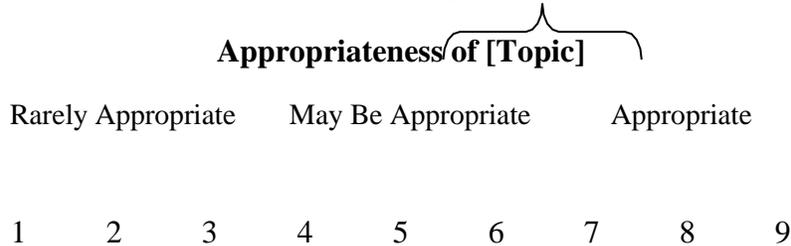
When rating the appropriateness of a scenario, the Voting Panel considers the following definition of appropriateness:

“An appropriate [Topic] is one for which the expected health benefits exceed the expected negative consequences by a sufficiently wide margin that the procedure is a reasonable approach for this clinical scenario.”

The panelists then rate each scenario using their best clinical judgment, and in consideration of the available evidence, for an average patient presenting to an average physician at an average facility as follows:

Rating	Explanation
7-9	<p style="text-align: center;">Appropriate:</p> <p>Appropriate for the indication provided, meaning treatment is generally acceptable and is a reasonable approach for the indication and is likely to improve the patient’s health outcomes or survival.</p>
4-6	<p style="text-align: center;">May be Appropriate:</p> <p>Uncertain for the indication provided, meaning treatment may be acceptable and may be a reasonable approach for the indication, but with uncertainty implying that more research and/or patient information is needed to further classify the indication.</p>
1-3	<p style="text-align: center;">Rarely Appropriate:</p> <p>Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e. procedure is not generally acceptable and is not generally reasonable for the indication).</p>

Each panelist uses the scale below to record their response for each scenario:



ROUND ONE VOTING

The Voting Panel rates the scenarios in the matrix via electronic ballot. There is no interaction between panel members while completing this round of voting. Panelists consider the following materials:

- The instructions for rating appropriateness (above)
- The completed literature review, containing references when evidence is available for a scenario

- The list of definitions and assumptions, to ensure consistency in the interpretation of the clinical scenarios

ROUND TWO VOTING

The second round of voting takes place after a face-to-face meeting of the Voting Panel. A member of the Appropriate Use Criteria Section moderates this meeting. Each panelist receives a personalized document (prepared by AAOS Staff) that includes their first round ratings along with summarized results of the first-round ratings for all members of the panel. These results indicate the frequency of ratings for a scenario from all panelists. The document contains no identifying information for other panelists' ratings. The moderator also uses a document that summarizes the results of the panelists' first round voting (with no identification of raters). These personalized documents serve as the basis for discussions about appropriateness of the scenarios at the face-to-face meeting.

The Voting Panel discusses each scenario/treatment that resulted in general disagreement. After the in-person meeting, the voting panel is afforded the opportunity to re-rate the scenarios/treatments with disagreement based on the discussion. There is no attempt to obtain consensus among the panel members.

FINAL RATINGS

The panelists second round ratings, based on the median value, determine the final levels of appropriateness. They are:

Level of Appropriateness	Description
Appropriate	<ul style="list-style-type: none"> • Median panel rating between 7-9 and no disagreement
May Be Appropriate	<ul style="list-style-type: none"> • Median panel rating between 4-6 or • Median panel rating 1-9 with disagreement*
Rarely Appropriate	<ul style="list-style-type: none"> • Median panel rating between 1-3 and no disagreement

* Disagreement among raters can affect the final rating and definitions provided by RAM determine disagreement:

Panel Size	<u>Disagreement</u>	<u>Agreement</u>
	# of ratings between 1-3 or 7-9	# of ratings outside of appropriateness rating range
8,9,10	≥ 3	≤ 2
11,12,13	≥ 4	≤ 3
14,15,16	≥ 5	≤ 4

Panels beyond these sizes require calculation of IPRAS (Interpercentile Range Adjusted for Symmetry) described in RAM.

APPROVAL

The AAOS Committee on Evidence-Based Quality and Value, the AAOS Council on Research and Quality, and the AAOS Board of Directors sequentially approve all Appropriate Use Criteria.

PUBLICATION

Publication of the primary document is on the AAOS website at [<http://www.aaos.org/research>]. Its goal is to provide interested readers with full documentation about not only the Appropriate Use Criteria, but also about how AAOS arrives at the ratings for the criteria.

Following completion of the AUC, an accompanying editorial and summary document will be authored by at least one member each from the Writing, Reviewing, and Voting Panels. The moderator can also collaborate on the effort at his/her discretion.

Shorter versions of Appropriate Use Criteria (AUC) are available in other venues. Announcement of AAOS AUCs will include Academy press release, articles published in the Journal of the American Academy of Orthopaedic Surgeons, and articles published in AAOS Now. Distribution of AAOS AUCs at the AAOS Annual Meeting occurs in various venues such as on Academy Row and at Committee Scientific Exhibits.

Dissemination of select AUCs will include mobile applications, webinars, an online module for the Orthopaedic Knowledge Online website, Radio Media Tours, Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

Other dissemination efforts outside of the AAOS will include submitting the criteria to the National Guideline Clearinghouse and distributing the criteria at other medical specialty societies' meetings.

REVISION

AAOS AUCs represent a cross-sectional view of the selected topic and may become outdated as new evidence becomes available or clinical decision-making indicators are improved. These criteria will receive updates or withdrawal in five years in accordance with the standards of the National Guideline Clearinghouse. Updates occur in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology.

Reference List

- (1) Fitch K, Bernstein SJ, Aguilar MD et al. *The RAND/UCLA Appropriateness Method User's Manual*. Santa Monica, CA: RAND Corporation; 2001.