

Methodology for Updating The ASAM Criteria®

Committee structure

- Editorial subcommittee
 - The editorial team will be comprised of the Editor-in-Chief (EIC) and section editors who have experience implementing The ASAM Criteria in practice.
- Writing groups
 - o 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 ASAM Criteria addresses the broad 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 by ASAM's 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 writers shall not $\underline{\text{vote}}$ 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. Mitigation plans will be developed for any permitted COIs among subcommittee and writing group members. 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 the appropriate scope of the literature review based on the following:

- A. The key question(s) are the subject of systematic reviews
- B. The key question(s) are not the subject of systematic reviews (e.g., staffing questions)
- C. The key question(s) for which there is unlikely to be direct research evidence (e.g., staffing ratios)

Based on the designation of A, B, or C above, the following literature review methodologies will be applied.

Methodology A: For key questions for which there are systematic reviews.

- The literature review will start with a search of systematic reviews.
- The search will expand to the primary literature for subtopics for which high quality reviews (as defined by the <u>NHLBI study quality assessment tools</u>) are not available and to capture literature released after the most recent high quality systematic review. Primary literature searches will be done defined search terms and exclusion criteria from the date of the last high-quality systematic review to the present.
- Limited to past 10 years unless the writing groups request to expand the range
- A targeted internet search of gray literature will also be conducted, including published and unpublished clinical guidelines and guidance documents.
 - The search will not be time limited, but where recommending bodies have published updates of guidelines, only the most recent will be included.
- Articles will be excluded if they meet the following criteria:
 - Abstract only
 - Brief report only
 - Case studies
 - Commentaries and editorials
 - Systematic reviews that have subsequently been updated (updated version will be included)
 - Guidelines that have subsequently been updated (updated version will be included)
 - Not in English
 - Wrong population (animal studies, neonatal abstinence syndrome)
 - Wrong condition (hangover, endocarditis)
 - Wrong outcome (cognitive, gene expression)
 - Studies addressing interventions not available in the United States

Methodology B: For key questions for which there are not systematic reviews

- The literature review will start a search of the primary literature.
- Limited to past 10 years unless the writing group asks to expand the range
- A targeted internet search of gray literature will also be conducted, including published and unpublished clinical guidelines and guidance documents.
 - o The search will not be time limited, but where recommending bodies have published updates of guidelines, only the most recent will be included.
- Articles will be excluded if they meet the following criteria:
 - Abstract only
 - Commentaries and editorials
 - Guidelines that have subsequently been updated (updated version will be included)
 - Not in English
 - Wrong population (animal studies, neonatal abstinence syndrome)
 - Wrong condition (hangover, endocarditis)
 - Wrong outcome (cognitive, gene expression)
 - Studies addressing interventions not available in the United States

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).
 - The search will not be time limited, but where recommending bodies have published updates of guidelines, only the most recent will be included.
- Targeted searches of the primary literature may also be conducted based on needs
 identified by the writing group. For example, for a key question regarding staff to patient
 ratios in residential treatment the guideline writing group may ask to review the methods
 from studies conducted in residential treatment settings.
- Document will be excluded if they meet the following criteria:
 - Guidelines that have subsequently been updated (updated version will be included)
 - Not in English
 - Wrong population (adolescents, neonatal abstinence syndrome)
 - Wrong condition (psychosis, endocarditis)
 - Documents addressing interventions not available in the United States
- The identified literature will be presented to the writing group in a spreadsheet that
 describes the purpose, study characteristics, and summary of findings for each study.

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

The writing groups 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 writing groups will start with the decision rules/standards from 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 writing groups and editorial subcommittee.

A modified Delphi process will be used to rate these draft recommendations. A group of 9+ experts chosen from among the editors and writers (without relevant COI) will vote on the decision rules/standards (voting panel). After the voting is complete, the members of the Voting Panel will discuss the decision rules/standards for which there is a lack of consensus. Decision rules/recommendation statements may be modified during these discussions to clarify their intent or to address the concerns raised based on the consensus of the panel. The panelists will be asked to re-rate the items as they are modified until consensus is reached.

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, policy makers, 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 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 and editorial teams to inform their recommendations.

Once the decision rules/standards have been developed by the writing groups, targeted stakeholder feedback will be solicited through an invited feedback process. The editorial team 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 ASAM's Quality Improvement Council. Significant changes from the 3rd Edition will also be approved by the ASAM Board of Directors.