Applying to Develop an Official ATS Document

Kevin C. Wilson, MD

ATS Chief of Documents and Medical Affairs

ATS Documents Editor

Associate Professor, Boston University



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)	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

Diagnosis and treatment of IPF

- Mechanical ventilation in ARDS
- Liberation from mechanical ventilation
- Treatment of COPD exacerbations

ATS Documents

Patient Care

• rrea	Treatment of COPD exacerbations			Recommendations
Clinical pri	Clinical practice recommendations for patient care (i.e., diagnosis and treatment)		Yes	
Policy Statement	s	Present ATS positions on public policy		No
Research Statement	s	Present ATS positions on research		No
Technical Statement	s	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

oal

 Low dose CT screening for lung cancer Tobacco control Conscientious objections in the ICU Pay for performance 		al	Patient Care Recommendations
		and make tient care (i.e., atment)	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

	Document Type	Purpose /Goal		Patient Care Recommendations
	Dariary the aridance and make			
	 Research needs in pulmonary fibrosis Advancing implementation science Comparative effectiveness research in pulmonary, critical care, and sleep medicine 			Yes
				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

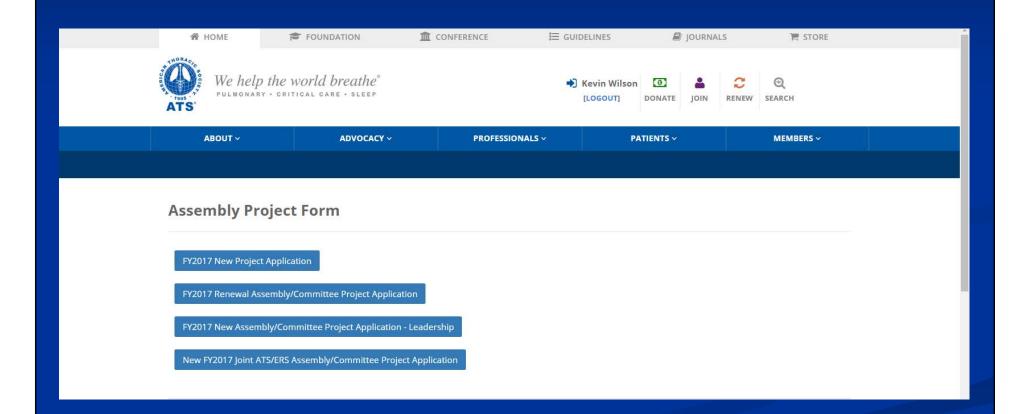
Document Type	Purpose /Goal		Patient Care Recommendations
Clinical practice guidelines	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment)		Yes
Six minute walk testPediatric bronchoscopyMeasurement of DLCO		ositions on public policy	No
		S positions on research	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
Clinical practice guidelines	Review the evidence and make recommendations for patient care (i.e., diagnosis and treatment)		Yes
Policy Statements	Present ATS positions on public policy		No
• Stem cells and cell-based therapies esearch			No
• Emergency preparedness in the ICO		de technical form a test or	No
Workshop Report on ATS-sponsored conferences or workshops			No

- The type of document affects the publication site.
- For ATS-only documents:
 - AJRCCM
 - Clinical practice guidelines
 - Policy Statements
 - Research Statements
 - Technical Statements
 - Ann ATS
 - Workshop Reports
- For multi-society documents:
 - Discussed later

Preparing your proposal

Application types



Secondary Assemblies

SECTION I - GENERAL PROJECT INFORMATION * 1. ATS PROJECT TITLE: * 2. PROJECT PRIMARY ASSEMBLY: Allergy Immunology & Inflammation 3. PROJECT SECONDARY ASSEBMLY: (choose up to 2) Allergy Immunology & Inflammation Behavioral Science and Health Services Research Critical Care Clinical Problems Environmental, Occupational and Population Health Microbiology, Tuberculosis & Pulmonary Infections Nursing Pulmonary Circulation Pediatrics ☐ Pulmonary Rehabilitation Respiratory Cell & Molecular Biology Respiratory Structure & Function ☐ Sleep Respiratory & Neurobiology ☐ Thoracic Oncology 4. ATS SECTION: (IF ANY) Section on Genetics & Genomics Section on Terrorism and Inhalation Disasters Section on Medical Education

- Cross-assembly collaboration is encouraged.
- Would not simply list every assembly that may be even remotely related, however.
- Each will provide comments.
- Each will rank the proposal.

Questions to be addressed

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/m²

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.

- Guidelines only.
- Must be in the PICO format.
 - P= Population
 - I= Intervention
 - C= Comparator
 - O= Outcomes
- Fewer than 10.
- Preferably 6-8.

Why project a priority?

- The number of proposals has increased each year for the past five years; very competitive.
- Most proposals describe why their topics are important in general.
- It is also helpful to make an argument about why it is important for the ATS right now.

Methodology

Guidelines

- PICO questions and outcomes
- Evidence synthesis (literature search, study selection, meta-analysis, evidence summary, evidence appraisal, evidence profiles).
- Formulating recommendations.
- Grading recommendations.
- Writing the manuscript.

Methodology

- Statements
 - Teleconferences
 - Face-to-face meeting
 - Working groups
 - Literature search and evaluation
 - Recommendations
 - Manuscript preparation

Methodology

- Workshop Reports
 - Pre-workshop confirmation of participants and agenda.
 - Workshop agenda (times, speakers and topics, breaks, discussions, etc.).
 - Post-workshop manuscript preparation.

Methodological Support



- Guidelines only.
- Individual with experience doing systematic reviews.
- Individual with experience using GRADE.
- Trainees from the guideline methodology training program, two or more per guideline.

Potential Participants

- Diversity of perspectives
 - Multidisciplinary (physicians, nurses, respiratory therapists, physical therapists, pharmacists).
 - Geographic
 - Gender
 - Seniority
- Patient representative

Timeline

- Expectations (for projects beginning 2018):
 - Guidelines
 - First year questions, outcomes, evidence synthesis, and evidence profiles (December 31, 2018)
 - Second year evidence to recommendations, manuscript preparation (December 31, 2019)
 - Non-guidelines
 - Submission for peer review within one year (e.g., December 31, 2018)

Budget

- Flights- only for those who would not otherwise attend the ATS Conference.
- Face-to-Face meeting options-
 - Hotel and per diem (full-day or half-day meeting)
 - Breakfast meeting
 - Lunch meeting
- Teleconferences
- Medical librarian (guidelines only)
- Publication costs

Budget

- Non-guidelines
 - Typical year #1 (new application)
 - Face-to-face meeting
 - Teleconferences
 - Typical year #2 (renewal application)
 - Teleconferences
 - Publication costs

Budget

Guidelines

- Typical year #1 (new application)
 - Face-to-face meeting (lunch or breakfast)
 - Teleconferences
 - Medical librarian
- Typical year #2 (renewal application)
 - Face-to-face meeting (full-day)
 - Teleconferences
- Typical year #3 (renewal application)
 - Teleconferences
 - Publication costs

What makes a good proposal?

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

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

August 1-19

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

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 Program Review Subcommittee

September

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 Program Review Subcommittee

September

Finance Committee determines funding threshold

October

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 Program Review Subcommittee

September

Finance Committee determines funding threshold

October

Applicants Notified (in-concept)

November-December

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 Program Review Subcommittee

September

Finance Committee determines funding threshold

October

Applicants Notified (in-concept)

November-December

Budget and, therefore, approvals confirmed by the Board of Directors

December

Post-approval

Post-approval

- Kick-off call with ATS Staff and DDIC leaders
 - Administrative
 - Budget
 - ATS Conference planning
 - Collaboration with other societies

Collaboration with other societies

- Other societies should NOT be approached by the applicants prior to project approval.
- All negotiations are contractual and MUST be done by the Executive Director and Chief of Documents and Medical Affairs.
- Two models:
 - Co-sponsorship
 - Endorsement

Co-sponsorship

- The co-sponsoring societies
 - are listed in the title
 - share cost of the project
 - perform their own peer review
 - approve the manuscript
- Usually, a co-sponsoring society wants to appoint a co-chair and a portion of the participants.
- Occasionally, a co-sponsoring society is willing to simply send a representative.

Co-sponsorship

- Publication is only in one society's journal.
- Publication site is determined by the societies, not the authors.
- The decision is usually related to who published the last co-sponsored document.

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.

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[†], 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

- Following the kick-off call.
 - Participant confirmation.
 - Conflict of interest disclosure and vetting.
 - · Organizational teleconferences common.

Questions?

kwilson@thoracic.org