# AASLD POLICY ON DEVELOPMENT AND USE OF PRACTICE GUIDELINES

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Steps in Guideline Development and Approval Process</td>
<td>2</td>
</tr>
<tr>
<td>Policies and Procedures of the Practice Guidelines Committee of the AASLD</td>
<td>3</td>
</tr>
</tbody>
</table>

## ATTACHMENTS:

1. Invitation Letter to Author                                  | 7    |
2. Instructions to Authors                                      | 8    |
3. Copyright Permission Request Form                            | 20   |
4. Policy on Disclosure of Potential Conflict of Interest      | 21   |
5. Disclosure of Potential Conflict of Interest Form attached to PDF |      |
AASLD POLICY ON DEVELOPMENT AND USE OF PRACTICE GUIDELINES

I. Introduction

The American Association for the Study of Liver Diseases (AASLD), recognizing the need to develop practice guidelines for liver diseases, has established a Practice Guidelines Committee. AASLD guidelines represent the official opinion of the Association, as reflected in the evidence based reviews and recommendations of the individuals involved in developing the guidelines.

AASLD guidelines deal with common problem areas for health care practitioners who care for patients with liver disease. These areas will include conditions (diseases, signs and symptoms) and technologies (diagnostic tests and therapeutic procedures). Guidelines are based on a formal review and analysis of relevant published data, carefully weighing the strength of the scientific evidence. However, there are situations in which such data are inconclusive or absent. Therefore, some recommendations will be based on expert opinion. The policy of the AASLD Practice Guideline Committee is to clearly identify the degree to which a guideline reflects facts or consensus opinion.

Practice guidelines can serve many useful purposes, including the development of logical aids to clinicians, hospitals, public health agencies, and managed care organizations in providing the most up to date highest standard of care for their patients, while taking into consideration the responsibilities for controlling medical costs. The published guideline should assist the physician in patient care decisions and hopefully improve clinical outcomes.

Practice guidelines should not be viewed as “standards of care” to be followed to the letter, but should be designed to aid clinics and organizations in the care of patients with liver diseases, as well as be flexible enough to allow clinicians to use them to aid in the management of patients with specific liver diseases. Guidelines have been and will continue to be used to define adequate or appropriate medical care. It is important, therefore, that the recommendations are worded carefully, and the situations in which they do or do not apply, be made clear.

In addition to the development of practice guidelines supported by scientific data, the AASLD Practice Guidelines Committee is empowered to develop, review and recommend the endorsement of position papers on topics in important areas of liver disease that present the state of the art of current clinical practice. In the absence of the availability of scientific data, the position papers may be based on expert opinion. A distinction will be made between guidelines and position papers.

II. Steps in Guideline Development and Approval Process

1. Selection of topics and writing group (comprised of a Chair and two to seven additional members).
2. Verification of individual author’s eligibility for writing group membership
3. Approval of writing group membership by Governing Board
4. Invitation extended to the writing group members by the Committee Chair.
5. Writing group prepares initial outline based on AASLD templates with preliminary recommendations and submits to the Committee Chair (1 month) for review and approval by Committee. Conference calls between the Writing group and Committee to discuss outline are permissible
6. Writing group submits initial draft of guideline and appends references \(\text{(no later than 1 month prior to next scheduled Committee meeting)}\).

7. Draft sent to Practice Guidelines Committee members at least 4 weeks prior to the scheduled semi-annual meeting. The chair assigns specific review responsibilities to committee members.

8. Document drafts may also be sent to appropriate external societies for input.*

9. Selection of external reviewers, if applicable (up to 3).*

10. Written comments from members (and external reviews, if applicable) are reviewed with the Chair of the writing group (and designated member or members, if appropriate) on site (preferred) or by conference call at the semi-annual meeting of the Committee.

11. Writing group revises document and submits second draft to the Committee chair (within 2 months of reviewing initial draft).

12. Discussion of second draft with Chair of writing group (and other members, if appropriate) by Committee conference call or in person (1 month).

13. Third draft prepared by the writing group* \((1 \text{ month})\).

14. Third draft circulated to Committee Chair and other members for comments and approval* \((1 \text{ month})\).

15. Additional conference calls or draft revision if necessary.*

16. Final document with accompanying cover letter by Committee Chair submitted to, and approved by, AASLD Governing Board \((\text{no more than 3 months})\).

17. After approval, document sent to external societies interested in endorsing it.*

18. Publication in HPATOTOLOGY or Liver Transplantation (or other journal). Publication in an AASLD associated journal will take place without further peer review and the document will be acknowledged as having undergone peer validation and be the expressed position of AASLD.

19. Existing guidelines and position papers reviewed annually by the writing group and updated as necessary on-line (AASLD web-site and web-site of collaborating society, if applicable). A letter to the editor/brief report will be published in the original journal of publication to alert readers to the update. Committee input into these revisions will occur via conference call or at one of the semi-annual meetings, at the discretion of the Chair.

20. Existing guidelines and position papers are to undergo mandatory revision and journal republication every 5 years.

*Need and timing determined by Committee and Chair.

### III. Instructions to Authors

A letter of invitation will be sent to the selected Chair and members of the writing group (Attachment 1). Included with this letter will be the detailed instructions (Attachment 2), a copyright release form (Attachment 3), and Conflict of Interest disclosure form (Attachments 4 and 5). The detailed instructions to the writing group will address guideline definitions, format, and the process and timeline for review, approval, and publication of the guideline.

### IV. Policies and Procedures of the Practice Guidelines Committee of the AASLD

#### A. Committee

The committee will be composed of one AASLD Governing Board Liaison to be assigned by the Governing Board, one Chair to be appointed by the AASLD leadership for a term of 3 years, and twelve additional members each to serve a term of 3 years. A trainee member will be appointed for a one or two-year term, will be exempt from selection criteria listed below for regular and associate members and shall be in addition to the twelve other committee members. Terms are
renewable at the discretion of the Governing Board. The Chair position will be filled by an individual with at least 1 year experience on the Committee prior to assuming Chair responsibility. At the discretion of the President-elect, the outgoing Chair may be invited to stay on the committee for a transition period of as long as one year.

Appointments to the Practice Guideline Committee will be made by AASLD leadership following standard AASLD procedures for selection of committee members. Appointment considerations for regular (non-trainee) members should include the seniority and expertise of the Committee candidate. A candidate should have been an AASLD member for at least 5 years before being considered for a Committee position. Recognizing the policy setting and editorial nature of the Committee, the AASLD is best served by Committee membership that is acknowledged as expert in clinical hepatology and clinical study methodology. Representation should also strive to include expertise in pediatrics, liver and transplantation surgery, pathology, and epidemiology. Such expertise is considered valuable for broad review of the clinical topics before the Committee.

B. AASLD Support
The Committee will receive support from AASLD in the form of an annually approved planned scope of work. Additionally, AASLD staff will be assigned to the Committee to

1. Assure full communication of the status of guideline development among all Committee members, AASLD leadership, and external societies with collaborative interests in guidelines before the Committee,
2. Arrange travel and accommodation for meetings including scheduled meetings at AASLD and at National AASLD meetings, and
3. Attend all meetings of the Committee to prepare minutes and distribute draft documents. AASLD staff shall also assist the Chair in report preparation, budget development, and correspondence.

C. Identification of Subjects for Practice Guidelines or Position Papers
The Committee will be responsible for selecting the topics of the Practice Guidelines or Position Papers, and for inviting writing groups comprised of a Chair and 2 to 7 additional members. The Committee will be expected to produce at least two new or rewritten guidelines per year.

Guidelines address the clinical care of patients with liver diseases for which sufficient evidence exists to support management recommendations. Position Papers also address the clinical care of patients with liver diseases, but their recommendations are based predominantly on expert opinion rather than on published evidence. The Committee determines whether a report is appropriate as a Guideline or as a Position Paper after the final review of a draft guideline.

D. Writing groups
Writing groups will consist of a Chair and 2 to 7 additional members, all selected by the Committee members and submitted to the Board for approval. Members may include representation from subspecialties other than Hepatology if appropriate, and individuals with expertise in pediatrics will be included whenever possible. The invited writing groups are acknowledged experts in the clinical area to be pursued. These individuals will also be required to disclose potential conflicts of interest to the AASLD that will be reviewed as part of the writing group selection process. Conflict of interest assessment will be performed according to policies and procedures established by the Ethics Committee in conjunction with the Governing Board of the AASLD.
The group’s Chair and other members must be able to commit to a timeframe of guideline development set by the committee. The Chair (and other member/members as appropriate) is expected to meet with the Committee when invited to revise the document and participate in committee conference calls as needed until the project is completed. A non-US Chair and/or member can be invited with the approval of the AASLD Governing Board.

Each member of the writing group, including the Chair, will serve a five-year term. The Chair and members may be reappointed for additional terms at the discretion of the Committee. Writing group members may be removed at the discretion of the Guideline Committee based on their inability to meet the Timetable for Guideline Development.

E. Timetable for Guideline Development
Guidelines should be published within 12 to 18 months of initiation by the Committee (see II. Steps in Guideline Development). Draft guidelines are expected to be delivered to the Committee from the Chair of the writing group no later than 1 month prior to next scheduled Committee meeting (within 4-6 months of invitation). The document will be reviewed at 1 or 2 committee meetings and revised accordingly. The same timetable would also apply to annual guideline updates that are to be posted on the AASLD website alone.

The Committee may seek external review of the guideline drafts prior to submission to the AASLD Governing Board.

Guidelines will be reviewed by the Governing Board within 3 months for approval and referred to HEPATOLOGY, Liver Transplantation, or another selected journal for publication. The Governing Board reserves the right to request an external review of the final guideline before approval. Approved guidelines may also be sent to appropriate external societies for approval. Recommendation of the desired journal for publication will be made by the Committee, and is subject to Governing Board approval.

F. Review of published AASLD Guidelines
Guidelines and position papers will be reviewed annually by the writing group members to determine the need for an updated guideline. Committee input into these revisions will occur via conference call or at one of the semi-annual meetings, depending on timing and at the discretion of the Chair. Attendance at a meeting by writing group members is not mandatory and will depend on the extent of the changes made, at the discretion of the Committee Chair. Each updated guideline will be submitted to the Governing Board for approval. The approved, updated guideline will be posted on the AASLD website, and a letter to the editor/brief report will be published in the original journal of publication to alert readers to the update.

Each guideline/position paper will undergo mandatory repeat publication (in print) every five years. Preparation will begin 3 years after the last publication, at which time the Committee members will determine whether the guideline/position paper should be completely rewritten, or simply updated.

G. Policies regarding Guidelines of other Professional Societies
1. The AASLD can be included in the development of guidelines proposed by other professional societies, as follows:
   a) inclusion of AASLD Practice Guidelines Committee members in the guideline planning phase by the sister society;
b) Inclusion of AASLD Practice Guidelines Committee members during the draft phase of guideline development by the sister society, where committee members will review and comment on the guidelines;

c) Abstention from involvement in the development of a guideline that does not appear to satisfy the procedures typical of the AASLD guidelines, particularly those pertaining to rigorous review of published evidence.

The AASLD practice guidelines endorsement policy shall also be applied to position papers authored by external societies (ACG, AGA, ASGE or other recognized groups). The committee shall distinguish between guidelines and position papers.

AASLD Practice Guideline Committee participation in the early development and review of liver-related practice guidelines and position papers is required. As such, the AASLD will only review and endorse those guidelines and position papers which are made available to the AASLD Practice Guideline Committee during their draft stage and prior to final approval by the originating society. Likewise, guidelines developed by the AASLD will be made available to sister societies expressing an interest in endorsement during the draft phase of guideline development.

2. Levels of Endorsement
AASLD may act on a submitted document in 3 ways:

a) Endorsement as a Guideline, which recognizes that the AASLD Practice Guideline Committee has fully reviewed and endorses the recommendations set forth in the guideline as being based primarily on peer-reviewed clinical evidence.

b) Reviewed and endorsed as a Position Paper whose recommendations the Practice Guideline Committee has judged to be largely based on expert opinion.

c) Reviewed but not endorsed. Rarely the Committee may not agree with the guidelines as proposed by another society, despite its active involvement and input during the development. In this situation, the Committee may elect not to endorse the guidelines.

H. Review of AASLD Guidelines by other Societies
Guidelines may be sent to the respective Practice Guidelines Committees of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), North American Society for Pediatric Gastroenterology Hepatology and Nutrition (NASPGHAN) and the American Society for Gastrointestinal Endoscopy (ASGE) for their review and approval. Drafts of practice guidelines may be sent to other societies for comment when such an interest is expressed. AASLD will link other Society’s guidelines it has endorsed to its website and ask the same courtesy of other societies.

All endorsement of guidelines and position papers is a formal decision of the AASLD Governing Board and as such expresses the support of the document as the official position of AASLD on the topic.
Attachment 1 – Author Invitation Letter

Dear

On the basis of your expertise and recognition in the field, the Practice Guidelines Committee of the AASLD invites you to prepare a [Practice Guideline][Position Paper] on []. You have been selected as the Chair/a member of a writing group comprised of X members. Enclosed please find three documents that you should review and agree to before accepting this invitation. They include:

1. Instructions to Guideline/Position Paper Authors
2. Copyright release form
3. A complete list of the writing group members.

Copyright of all material will belong to the AASLD. A copyright assignment signed by the Chair and members of the writing group should be submitted at the time of submission of the final draft of the [Guideline] [Position Paper].

The writing group members will receive written recognition for the scholarship of the [Guideline] [Position Paper] as authors of the guideline, while the AASLD will assume responsibility for the recommendations. It is the policy of the AASLD Practice Guidelines Committee to ask the writing group to review the published Guideline or Position Paper on an annual basis and to make changes to the document published on www.aasld.org when appropriate. This would occur over a 5 year period beginning from the time of invitation acceptance. The AASLD publishes approved guidelines and position papers in appropriate journals with first consideration given to HEPATOLOGY and Liver Transplantation. Practice guidelines/position papers that are developed in collaboration with another professional society will be simultaneously published in an AASLD journal and that society's journal.

We hope you will accept this invitation and look forward to working with you on this important project.

_______________________________
Chair, Practice Guidelines Committee

Please indicate your acceptance of this invitation by signing below, and send to:

Chair, Practice Guidelines Committee
C/O Staff Liaison
AASLD
1001 North Fairfax Street, Suite 400
Alexandria, VA 22314

____________________________________________  __________________
Signature        Date
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES  
Practice Guidelines Committee

Instructions to Practice Guideline and Position Paper Authors

I. DEFINITIONS

Clinical practice guidelines are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” [1] The AASLD has adapted this definition to include only those statements and recommendations that are supported by a high level of scientific evidence.

The AASLD makes a distinction between Practice Guidelines and Position Papers. Where published information is insufficient to make strongly evidence-based recommendations, clinically important topics may be considered for Position Papers, which may represent the state of the art of current practice, based on descriptive reports and expert opinions.

II. RESPONSIBILITIES OF THE AUTHORS

The writing group for a specific topic identified by the Practice Guidelines Committee is selected by consensus based on the qualifications of the individuals as recognized experts in the field, with peer reviewed publications on the subject.

A. The Chair and members of the writing group are invited by the Chair of the Practice Guidelines Committee to develop the Guideline or Position Paper.

B. The document is written on behalf of the AASLD. The invited Chair and writing group will remain the principal authors for the Guideline /Position Paper.

C. The writing group is fully responsible for the content and quality of the Guideline, and for conforming to the timeline for presentation and discussion.

D. The members of the writing group will have no significant potential conflicts of interest that would influence the preparation of an unbiased and balanced Guideline and Recommendations. These potential conflicts of interest will have been reviewed and approved by the Practice Guidelines Committee and/or Governing Board prior to inviting members to join a writing group.

E. The writing group prepares an initial outline based on AASLD templates with preliminary recommendations (1 month). Conference calls between the Writing group and Committee to discuss outline are permissible.

F. Following approval of the initial outline by the Committee, the writing group is requested to develop and submit the first draft of the Guideline/Position Paper for presentation to the Practice Guidelines Committee no later than 1 month prior to next scheduled Committee meeting (generally 4-6 months after agreeing to write the Guideline).

G. The Chair of the writing group is expected to present a draft of the Guideline /Position Paper in person at the next upcoming meeting of the Practice Guidelines Committee.

III. FORMAT OF THE GUIDELINES

A. AASLD Endorsement Statement

The following statement is to be inserted at the beginning of the document:

“This guideline has been approved by the American Association for the Study of Liver Diseases and represents the position of the Association.”
B. Preamble

The following standardized preamble (titled as such) must be included immediately following the AASLD endorsement statement.

"These recommendations provide a data-supported approach. They are based on the following: (1) formal review and analysis of the recently-published world literature on the topic [Medline search]; (2) American College of Physicians Manual for Assessing Health Practices and Designing Practice Guidelines [2]; (3) guideline policies, including the AASLD Policy on the Development and Use of Practice Guidelines and the AGA Policy Statement on Guidelines [3]; and (4) the experience of the authors in the specified topic.

Intended for use by physicians, these recommendations suggest preferred approaches to the diagnostic, therapeutic and preventive aspects of care. They are intended to be flexible, in contrast to standards of care, which are inflexible policies to be followed in every case. Specific recommendations are based on relevant published information.

To more fully characterize the available evidence supporting the recommendations, the AASLD Practice Guidelines Committee has adopted the classification used by the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) workgroup with minor modifications (Table 1) [4]). The strength of recommendations in the GRADE system are classified as strong (1) or weak (2). The quality of evidence supporting strong or weak recommendations is designated by one of three levels: high (A), moderate (B) or low-quality (C).

<table>
<thead>
<tr>
<th>Strength of Recommendation</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong [1]</td>
<td>Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost</td>
</tr>
<tr>
<td>Weak [2]</td>
<td>Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, higher cost or resource consumption</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>High [A]</td>
<td>Further research is unlikely to change confidence in the estimate of the clinical effect</td>
</tr>
<tr>
<td>Moderate [B]</td>
<td>Further research may change confidence in the estimate of the clinical effect</td>
</tr>
<tr>
<td>Low [C]</td>
<td>Further research is very likely to impact confidence on the estimate of clinical effect</td>
</tr>
</tbody>
</table>

C. Introduction

The introduction clearly defines the subject of the paper and describes the purpose and contents. It should outline the key questions being addressed and should indicate why this is an important area (e.g. patient outcomes, cost, etc.)

D. Outline of the Document

See the appendix for standardized outlines for guidelines focusing on disease/condition, interventional procedures, or diagnostic procedures.
E. Literature Review and Analysis
The literature review provides the basis for the guideline’s recommendations. This contains the writing group’s compilation and assessment of the literature relevant to the recommendations including experimental, clinical and epidemiological data whenever appropriate. Because guidelines are more clinically focused than review chapters, the reporting of the literature review is not to be exhaustive. The main goal of guidelines is to “allow users to understand the evidence and apply it to clinical practice.” References are cited principally to support the level of evidence (Table 1) for recommendations. This literature review should be included in the text of the document and specifically comment upon the following:
1. A description of the search strategy used to address the literature
2. The criteria used to include or exclude published works from consideration.
3. Short descriptions of the key studies being cited, including such factors as the study population, number of subjects, randomization method, types of controls and blinding. This information may be most effectively presented in tables.
4. When appropriate the limitations of the cited studies should be indicated.
All writing group members should review the literature cited to ensure completeness and appropriateness for the level of evidence. Writing should avoid the List of Error Prone Abbreviations, Symbols and Dose Designations from the Institute of Safe Medication Practices (see appendix).

F. Recommendations
A list of practice recommendations should follow each appropriate section of the guideline. Each recommendation should be accompanied by a designation of its strength (classified as strong [1] or weak [2]) and quality designated by one of three levels: high (A), moderate (B) or low-quality (C) (see Table 1). For example, a strong recommendation based on high-quality evidence would receive a designation of (1A) that would then be placed at the end of the text for that recommendation. These should be consistent with the evidence presented in the text and should explicitly define the patient population to which they do or do not apply.

G. Suggestions for Future Research
Although not a requirement, the authors may wish to include a suggestion for future research in areas with poor quality data, or where adequate studies are lacking.

H. References
The references are cited in the body of the document in numerical order and compiled at the end of the document according to the style used by HEPATOLOGY. (Refer to a recent issue of HEPATOLOGY or http://hepatology.aasldjournals.org/) Unpublished studies and articles from unreferred journals and non-English language references should not be used. Primary references are preferred over textbooks, reviews, and other secondary references. Letters, meeting abstracts, and case reports are discouraged and should not be used as the sole support for a recommendation. It is expected that key references supporting the recommendations be provided by the Chair of the writing group at the first meeting if they are not available on-line.

HEPATOLOGY Reference style
Number references in the order cited as Arabic numerals in parentheses on the line. Only literature that is published or in press (with the name of the publication known) may be numbered and listed; abstracts and letters to the editor may be cited, but they must be less than 3 years old and identified as such.

Use Index Medicus as the style guide for references and other journal abbreviations. List all authors up to seven, using seven and “et al.” when the number is greater than seven.
Articles in journals

Books

Book chapters

Abstract or article in a supplement

I. General Formatting
1. Each draft of the guideline should be dated.
2. Guidelines should be submitted with page numbers and line numbers.
3. Recommendations should be labeled consecutively throughout the document.
4. A guideline or position paper is not a review paper on a subject and is not intended to be structured as such. The maximum text word count should be limited to 10,000 – 15,000 words and 200 references. Decisions regarding the ultimate length of individual guidelines will fall under the discretion of the Committee.
5. References should be specific for the Recommendations, and not exhaustive.
6. Authors should identify key references that support each recommendation, and submit one copy of each with the first draft. References are to ordered numerically (1, 2, 3…) as they first appear in the text. Alternate ordering systems will not be allowed.
7. Follow formatting rules of HEPATOLOGY (http://hepatology.aasldjournals.org/)

IV. PERMISSIONS

Direct quotations, tables, or illustrations taken from copyrighted material must be accompanied by written permission for their use from the publisher and the original author. A standard permission request form is attached. The permission is presented as a footnote or addition to the legend and must provide complete information as to source. Photographs of identifiable persons must be accompanied by a signed release that indicates informed consent.

V. REVIEW PROCESS

A. The writing group prepares an initial outline based on AASLD templates with preliminary recommendations that will require Committee approval (1 month)
B. The Chair and writing group will then develop the first draft of the Guideline /Position Paper for presentation to the Practice Guidelines Committee 4 to 6 months after agreeing to write the Guideline.
C. The draft Guideline/Position Paper is circulated to the members of the Practice Guidelines Committee who will review it at a meeting of the Committee. The draft will be made available to Committee members at least 1 month before the face-to-face meeting of the Committee.
D. The Chair (and colleague(s) if desired by the Chair) will be present to discuss the Guideline/Position Paper in detail and in conformity with the methodology. If personal attendance is not possible, then discussion of the draft guideline may be done by conference call at the time of the Committee meeting.
E. Modifications to the Guideline/Position Paper based on the initial review are re-circulated among Committee members and distributed to sister societies for comment.

F. A Guideline/Position Paper may also be circulated among appropriate external societies for their approval.

G. The need for a review and discussion of a second or subsequent drafts with the Chair via conference call or in person will be determined by the Committee.

H. In select instances, the Committee may seek external review of the Guideline/Position Paper prior to seeking approval of the AASLD Governing Board.

VI. EVALUATION OF COMPLETENESS

As part of its review, the Practice Guidelines Committee will use the following list to evaluate the completeness of each guideline.

A. Guideline format and development
   1. Purpose specified
   2. Rationale and importance explained
   3. Participants in the development process and areas of expertise are specified (Determined by AASLD)
   4. Targeted health problem or technology is clearly defined
   5. Targeted patient population is specified
   6. Intended audience or users are specified
   7. Health outcomes are specified
   8. Method of external review is specified (determined by AASLD)

B. Identification and description of evidence
   1. Method of identifying scientific evidence is specified
   2. Time period from which evidence is reviewed is specified
   3. Evidence used is identified by citation and referenced
   4. Method for grading or classifying the scientific evidence is specified (strength and quality of evidence as shown in Table 1)
   5. Benefits and harms of specific health practices are specified
   6. Benefits and harms are quantified
   7. Costs are quantified, if data are available.
   8. Effect on health care costs for specific health practices is specified, if data are available.

C. Formulation of recommendations
   1. Role of value judgments in making recommendations is discussed
   2. Role of F(what is this ?) is discussed
   3. Recommendations are specific and apply to the stated goals of the guideline
   4. Recommendations are graded according to the strength and quality of the evidence (Table 1)
   5. Flexibility in the recommendations is specified

VII APPROVAL PROCESS

A. The Chair of the Practice Guidelines Committee will forward the approved document to the AASLD Governing Board for endorsement and recommendation for publication.

B. The expected time of the approval process by the Governing Board is up to 3 months.
VIII. PUBLICATION

A. The Guideline /Position Paper will be submitted preferably to the AASLD’s journals, HEPATOLOGY or Liver Transplantation, for publication. The Practice Guidelines Committee may choose another journal based on the appropriateness of the topic to the audience or an association with another society involved in guideline development.

B. Copyright releases will be signed by the authors of the publication.

C. Members of the Practice Guidelines Committee will be acknowledged in an Appendix to the document. Committee members are not eligible to be authors of guidelines while serving as active committee members unless approved by the Governing Board.

IX. ANNUAL UPDATES

Writing groups are responsible for reviewing newly published data on an annual basis and submitting modifications to the Practice Guidelines Committee Chair for approval. On approval, modifications will be posted on the AASLD website only. Subsequently, the AASLD membership will be notified of a guideline update through a brief communication to be published in the journal HEPATOLOGY, electronic newsletters sent to the membership by AASLD, and explicit announcements placed on the AASLD website.

The following approach should be used when determining the need for an update (based on Shekelle JAMA 2001):

1. Identify existing individual recommendations
2. Does new evidence sufficiently invalidate guideline recommendations?
3. Are there new recommendations that should be present?
4. Validity of existing/new recommendations based on:
   a. Have diagnostic or interventional interventions been superseded or replaced by other interventions?
   b. Has new evidence altered the relations between benefit and harms?
   c. Have outcomes not considered at the time of the guideline become important or have outcomes considered important now become unimportant?
5. Is there evidence that current performance is optimal and the guideline is no longer needed?

Data that must be incorporated into annual updates are as follows:

- New data that result in a new recommendation or changes to an existing recommendation (including the content or grading of the recommendation)
- New data from controlled clinical trials, even if the data do not result in a new recommendation or changes to an existing recommendation
- New data that affect package labeling

X. REFERENCES


Appendix A.

Standard Outlines for Practice Guidelines/Position Papers

1. Disease or Condition

<table>
<thead>
<tr>
<th>Standard Concepts</th>
<th>Possible Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Purpose of the guidelines</td>
</tr>
<tr>
<td></td>
<td>Scope</td>
</tr>
<tr>
<td>Definition of the disease/condition</td>
<td>Overview</td>
</tr>
<tr>
<td></td>
<td>Summary of Epidemiology</td>
</tr>
<tr>
<td></td>
<td>Classifications</td>
</tr>
<tr>
<td>Diagnosis and Testing</td>
<td>Clinical Evaluation</td>
</tr>
<tr>
<td></td>
<td>Noninvasive testing</td>
</tr>
<tr>
<td></td>
<td>Invasive testing</td>
</tr>
<tr>
<td></td>
<td>Laboratory testing</td>
</tr>
<tr>
<td></td>
<td>Risk assessment</td>
</tr>
<tr>
<td></td>
<td>Patient preference</td>
</tr>
<tr>
<td></td>
<td>Economic/cost implications</td>
</tr>
<tr>
<td>Treatment</td>
<td>Principles of management</td>
</tr>
<tr>
<td></td>
<td>Medication</td>
</tr>
<tr>
<td></td>
<td>Procedures</td>
</tr>
<tr>
<td></td>
<td>Other Interventions</td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
</tr>
<tr>
<td></td>
<td>Patient preference</td>
</tr>
<tr>
<td></td>
<td>Economic/cost implications</td>
</tr>
<tr>
<td>Special populations</td>
<td>Concomitant disorders</td>
</tr>
<tr>
<td></td>
<td>Patient groups (e.g., elderly, pregnancy, pediatric)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Discharge</td>
</tr>
<tr>
<td></td>
<td>Long-term management</td>
</tr>
<tr>
<td></td>
<td>Patient education</td>
</tr>
<tr>
<td>Suggestions for Future Research</td>
<td></td>
</tr>
</tbody>
</table>

2. Interventional Procedures

<table>
<thead>
<tr>
<th>Standard Concepts</th>
<th>Related Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Purpose of the guideline</td>
</tr>
<tr>
<td></td>
<td>Scope</td>
</tr>
<tr>
<td>Definition of intervention/procedure</td>
<td>General considerations</td>
</tr>
<tr>
<td></td>
<td>Background</td>
</tr>
<tr>
<td>Specific conditions</td>
<td>Clinical uses</td>
</tr>
<tr>
<td>Management strategies</td>
<td>Procedure-specific considerations</td>
</tr>
<tr>
<td></td>
<td>Associated medical therapies</td>
</tr>
<tr>
<td></td>
<td>Procedural complications</td>
</tr>
<tr>
<td></td>
<td>Reducing risk</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Definitions of success</td>
</tr>
<tr>
<td></td>
<td>Short-term and long-term outcomes</td>
</tr>
<tr>
<td></td>
<td>Comparisons with other interventions</td>
</tr>
<tr>
<td>Institutional/operator issues</td>
<td>Quality assurance/improvement</td>
</tr>
<tr>
<td></td>
<td>Volume considerations</td>
</tr>
<tr>
<td>Special populations</td>
<td>Patient groups (e.g., elderly, women, pediatric)</td>
</tr>
</tbody>
</table>
3. Diagnostic Procedures

<table>
<thead>
<tr>
<th>Standard Concept</th>
<th>Related Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Purpose</td>
</tr>
<tr>
<td></td>
<td>Scope</td>
</tr>
<tr>
<td>Description of the diagnostic tool</td>
<td>Specific procedures</td>
</tr>
<tr>
<td></td>
<td>Equipment</td>
</tr>
<tr>
<td></td>
<td>Sensitivity/specificity</td>
</tr>
<tr>
<td></td>
<td>General considerations</td>
</tr>
<tr>
<td></td>
<td>Comparison with other diagnostic tools</td>
</tr>
<tr>
<td>Specific conditions</td>
<td>Clinical uses (Note: Diagnostic guidelines are usually subdivided by the diseases/conditions that they can diagnose. These discussions include diagnosis, assessment, prognosis, risk stratification, screening, etc.)</td>
</tr>
<tr>
<td>Special populations</td>
<td>Patient groups (e.g., elderly, women, pediatric)</td>
</tr>
</tbody>
</table>
### Appendix B

The Institute for Safe Medication Practices List of Error Prone Abbreviations

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Intended Meaning</th>
<th>Misinterpretation</th>
<th>Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg</td>
<td>Microgram</td>
<td>Mistaken as “mg”</td>
<td>Use “mcg”</td>
</tr>
<tr>
<td>AD, AS, AU</td>
<td>Right ear, left ear, each ear</td>
<td>Mistake as OD, OS, OU (right eye, left eye, each eye)</td>
<td>Use “right ear,” “left ear,” or “each ear”</td>
</tr>
<tr>
<td>OD, OS, OU</td>
<td>Right eye, left eye, each eye</td>
<td>Mistake as AD, AS, AU (right ear, left ear, each ear)</td>
<td>Use “right eye,” “left eye,” or “each eye”</td>
</tr>
<tr>
<td>BT</td>
<td>Bedtime</td>
<td>Mistaken as “BID” (twice daily)</td>
<td>Use “bedtime”</td>
</tr>
<tr>
<td>cc</td>
<td>Cubic centimeters</td>
<td>Mistaken as “u” (units)</td>
<td>Use mL</td>
</tr>
<tr>
<td>D/C</td>
<td>Discharge or discontinue</td>
<td>Premature discontinuation of medications if D/C (intended to mean “discharge”) has been misinterpreted as “discontinued” when followed by a list of discharge medications</td>
<td>Use “bedtime”</td>
</tr>
<tr>
<td>IJ</td>
<td>Injection</td>
<td>Mistaken as “IV” or “intrajugular”</td>
<td>Use “injection”</td>
</tr>
<tr>
<td>IN</td>
<td>Intranasal</td>
<td>Mistaken as “IM” or “IV”</td>
<td>Use “intranasal” or “NAS”</td>
</tr>
<tr>
<td>IU</td>
<td>International unit</td>
<td>Mistaken as IV (intravenous) or 10 (ten)</td>
<td>Use “units”</td>
</tr>
<tr>
<td>o.d. or OD</td>
<td>Once daily</td>
<td>Mistaken as “right eye” (OD-ocular dexter), leading to an oral liquid medications administered to the eye</td>
<td>Use “daily”</td>
</tr>
<tr>
<td>OJ</td>
<td>Orange juice</td>
<td>Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye</td>
<td>Use “orange juice”</td>
</tr>
<tr>
<td>Per os</td>
<td>By mouth, orally</td>
<td>The “os” can be mistaken as “left eye” (OS-ocular sinister)</td>
<td></td>
</tr>
<tr>
<td>q.d. or QD</td>
<td>Every day</td>
<td>Mistaken as q.i.d., especially if the period after the “q” or the tail of the “q” is misunderstood as an “i”</td>
<td>Use “daily”</td>
</tr>
<tr>
<td>qhs</td>
<td>At bedtime</td>
<td>Mistaken as “qhr” or every hour</td>
<td>Use “at bedtime”</td>
</tr>
<tr>
<td>qn</td>
<td>Nightly</td>
<td>Mistaken as “qh” (every hour)</td>
<td>Use “nightly”</td>
</tr>
<tr>
<td>q.o.d. or QOD</td>
<td>Every other day</td>
<td>Mistaken as “q.d.” (daily) or “q.i.d. (four times daily) if the “o” is poorly written</td>
<td>Use “daily”</td>
</tr>
<tr>
<td>q1d</td>
<td>Daily</td>
<td>Mistaken as q.i.d. (four times daily)</td>
<td>Use “daily”</td>
</tr>
<tr>
<td>q6pm, etc.</td>
<td>Every evening at 6 PM</td>
<td>Mistaken as every 6 hours</td>
<td>Use “6 PM nightly” or “6 PM daily”</td>
</tr>
<tr>
<td>SC, SQ, sub q</td>
<td>Subcutaneous</td>
<td>SC mistaken as SL (sublingual); SQ mistaken as “5 every”; the “q” in “sub q” has been mistaken as “every” (e.g., a heparin dose ordered “sub q 2 hours before surgery” misunderstood as every 2 hours before surgery)</td>
<td>Use “subcut” or “subcutaneously”</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>ss</td>
<td>Sliding scale (insulin) or ½ (apothecary)</td>
<td>Mistaken as “55”</td>
<td>Spell out “sliding scale;” use “one-half” or “1/2”</td>
</tr>
<tr>
<td>SSRI</td>
<td>Sliding scale regular insulin</td>
<td>Mistaken as selective-serotonin reuptake inhibitor</td>
<td>Spell out “sliding scale (insulin)”</td>
</tr>
<tr>
<td>SSI</td>
<td>Sliding scale insulin</td>
<td>Mistaken as Strong solution of Iodine (Lugol’s)</td>
<td></td>
</tr>
<tr>
<td>t/d</td>
<td>One daily</td>
<td>Mistaken as “t’d”</td>
<td>Use “1 daily”</td>
</tr>
<tr>
<td>TIW or tiw</td>
<td>3 times a week</td>
<td>Mistaken as “3 times a day” or “twice a week”</td>
<td>Use “3 times weekly”</td>
</tr>
<tr>
<td>U or u</td>
<td>Unit</td>
<td>Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., 4U seen as “40” or 4u seen as “44”); mistaken as “cc” so dose given in volume instead of units (e.g., 4u seen as 4cc)</td>
<td>Use “unit”</td>
</tr>
</tbody>
</table>

### Dose Designations and Other Information

<table>
<thead>
<tr>
<th>Intended meaning</th>
<th>Misinterpretation</th>
<th>Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trailing zero after decimal point (e.g., 1.0 mg)</td>
<td>1 mg</td>
<td>Mistaken as 10 mg if the decimal point is not seen</td>
</tr>
<tr>
<td>Naked decimal point (e.g., .5 mg)</td>
<td>0.5 mg</td>
<td>Mistaken as 5 mg if the decimal point is not seen</td>
</tr>
<tr>
<td>Numerical dose and unit of measure run together (e.g., 10mg, 100mL)</td>
<td>10 mg 100 mL</td>
<td>The “m” is sometimes mistaken as the number 1 if written poorly</td>
</tr>
<tr>
<td>Abbreviations such as mg. Or mL. With a period following the abbreviation</td>
<td>mg mL</td>
<td>The period is unnecessary and could be mistaken as 1 if written poorly</td>
</tr>
<tr>
<td>Large doses without properly placed commas (e.g. 100000 units)</td>
<td>100,000 units</td>
<td>100000 has been mistaken as 10,000 or 1,000,000</td>
</tr>
<tr>
<td>Symbols</td>
<td>Intended meaning</td>
<td>Misinterpretation</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>x3d</td>
<td>For three days</td>
<td>Mistaken as “3 doses”</td>
</tr>
<tr>
<td>&gt; and &lt;</td>
<td>Greater than and less than</td>
<td>Mistaken as opposite of intended; mistakenly use correct symbol; “&lt; 10” mistaken as “40”</td>
</tr>
<tr>
<td>/ (slash mark)</td>
<td>Separates two doses or indicates “per”</td>
<td>Mistaken as the number 1 (e.g. “25 units/10 units” misread as “25 units and 110 units” units)</td>
</tr>
<tr>
<td>@</td>
<td>At</td>
<td>Mistaken as “2”</td>
</tr>
<tr>
<td>&amp;</td>
<td>And</td>
<td>Mistaken as “2”</td>
</tr>
<tr>
<td>+</td>
<td>Plus or and</td>
<td>Mistaken as “4”</td>
</tr>
<tr>
<td>°</td>
<td>Hour</td>
<td>Mistaken as a zero (e.g., 2° seen as q 20)</td>
</tr>
</tbody>
</table>

Copyright permission request form

From: Date:

Dear Permission Editor/Author:

I am preparing for publication an article entitled:
to be published in

I hereby request your permission for the nonexclusive right to reprint the following material:

Author/Editor:
Title of article or book:
Year of Publication:
Journal, Volume, and Issue (if applicable):
Material to be reproduced:
Page number(s) it appeared on:

Permission is sought to reprint the above material in all forms and media now and hereafter known, in all languages, throughout the world and to license such rights to others.

Sincerely yours,

I/We hereby grant permission to reprint the material(s) as provided above:

Signed: ____________________________

__________________________________

__________________________________

__________________________________
AASLD
Code for the Assessment and Management of Conflict of Interest

Purpose and Application:

Complex relationships with for-profit and not-for-profit organizations and entities may by their existence present a perceived or real conflict with the missions and values of the AASLD. In as much as the existence of real or perceived conflicts of interest serves to undermine the stature, integrity, creditability and function of the AASLD, AASLD must insure that its membership, leadership and the public-at-large understand the importance it places on identification and resolution of conflicts. The independence and the credibility of AASLD require implementation of a clear policy that can be enacted in a practical, fair and transparent manner.

Conflicts of interest are defined as any circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest. Primary interests are those associated with the stated mission of the AASLD. Secondary interests may be financial or non-financial in nature. (e.g. intellectual conflict of interest, membership in other organizations, or institutional or corporate associations).

Application of this policy is to be temporally phased in with addition of new members and reappointments (see for example, Section 1G). Further, the degree of permitted associations will be regulated in a fashion that is commensurate with the influence that the individual has in the creation, implementation or execution of AASLD functions. Since the AASLD plays roles of advocacy for clinical care, education and research in liver diseases, the policy shall cover all individuals who participate at any level in those functions. The definition of conflict, review of disclosures and the adjudication and resolution of conflicts needs to be a multi-layer effort that is charged to the Ethics committee. The policy outlined will require diligent interpretation in complex cases, with the goal of providing clarity for members as they engage in their functions. The overriding goal is to provide objective conflict management. The application of this Code is not intended to be punitive to the member. The process is by its nature fluid and ongoing reporting and review is necessary.

---

1 Conflict of interest in medical research, education and practices.
http://www.nap.edu/catalog/12598.html

Definitions

The following terms are defined for purposes of this Code:

**Company:** A Company is an entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and whose interests could reasonably be seen to overlap with the interests, missions and values of the AASLD. This definition is not intended to include entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.

**Direct Financial Relationship:** A Direct Financial Relationship is a compensated relationship with a Company held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.

**Educational Grant:** An Educational Grant is a sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the recipient. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME. An Educational Grant may also be “in-kind.”

**Gifts “in kind”:** Compensation in goods or services rather than money; non-monetary gifts of valued consideration (e.g. access to advisory or consultant services, specific resource allocation or access)

**Research Grant:** For purposes of this Code, a Research Grant is an award that is given by a Company or other funding agency to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide an individual, institution, or practice with programmatic support (e.g., an Educational Grant) designated for the specific purpose of funding Research Grants.

---

3 Modified from Council of Medical Specialty Societies, 230 E Ohio St. Suite 400 | Chicago, IL 60611
Principles and Practice

1. Independence

AASLD will develop all educational activities, scientific programs, products, services and advocacy positions aligned with the mission of the Association, independent of external influence, and will develop and adopt policies and procedures that foster this independence. AASLD will separate their efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from their programmatic decisions. The initial step in program development is the independent assessment by AASLD that a program is needed (e.g., to address gaps in care or knowledge). Once AASLD determines that a program is needed, it is permissible to assess the availability of funds.

A. The Ethics Committee of AASLD will be responsible for evaluating and adjudicating conflicts of interest and guiding the interactions of AASLD, and its Members, and monitoring the compliance with this Code by the Covered Individuals (See Appendix B).

B. Approval of a motion involving identification or management of a conflict of interest by the Ethics Committee requires a two-thirds majority of voting members.

C. The President, President-elect and the Editor-in-Chief, Hepatology, may not have Direct Financial Relationships with Companies during his or her term of service.

D. Other AASLD Members are permitted to have Direct Financial Relationships with Companies and must disclose any such Relationship and indicate whether it is in excess of $5000 per year when requested.

E. Nominees for Councilor will be informed that they will be required to terminate any Direct Financial Relationships with Companies prior to their term as President-elect.
F. The President, President-elect and the Editor-in-Chief, HEPATOLOGY, may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. The President, President-elect and the Editor-in-Chief, HEPATOLOGY, may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. Research support, uncompensated services and other permitted relationships must be disclosed to the AASLD, regardless of any monetary value or its equivalent. Membership as an officer or member of the governing board of a related professional association is not allowed.

G. AASLD may permit the President, President-elect and the Editor-in-Chief, HEPATOLOGY, who are elected or appointed prior to the time the AASLD approves this Code to maintain existing Direct Financial Relationships with Companies for the duration of their terms.

H. Covered Individuals will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants. Written agreements should specify what the funds are for, the amount given, and the roles of the Company and the Covered Individual. These agreements may be reviewed by the Ethics Committee.

2. Transparency

AASLD will make their conflict of interest policies available to their members and the public. AASLD, through the Ethics Committee, will manage conflicts of interest in a variety of ways. This may include disclosure alone, or other conflict of interest management mechanisms such as recusal, divestiture or AASLD-independent review. The Ethics Committee will select conflict of interest management mechanisms that are appropriate for the activity, type of relationship and role of the individual under consideration (see Appendix B).

A. AASLD, through the Ethics Committee, will provide written disclosure forms
to individuals who serve on behalf of the AASLD (see Appendix C), and will use the disclosed information to manage conflicts of interest in decision-making. AASLD will require volunteers to update disclosure information at least annually and when material changes occur.

B. AASLD will disclose all Direct Financial Relationships in excess of $5000 per year and uncompensated relationships with an equivalent monetary value held by the President, President-elect and the Editor-in-Chief, HEPATOLOGY, making this information available to their members and the public. AASLD is not required to disclose the relationships of other Board members elected prior to the time that AASLD approves this Code.

C. Disclosure forms obtained during any nominating process shall not be included as part of the review of the candidate by the Nominating Committee. The disclosures of the finalists selected by the Nominating Committee shall be reviewed by the Ethics Committee prior to review by the Governing Board.

3. Clinical Practice Guidelines

AASLD will base Clinical Practice Guidelines on scientific evidence and will follow a transparent Guideline development process that is not subject to Company or other external influence, including any intellectual conflict of interest. AASLD will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in AASLD Journals or on AASLD websites.

A. AASLD will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.

B. Permitted relationships and their disclosure for Clinical Practice Guidelines Committee members and Chairs are outlined in Appendix A.

C. AASLD will require that a majority (based on simple numerical majority) of Guideline development panel/writing group members are free of conflicts of interest relevant to the subject matter of the Guideline during the period of Guideline Development. If Guideline development
panel/writing group members and chairs have conflicts of interest at the time of adoption of the Code, AASLD may permit these individuals to remain involved in drafting the Guideline without voting privileges. However, each panel/writing group for which this exception is made must meet the requirements of this Code by the time of the next Guideline Update to remain a member of the Guideline development panel/writing group. For the minority of panel/writing group members who are not free of conflicts, AASLD will apply procedures for conflict of interest management developed in accordance with Section 2.

D. AASLD will require the panel/writing group chair (or at least one chair if there are co-chairs) to be free of conflicts of interest and to remain free of conflicts of interest during Guideline development up to the time of publication of the Guideline.

E. AASLD will require that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. AASLD will not select as reviewers individuals employed by or engaged to represent a Company.

F. AASLD will publish Guideline development panel/writing group members’ disclosure information adjacent to each Guideline and will identify voting members.

G. AASLD will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel/writing group, to disclose financial or other substantive relationships that may constitute conflicts of interest.

4. Adherence to the Code

Adherence to this Code will be promulgated by AASLD. All Members of the AASLD will be encouraged to adopt the principles of this Code and their application.
Appendix A
CONFLICT OF INTEREST: SPECIAL CONSIDERATIONS FOR PRACTICE GUIDELINES COMMITTEE CHAIR, COMMITTEE MEMBERS, AND WRITING GROUP MEMBERS

Disclosures
Disclosures must be made at least annually and when material changes occur.

<table>
<thead>
<tr>
<th></th>
<th>Review By</th>
<th>Made Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice Guidelines Committee Chair</td>
<td>Ethics Committee</td>
<td>Yes</td>
</tr>
<tr>
<td>Practice Guidelines Committee</td>
<td>Practice Guidelines Committee Chair (as delegated by the Ethics Committee)</td>
<td>Yes</td>
</tr>
<tr>
<td>Writing Group Members</td>
<td>Practice Guidelines Committee (as delegated by the Ethics Committee)</td>
<td>At time of guideline publication on web or in journals</td>
</tr>
</tbody>
</table>

Relationships with commercial entities whose interests may be impacted by guidelines:

<table>
<thead>
<tr>
<th></th>
<th>Practice Guidelines Committee Members</th>
<th>Writing Group Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock Ownership or Equity</td>
<td>Disclose and indicate if amount is greater than $5000</td>
<td>No, except in a diversified fund or independently managed</td>
</tr>
<tr>
<td>Employee, Officer, Director</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Scientific Consultant, Advisory Board</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>No</td>
</tr>
<tr>
<td>Promotional Advisor, Speakers’ Bureau</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>No</td>
</tr>
<tr>
<td>Research Grants</td>
<td>Disclose</td>
<td>Disclose</td>
</tr>
<tr>
<td>Travel Grants</td>
<td>Disclose</td>
<td>No</td>
</tr>
<tr>
<td>Intellectual Property Rights (Patents, Royalties, Licensing fees)</td>
<td>Disclose</td>
<td>No</td>
</tr>
<tr>
<td>Honoraria for CME Activities</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
</tr>
</tbody>
</table>
Appendix B

Policy and Criteria for Assessment of Conflicts of Interest by the Ethics Committee

Policy

The Ethics Committee will employ a policy of evaluating conflicts of interest that embodies the criteria of proportionality, transparency, accountability and fairness. Proportionality requires a policy to address the most important conflicts (i.e. direct financial relationships or financial relationships in-kind); the disclosure forms will reflect this policy. Transparency dictates that the policy be available and understood by the affected parties; this code and the attached appendices (outlining the criteria that will be employed for the assessment of conflicts) will be posted for all members to review and disclosure forms will be accompanied by clear instructions to allow members to understand the specific information required to fulfill full and accurate disclosure. Accountability requires divulging the details of who will be responsible for assessment and enforcement; this is reflected in the code stating that the Ethics Committee will be responsible for the assessment of conflicts and that enforcement of the management of conflicts will be via relevant sections of the Association’s By-laws and the joint actions of the Ethics Committee and the Governing Board. Fairness requires that a policy for the evaluation of conflicts apply to all relevant parties with equal measure; this criterion is met by the statement in this code indicating that the criteria employed to assess conflicts of interest will be independent of the individual or groups to whom they are applied but rather will vary by the set of circumstances around which a conflict arises.

Criteria for Assessment of Conflicts of Interest

Conflicts of interest are rarely, if ever, “absent” or “clearly present”, but rather vary in their severity and relevance to a particular circumstance. Accordingly, the Ethics Committee will assess potential conflicts from the perspectives of the chance that a conflict will impair impartial decision-making and the degree of harm that would arise from such impairment. Based on this Code’s definition of a conflict of interest as any circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest, the Ethics Committee will use the following criteria when assessing a conflict:

1. What is the financial value of the secondary interest involved?
2. What is the scope of the relationship(s) of the individual being assessed, with the party or parties associated with the secondary interest?
3. Is the circumstance one involving sole discretion of the particular individual being assessed?
4. What is the value (either direct financial or “in-kind”) to the AASLD of the interest that could be affected by a conflict?
5. What is the scope of the consequence to the AASLD resulting from public
Questions 1,2 and 3 evaluate the potential that a conflict could impair impartial decision-making, while questions 4 and 5 assess the degree of harm that could result from an impairment.

After review and discussion of an individual’s potential conflict(s) of interest and its (their) severity, the Ethics Committee will, by voting according to this Code, determine that a conflict exists and that the severity of the conflict rises to the point that management of the conflict requires more than simple disclosure. Based on the criteria outlined above, the Ethics Committee, by a two-thirds majority vote, will request recusal, withdrawal of consideration for a nominated position, AASLD-independent review, divestiture or any other appropriate management of the conflict. The recommendation of the Ethics Committee will be forwarded to the Governing Board for its approval and enforcement. If the matter involves an individual who is a Member of the Governing Board, that Member will recuse themselves from any deliberations involving that matter.
Appendix C

AASLD Conflict of Interest Disclosure Form attached.