Frequently Asked Questions (FAQs) and Answers about Official ATS Documents Development

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For more information, documents developers should see The 2010 Guidelines for Official ATS Documents (GATS): http://www.thoracic.org/statements/document-development/resources/guidelines.pdf.

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SECTION 1: SUBMITTING A NEW OR RENEWAL PROJECT

1. I have an idea for a new ATS document. Should I contact the editor of the AJRCCM/AJRCMB/PATS journal to discuss the idea?

ANSWER
Individuals interested in developing a new ATS document or updating an existing ATS document should consult a member of the Documents Development & Implementation Committee (DDIC) and an ATS staff member (either Judy Corn [jcorn@thoracic.org] or Jessica Wisk [jwisk@thoracic.org]) to learn about the procedures and policies for document development. If the individual decides to proceed, he or she must obtain approval and support for the project by submitting an Assembly/Committee Project Application. For information about the application, contact ATS staff member Miriam Rodriguez (mrodriguez@thoracic.org). Since official ATS documents are governed by the ATS Board of Directors, the DDIC, and the Documents Editor, the editors of the AJRCCM/AJRCMB/PATS journals should not be contacted.

2. Do I have to submit an Assembly/Committee Project application? I want to get started on this time-sensitive project right away!

ANSWER
All Assembly and Committee projects that will produce an official document need to go through the usual approval process, including the submission of an Assembly/Committee Project Application. This policy was approved by the ATS Board of Directors to ensure that all projects are in compliance with ATS regulations, particularly those related to conflict of interest, budget, and methodology.

3. We want to update an existing ATS document. Do we still need to submit an Assembly/Committee Project application? Isn't there an easier way, since the document already exists?

ANSWER
All Assembly and Committee projects that will produce an official ATS document need to go through the usual approval process, regardless of whether the document will be a new document or an update of an existing document. The purpose of this policy is to ensure that all projects are in compliance with ATS regulations, including those related to conflict of interest, methodology, and budget. The DDIC is in the process of crafting a policy and procedure for guideline updates that will be submitted to the Executive Committee in the coming months; this may simplify the process of updating guidelines in the future.

4. Why are there so many different types of documents and which one am I developing?

ANSWER

The ATS documents can be divided into:

1. Clinical Practice Guidelines
2. Other documents
   a. Policy and Research Statements
   b. Workshop Reports
   c. Systematic Reviews
   d. Technical Standards.

Clinical Practice Guidelines make diagnostic and treatment recommendations that assist physicians, other healthcare practitioners, and patients to make decisions about the appropriate course of action in specific clinical situations.
Policy Statements present ATS positions on issues related to bioethics, public health policy, healthcare financing and delivery, medical education, and governmental policy.
Research Statements present ATS positions on issues that pertain to governmental funding or research, future research needs or initiatives, and other issues that promote or hinder pulmonary, critical care, and sleep research.
Workshop reports are summaries of conferences and workshops that were sponsored by the ATS.
Systematic reviews answer a focused clinical question using well-established systematic methods to search the literature, select relevant studies, and appraise the evidence. The question is usually related to a diagnostic approach, test, device, or other intervention.
Technical standards describe how to perform a test or procedure. They do not compare tests or procedures, nor do they identify populations to which a test or procedure should be applied.

For a more detailed definition of the different types of documents, refer to the 2013Guidelines for Official ATS Documents: http://www.thoracic.org/statements/document-development/resources/guidelines.pdf and the companion 2013 GATS Primer, also on the website.

5. We'd like to partner with another organization (e.g. ERS, IDSA) to create a joint document. How do we set this up?

ANSWER
Individuals interested in working with other organizations on an official document should indicate this on their new or renewal Assembly/Committee Project Application to ATS. Project applications submitted to partner organizations should similarly acknowledge that an application was submitted to ATS (or the intent to submit an application to ATS). Contact ATS staff member Miriam Rodriguez (mrodriguez@thoracic.org) for more information about submitting Assembly/Committee Project Applications to ATS that include a partner organization. Once the project has been approved by the participating societies, a Memorandum of Understanding needs to be written, agreed upon, and signed by all co-sponsoring organizations as early as possible in the document development process. The organizations will then coordinate the development, peer review, approval, and publication processes.

6. Can I write a clinical practice guideline even if there are no randomized trials or large prospective cohort studies?

ANSWER

Yes, as long as you use a systematic approach to identify and summarize the evidence and the GRADE approach to develop recommendations. The key is to be transparent and to fully acknowledge the quality of available evidence. Retrospective cohort studies, case-control studies, case series, case reports, and a clinician's unsystematic observations (i.e. clinical experience) also provide evidence, but of lower quality due to an inherent larger risk of bias because of their design.

SECTION 2: DOCUMENT DEVELOPMENT

7. For a first time clinical practice guideline developer, what are some resources that I can review regarding the process and when should I get help from the DDIC?

ANSWER
The document developer's first-line resources include:

1) The 2013 Guidelines for Official ATS Documents: http://www.thoracic.org/statements/document-development/resources/guidelines.pdf

2) The DDIC leadership, members and staff to include:

- Michael Gould, DDIC Chair, Micheal.K.Gould@kp.org (for issues related to policy)
- Colin Cooke, DDIC Vice-Chair, CookeCR@med.umich.edu (for issues related to policy)
- Jan Brozek, ATS methodologist, brozekj@mcmaster.ca (for issues related to methods)
- Kevin Wilson, Documents Editor, kwilson@thoracic.org (for issues related to manuscript organization, submission, or review)
- Judy Corn, ATS Staff, jcorn@thoracic.org (for general issues or issues related to Board of Directors approval)

Jessica Wisk, ATS Staff, jwisk@thoraic.org (for issues related to project management).

Developers should reach out to these resources as soon as confusion or uncertainty arises. Other potentially useful resources are available at the DDIC website: http://www.thoracic.org/statements/document-development/index.php.

8. What are acceptable methods to determine the invite list for an "expert panel"?

ANSWER
1. Chair(s)
It is ideal for the document development group to be led by one or more chairs that have 1) an in-depth understanding of the scope of the prospective document, 2) the skills to guide the document development group, and 3) at least basic understanding of the methods used to develop a particular type of document.

2. Methodologist(s)
Depending upon the type of a document, it may be beneficial for the chair(s) or other group member(s) to have methodological skills and experience in developing similar documents for the American Thoracic Society or another organization. For clinical practice guidelines, it is

essential thatall panels include at least one member with working knowledge or experience in conducting systematic reviews or developing guidelines. It is also possible for the ATS methodologist to work with that designated individual to advise him or her on the document development process.

3. Group Members

It is important that the members of the group represent the perspectives of the healthcare and/or healthcare professionals involved in the management of patients that will be affected by the document. Among the content experts, it is generally beneficial to have a diversity of perspectives represented, including clinicians and researchers from a variety of specialties. Depending upon the type and topic of the document, it may be beneficial to include other stakeholders, such as patients, pharmacists, ethicists, nurses, rehabilitation specialists, respiratory technicians, and other health professionals. Special consideration should be given to potential conflicts of interest.

For further information on group composition, refer to:
http://www.health-policy-systems.com/content/4/1/15
For further information on the management of potential conflicts of interest, refer to an Official ATS Policy Statement on Managing Conflict of Interest in Professional Societies:
http://www.thoracic.org/statements/resources/other-interests/coi.pdf

9. I see that there are page limits for official ATS documents and they seem relatively short. Is there room for negotiation about the length of our document?

ANSWER

Limitations on the length of documents have evolved over the years to meet the needs of the readers. The current policy allows the following number of words:

- Policy and Research Statements: An Executive Summary (3,500 words or less) printed in the Am J Respir Crit Care Med and a full-length version (10,000 words or less) published online. Alternatively, the full version can be printed in the Am J Respir Crit Care Med if it is 3,500 words or less.
- Workshop reports: A full-length version (4,500 words or less) published in the online-only AnnATS.
- Systematic reviews: An Executive Summary (4,000 words or less) printed in the Am J Respir Crit Care Med and a full-length version (10,000 words or less) published online. Alternatively, the full version can be printed in the Am J Respir Crit Care Med if it is 4,000 words or less.
- Technical standards: An Executive Summary (4,000 words or less) printed in the Am J Respir Crit Care Med and a full-length version (10,000 words or less) published online. Alternatively, the full version can be printed in the Am J Respir Crit Care Med if it is 4,000 words or less.
- Clinical practice guideline: An Executive Summary (4,500 words or less) printed in the Am J Respir Crit Care Med and a full-length version (10,000 words or less) published

online. Alternatively, the full version can be printed in the Am J Respir Crit Care Med if it is 4,500 words or less.

If you are having difficulty adhering to these limitations, contact the Documents Editor to determine an acceptable word limit

10. I understand that specific methods are required when making healthcare recommendations such as when a document will be making clinical practice recommendations. What are these methods?

ANSWER
Specific recommendations for patient care should only be made in clinical practice guidelines, which require a full or pragmatic systematic review of the literature and following the GRADE approach to appraise the evidence and both formulate and grade recommendations.

Important steps in the development of recommendations include:

1) assembling a qualified panel of experts, methodologists, and other stakeholders
2) defining the clinical question using the patient, intervention, comparator, outcome (PICO) approach,
3) performing a full or pragmatic systematic review(s) to identify and select evidence,
4) using the GRADE approach to appraise the evidence,
5) using the GRADE approach to formulate the recommendations, and
6) using the GRADE approach to grade the recommendations (i.e., quality of evidence and strength of the recommendation).

11. The document development process is more labor intensive than I'd initially thought. What resources are available from ATS to assist me?

ANSWER
There are a number of resources to help you during the document development and post-development stages of ATS-approved projects. These include a) a liaison appointed from the DDIC committee to guide you through the process of document development, b) the methodologist to supervise (or, in select circumstances, to assist) with the formulation of clinical questions, identifying a search strategy, and using the GRADE approach to appraise the evidence, formulate recommendations, and grade recommendations, c) the Documents Editor to provide technical guidance during document development, review, and revision, as well as coordination with any co-sponsors; in select circumstances, the Documents Editor may also be able to assist with the tasks in “b” and d) the ATS staff to provide information about policies, procedures, budget, conflict of interest, meeting and conference call coordination, review, approval, and publication. The DDIC is also accessible to chairs on matters related to document-related policy.

12. Our project was approved several years ago and we have been working on our document ever since. The Guidelines for Official ATS Documents now include requirements that didn't exist when my project was approved. What should I do?

ANSWER
Documents not yet submitted to the Documents Editor that were originally approved several years ago should adhere to the most current Guidelines for Official ATS Documents
The 2013 Guidelines for Official ATS Documents (GATS) were developed to ensure that ATS document-related projects reflect the high standards and quality of the Society, while also being in compliance with other standards, such as the Committee for Medical Specialty Society (CMSS) and Institute of Medicine (IOM) standards. Complying with such standards requires that the most rigorous methodology feasible be used for all projects. For those projects initiated several years ago when our methods were in flux, we will work with developers to ensure that they are as rigorous as possible without compromising the time and effort spent to date by developers.

2.1 Systematic Reviews

13. The 2013 Guidelines for Official ATS Documents say that a systematic review is required for all guidelines. What exactly is a systematic review?

ANSWER
Evidence can be identified from the literature in a systematic or non-systematic way.
For the purpose of guideline development one can follow one of the 3 approaches:

1. Inform the recommendation with an existing, well-done and up-to-date systematic review
2. Perform a pragmatic systematic review
3. Perform a full systematic review

The last approach, a full systematic review, is methodologically the most sound and the least prone to bias; thus, it is the preferable approach.

A full systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific clinical or research question. It uses explicit and systematic methods for identifying and summarizing current evidence in order to minimize bias, thus providing more reliable findings from which conclusions can be drawn and decisions made.
A full systematic review involves:

1. Using explicit and reproducible methodology
2. Clearly stating the objectives
3. Pre-specifying search and study selection criteria
4. A systematic search for literature that attempts to identify all studies that would meet the eligibility criteria using multiple electronic databases, such as Medline, EMBASE, and the Cochrane Controlled Trials Register (CENTRAL)
5. An assessment of the validity of the findings of the included studies (e.g. the risk of bias)
6. A systematic synthesis and presentation of the characteristics and findings of the included studies

A full systematic review may contain meta-analyses. Meta-analysis is a set of statistical methods to summarize the results of individual studies. By combining information from all relevant studies, meta-analysis can provide more precise estimate of the effects of health care interventions than those derived from the individual studies. Use of meta-analysis also facilitates investigations of the consistency of evidence across studies and the exploration of any differences of results across studies. If the results of individual studies cannot be combined, authors of a full systematic review can qualitatively summarize results.

Sometimes it may not be feasible due to limited time and resources available for developing recommendations to perform a full systematic review. When a full systematic review cannot be performed, a pragmatic systematic review can be performed. A pragmatic approach to systematic review attempts to find balance between minimizing the risk of bias and time and resource expenditure required to perform a full systematic review. The most time and resource consuming step of a full systematic review is usually searching for the relevant studies and screening identified citations and full text publications for eligibility. A pragmatic approach to a systematic literature review involves searching at least one electronic database (e.g. MEDLINE) using more specific search strategies (i.e. reducing the number of citations to screen, but risking that some relevant studies can be missed). When searching MEDLINE, one can use Clinical Queries methodological filters in the PubMed interface that attempt to "concentrate" relevant citations (http://www.ncbi.nlm.nih.gov/sites/pubmedutils/clinical).

For further information on performing a systematic review refer to:

- The Cochrane Handbook for Systematic Reviews of Interventions: http://www.cochrane-handbook.org/
- Preferred Reporting Items for Systematic Reviews and Meta-analyses: The Prisma Statement (Ann Intern Med 2009; 151:264): http://www.prisma-statement.org/index.htm
- Contact a member of the DDIC leadership.

14. If I am not working on clinical practice guidelines, do I need to perform a systematic review?

ANSWER

While it is desirable to perform a systematic review whenever possible, this may be difficult because of limited resources. ATS clinical practice guidelines should always include a systematic review. Other documents are not required to perform systematic reviews, but should be explicit about the methods for identifying, appraising, and synthesizing evidence.

2.2 GRADE and Developing a Consensus

15. When do I need to use Grades of Recommendations, Assessment, Development, and Evaluation (GRADE) system?

ANSWER
The GRADE methodology is required to assess the quality of evidence and rate the strength of management (diagnosis or treatment) recommendations in all ATS clinical practice guidelines. See also response to #10 regarding recommendations in non-guideline documents.

You do not need to have randomized clinical trials or large observational studies to use GRADE. Non-systematic clinical observations (e.g., case series, case reports, and clinical experience) as well as, for instance, animal studies or laboratory experiments can form the basis of recommendations; GRADE defines such evidence as very low quality evidence, due to the risk of bias and indirectness of the evidence, and insists that the related recommendations be labeled as such.

Recommendations about the use of diagnostic methods or therapeutic interventions should be developed following the GRADE approach.

In contrast, GRADE is not required for the following:

- Research-related recommendations (e.g. "we recommend further investigation of . . .")
- Technical recommendations (e.g., "the BAL specimen should be centrifuged, decanted, and then stored on ice")
- "Motherhood statements" which are best practice recommendations or recommendations for which there are no reasonable alternative to the recommended intervention (e.g. "We recommend understanding patient preferences when deciding between treatment alternatives.").

Please contact the DDIC liaison assigned to your project for further information.

16. Is a trial of using GRADE necessary to work out questions and kinks?

ANSWER
For groups that plan to make recommendations, it is most efficient to include a panel member who has used the GRADE approach previously and understands it well enough the guide the panel through the process. In the absence of such a group member, it is useful to consult the ATS methodologist who can determine the extent of the group's need and guide them accordingly. The group should not expect to learn the GRADE approach without the assistance of the methodologist or someone else who is familiar with the approach.

For other groups that do not plan to make recommendations, but will still need an approach to reaching a consensus, the Delphi method, Nominal Group Technique, and structured discussion method seem to be the easiest (see resources for question 3 above).

17. What is the appropriate method to generate a consensus (in-person vs electronic)?

ANSWER

There is no right or wrong way to reach a consensus. Several formal approaches for reaching a consensus exist, and some organizations use these methods to develop clinical practice guidelines and other documents. Common methods include the Nominal Group Technique (NGT), the Delphi method, and Consensus Conferences, although there is considerable variation in how these techniques are implemented in practice. Several techniques may be used during the development of one document (e.g., a Delphi method may be used when communicating electronically and a structured discussion may be used during the face-to-face meetings). For comprehensive explanation of these techniques in guideline development please refer to Murphy et al. 1998 (http://www.hta.ac.uk/execsumm/summ203.htm).

It is possible that consensus may not be achieved by discussion and that voting may be necessary. This should be transparently conveyed by reporting the majority opinion, as well as the number of panel members who agreed, disagreed, or abstained.

For further information on group processes and consensus development techniques, refer to:
http://www.health-policy-systems.com/content/4/1/17
http://www.hta.ac.uk/execsumm/summ203.htm
http://www.bmj.com/content/337/bmj.a744.extract

18. We can't reach a consensus regarding several of our recommendations. How is this best handled?

ANSWER
It is not uncommon for a panel to find it difficult to reach a consensus, especially if the panel is large, the clinical question is controversial, or the evidence is inconsistent and of low quality. Experience of various guideline panels suggests that using transparent and explicit methods reduces disagreement. Using GRADE evidence tables presents the same evidence to every panel member focusing everyone on the same information. Another technique that may facilitate reaching the consensus is using so called “GRADE grid” (http://www.bmj.com/content/337/bmj.a744.extract). In order to be transparent and to convey to readers that there is a mixed opinion, the results of voting and the number of panel members who approve, disapprove, or abstain should be reported.

19. Applying the GRADE system has become very time consuming and labor intensive. Is there anything that we can do to expedite the process?

ANSWER
The GRADE approach is not more time consuming that any other systematic and transparent approach to developing health care recommendations. It is not the GRADE methodology itself but rather the requirement for a systematic, explicit and transparent process for judicious use of the evidence in making health care recommendations that requires time and resources.

As with any systematic method, the GRADE approach initially requires time for training and getting familiar with its application. If the group intends to make patient care recommendations,

it is desirable that at least one panel member has experience with the application of the GRADE approach. It may be helpful to solicit the guidance of the ATS methodologist or the DDIC liaison who can guide and focus the group on the necessities, so that unproductive effort can be avoided. An additional strategy includes prioritizing and developing fewer recommendations, perhaps by focusing on the clinical questions of greatest importance.

SECTION 3: PEER and BOARD OF DIRECTORS REVIEW

20. I would like an update on the status of my document. Should I contact the Editor of AJRCCM/ AJRCMB/ PATS to discuss my document?

ANSWER
Current Chairs who would like an update on the status of their project should contact ATS documents staff (Judy Corn [jcorn@thoracic.org] or Jessica Wisk [jwisk@thoracic.org]). The Editors of the AJRCCM, AJRCMB/PATS do not need to be contacted since official ATS documents are governed by the ATS Board of Directors, the DDIC, and the Documents Editor.

21. I submitted my document for review a few weeks ago and I haven't heard back from anyone. What is the usual turn around time for these documents?

ANSWER
Official ATS documents are governed by the ATS Board of Directors, the DDIC, and the Documents Editor. Thus, they go through a review and approval process that is different from that used by the Journals.

The expectation is that the review, approval, and publication of an official document will almost always require more time than a typical Journal manuscript because the process includes many steps. These steps include the Documents Editor's initial review of a newly submitted document, peer review by three or more peer reviewers, consideration of the peer reviewer's comments, and a final Documents Editor review following revisions. Occasionally, a revised document may be sent for repeat peer review. Once approved by the Documents Editor, the document is forwarded to the ATS Board of Directors, where it is reviewed by the Board of Directors subcommittee to make sure that the content is consistent with the mission and policies of the ATS. Following subcommittee approval, the Board of Directors votes to approve or disapprove the document.

The official ATS documents team is in the process of adopting a new system that will enhance the transparency behind the system. In the future, authors will have access to the status of their projects via ScholarOne. Currently, the peer review, Document Editor's review, Board of Directors subcommittee review, and Board of Directors vote collectively takes, on average, 12-15 weeks. This estimate does not include the time authors take to make revisions and assumes only one cycle of author revisions, although many documents require several cycles. Documents developed jointly with other professional organizations may require additional time for the review process.

22. What is the review process if my document was developed jointly with another society?

ANSWER

The ATS portion of the review process is identical to that described above for documents developed jointly with another society, even if the document will be published in a non-ATS journal. However, multi-organization documents must be submitted to each co-sponsoring organization, which will conduct in own review and approval process independently and in parallel with the ATS. Details of the review process are included in the Memorandum of Understanding prior to document development. To proactively manage the complexities associated with joint sponsorship, frequent communication between the developers and the ATS Documents Editor is encouraged.