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PULMONARY • CRITICAL CARE • SLEEP

FY2015 New Assembly/Committee Project Application

SECTION I - GENERAL PROJECT INFORMATION

1. PROJECT TITLE:

Role of Weight Management in the Treatment of Adult Obstructive Sleep Apnea

2. PROJECT PRIMARY ASSEMBLY:

Sleep Respiratory & Neurobiology

3. PROJECT SECONDARY ASSEMBLY: (IF ANY) --empty--

3a. ATS SECTION: (IF ANY) --empty--

4. ATS COMMITTEE SUBMITTING PROJECT APPLICATION: *N/A*

5. What official ATS document will be developed as part of this project (choose 1)?

Clinical Practice Guidelines

SECTION II - PROJECT DESCRIPTION

6. PROJECT DESCRIPTION

A. Describe the problem and define the goals and objectives of the project.

The majority of adults with obstructive sleep apnea (OSA) are overweight or obese. As the prevalence and magnitude of obesity has increased, the prevalence and severity of OSA has also increased. While upper airway management remains the mainstay of therapy for OSA, the increased prevalence of obesity-related OSA dictates that practitioners caring for OSA patients need to consider the importance of weight management as a therapeutic modality integral to modern Sleep Medicine practice. There are accumulating data illustrating the benefits of weight loss on the OSA symptom complex and on OSA-related cardio-metabolic co-morbidities.

These clinical practice guidelines will rigorously and systematically appraise the evidence and then use the evidence to form recommendations for clinical practice. Our goal is to improve the quality of care delivered to obese OSA patients by providing evidence-based recommendations for interventions that have been proven to improve clinical outcomes. The target audience is clinicians who care for adults with OSA.

B. What are the specific questions to be addressed? (for Clinical Practice Guidelines Only)

Applicants should list all questions relevant to daily clinical practice that are to be covered by the guideline.

Questions should be as specific as possible about the patients/populations to be included or excluded, types of diagnostic or therapeutic interventions to be considered or left out. Questions should be structured in PICO format, specifying the target patient population (P), the intervention or exposure (I), comparators (C), and outcomes of interest (O). While it is expected that the initial set of questions will undergo revision and refinement, applicants are encouraged to be as specific as possible about each one of the PICO elements.

Treatment

1. Should behavioral weight loss programs (i.e., diet and exercise) versus no weight loss programs be used in overweight patients with OSA?

1. P = Patients with an apnea-hypopnea index (AHI) >5 and a body mass index (BMI) >25 kg/m² - < 30kg/m².
2. I = Participation in a program whose goal is achieving weight loss through diet and exercise.
3. C = No participation in a program whose goal is weight loss.
4. O = Apnea/hypopnea index (AHI), oxygen desaturation index (ODI), respiratory disturbance index (RDI), BMI, 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.

1. Should behavioral weight loss programs (i.e., diet and exercise) versus no weight loss programs be used in obese patients with OSA?

1. P = Patients with an AHI >5 and a BMI >30 kg/m².
2. I = Participation in a program whose goal is achieving weight loss through diet and exercise.
3. C = No participation in a program whose goal is weight loss.

4. O = AHI, ODI, RDI, BMI, 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.

1. Should weight loss medication versus no medication be used in overweight patients with OSA?

1. P = Patients with an AHI >5 and a BMI >25 kg/m² -

2. I = Weight loss medication.

3. C = No medication or placebo.

4. O = AHI, ODI, RDI, BMI, 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.

1. Should weight loss medication versus no medication be used in obese patients with OSA?

1. P = Patients with an AHI >5 and a BMI >30 kg/m².

2. I = Weight loss medication.

3. C = No medication or placebo.

4. O = AHI, ODI, RDI, BMI, 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.

1. Should bariatric surgery versus no surgery be used in overweight patients with OSA?

1. P = Patients with an AHI >5 and a BMI >25 kg/m² - <30kg/m².
2. I = Bariatric surgery.
3. C = No surgery.
4. O = AHI, ODI, RDI, BMI, 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.

1. Should bariatric surgery versus no surgery be used in obese patients with OSA?

1. P = Patients with an AHI >5 and a BMI >30 kg/m².
2. I = Bariatric surgery.
3. C = No surgery.
4. O = AHI, ODI, RDI, BMI, 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.

2. Should weight management be primary or an ancillary treatment combined with pressure support, mandibular advancement or upper airway surgery?

a. P = Patients with AHI > 5 and a BMI > 25 kg/m².

b. I = Diet and exercise, bariatric surgery, weight loss medications.

i. C = No ancillary weight management

d. O = AHI, ODI, RDI, BMI, 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.

For questions in which the intervention is more effective than the control, we will evaluate each possible intervention. As an example, for question #6, if we find that bariatric surgery is more effective

that no surgery, we will then look at the magnitude of the effect of each possible intervention (i.e., Roux-en-Y, gastric bypass, gastric banding) to determine whether or not a particular intervention is superior.

Prevention:

1. Should weight loss medication versus no medication be used in obese patients to prevent OSA?

1. P = Patients with an BMI >30 kg/m².
2. I = Weight loss medication.
3. C = No medication.
4. O = Incident OSA.

1. Should bariatric surgery versus no surgery be used in obese patients to prevent OSA?

1. P = Patients with a BMI >30 kg/m².
2. I = Bariatric surgery.
3. C = No surgery.
4. O = Incident OSA.

C. Are you aware of any non-ATS activities in this area

Yes

» If Yes please describe:

Recent Past Activity: The American College of Physicians (ACP) published a CPG on the management of OSA in 2013 (Qaseem A et al. Ann Int Med 2013;159:471-83). The first recommendation was that overweight and obese OSA patients “should be encouraged to lose weight.” The literature review on the effect of weight loss on OSA severity was limited to a discussion of three calorie restriction diet studies. Thus, the literature on the impact of exercise, bariatric surgery and combined weight management + CPAP upon OSA severity was not considered. There was no review of literature on the effect of weight loss in OSA patients on cardiometabolic co-morbidities. The literature

was graded as “low evidence” (without details presented), but the weight loss recommendation was “strong”, without an explanation of the rationale for this conclusion. Most importantly, practitioners were not provided specific guidelines to assist their patients with the difficult task of weight management. Although the ACP's recognition that weight management is an aspect of care for overweight or obese OSA patients is to be applauded, much more detail in the literature review and practice guidelines is indicated. It is not new news that overweight and obese OSA patients would benefit by weight loss, but practitioners need guidance on how to accomplish this important goal.

D. Describe why this project should be a priority for the ATS?

The simultaneous increase in the incidences of both world-wide obesity (Ng M et al. *Lancet* 2014; [dx.doi.org/10.1016/50140-6736\(14\)60460-8](https://doi.org/10.1016/50140-6736(14)60460-8)) and OSA (Peppard PE et al. *Am J Epidemiol* 2013;177:1006-14) does not confirm a cause-and-effect relationship. However, demonstration that weight gain is associated with worsening of OSA severity (as indicated by an increase in the AHI) and that weight loss is associated with a decrease in the AHI (Peppard PE et al. *JAMA* 2000;284:3015-21, Young T et al. *J Appl Physiol* 2005;99:1592-9) strengthens the association and suggests that a cause-and-effect relationship may exist.

Studies have demonstrated that weight loss not only reduces the severity of OSA as measured by the AHI, but also improves OSA-related clinical outcomes:

- Behavioral weight loss (diet and exercise): Randomized trials evaluating very low calorie diets for a few weeks followed by close supervision in OSA patients have demonstrated a significant decrease in the AHI as well as improvement in both symptoms and co-morbidities in the very low calorie diet group (Kajaste S et al. *Sleep Med* 2004;5:125-31; Foster GD et al. *Arch Int Med* 2009;169:1619-26; Johansson K et al. *BMJ* 2009;339:b4609; Tuomilehto HPI et al. *Am J Respir Crit Care Med* 2009;179:1724-37; with meta-analysis: Anandam A et al *Sleep Breath* 2012 doi.org/10.1007/s11325-012-0677-3). In many cases, the improved outcomes occurred even though the AHI after weight loss remained within the diagnostic range for OSA (> 5 events/hr). In a long-term study of diabetic OSA patients, some weight was regained after four years but, despite this, the improvement in AHI that was seen at the one year persisted for an additional three years (Kuna St et al. *Sleep* 2013;36:641-9).
- Pharmacotherapy of obesity in OSA: Two medications are approved for short-term use in obesity – lorcaserin and phentermine/topiramate. Orlistat is approved for long-term use. Limited data are available on use of these agents in OSA. In a RCT, Winslow et al found that phentermine/topiramate treated obese OSA patients vs. placebo-treated patients had a decrease in AHI from 44 to 14 events/hr after 28 wks of treatment compared to a decrease from 45 to 27 events/hr in the placebo group (N = 45) (Winslow DH et al *Sleep* 2012;35:1529-39). BMI decreased in actively treated patients from 36 to 25 kg/m² while placebo-treated patients lost half as much weight. Importantly, there was a strong correlation between the percentage of weight lost and the decrease in AHI. There is concern that weight loss drugs may aggravate hypertension, but in this study systolic and diastolic BP actually fell with treatment, the systolic BP significantly so.

Also, increased sleep disturbance was not reported; in fact, there was some subjective improvement in sleep quality found in actively treated patients. In a prospective observational study Orlistat was added to a weight loss program in 63 OSA patients after an initial weight loss of 3.4 kg with diet alone (Svendsen M et al. *Nutrition J* 2011;10:21-7). After one year of treatment, an additional 3.5kg of weight loss occurred. There are no data in this study regarding changes in OSA severity with treatment. Although pharmacological weight loss treatment of OSA data appears limited, this could be a successful therapy for some overweight/obese OSA patients. Therefore, the topic deserves an evidence-based review.

- Surgical weight loss: Surgically-induced weight loss leads to a greater weight loss than behavioral weight loss programs in OSA patients (Dixon JB et al. *JAMA* 2012;308:1142-9). It also reduces the AHI (Dixon et al. *Intern J Obesity* 2005;29:1048-54) and is associated with improvement of OSA co-morbidities, especially Type 2 diabetes mellitus following the Roux-en-Y procedure (Mingrone G et al. *N Engl J Med* 2012;366:1577-85; Arterburn DE et al. *Obes Surg* doi.org/10.1007/s11695-080-08024; Sjostrum L et al. *N Engl J Med* 2007;357:741-52), the procedure considered most effective for weight loss (Hall JC et al. *Ann Surg* 1990;211:419-27). Of note, the AHI may not normalize following surgical weight loss and, depending on the duration of diabetes prior to surgery, there may some recurrence of the glucose intolerance if the diabetes had been long-standing (Arterburn DE et al. *Obes Surg* doi.org/10.1007/s1165-012-0802-1).
- Weight loss combined with CPAP: Recent RCTs have demonstrated that weight loss combined with continuous positive airway pressure (CPAP) therapy for OSA leads to more improvement of the OSA and cardiac risk factors than either treatment alone (Chirinos J et al. *N Engl J Med* 2014;370:2265-75). These findings are consistent with a meta-analysis that compared exercise plus CPAP treatment with exercise alone and found that the former improved OSA severity, symptoms, quality of life, and co-morbidities (Quan SF et al. *Sleep Breath* 2007;11:149-5; Kline CE et al. *Sleep* 2011;34:1631-40; Papandreou C et al. *Eur Respir J* 2012;39:1398-1404; Sengul YS et al. *Sleep Breath* 2011;15:49-56; Ackel-D'Elia C et al. *Sleep Breath* 2012;16:723-35; Iftikhar IH et al. *Lung* 2014;192:175-84).

Despite evidence suggesting that weight loss can reduce the OSA and the severity of its co-morbidities, weight management still has not entered the mainstream of OSA therapy, as suggested by its cursory reference in existing clinical practice guidelines (Epstein LJ et al. *J Clin Sleep Med* 2009;5:263-76, Fleetham J et al. *Can Respir J* 2011;18:25-47). Our guidelines will summarize and appraise existing evidence that addresses the effects of various weight loss interventions on OSA-related clinical outcomes and will also provide evidence-based recommendations that guide the practitioner regarding the use of various weight management approaches.

E. Describe the methodology that will be used to carry out the project objectives: For clinical practice guidelines (CPGs) include the following: Search Strategy, Review of Evidence, Grading of Evidence, Formulation of

Recommendations or other key activities leading towards completion of this project. See page 6 of the Guidelines for ATS Documents (GATS) on the ATS website at: <http://www.thoracic.org/statements/document-development/index.php> also see methodology for development of CPG's: <http://www.thoracic.org/statements/document-development/resources/methodologyforcpgdevelopment-6-15-12.pdf>

The project will begin by collecting conflict of interest disclosures from the invited committee members listed below. Our goal is to constitute a committee for which at least one co-chair and >50% of committee members are completely free from conflicts related to the topic of the guidelines, and that the remaining members have acceptable conflicts that can be managed as defined by the ATS. The co-chairs will work with ATS staff to achieve these goals.

Once the committee composition has been finalized, the methodologist will work with the co-chairs to construct two surveys. The first survey will ask the committee for ideas of important clinical questions that should be answered by the guideline. The methodologist will take suggested questions, put them into a PICO format, and then send a follow-up survey that lists all of the PICO questions (those listed above in part B above plus those identified by the survey of the committee) and asks the committee to prioritize the questions on a scale of 1-9. The questions will be ranked according to the committee's prioritization and the top six questions will be selected for inclusion in the guidelines. The second survey will ask the committee to list any clinical outcomes that may be important to each PICO question. The methodologist will organize the suggested outcomes and send a follow-up survey asking the committee to prioritize the outcomes on a scale of 1-9. The outcomes rated 7-9 will be considered critical outcomes, those rated 4-6 will be considered important outcomes, and those rated 1-3 will be discarded.

For each question, the co-chairs, methodologist, and medical librarian will work together to develop a sensitive search strategy. The search will be conducted by either the medical librarian or the methodologist in Medline, EMBASE, PsycInfo, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials. In addition, a search of key words will be conducted in major clinical trial databases, particularly www.clinicaltrials.gov and www.who.int/trialsearch. The methodologist will then work alone or with selected committee members to review the search results and select studies according to pre-specified search criteria. Published systematic reviews will be sought first, followed by randomized trials and controlled observational studies. Bibliographies of selected studies will be reviewed and the principal investigators of relevant studies will be contacted about additional results that may be considered for inclusion in these guidelines. If controlled evidence does not exist, the committee will either make a research recommendation or a clinical recommendation based upon case series, case reports, and clinical observation. Such clinical recommendations will be clearly rated as based upon very low quality evidence.

Once the studies have been selected, the methodologist will appraise the studies using the GRADE approach, extract crude data, pool the data via meta-analysis if appropriate, and then summarize the evidence in tables. Depending upon the nature of the data, the tables may include evidence tables that summarize the selected studies, summary of findings tables that display the effect of the intervention on each outcome, and/or quality assessment tables that summarize the quality of evidence.

The evidence synthesis will be presented to the full guideline committee by the methodologist. Under the leadership of the co-chairs, the committee will discuss the evidence and then decide whether to recommend for or against the intervention. The decision will be based upon 1) the balance of desirable consequences (i.e., benefits) versus undesirable consequences (i.e., harms, burdens), 2) quality of evidence, 3) patient values and preferences, and 4) costs and resource use. If a consensus cannot be reached by discussion alone, then voting will be performed with documentation of the voting results for transparency.

The committee will grade its recommendations using the GRADE approach. A recommendation will be rated as “strong” if the committee is certain that the upsides of the intervention outweigh the downsides (i.e., it is the right thing to do for >95% of patients) or “conditional” if the committee is uncertain that the upsides outweigh the downsides (i.e., it is the right thing to do for >50% of patients, but may not be the right thing to do for a sizable minority), which usually occurs if the evidence is low quality or the desirable and undesirable consequences are finely balanced.

Once the recommendations are formulated and graded, the guidelines will be written. The likely format of the manuscript is statement of a PICO question, followed by descriptions of the evidence and its quality, the rationale for the recommendation, and the rationale for the strength of the recommendation. Finally, the recommendation will be explicitly stated along with any accompanying remarks and values and preferences statements. The guidelines will be written within three months and then distributed to the entire guideline development committee for comments over two months. Final revisions by the co-chairs will be completed within two months and then the final document will be distributed to the entire guideline development committee pre-submission approval over one month.

F. Who will perform the systematic reviews? (for Clinical Practice Guidelines Only)

We encourage project teams to identify and make use of recently published, high quality systematic reviews performed by others. However, it is required that one or more members of the team have first-hand experience performing (and publishing) systematic reviews. Applicants are encouraged to recruit qualified individuals with adequate time to help perform systematic reviews. These may include junior members.

The systematic reviews will be performed by the project’s methodologist and medical librarian. Regarding the methodologist, we have communicated with Dr. Kevin Wilson, the ATS Documents Editor and Senior Director of Documents and Medical Affairs, who has promised to assign a trainee from the ATS’ guideline methodology training program to our project. The trainee will work with the supervision and mentorship of the ATS methodologist, Dr. Jan Brozek. In the unlikely event that the trainee is unable to complete the task, Drs. Wilson has agreed to assume the role. Regarding the medical librarian, Laurie Blanchard from the University of Manitoba has agreed to participate and has extensive experience performing systematic reviews.

G. HEALTH EQUALITY

Is the assembly project topic relevant to health equality?

No

If yes, how do you plan to incorporate the issue of health equality into your project. --empty--

H. All applicants who have or will have an official document as part of their Assembly/Committee project must:

Review a set of document-development vignettes prior to submitting this application. Please visit to access these vignettes. Note: Module A is for all document developers and Module B is also required for document developers who are preparing a clinical practice guideline. Yes, I have reviewed the ATS document development vignettes

Module A , Module B

I. FOR CME EDUCATIONAL PROJECTS/PRODUCTS ONLY: FOR MORE INFORMATION PLEASE SEE INSTRUCTIONS. PLEASE DESCRIBE THE FOLLOWING:

N/A

SECTION III - POTENTIAL PARTICIPANTS


If your project does NOT intend to develop a Systematic Review or Clinical Practice Guideline. Please skip next three paragraphs and enter project participants.

ATS requests proposals from multidisciplinary teams that include those with relevant clinical expertise and those with expertise in methods of critical appraisal of the literature, systematic literature review and guideline development. ATS encourages involvement of diverse stakeholders, each bringing a unique and important perspective to the process. A typical team should generally include clinical experts (including physicians, nurses and respiratory therapists), clinical investigators, one or more experts in systematic review and guideline development, and one or more external stakeholders, including a patient or patient representative. For some guidelines, it may also be useful to have a health economist, a medical librarian, an expert in group facilitation and/or project management, and/or one or more members to represent the perspective of governmental and non-governmental payer and health plans.

Evidence synthesis requires appropriate methodology. The ATS requires a systematic literature review for Systematic Reviews and Clinical Practice Guidelines and use of GRADE to assess the quality of evidence and to rate the strength of treatment recommendations for Clinical Practice Guidelines. Starting in 2012, the ATS strongly encourages NEW project applications that intend to develop a Systematic Review or Clinical Practice Guidelines to include 1 or more individuals with documented experience in these methodologies (i.e., have designed a systematic review; have applied GRADE for treatment recommendations); such individuals will be expected to provide methodologic support for document development in collaboration with the ATS Methodologist. Alternatively, NEW project applications may include 1 or more junior ATS members (e.g., Fellows or Assistant Professors) with an interest in learning how to perform an evidence synthesis using methods required by the ATS; such individuals ("ATS Evidence Synthesis Scholar") will be expected to work in collaboration with the ATS Methodologist to design the systematic literature review and, where applicable, apply GRADE for treatment recommendations. Finally, upon request, the ATS will provide a guideline methodology trainee who will work with the supervision of the ATS methodologist to perform the methodological work for your committee.

If your project intends to develop a Systematic Review or Clinical Practice Guideline, please indicate below which of the project participants meet the criteria described above. Also, please indicate if they have documented expertise in applying the ATS requirements for evidence synthesis OR will serve as an Evidence Synthesis Scholar. For more information, please discuss with the Document Development and Implementation Committee (contact Judy Corn, DDIC Staff) at least 1 week before submitting the application to PRS.

7. PROJECT PARTICIPANTS

Name	Institution	"Role" on Project committee	Area of Expertise	E-mail	Participant will require airfare	Participant will require Per Diem
David W. Hudgel	University of Manitoba	PI, Chair 	Member of several guideline and standards committees, producing evidence-based documents for cardiopulmonary sleep studies, ambulatory monitoring and CPAP use. Organized and chaired ACCP-sponsored International Conference on Ambulatory monitoring, resulting in 3 publications. PI on PG Day application on	hudgeldavid@yahoo.com		NO

Name	Institution	"Role" on Project committee	Area of Expertise	E-mail	Participant will require airfare	Participant will require Per Diem
Sanjay R. Patel	Harvard University	Co-PI	ATS document participation: comparative effectiveness and mild obstructive sleep apnea. AASM: CPG on PAP therapy in OSA. Two meta-analyses publications regarding CPAP and auto-PAP. Qualitative systematic review on sleep duration and weight.	spatel@partners.org		NO
Ronald Grunstein	Woolcock Institute for Medical Research, University of Sydney, AU	Senior Committee member	Participated in ATS CPG on OSA and driving risk and ATS/AASM/ACCP/ERS statement on OSA treatment research priorities. Numerous institutional, professional organization and government leadership positions	rrg@medusyd.edu.au		NO
Matthew Naughton	Monash University and Alfred Hospital	Senior Member	Past member of ATS committees, organized conferences for Australian Sleep Society and World Sleep Federation. Investigator in RCT's of bariatric surgery, CPAP and diabetes in OSA	m.naughton@alfred.org.au		NO
Christopher Lettieri	US Army	Senior Committee Member	Participant in CPG committees for AASM and US Army. Research focus on patient education	Christopher.Lettieri@us.army.mil		NO
Jean-Louis Pepin	CHU de Grenoble stie Nord-Hopital Albert Michallon	Senior committee member	Co-author of French OSA mamagemet guidelines, Member of European Respiratory Society task forces on CPAP OSA management, sleep hyperventilation, and scoring respiratory events in ambulatory monitoring	JPepin@chu-grenoble.fr		NO



Name	Institution	"Role" on Project committee	Area of Expertise	E-mail	Participant will require airfare	Participant will require Per Diem
Caroline M. Apovian	Boston University	Senior Committee Member, Nutritionist	Well-published academic physician-nutritionist. CPG and statement co-authorship for NIH, American Heart Association/American College of Cardiology, American Society of Clinical Endocrinologists, Obesity Society, American Society for Metabolic and Bariatric Surgery. Participated in development of obesity medication guidelines for the Endocrine Society.	Caroline.Apovian@bmc.org	Domestic	NO
Indira Gurubhagavatula	Univeristy of Pennsylvania	Senior Committee Member	Participant and co-author of commerical driver/OSA guidelines with the Mortor Carrier Safety Advisory Committee and Medical Review Board and a member of a joint task force of the ACCP, Occupational and Environmental Medicine and National Sleep Foundation on the same topic. Also, participant in RCT on mild OSA.	indira.gurubhagavatula@uphs.upenn.edu		NO
Vishesh Kapur	Univesity of Washington	Seior Committee Member, Cost effectiveness expert	Cost effectiveness expertise, MPH, Participant and Co-author in the Cardiovascular Health Study - focusing on elderly and obesity issues	vkapur@u.washington.edu		NO

Name	Institution	"Role" on Project committee	Area of Expertise	E-mail	Participant will require airfare	Participant will require Per Diem
Henri Tuomilehto	University of Eastern Finland	Senior Committee Member	Member of OSA CPG team for Finland. Participant in multicenter, European Union-funded study of sleep in T2D large cohort. PI of RCT of weight management in OSA	henri.tuomilehto@oivauni.fi	International	NO
Robert Owens	University of California, San Diego	ATS Evidence Synthesis Scholar	Sleep and respiration physiology research	rowens@partners.org		NO
Thomas B. Rice	University of Pittsburgh	ATS Evidence Synthesis Scholar	Sleep medicine investigator and clinician	ricetb@upmc.edu		NO
Melissa Coaker	Private Practice of Sleep Medicine in Des Moines, IA	ATS Evidence Synthesis Scholar, Advice to committee regarding practicality of recommendations	Clinical sleep medicine	mcoaker2000@yahoo.com		NO
Ms. Laurie Blanchard	University of Manitoba	Librarian, Participate in literature search strategy, Lead literature searches	Evidence-based guideline development and systematic and evidence-based literature searches and evidence table development	laurie.blanchard@umanitoba.ca	International	YES
Tracy R. Nasca	Am Sleep Apnea Association	Patient representative	Patient advocacy	tnasca@sleepapnea.org	Domestic	NO
To be named	To be named	Methodologist trainee	Guided by the ATS methodologists, focusing on literature searches, evidence table construction, and GRADE application	unknown@university.org	Domestic	NO

SECTION IV - TIMETABLE

8. TENTATIVE TIMETABLE FOR COMPLETION OF THE PROJECT PLEASE INCLUDE A PROJECT COMPLETION DATE FOR EACH FUNCTION OR ACTIVITY.

Function/Activity	Proposed Dates	Location	#of Participants	Function Completion Date
Construct, distribute and analyze 3 surveys to full committee to finalize PICO questions and desired outcomes	2/1/2015 - 4/30/2015	e-mail	4	4/30/2015
Begin search strategy and search criteria	05/16/2015	ATS annual meeting, Denver, CO	5	05/16/2015
Continue search strategy development. Conduct literature search and analyze results	05/17/2015 - 07/30/2015	Un.of Manitoba, e-mails, conference calls	15	07/30/2015

Function/Activity	Proposed Dates	Location	#of Participants	Function Completion Date
Select studies to be reviewed, contact PI's of selected studies 	8/1/2015 - 10/31/2015	e-mail, conference calls	12	10/31/2015
GRADE literature, construct evidence, summary of findings, and quality assessment tables	11/1/2015 - 4/30/2016	e-mails, conference calls	8	4/30/2016
Full committee discussion of evidence, Preparation and grading of recommendations	5/1/2016 - 5/30/2016	conference call, ATS annual meeting	16	5/30/2016
Writing guidelines 	6/1/2016 - 11/30/2016	e-mails, conference calls	6	11/30/2016
Distribution of guideline draft to full committee for comments	12/1/2016 - 1/31/2017	e-mails, conference calls	15	1/31/2017
Final guideline revision	2/1/2017 - 3/30/2017	e-mails, conference calls	8	3/30/2017
Final committee input	4/1/2017 - 4/30/2017	e-mails, conference calls	15	4/30/2017
Submission to ATS Documents Editor	5/1/2017 - 5/30/2017	e-mail	2	5/30/2017
Guideline final revisions	6/1/2017 - 6/30/2017	e-mails, conference call	2	6/30/2017
Develop patient education materials, web-based guide, monograph material	7/1/2017 - 10/30/2017	ATS, e-mails, conference calls	8	10/30/2017

9. Expected Project Completion Date
10/30/2017

SECTION V - PROJECT OUTCOMES

10. All products or works, whether in writing or in another form, that are created partly or completely with the assistance of funding provided by the American Thoracic Society will be the intellectual property of the ATS exclusively, unless otherwise stipulated in writing by the ATS. The disposition of these products or works will be at the sole discretion of the ATS. Recipients agree, as a condition of receipt of ATS funding, that ATS owns the copyright and all other rights to these products or works.

I- DERIVATIVES (please note that all printed documents are automatically posted on the ATS website)

AJRCCM Patient Information Series fact sheet (strongly encouraged for Clinical Practice Guidelines),
Guides for target audiences (strongly encouraged for Clinical Practice Guidelines)

II- Web Products


Specialized area of ATS website

III- Educational Products

CME monographs, Webcast

SECTION VI - BUDGETS

11. FY2015 PROPOSED ATS BUDGET

Round Trip Coach Airfare-Domestic (\$575 per person) Number of Persons? 

Round Trip Coach Airfare-International (\$2000 per person) Number of Persons? 1

Hotel and per diem (Full Day Meeting at ATS Conference Fri & Sat Only) (\$425 per person) Number of Persons? 

Breakfast Meeting at ATS Conference (\$50.00 Per Person) Number of Persons? 0

Lunch Meeting at ATS Conference (\$50.00 Per Person) Number of Persons? 5


Conference Calls (# of people x # minutes x 0.10)

of people 17

of minutes 60

of calls 6

Publication Costs (\$450.00 Per Page) Number of Pages? 

Medical Librarian  This item requires approval and justifications from document development staff (up to \$5000)
3000

Outside Meeting 1 - Must provide Budget justification

Please note that this section is only for meetings that will not take place at the ATS International Conference. Please list activities using budget parameters below.

N/A

Outside Meeting 2 - Must provide Budget justification

N/A

Other Project Expenses

Please note this section is only for expenses other than outside meetings.

N/A

12. FY2015 BUDGET FROM OTHER SOURCES (JOINT PROJECTS ONLY)

N/A

SECTION VII

13. IF THIS PROJECT IS BEING CO-SPONSORED BY ANOTHER NON-CORPORATE ORGANIZATION (Foundation, government, other non-corporate organizations), PLEASE COMPLETE THE FOLLOWING:

Organization	Contact Person	Funding Amount Requested	Funding Amount Approved
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SUPPORTING DOCUMENTS OR REFERENCES

ATS requires references for both chairs justifying their expertise in the field.

Documents (please merge all files into one file) ([download file](#))

SECTION VIII - Conflict of Interest Management

Conflicts of interest (COI) are direct personal financial or intellectual relationships with a company that has a business interest in the subject matter of the project. Disclosure and management of COI is an integral part of ATS project development because COI can lead to biased generation or assessment of evidence and misinform healthcare decision makers. Medical professional societies are obliged to rigorously manage potential COI, particularly in the development of official documents that affect health care.

Therefore, ATS requires that:

- For all proposed projects, **ATS must have on file (by time of consideration of this application) an up-to-date disclosure of any potential conflicts of interests of the proposed project chair or co-chair related to project subject matter.** Disclosure-to-ATS occurs through completion of the annual online disclosure questionnaire available at the ATS COI Disclosure website (<https://thoracic.coi-smart.com>).
Please note:
 - If you previously completed the 2014 ATS COI Questionnaire as part of requirements for another ATS activity (such as for the May 2014 San Diego International Conference, or for an ATS project approved for ATS fiscal year 2014), please return to the ATS COI Disclosure website to revise your online disclosure to (a) add to your answer to Question 1 that your disclosure can also be used for your consideration as a "Project Applicant" (simply click the box for that) and (b) make sure that the scope of your answers to the online COI questionnaire includes anything relevant to the subject matter of the project you are proposing through this application. Please use the ATS-issued site Log-in ID that was previously issued to you, and your self-determined password, to access the disclosure site, and then follow the posted instructions to revise/update your disclosure. If you've forgotten your Log-in ID, use the "Forgot Log-in ID" prompt on the website or contact John Harmon at ATS at coioffice@thoracic.org or 212-315-8611 for assistance.
 - If you have not yet completed the 2014 ATS COI, please contact John Harmon at ATS at coioffice@thoracic.org or 212-315-8611 to be registered to complete the questionnaire and receive site use instructions.

2. For all **projects intended to result in an ATS clinical practice guideline**(CPG), additional conditions must be met. These include:
- Some COI are prohibited for all members of a CPG panel, including the chair or co-chairs. These include holding stock or options, participating on speaker bureaus, consulting, or providing expert testimony for a company that has a business interest in the subject matter of the guideline.
 - Some COI are acceptable for members of a CPG panel, including the chair or co-chairs, but will need to be managed during guideline development (i.e., the conflicted individuals may participate in discussions about the evidence, but must be excluded from formulating and grading recommendations). These include participation on an independent data safety monitoring board or in research sponsored by a company that has a business interest in the subject matter of the guideline if payments are to the institution and has institutional oversight.
 - One type of COI is prohibited for the chair or co-chairs of a CPG panel, but acceptable for non-chair members of a CPG panel: participation on advisory committees of companies that have a business interest in the subject matter of the guideline, if the advisory committees are strictly scientific in nature and independent of marketing.
 - At least one co-chair of the CPG panel must be free of all COI relevant to the subject matter of the Guideline, even those COI that are considered acceptable. The co-chair must remain free of such conflicts for at least one year after publication of the Guideline.
 - A majority of members of a CPG panel must be free of all COI relevant to the subject matter of the Guideline. Members of the CPG panel must remain free of such conflicts for at least one year after publication of the Guideline. CPG project applicants that have questions about these requirements can contact Shane McDermott at ATS at smcdermott@thoracic.org or 212-315-8650 for assistance.

SECTION IX - Chair Acknowledgement

Submission of application constitutes Electronic signature. Electronic Signatures are considered binding.

SECTION X - Revising Application After Reviewer Feedback

Choose one of the following:

I have revised application based on reviewer feedback

Revision - Tell us what revisions have been made. Reviewer must submit a letter (word document) responding to how reviews from planning committees were addressed ([download file](#)) 

ATS BUDGET SUMMARY CHART

Line Item	Budget Parameters	Number of Persons	Total
Round Trip Coach Airfare-Domestic (<i>\$575 per person</i>)	\$575.00	0	\$0.00
Round Trip Coach Airfare-International (<i>\$2000 per person</i>)	\$2,000.00	1	\$2,000.00
Hotel and per diem (Full Day Meeting at ATS Conference Fri & Sat Only) (<i>\$425 per person</i>)	\$425.00	1	\$425.00
Breakfast Meeting at ATS Conference (<i>\$50.00 Per Person</i>)	\$50.00	0	\$0.00
Lunch Meeting at ATS Conference (<i>\$50.00 Per Person</i>)	\$50.00	5	\$250.00
Conference Calls (<i># of people x # minutes x 0.10</i>)	17 x 60 x 0.10 = \$102.00	(# Calls) 6	\$612.00
Publication Costs (<i>\$450.00 Per Page</i>)	\$450.00	0	\$0.00
<ul style="list-style-type: none"> • Policy Statement – 8 Pages Max • Conference Proceedings & Workshops – 8 Pages Max • Technology Reviews & Standards 8 Pages Max • Guidelines & Recommendations – 15 Pages Max 			
Medical Librarian – This item requires approval and justifications from document development staff (<i>up to \$5000</i>)	\$3,000.00	N/A	\$3,000.00
Outside Meeting 1 – Must provide Budget justification	N/A	N/A	N/A
Outside Meeting 2 – Must provide Budget justification	N/A	N/A	N/A
Other Project Expenses – Must provide Budget justification	N/A	N/A	N/A
<i>Note: Your proposed budget may be adjusted by staff and/or PRS to comply with ATS budgetary Policies and Procedures.</i>			Total \$6,287.00