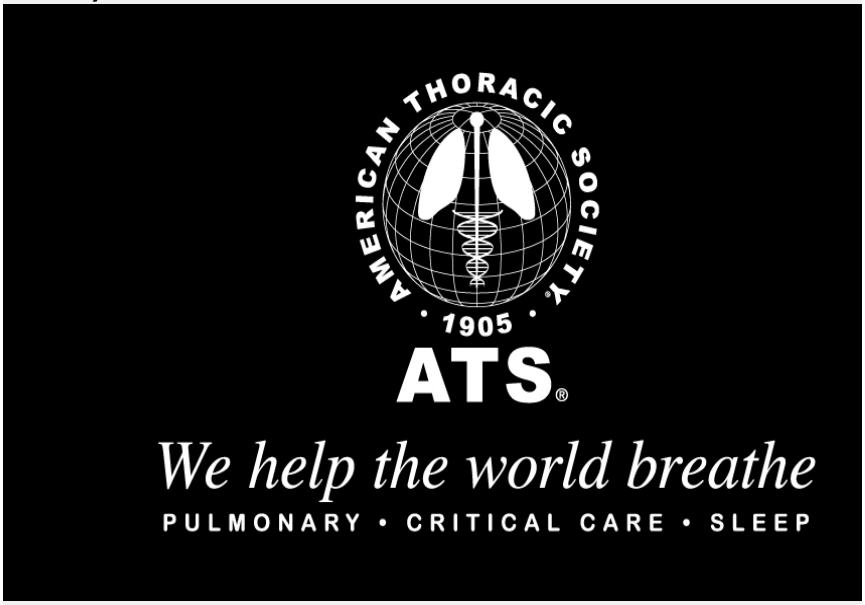
AMERICAN THORACIC SOCIETY GATS PRIMER: AN INTRODUCTORY GUIDE FOR APPLICANTS

Available at:
www.thoracic.org/statements/document-development/resources/guidelines.pdf)
or through the ATS Documents Unit,Tel.212/315-8691



GATS Primer: An Introductory Guide for Applicants

ATS Official Documents:

An Introductory Guide for Applicants

Official American Thoracic Society (ATS) Documents refer to a range of materials produced by ATS. These documents include: *Statements*; *Workshop Reports*; *Systematic Reviews* (SR's); *Technical Standards* (TS's); and *Clinical Practice Guidelines* (CPG's). (A summary of the various requirements of each is outlined in the Table.) These documents, which are supported by the ATS, undergo a rigorous peer review and approval process. Upon approval by the ATS Board of Directors, official documents carry the imprimatur and, therefore, reflect the policies of the ATS.

Proposal leaders should refer to the current "Guidelines for ATS Documents" (GATS), before planning to develop an official ATS document. Educational modules (Module A for all developers and Modules A & B for those developing CPG's) must be completed prior to submission of a new project application. These modules are available on the ATS Website at http://www.thoracic.org/statements/document-development/index.php. Frequently asked questions (FAQ) are also available on the website at http://www.thoracic.org/statements/document-development/resources/ats-documents-faq.doc. The FAQ document covers a range of topics of interest to document developers.

Basic Considerations in Project Development

1. **Type of document**: Determine the type of document to be developed. In the proposal, applicants should adequately describe the methodology that will be used to identify, appraise, summarize, and grade (when relevant) the evidence for their document type. Adhering to the ATS' methodological standards for systematic and/or pragmatic literature reviews, and use of the Grading, Recommendations, Assessment, Development, and Evaluation (GRADE) approach, are imperative components of successful applications proposing CPG's.

2. **Panel composition**: Choose team members with a balance of content and methodological expertise. Among the content experts, multiple disciplines should be represented. CPG's and SR's should include one or more individuals with experience leading SR's and/or a GRADE-based project. While the ATS has a part-time methodologist, his availability is limited.

3. **Authorship**: For <u>all</u> documents, the chair (and co-chair, if applicable) is listed first, followed by an alphabetical list of authors.

4. **Scope**: Develop a scope that is realistic. Statements, workshop reports, SR's, and TS's should be ready for submission after one year. In contrast, CPG's should be ready for submission after two years: the first year is used to perform the literature reviews, appraise the evidence, and develop evidence tables, while the second year is used to formulate and grade the recommendations, and write the manuscript. Figure 1 provides a detailed timeline for developing CPG's, while Figure 2 describes an approach for determining whether existing SR's may be used to inform the development of clinical recommendations.

5. **Multi-society documents**: Applicants interested in developing a document to be co-sponsored by ATS and one or more non-ATS organizations should submit a project application to each organization separately. The guideline directors and leadership of the organizations will then negotiate the key components of the project including; the site of publication, who will serve as the "host" organization, which organization's conflict of interest (COI) policy and methodology will be used, and how the project expenses should be managed. These points (after negotiation), will be codified in the form of a Memo of Understanding (MOU) signed by the Executive Directors of each organization. Additional information about MOUs is described on page 15, under *Jointly Sponsored Projects*.

Types of Documents

1. **Statements** – There are two types of statements; policy statements and research statements. Policy statements present ATS positions on issues that pertain to bioethics , public health policy, health care financing and delivery, medical education, and governmental policy. Example: *An Official ATS Policy Statement: Pay-for-Performance in Pulmonary, Critical Care, and Sleep Medicine* (Am J Respir Crit Care Med Vol 181, pp 752–761, 2010). Research statements present ATS positions on issues that pertain to governmental funding of research, future research needs and initiatives, and other issues that promote or hinder pulmonary, critical care, and sleep research. Example: *Multisociety Task Force for Critical Care Research: Key Issues and Recommendations* (Am J Respir Crit Care Med Vol 185, pp 96–102, 2012).

   Statements may make recommendations for policy and research, but may not make recommendations for patient care. They should be submitted within one year of the project start date. An Executive Summary is published in the **AJRCCM** (maximum 3,500 words) and the full document is published online only (maximum of 10,000 words). Alternatively, the full document may be published in the AJRCCM if it is less than 3,500 words. The word limits are strictly enforced.

2. **Workshop reports** – Workshop reports are summaries of conferences and workshops that were sponsored by the ATS. While most of the content in the report should derive from the conference or workshop, additional discussions and further development of ideas following the conference or workshop are acceptable. As an example, see "An Official ATS Workshop Report: Climate Change and Human Health, Proc Am Thorac Soc 2012; 9:3-8."

Workshop reports may not make recommendations for patient care. They should be submitted within one year of the project start date. Workshop reports are published in the online only journal, Annals of the American Thoracic Society (maximum 4,500 words) The word limits are strictly enforced.

3. **Systematic reviews**– SR's 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, treatment, or other intervention. SR's may be qualitative or quantitative (i.e., data is extracted and pooled via meta-analysis).

   The **GRADE** (http://www.gradeworkinggroup.org/index.htm) approach must be used to appraise the evidence and the document must be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (**PRISMA** at http://www.prisma-statement.org/statement.htm) statement. Therefore, the project committee should include one or more individuals who have prior experience with SR's and/or a GRADE-based project.

   SR's may not make recommendations for patient care. They should be submitted within one year of the project start date and updated as-needed in response to changes in practice. An Executive Summary is published in the AJRCCM (maximum of 4,000 words) and the full document is published online only (maximum of 10,000 words). Alternatively, the full document may be published in the AJRCCM if it is less than 4,000 words. The word limits are strictly enforced.

4. **Technical Standards** – TS's 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. TS's should be based upon evidence, but they do not require a full or pragmatic systematic review of the literature.

TS's may not make recommendations for patient care (other than standards for how to perform the test). They should be submitted within

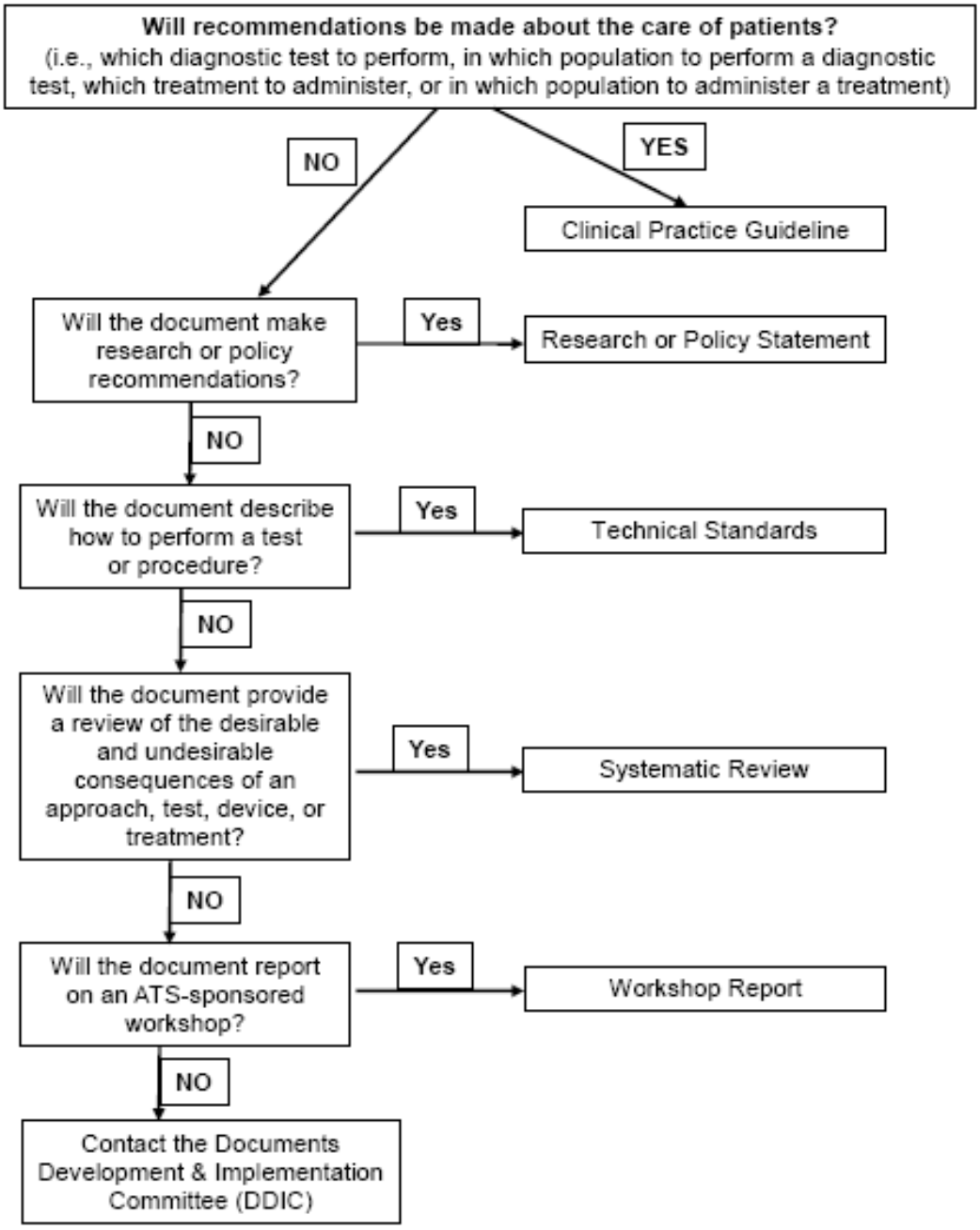
one year of the project start date. An Executive Summary is published in the AJRCCM (maximum of 4,000 words) and the full document is published online only (maximum of 10,000 words). Alternatively, the full document may be published in the AJRCCM if it is less than 4,000 words. The word limits are strictly enforced

5.Clinical practice guidelines – CPG's 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. CPG's are developed by a multidisciplinary committee, which must include individuals with prior experience in the development of guidelines, systematic reviews, and/or a GRADE-based project. As examples, see "An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management. Am J Respir Crit Care Med 2011; 183:788-824"

Guidelines are expected to be submitted within two years. The first year is dedicated to formulating clinical questions using the patient, intervention, comparator, outcome (**PICO**) format, searching the literature, selecting relevant studies, and then appraising and summarizing the evidence using the **GRADE** approach. The second year focuses on developing and grading recommendations using the **GRADE** approach, as well as writing the guidelines. Sufficient progress must be deomonstrated during the first year for consideration for a second year of funding.

An Executive Summary is published in the **AJRCCM (**maximum of 4,500 words) and the full document is published online only (maximum of 10,000 words). Alternatively, the full document may be published in the AJRCCM if it is less than 4,500 words. The word limits are strictly enforced. Guidelines should be routinely assessed for currency and updated at least every 3 years.

Deciding upon the type of document



Project Submission

Most official documents of the ATS are initiated from assemblies or committees. The process begins with completion of an application packet (http://www.thoracic.org/assemblies/project-application.php).

All assembly-initiated projects are reviewed for scientific, clinical, and educational merit by the Assembly Planning Committees. The Assembly Planning Committee reviews are usually provided to the applicant so that the application can be modified and resubmitted. Documents may also be reviewed by the Education Committee, the Documents Development and Implementation Committee (DDIC), or other segments of the ATS as deemed necessary.

Joint projects involving other societies may require prior review by the leadership of the respective organizations. All reviews are forwarded to the Program Review Subcommittee (PRS), which performs a programmatic and budgetary review and ranking. Recommendations from the PRS are forwarded to the Finance Committee for approval, as part of the entire ATS budget.

Final authority and responsibility for approval of the ATS budget rests with the ATS Board of Directors. The process begins with the application submission by the assembly or committee in July or August, and concludes with a Board of Directors decision made by December of the same year.

Qualifications to Apply

Any ATS member may apply for support to develop an Official ATS Document. Most applicants belong to an assembly or a committee, meaning pre-approval of their concept and draft application is made through their assembly or committee prior to submission.

The following personnel are typically involved in projects and their participation is documented in the submitted application:

1. Chair(s)

Ideally, the document group should be led by one or more chairs who have; 1) an in-depth understanding of the scope of the prospective document, 2) the skills to guide the document development group, and 3) an understanding of the methods used to develop a particular type of document. For CPG's, ATS' COI policy requires the panel chair (or at least one chair if there are co-chairs) be free of COI's relevant to the subject matter of the CPG, and to remain free of such COI's for at least one year after publication of the CPG.

Chairs should consider the process for, and who will be responsible for, updating the document. Documents require an ongoing commitment. Developers are expected to periodically review and update their document as new information is published that impacts clinical practice and/or the accuracy of the contents. It is preferable to perform frequent, targeted updating of a CPG's, than to infrequently revise the entire CPG.

2. Group Members

Members of the project should represent the perspectives of the healthcare professionals and organizations involved in the management of patients who will be affected by the document, as well as the patients themselves. Among the content experts, it is beneficial to have a diversity of perspectives represented, including clinicians and researchers from a variety of specialties. Consider the type and topic of the document, and include other stakeholders such as; patients, nurses, rehabilitation specialists, respiratory technicians, pharmacists and ethicists, as well as regulators and payers. The chair should ensure that all group members disclose potential COI's to the ATS and to other members of the committee at the onset of the project (see page 12, COI). Questions regarding COI of a member should be discussed with the ATS staff involved with the document or Shane McDermott (smcdermott@thoracic.org**),** Senior Director, Ethics & Conflict of Interest Management. Also refer to the ATS

Conflict of Interest Management site at http://www.thoracic.org/about/coi-management/index.php

3. Methodologist(s)

Depending upon the type of a document, it is often necessary for the chair(s) or other group member(s), to have methodological skills and experience in developing similar documents. The ATS will help identify methodological support for any project funded by the ATS, including (in some cases) assistance from the ATS methodologist. It is often helpful for the ATS methodologist to be involved early in the development process to provide guidance in methodology and to identify any additional resources that might be required for the team. CPG project teams should ideally include junior members with an interest in developing skills in SR's and CPG development.

Resources Available to Project Applicants

There are a number of resources to help you during the application, document development, and post-development stages of ATS-approved projects. These include a) a DDIC member available to guide you through the process of document development, b) the ATS methodologist to advise you regarding the formulation of clinical questions, development of a search strategy, and use of the **GRADE** approach to appraise the evidence, formulate recommendations, and grade recommendations, c) the Documents Editor to answer questions related to the application, document development, peer review, revision, and approval processes, as well as coordination with any co-sponsors, and d) the ATS staff to provide information about policies, procedures, budget, conflict of interest, meeting and conference call coordination, and publication. The DDIC is also accessible to chairs on matters related to document-related policy. The Documents Team's contact information:

Judy Corn (Jcorn@thoracic.org) & Jessica Wisk (Jwisk@thoracic.org), ATS Documents Staff

Miriam Rodriguez, ATS Assembly Programs and Program Review Subcommittee Staff (for questions about the application, application process, or application review), (mrodriguez@thoracic.org)

Kevin Wilson, MD, Documents Editor (Kwilson@thoracic.org)

Jan Brozek, MD, ATS Methodologist (BrozekJ@mcmaster.ca)

Michael Gould, MD – DDIC Chair (Michael.k.gould@kp.org)

Colin Cooke, MD, DDIC Vice-Chair (cookecr@med.umich.edu)

DDIC Liason, a DDIC member assigned by the chair of the DDIC to each project

Application, Approval and Notification

New applications are evaluated based upon standardized criteria including: *Topic* (relevant to mission of ATS i.e. patient care, public health, research, advocacy, etc.) *Scope* (sufficiently focused and achievable), *Methods* (appropriate methodology for the project and document type), *Panel* (project participants are appropriate in terms of COI, expertise, diversity; for CPG's, one or more individuals with methodological expertise will be needed), and *Budget* (reasonable to carry out the project). Renewal applications are evaluated based upon the demonstration of: *Progress* (project is moving forth), *Timeline* (project goals/objectives are being met in a timely way), *Focus* (project has not fallen prey to "mission creep" or strayed from its original focus unless such a change has been approved), and *Methods* (methods remain appropriate for the project and the document type).

Applications that are approved and funded will be notified by a letter from the ATS Staff and the PRS. This letter describes the terms and conditions of the project funding, and supplementary background materials prior to the start date of their projects. Project letters are generally transmitted in mid-January.

Step-By-Step Application Process

Application/Submission

1. Project chair accesses the Project Application at http://www.thoracic.org/assemblies/project-application.php

2. The form is completed as a project proposal, and submitted online by the project chair prior to the deadline (generally June or July). The proposal must address whether or not the project involves collaboration with other societies. In cases of collaboration, the application must identify the role of the ATS (i.e. as a primary or secondary applicant).

3. ATS staff reviews the project proposals for completeness and clarity. To facilitate timely processing of the proposal, applicants may be contacted by staff for additional information.

Project Proposal Approval and Notification Process

1. ATS staff distributes the project proposal to the Assembly Planning Committee from which it originated. Proposals are reviewed by the planning committees via conference call in August or September. Committee initiated proposals are excluded from this step. Following this review, the DDIC reviews the projects via conference call focusing on the methods. Other groups may also review the application as-needed.

2. The Assembly Planning Committee reviews are usually returned to the applicant, who is given an opportunity to modify the project proposal and resubmit.

3. Feedback from the preliminary review process is submitted, along with the revised project proposals, to the PRS for review, usually in September or October.

4. The PRS meets to evaluate and rank the project proposals. The final recommendations of the PRS are forwarded to the Finance Committee, usually in October or November.

5. The Finance Committee meets and forwards final recommendations for the entire budget, including assembly and committee proposals, to the ATS Board of Directors in November or December.

6. The ATS Board of Directors reviews and approves the budget with or without changes at their Board meeting in December.

7. Applicants are notified that their project proposal has been approved in concept (pending COI, refer to #8), approved or not approved. This decision is generally communicated in January.

8. The Chair of approved in-concept projects must submit an updated list of proposed ad hoc project committee members. Proposed project committee members must declare all potential project-specific COI's for review and management by project Chairs and the ATS COI Office. Proposed project committee members are ineligible to participate in project activities until their project-specific disclosure has been submitted and reviewed.

Miscellaneous Administrative Issues

Funding

Funding for projects is not to be considered an ATS grant, but rather funding that the ATS earmarks for one year. Funding is for routine expenses incurred during project development. Projects anticipated to extend beyond one year must be renewed annually. In the case of CPG's, a second year of funding is contingent on evidence of satisfactory progress during the first year.

Jointly Sponsored Projects

All jointly sponsored Assembly/Committee projects will have a signed agreement (i.e. "joint project agreement" or an MOU) that will describe and confirm key project elements, for example: content, scope, outcome of project, site of publication, resource allocation (financial, staff, corporate), location and timing of meetings, continuing medical education (CME)/Derivatives, use of pre-publication drafts, embargo policy, review and approval process, dissemination plans, patient education material, web-based material, translation of approved documents, delineation of staff & ad hoc committee responsibilities, and copyright/intellectual capital. Signed copies of joint project agreements (i.e., MOUs) are kept on file with the Executive Office of each organization.

Conflict of Interest (COI)

Declaration to the ATS of potential COI relevant to the project's subject matter is required of all individuals who are in a position to control the outcome of an official ATS project (in part or in full), including all ad hoc project committee members. First, project specific disclosure by the project applicant (Chair) is required as part of the application process. Next, upon project approval (in concept), disclosure is required of all proposed ad hoc project committee members. Project chairs review all potential conflicts disclosed by members of their respective project committee and then report to the ATS how these potential conflicts will be managed in accordance with ATS policy. (An example of acceptable management is an individual being recused from authoring or voting on a particular treatment recommendation due to relevant commercial interests). Instructions for COI review and management are issued to project chairs by ATS. Annual

updating of disclosures by members is required of projects that extend beyond the original calendar year. Updating (if necessary) will also be requested at the time the final document is submitted to the ATS office for peer review. In addition,

Other Considerations

Time Commitment

Applicants who are approved to conduct an ATS project do so as volunteers of the ATS. This requires at a minimum a 2 year commitment and may require a substantial amount of time and effort to bring the project to completion. Applicants may wish to confer with a member of the Documents Team or an assembly or committee colleague who has participated in an official document in the past to gain a true understanding of the endeavor prior to submitting a final application.

Table: Summary of Document Types

	Policy & Research Statements	Workshop Reports	Technical Standards	Systematic Reviews	Clinical Practice Guidelines
Purpose	State the ATS position on matters of research and/or public health policy	Summarize ATS-sponsored workshops and conferences	Describe how a test or procedure should beperformed.	Use a systematic approach to identify, appraise, and summarize evidence related to the safety and effectiveness of an approach, test, treatment, or device	Provide evidence-based recommendations for clinical practice
Development team **includes ≥1** methodologist (expertise in Systematic Reviews and GRADE)	Optional	Optional	Optional	Mandatory	Mandatory
Interaction with Documents Committee Liaison and/or Methodologist	Limited (Every 6 months)	Limited (Every 6 months)	Limited (Every 6 months)	Moderate (Every 3-6 months)	Extensive (Every 1-3 months)
Systematic Reviews (full or pragmatic)	Optional	Optional	Optional	Mandatory (use PRISMA to report)	Mandatory
Use of GRADE to assess quality of evidence and rate strength of treatment recommendations	Optional	Optional	Optional	Use GRADE to evaluate the quality of evidence; documents should not include recommendations for patient care.	Mandatory
Describes implementation and implications for quality improvement	Optional	Optional	Optional	Optional	Mandatory
Development of derivatives, e.g. flow sheets, checklists, order sets, slide presentations.	Optional	Optional	Optional	Optional	Mandatory
Length of document	3500 words	3500 words	4000 words	4000 words	4500 words
Expected duration until submission	1 year	1 year	1 year	1 year	2 years
Journal	AJRCCM	Ann Am Thorac Soc	AJRCCM	AJRCCM	AJRCCM
Updating document	As applicable for changes in practice	Not applicable	As applicable for changes in practice	As applicable for changes in practice	Routinely every 3 years and as needed for changes in practice

Figure 1: Clinical Practice Guideline Development Process

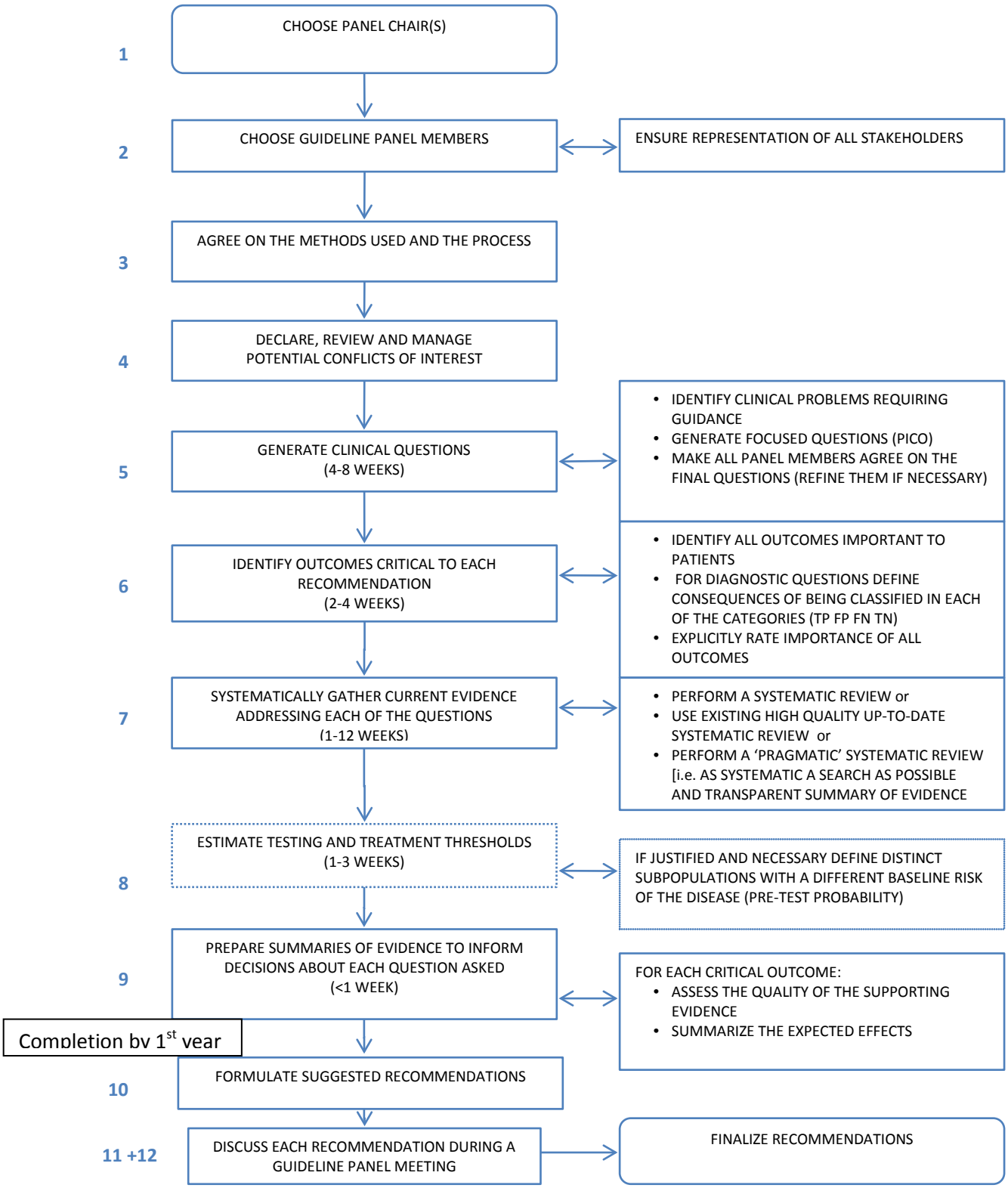
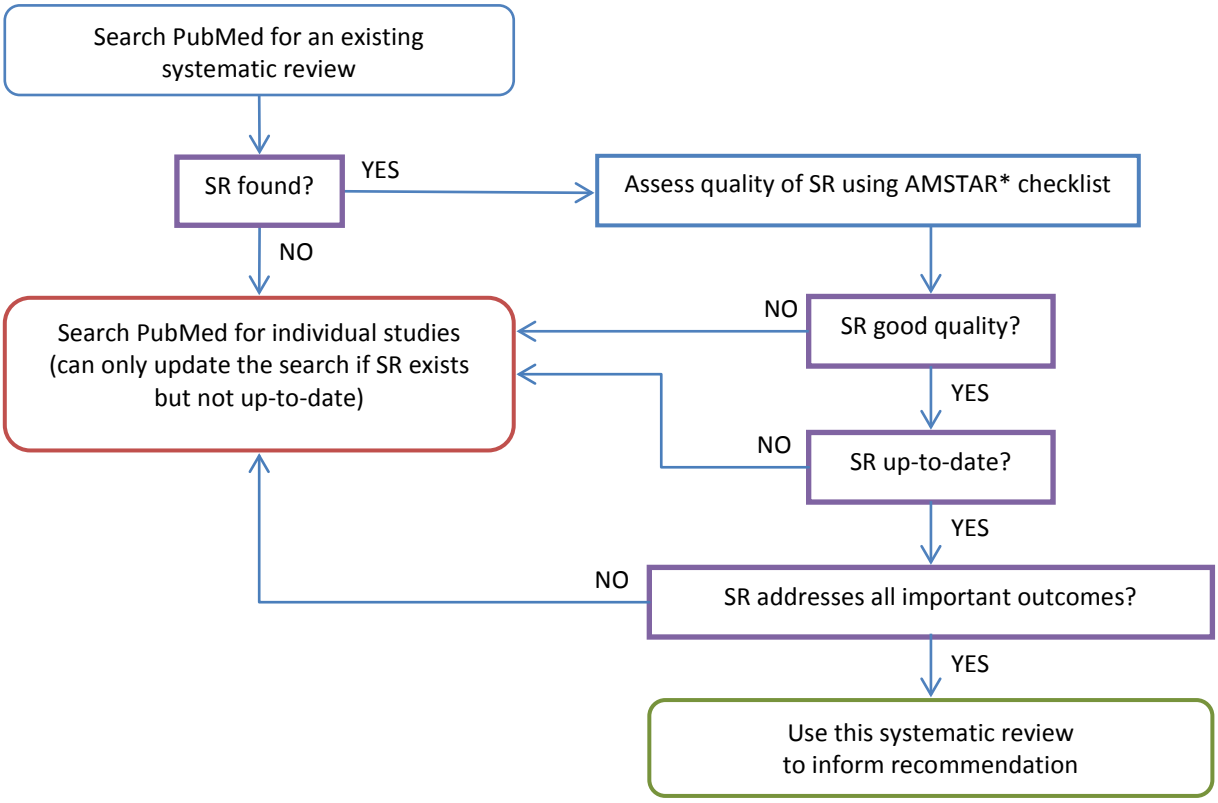


Figure 2: Searching for Existing Systematic Reviews (SR)



*Shea BJ et. al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Method 2007;7:10

PubMed filter: (review[pt] OR meta-analysis OR search*[tiab]) AND …
Cochrane Library http://www.thecochranelibrary.com/