



ISHLT

Recommendations for Guidelines Production

*A document for ISHLT Writing Group Members Responsible for the
Production of ISHLT Guidelines*

*From the ISHLT Committee for Standards and Guidelines
(Henceforth the "Committee")*

Adopted July 23, 2009

1 Introduction and Preamble

Guidelines aim to present all the relevant evidence on a particular clinical issue in order to help clinicians weigh the benefits and risks of a particular diagnostic or therapeutic procedure. They should be helpful in everyday clinical decision-making.

A great number of guidelines have been issued in recent years by different national and international organizations, and other related societies. Several hundred guidelines are now available; however, this profusion of documents can endanger the authority and validity of all guidelines, which can only be guaranteed if they have been developed by an unquestionable decision-making process. This is one of the reasons why the ISHLT and others have issued recommendations for formulating and issuing guidelines.

Guidelines originating with the ISHLT should reflect the core competencies of our society, i.e. expertise in the management of patients waiting for and/or having undergone heart and/or lung transplant, and for those patients implanted with MCSs (mechanical circulatory support devices).

In spite of the fact that standards for issuing good quality guidelines are well defined, recent surveys of guidelines published in peer-reviewed journals between 1985 and 1998 have shown that methodological standards were not complied with in large numbers. It is therefore of great importance that guidelines and recommendations are presented in formats that are easily interpreted. The ISHLT feels strongly that our guidelines should be succinct compilations of evidence-based recommendations. Gaps in evidence should be so stated, ideally in a table, and not detailed in long paragraphs with numerous examples of what has been tried but not proven. Adherence to the ISHLT's guideline development guide, contained herein, will help to ensure useful documents that will aid in clinical decision-making.

2 Definitions, Details, and Deliberations.

The term guidelines can be broadly applied to several different types of ISHLT papers, including:

Policies statements.

These documents present ISHLT positions on issues that pertain to public health policy, healthcare financing and delivery, medical education, and governmental policy.

Suggested length: 3000 and words/10 double spaced manuscript pages including references.

Conference proceedings and workshop summaries.

Documents that report the proceedings of conferences and workshops sponsored by the ISHLT. These documents may include recommendations requiring rigorous description of the applied methodology.

Suggested length: 4500 words/15 double spaced typed pages including references.

Technology reviews, assessments, and standards and systematic reviews.

Statements that review or assess technologies or present recommendations for technology standardization.

Suggested length: 4500 words/15 double spaced typed pages including references.

Guidelines and recommendations.

Documents that include recommendations, strategies, or information that assist physicians and/or other healthcare practitioners and patients make decisions about appropriate measures of care for specific clinical circumstances.

Necessary elements of their development are:

1. A multidisciplinary development process,
2. Comprehensive literature search for evidence,
3. The formal grading of recommendations on the quality of the evidence.
4. Grading the strength of recommendations: A careful evaluation of benefits, harms, burdens and costs.

Suggested length: Guidelines will result in two different documents: a full version of the guidelines which may be quite extensive (see below) and an executive summary of the guidelines. *The executive summary of the guidelines should be no more than 4500 words/15 double spaced typed pages including references.*

Educational materials and coursework.

Various writing groups may also produce other products, such as slide-sets, posters, CD-ROMs, books, etc. These derivative products are also official ISHLT documents. Prior to initiation of such ancillary products, the writing groups must seek approval from the Committee, with a budget outlining the costs of such production.

3 Rules for Writing Group Organization

Selection of Topics

As mentioned above, subjects chosen for ISHLT Guidelines are usually broad medical and clinical issues within our discipline and our core competencies, related to the topics where there is a clear need for guidelines to assist physicians/clinicians in diagnosis and/or clinical management. They can encompass public health issues, epidemiology, prevention, management strategies, health policies, etc.

The ISHLT Committee for Standards and Guidelines (henceforth the “Committee”) will seek the advice of the appropriate committees and Councils of the ISHLT for the choice of new guideline topics. Importantly, ideas and proposals for guidelines may be initiated from within one of the ISHLT Councils, and submitted to the Committee. The Committee may also ask for advice and input from other bodies within the ISHLT, in particular from the Board of the ISHLT as well as from other entities.

Once all suggestions and ideas have been collected, a range of topics is selected by internal decision within the Committee.

- The subjects are ranked by degree of interest.

- Duplication of good quality, previously existing guidelines issued by other societies is discouraged, unless new data exists which make previous guidelines out of date.
- Updates of previously published guidelines have high priority when new data have emerged in the relevant field.

Once the list of topics has been established, the final decision of which Writing Groups should be initiated is made by consensus among the members of the Committee and is validated by the Board of the ISHLT, only if budgetary issues mandate the Board's involvement. The process of choosing a chairperson and members for each Writing Group can then begin.

Writing Group Creation and Selection of Writing Group Members

The Chairperson and the (optional) Co-Chairperson of the Writing Group are both proposed by the Committee. The choice may be informed by the original proposal to develop a new guideline.

The Chairperson of the Writing Group then works in conjunction with the Committee to establish a list of members. A maximum of 10 to 15 members is recommended. There are several considerations in the choice of members for a specific Writing Group:

- The chosen members must be renowned for their scientific expertise in the field. *They must be members of the ISHLT.*
- If possible, there must be an even geographical distribution of the Writing Group members, so as to include representatives from all parts of the ISHLT.
- The Writing Group members are also chosen according to their willingness and availability to participate actively, i.e. in the meetings and in the production of a part of the final manuscript.
- In cases where the subject area is felt to concern other disciplines, a representative of the relevant related society (ies) can be invited to participate. This should be a rare occurrence, as the guidelines emanating from the ISHLT should be representative of the ISHLT's expertise. Representatives from related societies may be invited to participate as full members or can be invited at a later stage to review the Writing Group document. Likewise, appropriate representation from the various ISHLT Councils should be sought for representation. Especially important to represent in many of the guidelines will be allied health care workers (e.g. nurses) and pediatric clinicians.
- Writing Group members must be willing to disclose all relationships with industry that might represent a potential conflict of interest. (see below)

The Writing Group members are expected to participate in all of the Writing Group meetings, and adhere to the time schedule of the document production. If a member cannot attend (or participate in) two meetings in a row, he or she may be asked to stand down from this Writing Group at the discretion of the Chairperson. To increase efficiency, one or several Sub-Writing Groups of 4 to 6 members can be appointed within the Writing Group.

All in all, this selection and setting up process should not last more than **3 months**, from the first step in the creation of the Writing Group to its final composition and the beginning of the writing process.

Budget

The Writing Group is financed by the ISHLT. A fixed budget is set and must be adhered to by the Writing Group members. The ISHLT Board must approve beforehand significant expenses (such as cost estimates for meetings held outside the annual ISHLT meeting, etc.).

4 Rules for Guidelines Writing

Evidence Gathering and Review

The prerequisite for data to be considered for inclusion and integration into Guidelines is their credibility, and an important undertaking of the Writing Group should be to gather and weigh the available evidence. To this end, new tools are now available for literature searching which can make this process much easier, i.e. advanced PubMed, Medline, Embase, Cochrane, LocatorPlus, etc.

A *formal literature review* must be performed. If deemed necessary and appropriate, the Writing Group can undertake a formal meta-analysis.

With regard to evidence gathering, the following rules apply:

- Only peer reviewed published literature will be considered.
- **The use of abstracts should be avoided except in very rare instances.** Abstracts older than 2 years will not be accepted as reference and quotation of any abstract must clearly indicate that it is an abstract and not a full paper.
- **Unpublished clinical trials cannot be quoted unless they have been formally presented at a major international meeting and on condition that the authors of the trial have provided the Writing Group with a draft of the final document to be submitted for publication.** Quotation of such trials must indicate at which international meeting it has been presented.

The *levels of evidence* against or in favor of a particular treatment or diagnostic procedure must be cited. The levels of evidence will be ranked in three levels according to the type of available data (see table below).

Recommendations will be graded according to four different classes: I, IIa, IIb and III.

Recommendations should be linked to their level of evidence or highlighted by comment stating for example: "...this recommendation is based on level of evidence A".

The classes of recommendations and the levels of evidence are graded as follows:

Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective;
Class II	Conflicting evidence and/or divergence of opinion about the usefulness/efficacy of the treatment or procedure;
<i>Class IIa</i>	Weight of evidence/opinion is in favor of usefulness/efficacy;
<i>Class IIb</i>	Usefulness/efficacy is less well established by evidence/opinion;
Class III	Evidence or general agreement that the treatment or procedure is not useful or effective and in some cases may be harmful.
Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Consensus Achievement

Consensus can be achieved for recommendations without much discussion when strong evidence exists. However, the Writing Group must also critically consider the applicability of the recommendations to a specific field or area. For example, recommendations on particular treatments based on trials carried out in patients aged 70 years or younger cannot be extended to patients older than 70 years.

In controversial areas, or in issues without evidence other than usual clinical practice, different processes can achieve consensus:

- Expert panel discussion and common sense.
- Quantification of expert opinions. These are interesting but time-consuming methods.

It should be emphasized that ISHLT guidelines should be succinct summaries of *evidence based recommendations*. There should *not* be long paragraphs about controversies or various schema that institutions have used (dealing with pre-sensitized patients prior to transplant, as an example) where no definitive evidence exists. The Writing Group may present, instead, a table of “Gaps in Evidence” summarizing areas that are not clarified by trials. *As a rough guide, no more than half of the recommendations may be at a Level of Evidence C.*

Format of Documents

In general, each Writing Group will produce two different documents:

1. A full version of the guidelines.
2. An executive summary of the guidelines.

The full version of the guidelines should be a maximum of 50,000 words, including references. This corresponds to 50 ISHLT formatted pages (1000 words per page, 40 references per page). *The executive summary of the guidelines should be no more than 4500 words/15 double spaced typed pages including references.*

The document must be written in English. Simple and clear wording is essential to aid comprehension and avoid ambiguity. The use of tables, drawings, figures, decision-making algorithms and other illustrations is encouraged. **In particular, tables summarizing “Gaps in Evidence” are strongly supported.**

The body of the guidelines should contain the following items:

- Background and aim of the document.
- Scope of the problem with relevant epidemiological information.
- Grading of recommendations (Class I, IIa, IIb, or III) and levels of evidence (A, B or C) for all recommendations. The use of summary tables is recommended.
- Treatment goals and/or other indicators of “best practice”.
- Reference to relevant changes or discrepancies with older versions of the guidelines. The use of tables illustrating the differences with older versions of the guidelines is encouraged, if applicable.

- Suggestions for implementing the recommendations of the guidelines in clinical practice.
- Identification of ongoing research that may change some of the recommendations.
- Proposal for date of guidelines update.

In addition to the body of the report described above, the final guidelines document should include the following general issues and points:

- Names of the Writing Group members (plus affiliations in case of members from related societies), names of the Committee members and names of the reviewers on the first page.
- Preamble common to all ISHLT Guidelines (*to be developed*).
- Description of methodology used, including:
 - Selection of evidence – how the literature search/review was conducted.
 - Types of papers considered (abstracts, randomized studies, meta-analyses, cost-effectiveness studies, etc.)

The final document is then submitted to the Committee for review.

Abbreviations, Units and Standards

ISHLT Guidelines need to be endorsed and – when appropriate – translated by national societies according to Standard Operating Procedures (*to be developed*). In this process, annotations and other explanatory notations may need to be made to adapt them to each individual country and/or health system. Annotations should not modify recommendations or their *Classes of Recommendations and Levels of Evidence* but should simply adapt the guidelines to that country’s specific practices. Given the many countries that the ISHLT represents, Writing Groups must be sure to write their guidelines with *appropriate international units and standards in mind*. An example might be for pounds to be likewise translated into kilograms, etc.

The Writing Group chair must develop, in conjunction with the Writing Group, a *standardized list of abbreviations* before anyone starts to write. These abbreviations, and only those agreed upon abbreviations, will be acceptable in the publication of the ultimate product. A brief list of abbreviations to be found in each document will be found in the preface of the documents. Each Writing Group is encouraged to consult the Journal of Heart and Lung Transplant for their guidelines about abbreviations, units and standards as well.

Guidelines comprise a series of documents, produced over a time period of approximately 12 to 24 months. That is, from the original approval of the budget and writing group members to final submission to the Committee for review should be no longer than **24 months**. The documents are then submitted to the Committee for approval.

Conflict of Interests

The Writing Group makes every effort to avoid any actual or potential *conflicts of interest* that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, before being appointed by the Committee, all the proposed members of Writing Group are asked to provide disclosure statements of all relationship that might be perceived as real or potential conflicts of interested. Once they have verbally accepted to become members of the Writing Group, they are asked to sign a written consent form as well as a form disclosing any potential conflict of interest. The disclosure form must be updated if any changes occur during the elaboration of the document.

The documents produced must contain a statement of relationship with industry and conflicts of interest for each writing group member and each reviewer whose name will appear on the document. Format consistent with the Journal of Heart and Lung Transplant should be followed.

Review Process

When the guidelines are almost finalized and ready for review, a review coordinator is appointed within the Committee. This review coordinator, in conjunction with the Committee, the Writing Group and representatives of the Board of the ISHLT, choose additional document reviewers. These reviewers will have to disclose any potential conflicts of interest they may have and send in their review comments within a set timeframe. If they do not follow these procedures, they will not appear in the final document in the reviewers' list.

The Writing Group integrates the reviewers' comments and returns the revised version for Committee approval (there can be several rounds of this process). A period of 6 to 8 weeks must be planned for the review and subsequent revisions of the final document. English language reviewers and proofreaders are called upon when necessary after completion of all revisions. The final approval of the various documents is given by the Committee.

The Committee will send what it legitimately believes to be the final draft to the Board of the ISHLT with their recommendations for approval. All guidelines must be approved by the Board, and must be done so in a timely manner.

5. Acknowledgement

The Committee acknowledges that many portions of this guideline are patterned closely after the European Society of Cardiology's and the American Transplant Society's document of a similar name. We are indebted to the wisdom of these Societies in formulating their document, available on their web site.