Policies and Procedures: Development of Official Clinical Practice Documents

American Academy of Sleep Medicine

I. Introduction

Evidence-based medicine (EBM) refers to the preferential use of diagnostic techniques and treatment modalities for which systematic empirical research has provided proof of statistically significant benefit in specified clinical situations. Important elements in developing and using EBM documents include defining specific questions (prompted by commonly-encountered clinical problems or the results of hypothesis-generating research of relatively low quality, e.g. case reports, series, or retrospective studies), defining the level and types of evidence to be used (usually involving a standardized grading system), and the assessment of effectiveness after the document is disseminated.

The American Academy of Sleep Medicine (AASM) has, for many years, expended considerable effort in the development and promulgation of 2 types of EBM documents. **Practice Parameters** provide physicians with clear recommendations for the evaluation and management of patients with sleep disorders, and are crafted according to the recommendations of the Agency for Healthcare Research Quality and the National Guideline Clearinghouse. Practice parameters are based on an exhaustive review of the scientific literature that is conducted by a task force of experts, and which is published in the form of the second type of document, **Standards of Practice Reviews**. Subjects for parameter development are either proposed by the Standards of Practice Committee and approved by the Board of Directors as part of the plan of work for that committee, or generated by action of the Board and assigned to either the Standards of Practice committee or an ad hoc task force. Both the review paper and the practice parameters
undergo a peer-review process by outside reviewers before they are submitted to the AASM Board of Directors for approval. The approved review paper and practice parameters are published in the journal SLEEP. In some cases both papers are combined and published as a single report.

More recently, the AASM has commissioned and published a third type of document, the **Clinical Guideline**. Clinical Guidelines were designed to be broad reviews of the evaluation, diagnosis, treatment and long-term management of specific sleep disorders presented in a manner similar to a textbook chapter. They incorporate all applicable elements of existing AASM evidence-based Practice Parameters supplemented by consensus-based recommendations from a task force of experts based on a review of available medical research literature of whatever quality exists. A formal review of the topic is incorporated into the document rather than appearing separately. The Board of Directors generally identifies the need for Clinical Guidelines and assigns the development to a task force by action of the Board. The guidelines are reviewed by independent content experts before they are submitted to the AASM Board of Directors for approval. The approved clinical guidelines are then published in the Journal of Clinical Sleep Medicine. This process has also been applied to several narrow practice areas that required urgent guidance due to development of new technologies or treatment techniques (e.g. portable monitors and multiple positive airway pressure technologies)

The AASM endeavors to review Practice Parameters and Standards of Practice Reviews every three to five years and publishes updates when necessary; a formal review and update process for Clinical Guidelines has not yet been defined.
As the field of sleep medicine continues to develop, the number of topics for document development and the need to review and revise past documents has increased substantially. The former need has been addressed, to some extent, by Clinical Guidelines commissioned by the Board of Directors and assigned to ad hoc task forces rather than the Standards of Practice committee. However, concern has been expressed by the Board over the number and scope of these proposals and whether sufficient oversight of this process exists in the absence of Standards of Practice committee involvement. Moreover, the Board recognized that the burden of review and revision of documents already in existence was overtaking the capacity of the Standards of Practice committee. Recently, the AASM Board of Directors directed an ad hoc task force to explicitly define the systems and policies to be used in future EBM efforts. This Policies and Procedures document represents the final report of this task force.

II. Types of Documents Defined

A. Standards of Practice Review: A systematic review of a relatively focused subject targeting an audience of sleep medicine specialists. A significant number of generally high-quality research studies are available in the peer-reviewed literature that is pertinent to the subject. Standards of Practice Reviews are submitted for publication in SLEEP.

B. Practice Parameters: A summary of recommended strategies for evaluation and management of a relatively focused area of sleep medicine, targeting an audience of sleep medicine specialists. Practice Parameters are derived from a Standards of Practice
Review and utilize a standardized system of grading levels of evidence and recommendations. Practice Parameters are submitted for publication in SLEEP.

C. **Clinical Guideline:** A systematic review and compilation of recommended evaluation and management strategies for a specific sleep disorder, presented in a manner similar to a textbook chapter, and targeting a general medical audience as well as sleep medicine specialists. The level of evidence may be lower than that used in a Systematic Review/Practice Parameter and may rely heavily on consensus. No formal grades are assigned to the recommendations, but the document does require Board of Directors approval and represents an official position by the AASM. Clinical Guidelines are generally published in the Journal of Clinical Sleep Medicine.

D. **Best Practice Guide:** A systematic review and compilation of recommended evaluation or management strategies covering a narrow, focused subject area in which there is insufficient evidence to warrant a practice parameter. Best Practice Guides should be completed within a short time frame, and may reference all levels of evidence including consensus. No formal grades are assigned to the recommendations, but the document does require Board of Directors approval and represents an official position by the AASM. Best Practice Guides are generally meant for publication in the Journal of Clinical Sleep Medicine.

**III. Documents Committee**
A. A standing committee of the AASM (Documents Committee) will be created that will subserve a number of functions, including the initial handling of proposals for official documents of all types. The Documents Committee will be comprised of 7 members: the Standards of Practice Committee (SPC) chair and vice chair, the Board liaison to the SPC, one additional director chosen by the Board of Directors, and 3 members-at-large chosen from AASM membership for their expertise in the development of clinical practice guidelines. The Board of Directors will designate the Chair of the committee as one of the 3 at-large members.

B. Staff support: The Documents Committee will initially require up to 0.25 FTE staff support. In addition to general support duties, this individual will be responsible for assembling a dossier of abstracts for articles specified in the web-based project proposal process (see below).

IV. Project Initiation Process

A. A web-based project proposal site will be created by the Documents Committee, containing a proposal form that will request appropriate information.

For proposed collaborative projects between the AASM and other professional societies, a draft Joint Project Agreement or Memorandum of Understanding (MOU) using an AASM-approved model format must be appended to the application. The MOU will describe the precise nature of the collaboration and should include, but may not be limited to, the following parameters: content, scope, outcome of project, site of
publication, resource utilization (financial, staff, corporate), location and timing of
meetings, CME, use of pre-publication drafts, embargo policy, review and approval
process, dissemination plans, patient education material, web-based material, translation
of approved documents. The author of a joint project proposal is encouraged to
informally discuss the idea with members of the Board of Directors prior to completing
the web based project proposal form, as joint projects will be subject to more rigorous
review then those to be executed internally.

B. The following AASM entities will be eligible to initiate projects, and will have access
to the proposal website: Board of Directors, Chairs of AASM committees, Chairs of
AASM sections

C. Submitted applications will be forwarded to the Documents Committee for initial
review. Staff support will print out abstracts of the publications listed in IV.A.3, above.
The committee will review the proposals and abstracts at regularly-scheduled conference
calls. Those projects felt to have merit will be forwarded to the Board of Directors, along
with the committee’s recommendation for document type(s) and entity that would
execute the project.

D. The Board of Directors will accept or reject the proposal, and if accepted edit the
proposal as deemed necessary. The Board will specify the entity that would execute the
project. The Board will specify the type of document.
E. Committee and task force membership will be strictly governed by AASM Conflict of Interest (COI) Policies now in effect and as may be amended from time to time.

V. Process for Review and Approval of New Documents

A. Project chairs will forward the final draft document(s) (types C and D) (electronic and hard copy) to the AASM Documents Committee staff member and Chair. Documents of types A and B will be submitted through the SPC process. All final draft documents must be formatted in AASM style, including reference format as specified by SLEEP and JCSM, keywords consistent with MESH terms, and complete Conflict of Interest statements for each author of the document and/or ad-hoc committee member.

B. Draft documents should preferably be submitted at least 4 months prior to a regularly scheduled meeting of the Board of Directors to ensure timely completion of the review process, including revisions based upon peer review.

C. The draft document(s) will be forwarded to at least 2 peer-reviewers, one of whom will be from the list specified in the original proposal, and others as chosen by the Documents Committee/Standards of Practice Committee.

D. The peer-reviewers’ responses will be forwarded to the project Committee or task force chair, with an appropriate deadline specified for receipt of the edited document(s). The deadline must preferably be at least 6 weeks prior to the Board of Directors meeting at which the document(s) will be presented for approval.
E. The Documents Committee/Standards of Practice Committee will review the edited draft document(s). At this stage, the Documents Committee/SPC may decide that the Committee or task force has not adequately addressed the concerns of the peer-reviewers and can send the document(s) back to the Committee or task force for additional revision.

F. Simultaneously, the document(s) will be distributed to the members of the Board of Directors.

G. The Board of Directors will take one of the following actions after presentation of the document(s): Approve; Approve with specified revisions; Return to the Documents Committee/Standards of Practice Committee for specified revisions by the originating Committee or task force; Table the document(s) indefinitely (only under extraordinary circumstances)

H. Approved document(s) will be forwarded to the appropriate Journal editor for publication.

VI. Process for Review and Revision of Existing Documents

A. The Documents Committee mandate will include the periodic review (at intervals not to exceed 5 years) of existing Clinical Guidelines and Best Practice Guides in order to determine whether revision is necessary.
B. The Standards of Practice Committee will be responsible for executing the revision process unless otherwise directed by the Board of Directors.

C. Whenever possible, the original Committee or task force members responsible for the document(s) to be revised will be invited to participate in the new project.

VII. Elements and Style of Document Manuscript

A. The AASM will follow the recommendations of the Agency for Healthcare Research Quality (AHRQ) and National Guideline Clearinghouse (NGC) for the development of practice parameters. Practice parameters are strategies for patient management, developed to assist clinicians in clinical decision making, and are the result of systematic review or meta-analysis of available clinical evidence combined with synthesis by experts in the field represented on the Standards of Practice Committee and any appointed task force members.

B. All AASM documents will adhere to the NGC and AHRQ’s attributes to ensure that practice parameters are scientifically sound, clinically relevant, and applicable in the day-to-day practice of medicine. The attributes are as follows:

   1. Practice parameters are developed by or in conjunction with physician organizations

   2. Reliable methodologies that integrate relevant research findings and appropriate clinical expertise are used in their development
3. Recommendations will be comprehensive and as specific as possible, are based on current information, and will be widely disseminated.

C. AASM guidelines will be written primarily for physicians. With appropriate adaptation, the guidelines may also be useful in establishing reimbursement policies; in utilization and systems management; in hospital purchasing decisions; and in forming research agendas.

D. AASM practice parameters are provided for the continuing education of physicians and other healthcare workers. Their purpose is to improve clinical practice and the efficiency of medical practice by ensuring proper clinical approaches to specific medical situations and reducing the use of unnecessary tests, procedures, and treatments.

E. The Documents Committee may specify additional processes, style, and format for official documents subject to approval by the Board of Directors.

VIII. Strategies for Evaluating Outcomes of Official Document(s)

A. It is becoming widely recognized that creation and publication of evidence-based guidelines may not result in improved outcomes unless attention is also paid to evaluating the effects of the guidelines on subsequent practice. Consequently, the AASM supports the inclusion of a plan for evaluating the effects of any document that is officially endorsed by the Academy.
B. All project proposals must include a plan for evaluating outcomes

C. Initially, the AASM supports the use of surveys to assess whether guidelines are being adopted by its membership. These may include:

1. Web-based or other types of survey instruments distributed to a random sample of AASM members and member centers/laboratories
2. Surveys distributed with accreditation and re-accreditation materials for centers and laboratories that must be completed and included with the accreditation or re-accreditation application in order for the application to be considered
3. Data collection instruments that are distributed as in item 2, above

D. Originators of project proposals are encouraged to plan other means for assessing outcomes, subject to approval by the Board of Directors.