

# Applying to Develop an Official ATS Document

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ATS Chief of Guidelines and Documents

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### Agenda

- Types of Official ATS Documents
- Preparing the proposal
- Post-submission
- Post-approval





Document Type	Purpose /Goal	Patient Care Recommendations
Clinical practice guidelines	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment) using GRADE approach	Yes
Clinical Statement	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment) without GRADE	Yes
Policy Statements	Present ATS positions on public policy	No
Research Statements	Present ATS positions on research	No
Technical Statements	Review the evidence and provide technical information about "how to" perform a test or procedure	No
Workshop Reports	Report on ATS-sponsored conferences or workshops	No



American Thoracic Society Clinical Practice Guidelines and Clinical Statements: Objectives and Methodologic Requirements					
Document		Clinical practice guideline	Clinical statement		
Document objective		Asks 1) who to treat, 2) which treatment to use, 3) who to perform diagnostic testing on, or 4) which diagnostic test to perform.	Creates 1) clinical pathways, 2) definitions, 3) diagnostic criteria, 4) classification schema, or addresses 5) emerging topics.		
Methodological requirements	PICO questions	Required	Optional*		
	Evidence synthesis	Systematic review	Pragmatic evidence synthesis		
	GRADE approach	Required	Optional*		
	Types of recommendations	Clinical	Clinical		

PICO = Patient, Intervention, Comparator, Outcome; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation.

\*PICO questions and the GRADE approach are appropriate if addressing who to treat, which treatment to use, who to perform diagnostic testing on, or which diagnostic test to perform in the context of a clinical pathway or emerging topic; methodological support may be required.



## Typ

- Diagnosis and treatment of IPF
- Mechanical ventilation in ARDS
- Liberation from mechanical ventilation

### Documents

• Treatment of	COPD exacerbations se /Goal	Patient Care Recommendations
Clinical practice guidelines	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment) using GRADE approach	Yes
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Document Type	Purpose /Goal		Patient Care Recommendations
<ul> <li>Evaluation and Management of Interstitial Lung Abnormalities</li> </ul>		ake recommendations for patient care (i.e., eatment) using GRADE approach	Yes
Clinical Statement	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment) without GRADE		Yes
Policy Statements	Present A	No	
Research Statements	Present ATS positions on research		No
Technical Statements	Review the evidence and provide technical information about "how to" perform a test or procedure		No
Workshop Reports	Report on ATS-sponsored conferences or workshops		No



Document Type	Purpose /Goal		Patient Care Recommendations
•Low dose CT screeni		ake recommendations for patient care (i.e., atment) using GRADE approach	Yes
<ul> <li>Tobacco control</li> <li>Conscientious objections in the ICU</li> <li>Pay for performance</li> </ul>		ake recommendations for patient care (i.e., I treatment) without GRADE	Yes
Policy Statements Present ATS positions on public policy		No	
Research Statements	Research Statements Present ATS positions on research		No
Technical Statements  Review the evidence and provide technical information about "how to" perform a test or procedure		No	
Workshop Reports Report on ATS-sponsored conferences or workshops		No	



	Document Type	Purpose /Goal		Patient Care Recommendations
Clin	nical practice guidelines  Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment) using GRADE approach		Yes	
Clin	<ul><li>Research needs in</li><li>Advancing implem</li></ul>		e recommendations for patient care (i.e., reatment) without GRADE	Yes
Poli	Comparative effectiveness research in pulmonary, critical care, and sleep medicine		ositions on public policy	No
Res	earch Statements	Present ATS positions on research		No
Teci	Technical Statements  Review the evidence and provide technical information about "how to" perform a test or procedure		No	
Wo	Workshop Reports Report on ATS-sponsored conferences or workshops		No	



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Six-minute walk test     Pediatric bronchoscopy     Measurement of DLCO		ositions on public policy	No
		positions on research	No
Technical Statements	Review the evidence and provide technical information about "how to" perform a test or procedure		No
Workshop Reports Report on ATS-sponsored conferences or workshops		No	



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Policy Statements	Present ATS positions on public policy		No
<ul> <li>Stem cells and cell-based therapies</li> <li>Addressing multiple conditions in guidelines</li> <li>Emergency preparedness in the ICU</li> <li>Climate change and respiratory health</li> </ul>		ATS positions on research	No
		le technical information about "how to" perform test or procedure	No
Workshop Reports	Report on ATS-sponsored conferences or workshops		No



# Preparing your proposal



### Application types

https://site.thoracic.org/membership/assemblies-sections/about-the-assemblies/renewal-project-applications

Assembly/Committee project applications must be submitted electronically on the ATS website. The deadline for submissions is **July 31, 2024** at 11pm Eastern Time. Late submissions will not be accepted.

To begin a NEW or RENEWAL application, please click <u>here</u>. To begin a Joint ATS/ ERS application, please click <u>here</u>.

- NEW Assembly/Committee Project Application Applications are New Projects that require funding and approval for the first time.
- NEW Joint ATS/ERS Project Application Applications are only for joint project between the two
  societies.
- RENEWAL Assembly/Committee Project Application Applications are for those projects that were approved by the Program Review Subcommittee and the ATS Board of Directors during the FY2024 Funding Cycle.

Visit the **Project Application Resource Center** for instructions on how to submit your project application, how to navigate the project application website and detailed instructions for completing the application.



### Section I - General information

- Project title
- Assembly
- Document type
- Can the project move forward as a virtual project?



### Section II - Relevance to the ATS

- Importance to the mission of the ATS
  - Why is the project a priority?
    - The number of proposals has increased each year; very competitive.
    - Most proposals describe why their topics are important in general.
    - Make an argument about why it is important for the ATS right now.
- Other ATS or non-ATS related projects
- Relevance to health equity



### Section III - Methodology

- How will the document be created?
  - Work plan in detail
  - Distribution of tasks
  - Rationale ...
    - Can the project be completed successfully on-time?
- Proposed participants.
  - Name
  - Role
  - Expertise
  - Rationale...
    - Do the skills and expertise match the goals of the project?
    - Will there be a diversity of perspectives?



### Clinical practice guideline methodology

- Guidelines (and some clinical statements)
  - PICO questions
  - Systematic review(literature search, study selection, meta-analysis, evidence summary, evidence appraisal, evidence profiles).
  - GRADE approach
    - Formulating recommendations.
    - Grading recommendations.
    - Writing the manuscript.



### Clinical practice guideline methodology

- PICO questions
- Arguably the most important aspect of the methodology.
- What are they:
  - P= Population
  - I= Intervention
  - C= Comparator
  - O= Outcomes

Maximum of 6 questions.

Should behavioral weight loss programs (i.e., diet and exercise) be used in overweight patients with OSA?

P= Patients with an apnea-hypopnea index >5 events per hour and a body mass index >25 kg/m<sup>2</sup>

I= Participation in a program whose goal is achieving weight loss through diet and exercise

C= No participation in a program whose goal is weight loss

O= Apnea-hypopnea index, oxygen desaturation index, respiratory disturbance index, body mass index, excessive daytime sleepiness, cognitive performance, mood, quality of life, and incidence of motor vehicle crashes, hypertension, myocardial infarction, cardiac arrhythmias, sudden cardiac death, stroke, and diabetes.



### Clinical practice guideline methodology

- All guidelines must have an on-committee guideline methodologist.
- Individual with experience doing systematic reviews.
- Individual with experience using GRADE.
- If you don't know a guideline methodologist, you can utilize the ATS Guideline Methodology Training Program.



#### The American Thoracic Society Guideline Methodology Training Program

Kevin C. Wilson<sup>1</sup>, Marya Ghazipura<sup>2,3</sup>, Tanzib Hossain<sup>4</sup>, David J. Feller-Kopman<sup>5</sup>, Derrick Herman<sup>6</sup>, Narayan P. Iyer<sup>7</sup>, Ann L. Jennerich<sup>8</sup>, Madalina Macrea<sup>9,10</sup>, Richard Mularski<sup>11</sup>, and Charlie Strange<sup>12</sup>

<sup>1</sup>Department of Medicine, Boston University School of Medicine, Boston, Massachusetts; <sup>2</sup>ZS Associates, Global Health Economics and Outcomes Research, New York, New York; <sup>3</sup>Divisions of Epidemiology and Biostatistics, Department of Population Health, New York University Langone Health, New York, New York; <sup>4</sup>Division of Pulmonary, Critical Care, and Sleep Medicine, Department of Medicine, New York University Grossman School of Medicine, New York University Langone Health, New York, New York; <sup>5</sup>Department of Medicine, Dartmouth-Hitchcock Medical Center and Geisel School of Medicine, Dartmouth College, Lebanon, New Hampshire; <sup>6</sup>Department of Medicine, The Ohio State University, Columbus, Ohio; <sup>7</sup>Fetal and Neonatal Institute, Division of Neonatology, Children's Hospital Los Angeles, Department of Pediatrics, Keck School of Medicine, University of Southern California, Los Angeles, California; <sup>8</sup>Division of Pulmonary, Critical Care, and Sleep Medicine, Department of Medicine, University of Washington, Seattle, Washington; <sup>9</sup>Division of Pulmonary and Sleep Medicine, Salem Veterans Affairs Hospital, Salem, Virginia; <sup>10</sup>Department of Medicine, University of Virginia, Charlottesville, Virginia; <sup>11</sup>Center for Health Research, Kaiser Permanente Northwest, Portland, Oregon; and <sup>12</sup>Department of Medicine, Medical University of South Carolina, Charleston, South Carolina

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### Methodology

- Statements
  - Teleconferences
  - Working groups
  - Literature search and evaluation
  - Recommendations
  - Manuscript preparation
- Workshop Reports
  - Pre-workshop confirmation of participants and agenda.
  - Workshop agenda (times, speakers and topics, breaks, discussions).
  - Post-workshop manuscript preparation.



### Section IV - Timeline

- Expectations, which are strictly enforced:
  - Guidelines and clinical statements
    - Submission for peer review within two years.
      - First year questions, outcomes, begin evidence synthesis.
      - Second year complete evidence synthesis, evidence profiles, evidence to recommendations, manuscript preparation .
  - All other document types
    - Submission for peer review within one year.



### Other topics

#### In-person meetings

• Do not build your proposal around an in-person meeting. We are currently only able to host four meetings at the ATS Conference, which is typically allocated to second-year guidelines.

#### Publication site

• In the past, workshop reports were published in the *Ann Am Thorac Soc* and all other document types were published in the *Am J Respir Crit Care Med*. Beginning with new projects in 2026, the journal editors will determine the publication site.



### Other topics

#### Co-sponsorship

All applications (except ATS/ERS) are approved as ATS-only projects.
There is a formal process to request co-sponsorship, but only after a
project is approved. Applicants should not approach other
organizations.



### What makes a good proposal?

- Important and timely topic
- Well-constructed proposal (sufficient detail)
- Achievable scope
- Diverse participants





Review by Assembly Planning Committees and the Document Development and Implementation Committee (DDIC)

August 1-19



### Proposal revisions

- Consider each comment carefully.
- Revise proposal as deemed appropriate.
- Respond to comments in a point-by-point fashion.
- Attach point-by-point responses to the resubmission.
- Responsiveness to comments is considered when the proposal is reviewed and scored.
- Conflicting comments reach out for clarification.



Review by Assembly Planning Committees and the Document Development and Implementation Committee (DDIC)

August 1-19

Applicants revise proposals, respond to comments, and re-submit proposal

August 20-29



Review by Assembly Planning Committees and the Document Development and Implementation Committee (DDIC)

August 1-19

Applicants revise proposals, respond to comments, and re-submit proposal

August 20-29

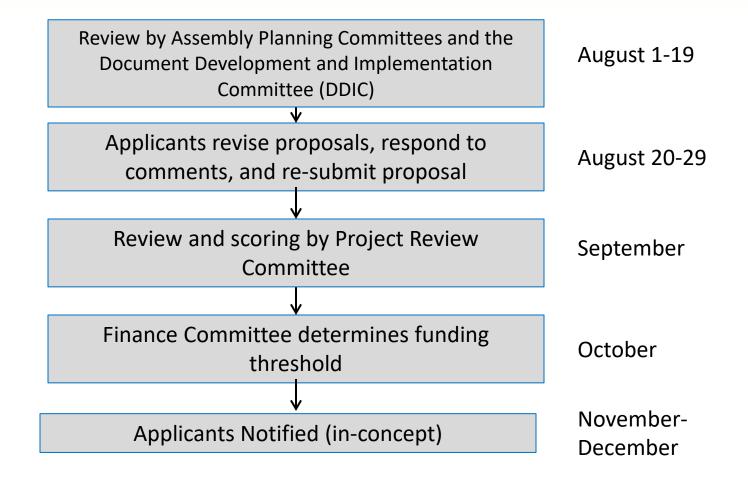
Review and scoring by Project Review
Committee

September



Review by Assembly Planning Committees and the August 1-19 **Document Development and Implementation** Committee (DDIC) Applicants revise proposals, respond to August 20-29 comments, and re-submit proposal Review and scoring by Project Review September Committee Finance Committee determines funding October threshold











# Post-approval



### Post-approval

- Kick-off call with ATS Staff and DDIC leaders
  - Administrative
  - Deadlines
    - Committee composition
    - COI disclosures
    - Requesting collaboration with other societies
      - Contract negotiations
      - ATS may not publish the document
      - Co-sponsoring organizations may add their own co-chairs
      - Co-sponsoring organizations may add their own committee members
      - Peer review will take longer (more reviewers, more comments)
      - Approval will take longer



# AMERICAN THORACIC SOCIETY DOCUMENTS

### An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis

An Update of the 2011 Clinical Practice Guideline

Ganesh Raghu, Bram Rochwerg, Yuan Zhang, Carlos A. Cuello Garcia, Arata Azuma, Juergen Behr, Jan L. Brozek, Harold R. Collard, William Cunningham\*, Sakae Homma, Takeshi Johkoh, Fernando J. Martinez, Jeffrey Myers, Shandra L. Protzko, Luca Richeldi, David Rind, Moisés Selman, Arthur Theodore, Athol U. Wells, Henk Hoogsteden, and Holger J. Schünemann; on behalf of the ATS, ERS, JRS, and ALAT

This guideline is dedicated to the memory of Mr. William Cunningham (June 7, 1935-October 23, 2014)

THIS OFFICIAL CLINICAL PRACTICE GUIDELINE OF THE AMERICAN THORACIC SOCIETY (ATS) WAS APPROVED BY THE ATS, MAY 2015, THE EUROPEAN RESPIRATORY SOCIETY (ERS), APRIL 2015, THE JAPANESE RESPIRATORY SOCIETY (JRS), APRIL 2015, AND THE LATIN AMERICAN THORACIC ASSOCIATION (ALAT), APRIL 2015

Background: This document updates the American Thoracic Society/European Respiratory Society/ Japanese Respiratory Society/Latin American Thoracic Association guideline on idiopathic pulmonary fibrosis treatment.

Methods: Systematic reviews and, when appropriate, meta-analyses

applied, and recommendations were formulated, written, and graded exclusively by the nonconflicted panelists.

**Results:** After considering the confidence in effect estimates, the importance of outcomes studied, desirable and undesirable consequences of treatment, cost, feasibility, acceptability of the intervention, and implications to health equity, recommendations



### Endorsement

- Developed like an ATS-only document.
- As it approaches completion, it is sent to other societies to be considered for endorsement.
- Endorsing societies are listed on the document.
- Not all societies endorse.
- Publication always in an ATS journal.
- Committee composition, peer review, and approval are unaffected.



# AMERICAN THORACIC SOCIETY DOCUMENTS





# An Official American Thoracic Society Clinical Practice Guideline: Diagnosis, Risk Stratification, and Management of Pulmonary Hypertension of Sickle Cell Disease

Elizabeth S. Klings\*, Roberto F. Machado\*, Robyn J. Barst<sup>†</sup>, Claudia R. Morris, Kamal K. Mubarak, Victor R. Gordeuk, Gregory J. Kato, Kenneth I. Ataga, J. Simon Gibbs, Oswaldo Castro, Erika B. Rosenzweig, Namita Sood, Lewis Hsu, Kevin C. Wilson, Marilyn J. Telen, Laura M. DeCastro, Lakshmanan Krishnamurti, Martin H. Steinberg, David B. Badesch, and Mark T. Gladwin; on behalf of the ATS *Ad Hoc* Committee on Pulmonary Hypertension of Sickle Cell Disease

THIS OFFICIAL CLINICAL PRACTICE GUIDELINE OF THE AMERICAN THORACIC SOCIETY WAS APPROVED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 2013. THESE GUIDELINES WERE ALSO ENDORSED BY THE AMERICAN COLLEGE OF CHEST PHYSICIANS, OCTOBER 2013, AND BY THE PULMONARY HYPERTENSION ASSOCIATION, NOVEMBER 2013

**Background:** In adults with sickle cell disease (SCD), an increased tricuspid regurgitant velocity (TRV) measured by Doppler echocardiography, an increased serum N-terminal pro-brain natriuretic peptide (NT-pro-BNP) level, and pulmonary hypertension (PH) diagnosed by right heart catheterization (RHC) are independent risk factors for mortality.

**Methods:** A multidisciplinary committee was formed by clinicianinvestigators experienced in the management of patients with PH first-line therapy and a weak recommendation for chronic transfusions as an alternative therapy. For all patients with SCD with elevated TRV alone or elevated NT-pro-BNP alone, and for patients with SCD with RHC-confirmed PH with elevated pulmonary artery wedge pressure and low pulmonary vascular resistance, we make a strong recommendation against PAH-specific therapy. However, for select patients with SCD with RHC-confirmed PH who have elevated pulmonary vascular resistance and normal pulmonary capillary wedge pressure, we make a weak recommendation for either prostacyclin.



# Post-approval

• Once the COI vetting is completed, the project may begin.



### Questions?

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