



FY2023 New Assembly/Committee Project Application

Submitter: **Christopher Baker**

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Collaboration: There will be opportunities for other organizations to co-sponsor the document. The ATS prefers that the project not be discussed with potential co-sponsoring organizations until the project has been approved because premature discussions may jeopardize a final agreement. All negotiations for collaboration will be handled by ATS staff following project approval.

SECTION I - GENERAL PROJECT INFORMATION

* 1. ATS PROJECT TITLE:

[Care of Infants and Children with Tracheostomies: An Official ATS Clinical Practice Guideline](#)

* 2. PROJECT PRIMARY ASSEMBLY:

[Pediatrics](#)

* 3. ATS SECTION:

-- empty --

* 4. ATS COMMITTEE SUBMITTING PROJECT APPLICATION:

-- empty --

* 5. What official ATS document will be developed as part of this project?

Clinical Practice Guidelines

- * 6. Can the project move forward as a virtual project if necessary?

Yes

SECTION II - RELEVANCE to ATS

PROJECT DESCRIPTION

- * A. Clearly and concisely describe the project's goals, objectives, and relevance/importance to the ATS. Goals and objectives should be focused and feasible to achieve. Do NOT include your meeting agenda here. If you are proposing a clinical practice guideline, this section should include your PICO question(s). (maximum of 6 questions are permitted)

Assembly: Pediatrics (primary); Nursing (secondary); Co-sponsoring society: ENT: American Association of Otolaryngology Head and Neck Surgery (in accordance with the ATS Co-Sponsorship Policy; see Methodology section)

INTRODUCTION: The population of infants and children requiring a tracheostomy tube has been rapidly growing over the past two decades due to advances in medical care as well as patient and family preferences. These children are medically complex and have a high burden of healthcare utilization in the hospital, community, and at home. In an American cohort of 502 children with tracheostomy tubes, the total healthcare spending in the 2 years following tracheostomy was \$53.3 million. (1) These children are at risk of significant morbidity and mortality. Rates of in-hospital mortality and tracheostomy related complications in the two years following tracheostomy tube insertion are 9% and 38.8%, respectively. (1) Even short delays in recognition and response to an emergency can have deleterious or fatal consequences. Thus, the need for evidence-based guidelines to standardize pediatric care remains an urgent priority. (2) In accordance with the American Thoracic Society's mission to improve health worldwide by advancing research, clinical care, and public health in respiratory disease, critical illness, and sleep disorders, our aim is to improve clinical care and patient outcomes for this 'high stakes' population. This Clinical Practice Guideline will be applicable to both children with tracheostomies and mechanical ventilation as well as those with tracheostomies alone. Thus, they will be complementary to the 2016 ATS guidelines for pediatric home ventilation. (3) Through its development, we aim to standardize and streamline care while identifying the many disparities which contribute to inequitable healthcare.

BACKGROUND: In 1999, the ATS published a document entitled *Statement on the Care of the Child with a Chronic Tracheostomy Tube* which provided a comprehensive, consensus-based review of the essential equipment, caregiver competencies and potential complications. (4) This document, structured as an

'official statement' rather than a Clinical Practice Guideline, has been highly used and is a key clinical tool for pediatric pulmonologists, critical care clinicians, rehabilitation specialists, and other healthcare providers who care for children with tracheostomy tubes. The American Academy of Otolaryngology-Head and Neck Surgery published a Clinical Consensus Statement on Pediatric and Adult Tracheostomy Care in 2013. (5) A modified Delphi method was used to achieve consensus on 77 clinical care statements, only eight of which applied directly to children. A literature review (completed in 2011) was used to guide the items included in the Delphi survey, but recommendations were based on expert opinion alone. Notably, the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) methodology was not used. In addition, there were critical gaps in the content of the 2013 consensus statement. These include a lack of guidance pertaining to: caregiver monitoring of a child with a tracheostomy, management of tracheitis, and importantly, considerations towards the ethics and health disparities which affect children with tracheostomies. Furthermore, there has been a significant increase in the available literature in this field in accordance with the growth of this population over the past twenty years, especially in the last decade (over half of the available literature [1703 of 2552 manuscripts in PubMed pertaining to search terms "tracheostomy" AND "pediatric"] were published since the literature review for the most recent statement in April 2011). This highlights the need and opportunity for up-to-date, rigorously developed, comprehensive guidance for practicing clinicians taking into account regional differences in healthcare with particular attention to resource poor settings.

We have assembled a diverse, international, multidisciplinary panel to develop recommendations for the care of infants and children with tracheostomy tubes using the GRADE methodology, a transparent framework for developing and presenting evidence-based summaries and a systematic approach for making clinical practice recommendations. (6, 7) By starting with the GRADE approach, we will ensure that our recommendations incorporate all relevant scientific evidence. However, in cases where such evidence is lacking, a modified Delphi method will be utilized to achieve consensus among the expert panel using cycles of anonymous questionnaires and discussion until a convergence of opinion is achieved or a lack of consensus is identified. (8, 9) The focus of the proposed clinical practice guidelines will be on clinical topics that have not been addressed by prior consensus statements. PICO questions have been chosen based on a combination of clinical priority topics and available literature. Important areas for future research will also be identified. In addition, we have chosen our objectives, PICO questions, and panel membership to reflect a team approach to clinical care and best practice for medically complex patients with tracheostomy tubes. This population is diverse, ranging from patients requiring tracheostomies for airway issues alone to patients with additional pulmonary issues including dependence on mechanical ventilation.

SPECIFIC OBJECTIVES:

1. Develop a state-of-the-art Clinical Practice Guideline that will identify the current state of tracheostomy care for infants and children.
2. Describe the impact of health disparities, limited resources, and supply chain deficiencies on equitable access to care among diverse populations.
3. Provide recommendations for best practice inclusive of healthcare inequities and limited access to care.
4. Define areas where future research would help improve care for these medically complex children.

PICO QUESTIONS: We have drafted specific clinical questions, in the PICO format, based on an initial literature review. The questions cover clinical priority areas and major challenges in the clinical care of infants and children with tracheostomy tubes that have not been covered by earlier consensus statements in combination with available literature or significant gaps (4, 5). The multidisciplinary committee we describe in this proposal will further refine these PICO questions during a videoconference meeting before the first proposed face-to-face meeting, following the approval of this proposal.

Proposed PICO questions:

1. Should infants and children with tracheostomies always have an awake and attentive trained caregiver present with them?
 - a. Population: All infants and children less than 18 years old with a tracheostomy
 - b. Intervention: Arranging for awake and attentive trained caregivers to always care for the child (likely a combination of adult family members and in-home professionals)
 - c. Comparator: Allowing an infant or child with a tracheostomy to be cared for by a sleeping caregiver with or without monitoring/alarms (e.g., pulse oximetry)
 - d. Outcome: Cardiopulmonary arrest, anoxic brain injury, death (as a result of an unobserved/preventable event), patient/family quality of life (well-described in recent medical literature)
2. Should tracheal aspirate cultures be obtained for infants and children with tracheostomies during routine clinic visits and acute respiratory illness?
 - a. Population: All infants and children less than 18 years old with a tracheostomy
 - b. Intervention: Obtaining tracheal aspirates for gram stain analysis and aerobic bacterial culture routinely and during illness
 - c. Comparator: Managing infants and children with tracheostomies without tracheal aspirate culture results

- d. Outcome: Frequency of tracheitis/lower respiratory infections, severity of respiratory infection, emergency department visits, hospitalization, death
3. Should all infants and children undergoing tracheostomy decannulation undergo airway evaluation with bronchoscopy (rigid and/or flexible) to evaluate the airway?
- a. Population: All infants and children less than 18 years old with a tracheostomy who are being considered for tracheostomy decannulation
 - b. Intervention: Performing flexible fiberoptic bronchoscopy, rigid microlaryngoscopy and bronchoscopy, or both before decannulation is attempted.
 - c. Comparator: Attempting decannulation without bronchoscopy
 - d. Outcome: Need for tracheostomy to be replaced, severe adverse event due to failed decannulation attempt
4. Should all infants and children undergoing tracheostomy decannulation undergo capped polysomnography?
- a. Population: All infants and children less than 18 years old with a tracheostomy who are being considered for tracheostomy decannulation
 - b. Intervention: Performing a polysomnogram with the tracheostomy tube capped before tracheostomy decannulation
 - c. Comparator: Attempting decannulation with alternative monitoring (such as pulse oximetry, capnography, blood gas analysis) rather than obtaining a formal polysomnogram
 - d. Outcome: Need for tracheostomy to be replaced, severe adverse event due to decannulation attempt
5. Should ethical criteria be applied to determine which infants and children are candidates for tracheostomy tube placement and how best to involve the family in shared decision-making and tracheostomy tube education?
- a. Population: All infants and children less than 18 years old being considered for tracheostomy
 - b. Intervention: Applying ethical criteria to determine eligibility for tracheostomy and family shared decision-making
 - c. Comparator: Not applying ethical criteria, placing tracheostomy whenever endotracheal tube extubation cannot occur and/or a child is requiring 24 hour invasive or noninvasive ventilation, and not involving the patient and family in the decision-making process
 - d. Outcome: Family satisfaction, alignment with family goals of care, quality of life of the patient and family, professional caregiver moral distress, ICU length of stay, hospital length of stay

REFERENCES:

1. Watters K, Neill M, Zhu H, Graham RJ, Hall M, Berry J. Two-year mortality, complications, and healthcare use in children with medicaid following tracheostomy. *The Laryngoscope* 2016; 126: 2611-2617.
2. Verma R, Mocanu C, Shi J, Miller MR, Chiang J, Wolter NE, Propst EJ, St-Laurent A, Amin R. Decannulation following tracheostomy in children: A systematic review of decannulation protocols. *Pediatr Pulmonol* 2021; 56: 2426-2443.
3. Sterni LM, Collaco JM, Baker CD, Carroll JL, Sharma GD, Brozek JL, Finder JD, Ackerman VL, Arens R, Boroughs DS, Carter J, Daigle KL, Dougherty J, Gozal D, Kevill K, Kravitz RM, Kriseman T, MacLusky I, Rivera-Spoljaric K, Tori AJ, Ferkol T, Halbower AC, Workgroup APCHV. An Official American Thoracic Society Clinical Practice Guideline: Pediatric Chronic Home Invasive Ventilation. *American Journal of Respiratory and Critical Care Medicine* 2016; 193: e16-35.
4. Sherman JM, Davis S, Albamonte-Petrick S, Chatburn RL, Fitton C, Green C, Johnston J, Lyrene RK, Myer C, Othersen HB, Wood R, Zach M, Zander J, Zinman R. Care of the child with a chronic tracheostomy. This official statement of the American Thoracic Society was adopted by the ATS Board of Directors, July 1999. 2000. p. 297-308.
5. Mitchell RB, Hussey HM, Setzen G, Jacobs IN, Nussenbaum B, Dawson C, Brown CA, Brandt C, Deakins K, Hartnick C, Merati A. Clinical Consensus Statement: Tracheostomy Care. *Otolaryngology -- Head and Neck Surgery* 2013; 148: 6-20.
6. Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ, Group GW. What is "quality of evidence" and why is it important to clinicians? *BMJ* 2008; 336: 995-998.
7. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schunemann HJ, Group GW. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008; 336: 924-926.
8. Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. *Am J Public Health* 1984; 74: 979-983.
9. Vonk Noordegraaf A, Huirne JA, Brolmann HA, van Mechelen W, Anema JR. Multidisciplinary convalescence recommendations after gynaecological surgery: a modified Delphi method among experts. *BJOG* 2011; 118: 1557-1567.

* B. Describe any related ATS / non-ATS activities relevant to your project.

The Global Tracheostomy Collaborative (GTC; globaltrach.org) is a community of multi-disciplinary healthcare professionals, patients, and families dedicated to improving the quality of care and clinical outcomes of individuals with tracheostomy tubes. The Global Tracheostomy Collaborative cites 5 best practice pillars. These include: 1) a team-based approach; 2) development of standard care protocols; 3) staff education; 4) patient and family involvement and; 5) data collection. This proposed ATS Clinical Practice Guideline is aligned with the mission of the GTC and would synergistically improve quality of

care for infants and children with tracheostomy tubes. In addition, to ensure timely knowledge and translation of the proposed ATS Clinical Practice Guidelines, several of the panelists for our committee are active GTC members. These include co-chair, Dr. Christopher Baker, as well as Dr. Michael Brenner (current GTC President), Dr. Hannah Zhu, and Dr. Karen Watters.

The Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network (palisi.org) is a research network dedicated to identifying preventive, therapeutic, and preventive strategies for acute respiratory distress syndrome, sepsis, multi-organ failure, and other acute, life-threatening pulmonary or systemic inflammatory syndromes that affect infants and children. Infants and children with tracheostomy tubes requiring mechanical ventilation are a subset of the population of focus for this research network. Dr. Robert Graham (panelist) is the director of the PALISI subgroup for long-term ventilation. Dr. Graham will ensure rapid access to the results of ongoing, relevant clinical trials and will facilitate broad dissemination of the ATS Clinical Practice Guidelines across his clinical and research networks.

The Bronchopulmonary Dysplasia (BPD) Collaborative

(nationwidechildrens.org/specialties/comprehensive-center-for-bronchopulmonary-dysplasia/bpd-collaborative) is comprised of 30 institutions with multidisciplinary teams dedicated to optimizing outcomes of infants and children with severe BPD. Infants and children with tracheostomy tubes will be a subset of patients included in the BPD Collaborative. Many panelists including Co-Chair, Dr. Baker, are also members of the BPD Collaborative. This will ensure rapid knowledge translation of the ATS Clinical Practice Guideline recommendations. The future research directions that the panel identifies will serve as a catalyst for research protocol development within the collaborative.

*** C. How does this project relate to health equality? How will health equality be addressed in this project?**

This Clinical Practice Guideline will integrate the Diversity, Equity, and Inclusion lens into all the PICO questions and related panel discussions. We will highlight how advancements in medical care have both enabled medically complex children with tracheostomy tubes to be able to live at home with their families and simultaneously exacerbated healthcare disparities. The impact of socioeconomic status and geography on access to home healthcare services as well as funding for the provision of medical supplies (e.g., tracheostomy tubes and suction catheters) will be highlighted. Appreciating that these clinical practice guidelines will have international reach, a lack of homecare nurses as well as alternative home health care providers such as personal support workers and unregulated care providers will be discussed especially given the pandemic and the recent homecare nursing crisis. In addition, we will systematically review the impact of socioeconomic factors on morbidity and mortality rates of this population. In a Canadian cohort of children with tracheostomy tubes receiving ventilation,

income quintile was a significant predictor of survival, using health administrative data.

Equity considerations for the Clinical Practice Guideline recommendations will be integrated into the PICO related discussions. (10) We will review whether the recommendations can ensure equitable provision of healthcare for all, given the potential for Clinical Practice Guidelines to inadvertently introduce health inequities. (11, 12). In the Clinical Practice Guidelines document, we will add a new “Impact on Under-Represented Groups” section to each PICO question after “Implementation” and before “Justification” that describes the existing disparities as well as the positive and negative ways the “ATS recommendation” will affect these at-risk populations.

Finally, we will leverage the diverse experiences of panelists being from multiple ethnic backgrounds from five different countries across four different continents, for these discussions. We have also ensured inclusive representation on this committee from underrepresented racial groups including African Canadian and Hispanic.

REFERENCES:

10. Shi C, Tian J, Wang Q, Petkovic J, Ren D, Yang K, Yang Y. How equity is addressed in clinical practice guidelines: a content analysis. *BMJ Open* 2014; 4: e005660.
11. Aldrich R, Kemp L, Williams JS, Harris E, Simpson S, Wilson A, McGill K, Byles J, Lowe J, Jackson T. Using socioeconomic evidence in clinical practice guidelines. *BMJ* 2003; 327: 1283-1285.
12. Dans AM, Dans L, Oxman AD, Robinson V, Acuin J, Tugwell P, Dennis R, Kang D. Assessing equity in clinical practice guidelines. *J Clin Epidemiol* 2007; 60: 540-546.
13. Cristea AI, Ren CL, Amin R, Eldredge LC, Levin JC, Majmudar PP, May AE, Rose RS, Tracy MC, Watters KF, Allen J, Austin ED, Cataletto ME, Collaco JM, Fleck RJ, Gelfand A, Hayes D, Jr., Jones MH, Kun SS, Mandell EW, McGrath-Morrow SA, Panitch HB, Popatia R, Rhein LM, Teper A, Woods JC, Iyer N, Baker CD. Outpatient Respiratory Management of Infants, Children, and Adolescents with Post-Prematurity Respiratory Disease: An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med* 2021; 204: e115-e133.

* D. All applicants must review a document development video (<https://www.thoracic.org/members/assemblies/about/assembly-project-application-resource-center.php>) and set of document-development vignettes prior to submitting this application.

Yes, I have review the document development video

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

Not Applicable

SECTION III - METHODOLOGY

* A. Please describe the approach for creating the document. This section should demonstrate that the scope of work can be completed on time. There should be a clear plan for how tasks, such as paper writing, will be completed (e.g., how will writing tasks be divide? what are the opportunities for the committee to provide feedback?). Please include why you feel the selected document type is the most appropriate.

Once our proposal is approved by the ATS, the co-chairs will submit a formal request to the ATS DDIC supporting the inclusion of the American Association of Otolaryngology Head and Neck Surgery as a co-sponsoring society (in accordance with the ATS Co-Sponsorship Policy). As instructed, the co-chairs have made no such commitment to any member of the co-sponsoring society at this time.

A virtual meeting will be organized to e-introduce all the panelists and refine the PICO questions for this Clinical Practice Guideline. In addition, we will include patient and family presence for a portion of the virtual meeting. We will attempt to have representation from at least one patient/family from each continent. We have included several parents on our committee to ensure that the outcomes chosen are of primary relevance to patients and families, including a family who elected not to pursue tracheostomy for their child. After this meeting the co-chairs and methodologist will conduct a preliminary literature review in preparation for the in-person meeting. The findings of this literature search will be shared with panel members several weeks before the meeting for their review.

An in-person meeting will be arranged just prior to the annual 2023 ATS International Meeting in Washington, DC. The meeting will facilitate in-depth discussions based on the PICO questions. During this meeting the panelists will also be subdivided into groups for each PICO question. We anticipate that the subsequent webinar/teleconferences will allow further refining of our questions and outcomes. In addition, after the meeting, the list of questions and outcomes drafted by the committee will be reviewed by the Parent Advisory Boards at Children's Hospital Colorado and The Hospital for Sick Children to further ensure a patient- and family-centered approach.

Immediately following the in-person meeting, the methodology team led by Narayan Iyer and a librarian (to be selected by the ATS) will initiate the literature search, summarize the evidence, and rate the quality of evidence. After review by the Parent Advisory Boards, the list of potential outcomes will be presented as a survey to the committee members to confirm the prioritized selection of outcomes. During the summer months following the in-person meeting, we expect to receive intermittent email communications from the methodology team asking for input about specific issues as they arise. Once the data synthesis is complete, subsequent webinars will be convened.

During the webinars, the methodology team will present the evidence to the PICO sub-committee and the co-chairs. Each PICO sub-committee will interpret, discuss the evidence, make initial recommendations, write the PICO related section of the manuscript. Each sub-committee will circulate its recommendations to the larger group in the form of an anonymous Delphi questionnaire (sent via email). Composite Likert scale results (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) will be tabulated and returned to the larger group for discussion at subsequent virtual meetings to ensure consensus. Delphi rounds will continue until $\geq 70\%$ of panelists agree or strongly agree with the recommendations. The co-chairs will provide oversight of all the sub-committees, lead discussions to interpret and discuss the evidence, write the executive summary as well as the introduction, methods, and conclusions for the guidelines. The co-chairs will edit all manuscript drafts.

In addition, our committee will draw on the expertise of Dr. Christopher Baker (co-chair, senior author) and Dr. Narayan Iyer (methodologist) as they have worked together on the Guidelines for Outpatient Respiratory Management of Infants, Children, and Adolescents with Post Prematurity Respiratory Disease. (12) Their team was able to meet all the relevant milestones within the recommended timeframes.

* B. If you are requesting a face-to-face meeting, please provide a detailed agenda that includes:

- the topic/activity
- the presenter/discussant/group leader name(s),
- start time
- duration (if not clear from the next topic/activity's start time).

Tip. In person meetings are most successful when there is ample time for discussion spread throughout the meeting. It is often helpful to document group/sub-group discussion as a separate topic/activity.

[\[FY2023_ATS_CPG_Meeting_Agenda_Trach.docx\]](#)

* If you have chosen to develop a Workshop Report as part of this project, please complete a draft agenda below for the workshop. Please click "add new" to add a new agenda item.

* C. PROPOSED PARTICIPANTS - *Every guideline must have a methodologists. Please include all proposed participants. For more details contact ATS Documents Department documents@thoracic.org*

- Include a list of all planned participants. For '**area of expertise relevant to the project**', provide sufficient detail to justify the person's inclusion on this project and to demonstrate their role on the project. For example, this could include specific clinical or research expertise and/or prior experience with document development.
- Before beginning work on the project all participants will have their conflict of interest disclosures vetted by the ATS. If the project is co-sponsored by other societies or groups, there may be

approvals required before a participant can be formally added to the project committee.

Name : Christopher D Baker, MD

Institution : University of Colorado School of Medicine | Children's Hospital Colorado

"Role" on Project committee : Co Chair

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care and chronic mechanical ventilation

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Airfare : Domestic

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Name : Reshma Amin, MD

Institution : University of Toronto | The Hospital for Sick Children

"Role" on Project committee : Co Chair

Area of Experties relevant to project : Pediatric Respirology and Sleep Medicine; Tracheostomy care, home ventilation program director, sleep medicine

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Airfare : International

Country : Canada

Name : Narayan Iyer, MD

Institution : Children's Hospital of Los Angeles

"Role" on Project committee : Methodologists

Area of Experties relevant to project : Neonatologist; Methodologist

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Airfare : Domestic

Country : United States

Name : A. Ioana Cristea, MD

Institution : Riley Children's Hospital

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, chronic mechanical ventilation, bronchopulmonary dysplasia, home ventilation program director

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Airfare : Domestic

Country : United States

Name : Howard Panitch, MD

Institution : Children's Hospital of Philadelphia

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, chronic mechanical ventilation, neuromuscular disease

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Airfare : Domestic

Country : United States

Name : Jennifer Henningfeld, MD

Institution : Children's Hospital of Wisconsin

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, chronic mechanical ventilation, home ventilation program director

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Airfare : Domestic

Country : United States

Name : J. Michael Collaco, MD

Institution : Johns Hopkins Medical Institute

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, epidemiology of lung disease, bronchopulmonary dysplasia

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Airfare : Domestic

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Name : Dan Benscoter, MD

Institution : Cincinnati Children's Hospital

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, chronic mechanical ventilation, pediatric airway, fiberoptic bronchoscopy

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Name : Amit Agarwal, MD

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"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Tracheostomy care, chronic mechanical

ventilation, home ventilation program director

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Airfare: Domestic

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Name: Maria Castro Codesal, MD

Institution: Stollery Children's Hospital

"Role" on Project committee: Member

Area of Experties relevant to project: Pediatric Respiriology; Sleep Medicine, home ventilation program director

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Airfare: International

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Name: Adetayo Adeleye, MD

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"Role" on Project committee: Member

Area of Experties relevant to project: Pediatric Respiriology; Tracheostomy Care; Sleep Medicine

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Airfare: International

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Name: Cori Daines, MD

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Area of Experties relevant to project: Pediatric Pulmonology; Home ventilation program director, division chief of a smaller (but well-known) program in a small town (Tucson, AZ)

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Airfare: Domestic

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Name: Sheila Kun, RN

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"Role" on Project committee: Member

Area of Experties relevant to project: Pediatric Pulmonology (retired, agreed to be on panel); Nurse; Tracheostomy care and chronic mechanical ventilation

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Airfare: Domestic

Country : United States

Name : Jessica Dawson, RN

Institution : Children's Hospital Colorado

"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Pulmonology; Clinical coordinator; Tracheostomy care and chronic mechanical ventilation

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Name : Shari Simone, DNP, CPNP

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"Role" on Project committee : Member

Area of Experties relevant to project : Pediatric Critical Care; Nurse Practitioner; mechanical ventilation

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Airfare : Domestic

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Name : Natalie Napolitano, RRT

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"Role" on Project committee : Member

Area of Experties relevant to project : Registered Respiratory Therapist; Neonatology; Tracheostomy care and chronic mechanical ventilation

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Area of Experties relevant to project : Registered Respiratory Therapist; Pediatric Pulmonology; chronic mechanical ventilation

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Airfare : International

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Name : [Robert Graham, MD](#)
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Name : [Jeffrey D Edwards, MD](#)
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Name : [Hannah Zhu, MD](#)
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Name : [Sarah A Sobotka, MD](#)
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"Role" on Project committee : [Member](#)
Area of Experties relevant to project : [Developmental Pediatrics; Children with complex medical conditions; Children with complex medical conditions; tracheostomy and chronic ventilation](#)

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Airfare : Domestic

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Name : Michael J. Brenner, MD

Institution : University of Michigan School of Medicine; Global Tracheostomy Collaborative President

"Role" on Project committee : Member

Area of Experties relevant to project : Adult Otolaryngology (ENT); Tracheostomy care; Tracheostomy care; advanced surgical airway care

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Name : Jeremy D Prager, MD

Institution : Children's Hospital Colorado

"Role" on Project committee : Member

Area of Experties relevant to project : Otolaryngology (ENT); Tracheostomy care; pediatric airway; aerodigestive medicine

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Airfare : Domestic

Country : United States

Name : Karen Watters, MD

Institution : Boston Children's Hospital

"Role" on Project committee : Member

Area of Experties relevant to project : Otolaryngology (ENT); Tracheostomy care; pediatric airway; bronchoscopy

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Airfare : Domestic

Country : United States

Name : Karthik Balakrishnan, MD

Institution : Stanford University; Lucille Packard Children's Hospital

"Role" on Project committee : Member

Area of Experties relevant to project : Otolaryngology (ENT); Tracheostomy care; pediatric airway; aerodigestive medicine; Delphi consensus process

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Airfare : Domestic

Country : [United States](#)

Name : [Romaine F. Johnson, MD](#)

Institution : [University of Texas Southwestern](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Otolaryngology \(ENT\); Tracheostomy care; pediatric airway; aerodigestive medicine](#)

Email : romaine.johnson@utsouthwestern.edu

Airfare : [Domestic](#)

Country : [United States](#)

Name : [Evan Propst, MD](#)

Institution : [The Hospital for Sick Children](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Otolaryngology \(ENT\); Tracheostomy care; pediatric airway; aerodigestive medicine](#)

Email : evan.propst@sickkids.ca

Airfare : [International](#)

Country : [United States](#)

Name : [Alvaro Pacheco, MD](#)

Institution : [Hospital Luis Calvo Mackenna](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Otolaryngology \(ENT\); Pediatric airway](#)

Email : drpachecot@gmail.com

Airfare : [International](#)

Country : [Chile](#)

Name : [Marlene Soma, MD](#)

Institution : [Sydney Children's Hospital](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Otolaryngology \(ENT\); Tracheostomy care; pediatric airway](#)

Email : marlene.soma@health.nsw.gov.au

Airfare : [International](#)

Country : [Australia](#)

Name : [Jenny Shi, MD](#)

Institution : [The Hospital for Sick Children](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Pediatric Pulmonology; Fellow trainee](#)

Email : jenny.shi@sickkids.ca

Airfare : [International](#)

Country : [Canada](#)

Name : [Nadia Hoekstra, MD](#)

Institution : [Children's Hospital Colorado](#)

"Role" on Project committee : [Member](#)

Area of Experties relevant to project : [Pediatric Pulmonology; Fellow Trainee; global health \(2022-2023 in Malawi, Africa\)](#)

Email : Nadia.Hoekstra@med.unc.edu

Airfare : [Domestic](#)

Country : [United States](#)

Name : [Nathan \(patient\) and Crystal Hutchinson](#)

Institution : [Followed at The Hospital for Sick Children](#)

"Role" on Project committee : [Patient Advocate](#)

Area of Experties relevant to project : [Parent of a child with a tracheostomy](#)

Email : c.costante@hotmail.com

Airfare :

Country : [Canada](#)

Name : [Alex \(patient\), Uriah and Jody Koleski](#)

Institution : [Followed at Children's Hospital Colorado](#)

"Role" on Project committee : [Patient Advocate](#)

Area of Experties relevant to project : [Parent of a child with a tracheostomy](#)

Email : mobikole@gmail.com

Airfare :

Country : [United States](#)

Name : [Benjamin \(patient\), Sara Pedot and Gregory Futia](#)

Institution : [Followed at Children's Hospital Colorado](#)

"Role" on Project committee : [Patient Advocate](#)

Area of Experties relevant to project : [Parent of a child who elected NOT to pursue tracheostomy](#)

Email : sarapedot@gmail.com

Airfare :

Country : [United States](#)

* D. The ATS encourages diversity and inclusion on all its committees and projects and has identified several groups that have been historically under-represented on ATS committees. It may not be possible or needed to include all these groups on this project and there is no expected quota for diversity and

inclusion. To facilitate the review of the proposed committee, please complete this summary of diversity and inclusion. Please indicated if your proposed participants include any of the following [Underrepresented in Medicine Definition](#). Underrepresented in medicine means those racial and ethnic populations that are underrepresented in the medical profession relative to their numbers in the general population. [Underrepresented Group](#) Group underrepresented in the biomedical, clinical, behavioral, and social sciences, such as people with disabilities, people from disadvantaged backgrounds, and underrepresented racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders.

<p>Diversity : Women</p> <p>How Many? : 16</p> <p>Comments/Clarifications : Co-Chair and 50% of panelists (# not including patient advocates)</p>
<p>Diversity : Underrepresented minorities in medicine</p> <p>How Many? : 5</p> <p>Comments/Clarifications : African American, Hispanic/Latino, Black/African Canadian; hoping to add to this</p>
<p>Diversity : International representatives</p> <p>How Many? : 9</p> <p>Comments/Clarifications : Canada, UK, Australia, Italy, Chile (# not including patient advocates)</p>
<p>Diversity : Non-MD/DO professionals</p> <p>How Many? : 7</p> <p>Comments/Clarifications : Respiratory Therapists, Registered Nurses, Nurse Practitioners, Speech and Language Pathologists</p>
<p>Diversity : Patient/Family</p> <p>How Many? : 3</p> <p>Comments/Clarifications : 3 patients and their families; more may be involved</p>
<p>Diversity : Early career representatives</p> <p>How Many? : 2</p> <p>Comments/Clarifications : 2 pediatric pulmonology and long-term ventilation fellows</p>

SECTION IV - TIMELINE

Tentative timetable. Please provide a sufficiently detailed timeline to support that the necessary activities/tasks needed to complete the project will be completed within the expected timeframe (e.g., CPGs submitted for publications within 2 years; all other documents submitted within 1 year). This should include pre- and post meeting work, such as conference calls, in-person meetings, literature review, writing deadlines (outlines, first drafts, review by co-authors etc.). This section should NOT include meeting agendas. Please include a completion date for each task through submission for peer review (for

document projects) or completion (for non-document projects)

Activity/Task : [ATS Approval of CPG](#)

Location/Communication modality : [Email](#)

of Participants : 2

Anticipated Started Date (MM/DD/YYYY) : 12/01/2022

Anticipated Completion Date (MM/DD/YYYY) : 12/01/2022

Activity/Task : [Coordinate co-sponsorship of CPG by American Association of Otolaryngology Head and Neck Surgery](#)

Location/Communication modality : [email](#)

of Participants : 2

Anticipated Started Date (MM/DD/YYYY) : 12/02/2022

Anticipated Completion Date (MM/DD/YYYY) : 12/31/2022

Activity/Task : [Finalize PICO questions \(Amin, Baker\)](#)

Location/Communication modality : [email, virtual conference calls](#)

of Participants : 2

Anticipated Started Date (MM/DD/YYYY) : 01/01/2023

Anticipated Completion Date (MM/DD/YYYY) : 02/28/2023

Activity/Task : [Confirm PICO questions w/ full group, beging discussing outcomes](#)

Location/Communication modality : [Virtual Conference Call](#)

of Participants : 32

Anticipated Started Date (MM/DD/YYYY) : 03/11/2023

Anticipated Completion Date (MM/DD/YYYY) : 03/11/2023

Activity/Task : [Preliminary literature search in preparation for in-person CPG meeting \(Amin, Baker, methodologist\)](#)

Location/Communication modality : [email](#)

of Participants : 3

Anticipated Started Date (MM/DD/YYYY) : 03/12/2023

Anticipated Completion Date (MM/DD/YYYY) : 04/30/2023

Activity/Task : [In-person CPG Meeting \(see agenda; discuss search strategy and search criteria\)](#)

Location/Communication modality : [ATS annual meeting, Washington, DC](#)

of Participants : 32

Anticipated Started Date (MM/DD/YYYY) : 05/20/2023

Anticipated Completion Date (MM/DD/YYYY) : 05/20/2023

Activity/Task : [Conduct literature search and analyze results \(Amin, Baker, methodologist, librarian,](#)

PICO subgroup members)

Location/Communication modality: email, virtual conference calls

of Participants: 10

Anticipated Started Date (MM/DD/YYYY): 05/20/2023

Anticipated Completion Date (MM/DD/YYYY): 07/31/2023

Activity/Task: Select studies to be reviewed (Amin, Baker, methodologist, librarian, PICO subgroup members)

Location/Communication modality: email, virtual conference calls

of Participants: 10

Anticipated Started Date (MM/DD/YYYY): 08/01/2023

Anticipated Completion Date (MM/DD/YYYY): 08/31/2023

Activity/Task: GRADE literature, construct evidence, summary of findings, quality assessment tables, modified Delphi

Location/Communication modality: email, virtual conference calls

of Participants: 10

Anticipated Started Date (MM/DD/YYYY): 09/01/2023

Anticipated Completion Date (MM/DD/YYYY): 01/31/2024

Activity/Task: Full committee discussion of evidence. Preparation and grading of recommendations.

Location/Communication modality: Virtual Conference Call

of Participants: 32

Anticipated Started Date (MM/DD/YYYY): 02/01/2024

Anticipated Completion Date (MM/DD/YYYY): 05/31/2024

Activity/Task: Writing guidelines (Amin, Baker, PICO subgroup members)

Location/Communication modality: email, virtual conference calls

of Participants: 8

Anticipated Started Date (MM/DD/YYYY): 06/01/2024

Anticipated Completion Date (MM/DD/YYYY): 07/31/2024

Activity/Task: Distribution of guideline draft to full committee for comments

Location/Communication modality: email, virtual conference calls

of Participants: 32

Anticipated Started Date (MM/DD/YYYY): 08/01/2024

Anticipated Completion Date (MM/DD/YYYY): 09/30/2024

Activity/Task: Final guideline revision

Location/Communication modality: email, virtual conference calls

of Participants: 8

Anticipated Started Date (MM/DD/YYYY): 10/01/2024

Anticipated Completion Date (MM/DD/YYYY): 10/31/2024

Activity/Task: Submission to ATS Documents Editor

Location/Communication modality: email

of Participants: 2

Anticipated Started Date (MM/DD/YYYY): 11/01/2024

Anticipated Completion Date (MM/DD/YYYY): 11/30/2024

Activity/Task: Guideline final revisions

Location/Communication modality: email, virtual conference calls

of Participants: 32

Anticipated Started Date (MM/DD/YYYY): 12/01/2024

Anticipated Completion Date (MM/DD/YYYY): 12/31/2024

Activity/Task: Submission for peer review Preliminary literature search in preparation for in-person CPG meeting (Amin, Baker, methodologist)

Location/Communication modality: email

of Participants: 2

Anticipated Started Date (MM/DD/YYYY): 12/31/2024

Anticipated Completion Date (MM/DD/YYYY): 12/31/2024

SECTION V - BUDGETS

FY2023 PROPOSED ATS BUDGET

- * Round Trip Coach Airfare-Domestic (\$575 per person) Number of Persons? 0
- * Round Trip Coach Airfare-International (\$2000 per person) Number of Persons? 0
- * Hotel and per diem (Full Day Meeting at ATS Conference Fri & Sat Only) (\$425 per person) Number of Persons? 32
- * Breakfast Meeting at ATS Conference (\$75.00 Per Person) Number of Persons? 32
- * Lunch Meeting at ATS Conference (\$75.00 Per Person) Number of Persons? 32

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

* # of people 32

* # of minutes 90

* # of calls 6

* Medical Librarian - This item requires approval and justifications from document development staff (up to \$5000) 5000.00

Other Project Expenses

* Other Expense Budget Amount 1.00

* Other Expense Justification

NOTE: If accepted, the co-sponsoring society (AAOHNS) may also provide financial support for the eight Otolaryngology (ENT) committee members. Airfare is not being requested for panel members traveling to the 2023 ATS International Meeting. At our one in-person meeting, should any panel members not be able to attend, we will make arrangements for virtual attendance.

SECTION VI - Conflict of Interest Management

ATS members and others participating in official ATS projects have diverse experiences and relationships that positively contribute to project development. Disclosure and consideration of potential “conflicts of interest” (COI) relationships and personal interests that could be perceived as unduly influencing a participant’s generation or assessment of evidence, and thereby potentially misinforming healthcare decision makers is essential to assure that official ATS projects always reflect the best available evidence and scientific rigor. Therefore, for all proposed projects:

- Yes, I agree to follow COI rules

SECTION VII - Chair Acknowledgement

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

SECTION VIII - Revising Application After Reviewer Feedback

Please do not complete until Planning Committee reviews are received.

* Revision - Tell us what revisions have been made and how reviews from Planning Committee were addressed

We appreciate that the Pediatrics Assembly’s Planning Committee understands the need for this CPG and its timeliness. Additionally, their concerns have enabled us to strengthen the proposal through a revision. In response to the noted weaknesses, we have made the following changes:

1. Relevance Weakness 1: “Perhaps discussion, relationship to with/without ventilator use should be

considered.”

Co-chair response 1: Thank you. We added that this CPG will apply to all children with tracheostomies, including those with and without home ventilator use. We also mention the 2016 CPG for Pediatric Home Mechanical Ventilation (Sterni L, AJRCCM, 2016) which provides complementary guidance.

2. Relevance Weakness 2: There is “not a particular theme as to why the particular questions were chosen.”

Co-chair response 2: We have clarified in the proposal that the chosen questions pertain to urgent issues (those not addressed by prior consensus statements or those that warrant further guidance). Per standard CPG methodology, the panel will vote on the proposed PICO questions and are permitted to modify them as needed.

3. Relevance Weakness 3: “No clarity on how to ensure research sufficiently includes under-represented groups.”

Co-chair response 3: This is so important. By definition, the available research often fails to include under-represented groups. Our literature search will not exclude studies with this focus. Furthermore, we have a diverse panel to provide critical perspectives into these disparities. In the CPG manuscript, we will add a new “Impact on Under-represented Groups” section to each PICO question after “Implementation” and before “Justification” that describes existing disparities as well as the positive and negative ways the “ATS recommendation” will affect these at-risk populations.

4. Relevance Weakness 4: “The “ethics” of tracheostomy placement seems like a difficult question to address in a CPG. Perhaps the question should be centered around family-centered care and the involvement of the family in the decision and how best to educate the family - on both the pros and cons of placement prior to placement?”

Co-chair response 4: We agree that this PICO question will be difficult to address, yet has so much clinical relevance that we feel obligated to include it. Per the suggestion, we have reframed the question to focus on the involvement of families in the decision-making process.

5. Relevance Weakness 5: Some have “tracheostomies placed for airway issues who do not require pediatric pulmonary involvement.”

Co-chair response 5: Although this has historically been true in some cases, the co-chairs argue that a child who requires a device to breathe should be followed by a respiratory specialist (rather than by a surgeon alone). This team approach to care has been added to the proposal (and is the rationale behind this CPG being co-sponsored by an ENT society).

6. Relevance Weakness 6: Have “committee members from both small and large programs.”

Co-chair response 6: We have added a panel member from a small but well-known academic program in a small town (Tucson, AZ) with hope of adding this valuable perspective.

1. Methodology Weakness 1: “A few of the proposed personnel have retired”

Co-chair response 1: The panel has been updated. Anyone who is retired has agreed to participate if the CPG is funded.

2. Methodology Weakness 2: “Limited minority representation on the committee”

Co-chair response 2: The panel has been updated.

3. Methodology Weakness 3: “Consider deletion of PICO 5.”

Co-chair response 3: See response to Relevance Weakness 4. We agree PICO 5 will be challenging and are modifying it accordingly.

4. Methodology Weakness 4: Given the home nursing crisis, “consider a PICO to include recommendations about home nursing.”

Co-chair response 4: We absolutely agree that the home nursing crisis must be addressed. We will do so in PICO 1 which pertains to the need for an awake trained caregiver which is often not possible without home nursing.

5. Methodology Weakness 5: "7 representatives are from Children’s Hospital Colorado"

Co-chair response 5: The panel has been updated (with fewer Colorado representatives).

6. Methodology Weakness 6: “Unclear how much new evidence there is since the previous guidelines were published.”

Co-chair response 6: Although the paucity of relevant studies is a valid concern, many studies have been published during the past decade. Of the 2552 relevant publications in PubMed (search: tracheostomy AND pediatric), 1703 of them were published since April 2011 (the date of the literature search for the most recent consensus statement).

1. Project Scope Weakness 1: “Doesn't directly state specific expertise of all members”

Co-chair response 1: Each panel member’s “Area of Expertise” has been made more specific.

2. Project Scope Weakness 2: “May be better to plan more documents... decannulation alone ... could easily be its own CPG.” “Might be good to break this down and just focus on the first 2-3 PICO questions.”

Co-chair response 2: This is certainly a valid perspective. We also see the importance of addressing as many issues as possible when convening such a large group of experts. We are hoping to find balance with this and may end up removing one or more PICO questions for this reason. However, this suggestion

would involve completely restructuring the proposed methodology. For now, we hope to move forward as proposed, but will commit to adopting this approach if the panel and its methodologist see the need to do so.

3. Project Scope Weakness 3: “Not currently considering a second face-to-face meeting at the IC in year two”

Co-chair response 3: The co-chairs have participated in successful CPG development with more than one face-to-face meeting as well as with a single in-person meeting (due to the COVID-19 pandemic). Given the expense, we propose completing this CPG with a single meeting. However, were the need to arise, we would petition the ATS (and co-sponsoring society) for addition funding to meet again.

4. Project Scope Weakness 4: “Proposed timeline is somewhat vague... consider literature search preparatory to full committee meeting.”

Co-chair response 4: Detail added to timeline (including preliminary literature search before the in-person meeting).

* Can we share your application with ATS members if it is deemed a model application by the Program Review Subcommittee (PRS)?

Yes

ATS BUDGET SUMMARY CHART

Line Item	Budget Parameters	Number of Persons	Total
Round Trip Coach Airfare-Domestic (\$575 per person)	\$575.00	0	N/A
Round Trip Coach Airfare-International (\$2000 per person)	\$2,000.00	0	N/A
Hotel and per diem (Full Day Meeting at ATS Conference Fri & Sat Only) (\$425 per person)	\$425.00	32	\$13,600.00
Breakfast Meeting at ATS Conference (\$75.00 Per Person)	\$75.00	32	\$2,400.00
Lunch Meeting at ATS Conference (\$75.00 Per Person)	\$75.00	32	\$2,400.00
Conference Calls (# of people x # minutes x 0.10)	$32 \times 90 \times 0.10 =$ \$288.00	(# Calls) 6	\$1,728.00
Medical Librarian – This item requires approval and justifications from document development staff (up to \$5000)	\$5,000.00	N/A	\$5,000.00
Other Project Expenses – Must provide Budget justification	\$1	N/A	\$1.00
Note: Your proposed budget may be adjusted by staff and/or PRS to comply with ATS budgetary Policies and Procedures.		Total	\$25,129.00