



ASAM American Society of
Addiction Medicine

Methodology for Development of The ASAM Criteria®

Committee structure

- Editorial subcommittee
 - The editorial subcommittee will be comprised of the Editor in Chief (EIC) and eight section editors including both physicians and non-physician clinicians with experience implementing *The ASAM Criteria*.
- Writing groups
 - Each writing group will be comprised of at least three experts in the specific topic.
 - Guidance will be provided by the relevant section editors.

Conflict of interest

COI cannot be completely avoided since the book addresses the entire addiction treatment system. All members of the editorial subcommittee and writing groups must make disclosures on appointment and provide updates with any significant changes during their terms. Staff, with oversight from the ASAM Quality Improvement Council (QIC), will review and grade all COI as low, moderate, or high-level.

- Low:
 - Inactive high-level conflict (e.g., served on advisory board for a pharmaceutical company but stepped down over a year ago)
 - An intellectual interest that is tangentially related to the clinical topic area (e.g., for guideline on stimulant use disorder, served within previous 3 y as investigator on study evaluating effects of cocaine use on cardiovascular disease)
- Moderate:
 - Intellectual interest that may lead to cognitive bias (e.g., for guideline on OUD, served as investigator on study evaluating medications for opioid withdrawal within previous 3 y)
 - Relationships with entities that may seek to profit by association with guidelines but are not vested in clinical conclusions of guidelines (e.g., proprietary interest in health IT software related to clinical decision making)
- High:
 - Any active relationship (financial or otherwise) with a high-risk entity (e.g., currently serving on an advisory board for a health plan)

Editors and writing group members shall not vote on any area where they have a high-level COI (including employment with industry). Whenever possible, they should not have moderate-level COI related to the topics on which they will vote. In some circumstances, the subcommittee or writing group may not be able to perform its work without members who have COIs. In these

instances, members with COIs should not represent more than a minority of the voting panel. The QIC will develop mitigation plans for any permitted COIs among subcommittee and writing group members. Plans will be reviewed and approved by the ASAM Ethics Committee. COIs and summaries of mitigation plans for ASAM Criteria editors and writers will be made publicly available.

Literature reviews

Structured literature reviews will be used to inform updates to *The ASAM Criteria*. Key questions will be defined for each topic area. For each topic area, staff will do a brief literature search to determine what level of evidence could be expected to inform each key question:

- A. The question could be the subject of high-quality studies (e.g., RCTs)
- B. The question is not amenable to or likely to be the subject of RCTs (e.g., staffing questions)
- C. The question is not likely to have research evidence (e.g., setting standards)

Based on the designation of A, B, or C above, the committee will determine the scope of the literature review as described below. The committee may also decide that the key question does not require a literature review (e.g., appropriate documentation standards) and will proceed to develop the draft standards without an evidence review.

Methodology A: For key questions for which there are controlled trials

- The literature review will start with a search of systematic reviews using key terms defined by the committee.
- The search will expand to the primary literature for subtopics for which high quality reviews are not available and to capture literature released after the most recent high quality systematic review.
- Limited to past 10 years unless the committee asks to expand the range

Methodology B: For key questions for which there are not controlled trials

- The literature review will start a search of the primary literature using the search terms and exclusion criteria defined by the committee (see below).
- Limited to past 10 years unless the committee asks to expand the range

Methodology C: For key questions for which there is unlikely to be direct research evidence.

- The literature review will focus on gray literature, both published and unpublished.
- A targeted Internet search of gray literature will be conducted, focusing on published and unpublished clinical guidelines, guidance documents, and policy documents (e.g., state regulations and licensing requirements).

Additional Targeted Searches

Targeted searches of the primary literature may also be conducted based on needs identified by the guideline writing committee. For example, for a key question regarding staff to patient ratios in residential treatment the guideline committee may ask to review the methods from studies conducted in residential treatment settings.

Quality Ratings

Identified studies will be rate for quality using a standardized framework that defines the studies as good, fair, or poor quality based on methodology, size, and potential for bias.

The literature review will inform the committee members as they develop or modify decision rules/standards.

Developing decision rules/standards

The writing committees will review the literature review findings and other available data (including data from the ASAM Continuum and findings from the ASAM Level of Care Certification program) to develop draft decision rules/standards. The committees will start with the decision rules/standards that are currently in *The ASAM Criteria* 3rd edition and will recommend modifications or additions as needed. These recommendations will be informed by both the available data and the expertise of the committee.

A modified Delphi process will be used to rate these draft recommendations. A group of experts chosen from among the editors and writers (without relevant COI) will vote on the decision rules/standards (voting panel). Each of the decision rules/standards will be rated for appropriateness. Raters will be asked to recuse themselves from voting on any statements outside their expertise.

External stakeholder feedback

Since the release of the 3rd edition in 2013 there has been widespread adoption of *The ASAM Criteria* by treatment programs as well as payors and managed care organizations. It is critical that the 4th Edition is informed by these stakeholder experiences in implementing *The ASAM Criteria* in the real world.

ASAM will seek comments from diverse stakeholders including treatment providers, system administrators, health plans, policymakers, and patients and families on experiences with *The ASAM Criteria*. A survey will be issued to ask stakeholders what is working well, what barriers or challenges they have faced with implementation, and what can be improved in the next edition. Stakeholder input will also be solicited regarding any major changes proposed for the 4th edition (e.g., changes to the continuum of care or dimensions). This feedback will be used by the writing groups and editorial subcommittee to inform their recommendations.

Once the decision rules/standards have been developed by the writing committees targeted stakeholder feedback will be solicited through an invited feedback process. The editorial subcommittee will analyze the feedback and identify issues that need to be addressed before finalization and publication.

Approval Process

Before finalization and publication, the decision rules/standards will be reviewed and approved by the ASAM Criteria Strategy Committee who will recommend approval to ASAM's QIC. The QIC will review and approve and will send significant changes to the ASAM Board of Directors for approval. The QIC or board may send refer items back to the committees as necessary if they do not approve. A 2/3 vote will be needed to approve the proposed decision rules/standards.

The QIC must approve before publication. Sets of decision rules/standards will be sent to the QIC for approval as they are completed.