

AMERICAN THORACIC SOCIETY DOCUMENTS

Optimizing Home Oxygen Therapy An Official American Thoracic Society Workshop Report

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Abstract

More than 1.5 million adults in the United States use supplemental oxygen for a variety of respiratory disorders to improve their quality of life and prolong survival. This document describes recommendations from a multidisciplinary workshop convened at the ATS International Conference in 2017 with the goal of optimizing home oxygen therapy for adults. Ideal supplemental oxygen therapy is patient-specific, provided by a qualified clinician, includes an individualized prescription and therapeutic education program, and offers oxygen systems that are safe, promote mobility, and treat hypoxemia. Recently, patients and clinicians report a growing number of problems with home oxygen in the United States. Oxygen users experience significant functional, mechanical, and financial problems and a lack of education related to their oxygen equipment—problems that impact their quality of life. Health care providers report a lack of readily accessible resources needed to prescribe oxygen systems correctly and efficiently.

Patients with certain lung diseases are affected more than others because of physically unmanageable or inadequate portable systems. Analysis is needed to quantify the unintended impact that the Centers for Medicare and Medicaid Services Competitive Bidding Program has had on patients receiving supplemental oxygen from durable medical equipment providers. Studies using effectiveness and implementation research designs are needed to develop and evaluate new models for patient education, identify effective ways for stakeholders to interface, determine the economic benefit of having respiratory therapists perform in-home education and follow-up testing, and collaborate with technology companies to improve portable oxygen devices. Generation of additional evidence of the benefit of supplemental oxygen across the spectrum of advanced lung diseases and the development of clinical practice guidelines should both be prioritized.

Keywords: advocacy; competitive bidding; durable medical equipment; mobility; oxygen

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Overview

The American Thoracic Society (ATS) Workshop on Optimizing Home Oxygen Therapy was funded by the ATS and convened at the 2017 ATS International Conference for the purpose of addressing the increased frequency of patient and clinician reports of problems with home oxygen in the United States. A group of experts was assembled and charged with the following goals: 1) develop a consensus definition for optimal home oxygen therapy; 2) identify key barriers to optimal home oxygen use; and 3) conceptualize potential strategies and solutions. This report summarizes the content of the full workshop.

The key conclusions are as follows:

- **Oxygen users frequently experience significant and clinically unacceptable problems** related to their oxygen equipment that decrease their quality of life. These include functional, mechanical, financial, and educational dimensions that affect their ability to work, exercise, travel, and interact with their families and community. Most patients are unaware of mechanisms by which to report and resolve their problems.
- **Many health care providers that prescribe oxygen lack the resources and knowledge needed to prescribe oxygen delivery systems and devices** correctly and efficiently to meet the specific needs of their patients. Clinicians and patients need better access to durable medical equipment (DME) personnel; existing prescriptions; guidelines on quality assurance, prescribing, and documentation; and educational programs and materials. Studies using effectiveness and implementation research designs are needed to develop and test educational programs for clinicians and to design seamless interfaces between clinicians, suppliers, payers, patients, and caregivers.
- **Patients with certain lung diseases and patients with higher oxygen needs are impacted to a greater degree than others** because of physically unmanageable and inadequate portable systems. Increased access to small, lightweight, higher flow systems is needed to optimize patient mobility in a framework that considers existing reimbursement constraints.
- **In the current health care climate, the services provided and business decisions made by DME companies constrain patients by restricting choices of stationary and portable oxygen equipment.** Transparency is needed around the processes and criteria that qualify DME personnel to educate patients about oxygen therapy and around how DME companies define, assess, and address quality assurance metrics. Moreover, we need to learn why current guidelines promulgated by the Center for Medicare and Medicaid Services (CMS) within the context of supplemental oxygen are not consistently being followed.
- **Analysis is needed to quantify the unintended impact that the Centers for Medicare and Medicaid Services competitive bidding (CB) policy has had on patients receiving supplemental oxygen from DME providers.** Several problems due, in part, to increasing financial constraints experienced by DME providers include the following: lack of availability of liquid oxygen (LOX), unreliable equipment, tighter limits on numbers of tanks and delivery schedules, inaccessibility of DME staff to field phone calls from patients, patient concerns regarding poor communication, and the removal of respiratory therapists to educate, test, and retest patients at home. Assessment of compliance by DME companies with current CMS quality control guidelines is needed to ensure appropriate matching of supplemental oxygen resources with each patient in competitive bidding areas and more recently in rural, noncompetitive bidding areas that are now subject to “competitive bidding–like” rate decreases.
- **Future research** should focus on developing and evaluating new models for therapeutic oxygen patient education, identifying effective ways for stakeholders to interface, determining the economic benefit of having respiratory therapists perform in-home education and follow-up testing to confirm that patients continue to meet predefined criteria, and collaborating with technology companies to improve portable oxygen devices. Evidence supporting selection of patients who benefit from oxygen is lacking and future investigations are needed to gain this understanding.

The Patient Experience: *"I am a 69-year-old woman with lymphangiomyomatosis who uses oxygen with exertion, sleep, and air travel. I am retired but still travel frequently for meetings related to my volunteer work for two patient advocacy organizations. The obstacles I have encountered started with a 4-week delivery delay when I was first prescribed my oxygen. While I had been tested on a continuous-flow, liquid oxygen system, my supplier could only provide me with pulse-dose compressed air tanks and a heavy floor concentrator. When I flew I was charged an extra \$300/week out of pocket for rental of a portable oxygen concentrator [POC] and had to make a 40-mile round trip to pick it up and return it. Finally, I purchased my own POC for nearly \$4,000, but I am afraid to let my supplier know due to concerns that they might remove all of my rented home oxygen equipment. I cannot make any other plans on delivery day since I do not know what time they will come. I find it very frustrating and disheartening that there seems to be an assumption that all people who require oxygen do nothing but sit at home tethered to an oxygen hose. In fact, if provided with sufficient oxygen, we tend to be healthier and can continue to contribute to our families and to society."*

Introduction

More than 1.5 million Americans use supplemental oxygen, a therapy that can improve the quantity and quality of life for adults living with chronic lung diseases (1–3). There are reports of inconsistent symptomatic and functional improvements from oxygen in patients with interstitial lung disease (ILD) (4–6) and chronic obstructive pulmonary disease (COPD) (7, 8), making it challenging for clinicians to identify which patients will benefit most from supplemental oxygen. Despite unpredictable responses, oxygen remains a treatment option for those who meet prespecified criteria and who seek relief from dyspnea and hypoxemia.

Although there are no formal published data, advocacy groups, health care professionals, and patients anecdotally report an alarming frequency of implementation gaps in home oxygen. These include insufficient education and training programs, receiving equipment different from that prescribed, malfunctioning equipment, delays in receiving services, insufficient

reimbursement, and lack of longitudinal monitoring. Patients requiring high-flow oxygen (>3 L/min) are limited to inadequate and physically unmanageable portable oxygen delivery options, especially since the consensus of this panel confirms that LOX has virtually disappeared from some parts of the United States as an option, despite it being listed as a provided benefit (CMS Publication No. 11045) under the CMS Competitive Bidding Program. This major barrier to adequate health care results from the high cost of LOX relative to the fixed reimbursement to oxygen suppliers from CMS. Without LOX, patients who require higher flow oxygen for mobility, and cannot lift heavier metal tanks, now often find themselves homebound.

Besides creating a *de facto* restriction on access to liquid oxygen, the significant cuts in reimbursement to DME suppliers that accompanied CMS's Competitive Bidding Program have contributed to decreased patient services such as education

and in-home assessment and monitoring by respiratory therapists (9–13). A significant number of patients do not need long-term oxygen therapy (LTOT) indefinitely after hospital discharge, but few patients are reassessed after discharge (14) or have adequate evaluation and documentation of their oxygen needs (15).

Patient advocacy groups and foundations are attempting to address patient concerns and advocate on their behalf to improve reimbursement to DME suppliers in the hope of elevating the quality of home oxygen services to patients (13, 16). Work with the CMS Competitive Acquisition Ombudsman (CAO) and patient advocacy efforts have generated additional documentation of the experiences of beneficiaries. Even though specific guidelines for quality and service are described in CMS's "Supplier Quality Standards and Beneficiary Protections," compliance with existing standards is low (17–19). A variety of customer assistance call-in or web-based "action lines" are also

in place, including the COPD Info Line, 1-800-MEDICARE, case management and problem resolution assistance from the CAO, and "People for Quality Care" advocacy group. Unfortunately, quantitative or qualitative data on the use and effectiveness of these service and reporting systems are not published or shared with patients or clinicians. Nor have they resulted in any change in oxygen service or in the Competitive Bidding Program. In stark contrast to an increasing number of anecdotal and published reports by patients and clinicians of the wide-ranging problems with supplemental oxygen, a 2016 CMS report about the impact of CB on supplemental oxygen users stated that "Medicare has saved approximately \$3.6 billion while health monitoring data indicate that its implementation is going smoothly with few inquiries or complaints and no negative beneficiary health outcomes" (20).

Crucial impetus for this workshop was provided by findings from the May 2016 ATS Nursing Assembly *ad hoc* Oxygen

Table 1. Key comments from the Centers for Medicare and Medicaid Services

Topic	CMS Comments
Federal regulations	<ul style="list-style-type: none"> Federal regulations at 42 CFR 414.422(e) specify that as a term of their contracts, suppliers under the DMEPOS Competitive Bidding Program (CBP) must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the competitive bidding area (CBA) and who requests those items from that contract supplier. Liquid oxygen (HCPCS codes E0442 and E0444) and liquid oxygen equipment (HCPCS codes E0433, E0434, and E0439) are items under the contracts for furnishing respiratory equipment and a contract supplier for this product category must furnish these items to any beneficiary living in or visiting the CBA if they request these items from the contract supplier. As a term of the contract, the supplier cannot refuse to furnish liquid oxygen and oxygen equipment
Complaint reporting mechanisms	<ul style="list-style-type: none"> It is important for discharge planners, physicians, and beneficiaries to use the existing inquiry and complaint mechanism to inform CMS if contract suppliers are not furnishing items as required. While we appreciate the feedback from stakeholders, the most effective way of resolving any potential conflict is to contact 1-800-MEDICARE or the Competitive Bidding Implementation Contractor (responsible for competitive bidding contractor oversight)
Clinician provider resources	<ul style="list-style-type: none"> Since the start of this work a number of system enhancements have been authorized, including the following: <ol style="list-style-type: none"> The initiative "Patients over Paperwork" with a goal to reduce unnecessary burden, increase efficiencies, and improve beneficiary experience Establishment of new medical review strategies to reduce claims denials and appeals (Targeted Probe and Educate) Efforts to simplify medical documentation include gathering feedback from stakeholders (reducingproviderburden@cms.hhs.gov) Resource updates including Medicare Learning Network materials "Home Oxygen Therapy" and Joint DMEMAC (supplier) and A/B MAC (physician) educational programs Development of clinical templates to be used by physicians to improve medical information used to place orders for DME, reduction of appeals backlog, prior authorization of certain products, and tailored education and training by DMEMACs
Reimbursement	<ul style="list-style-type: none"> The internal review and analysis of inquiries and complaints has helped to inform these changes and improvements CMS issued an Interim Final Rule with comment to deliver relief to providers through increased fee schedule rates from June to December 2018 furnished in noncompetitive bidding areas

Definition of abbreviations: A/B MAC = Jurisdiction A/Region B Medical Equipment Administrative Contractor; CBA = competitive bidding area; CBP = Competitive Bidding Program; CFR = Code of Federal Regulations; CMS = Centers for Medicare and Medicaid Services; DMEMAC = Durable Medical Equipment Medicare Administrative Contractor; DMEPOS = Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; HCPCS = Healthcare Common Procedure Coding System.

Working Group that addressed the many, widespread problems experienced by supplemental oxygen users.

This ATS Oxygen Workshop was created with the following goals:

1. Define optimal home oxygen therapy.
2. Characterize the existing barriers to optimal home oxygen therapy at the patient, health care provider, DME oxygen provider, and health care system levels and propose solutions to overcome these barriers.
3. Propose strategic advocacy and lobbying efforts integrated across the many stakeholders in this area, aiming to improve patient access to optimal home oxygen therapy.
4. Identify evidence gaps and propose focused areas for future investigation and device development.

Methods

Preworkshop

After confirmation of funding, the two co-chairs convened a multidisciplinary team with diverse expertise and viewpoints related to the proposed workshop goals. The group was composed of respiratory physicians and nurses, respiratory therapists, patient oxygen users, representatives from multiple patient advocacy groups, and the American Lung Association, ATS Health Policy Committee, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the American Association for Respiratory Care, Apria Healthcare, and the CMS.

Four working groups, led by the subgroup chairs, addressed oxygen-related issues specific to 1) patients (four patient advocacy group representatives, two patients,

one clinician, and one CMS representative), 2) clinicians (eight clinicians), 3) DME oxygen providers (one national provider representative, two clinicians, one American Association for Respiratory Care leader, and one FDA representative), and 4) payers/ lobbyists (five representatives involved in various ATS, patient, and lobbying organizations). The four working groups reviewed available literature to establish an evidence base, conducted conference call discussions within their subgroups, and prepared a summary before the workshop. A systematic literature review was not undertaken because of the scant literature available in this area.

Workshop

The workshop schedule (*see* the online supplement) started with a morning session

Table 2. Current advocacy efforts and concerns: select statements*

Advocacy Group	Comments
American Lung Association	<ul style="list-style-type: none"> ● The American Lung Association is committed to ensuring that education of both CMS and Congress continues regarding patients’ differing oxygen needs, the lack of liquid oxygen, and the challenges patients face in understanding how to properly use their devices. Patients who require oxygen have different needs, which require different measures
Alpha-1 Foundation	<ul style="list-style-type: none"> ● A thorough examination and appropriate adjustment of reimbursement rates to allow suppliers to maintain patient-centric service is vital to meaningful impact. Data-driven responses by both CMS and Congress are now possible, and improvement of modality availability (per prescription), resolution of sub-par equipment, adequate supply, and timely distribution should be legislative targets with appropriate budgetary backup
American Thoracic Society	<ul style="list-style-type: none"> ● Quality measures and standards for oxygen delivery are unclear; we need to determine what essential elements should be measured in order to improve oxygen delivery. Example: CB rules established quality standards for providers to meet before participating in the CB program. The rules could be changed to require ongoing collection of data that measures the quality of service provided
COPD Foundation	<ul style="list-style-type: none"> ● There is a need to work with CMS to access and use data from Certificate of Medical Necessity (CMN) forms (e.g., how many patients have had to discontinue use of liquid oxygen, reasons for discontinuance of liquid oxygen, the breakdown of diagnoses of supplemental oxygen users, and any available survival data for oxygen users). Such data are desperately needed to inform policy change
LAM Foundation	<ul style="list-style-type: none"> ● Patients who are <65 yr old and in need of supplemental oxygen often lead active lives and can sustain better health when proper supplemental oxygen devices and prescriptions are available. These patients have little to no recourse for support when their insurers or DME suppliers fail to deliver. Supplemental oxygen must be regulated and treated as a necessary prescription for certain conditions such as LAM. Patients are at a disadvantage when they are dealing with a DME or insurance provider who has control of their oxygen supply (and their life)
Pulmonary Fibrosis Foundation	<ul style="list-style-type: none"> ● The Pulmonary Fibrosis Foundation advocates for a revised reimbursement structure that ensures that patients receive enough supplemental oxygen to maintain adequate oxygen saturation levels while engaging in activities in their homes and the community. This reimbursement structure should be flexible enough to address the needs of patients on high-flow oxygen (especially patients who require liquid oxygen), patients who need portable oxygen systems, and patients whose needs change over the disease course
Pulmonary Hypertension Association	<ul style="list-style-type: none"> ● Some people with PH receive Medicare due to age or disability, whereas others with well-managed disease continue to work. Those who work not only need access to their oxygen equipment at home and in their workplace, they may also have professional travel requirements
National Association for Medical Direction of Respiratory Care	<ul style="list-style-type: none"> ● CMS refers to “home oxygen therapy” but the goal for patients is to be able to get <i>out</i> of their home. Consider renaming this workshop as “supplemental” oxygen therapy and recommend that CMS consider renaming their written resources as well
American Association for Homecare	<ul style="list-style-type: none"> ● The American Association for Homecare will encourage and promote professional excellence, advance the science and practice of respiratory care, and serve as an advocate for patients to have improved access to oxygen delivery systems and devices

Definition of abbreviations: CB = competitive bidding; CMN = certificate of medical necessity; CMS = Centers for Medicare and Medicaid Services; COPD = chronic obstructive pulmonary disease; DME = durable medical equipment; LAM = lymphangioliomyomatosis; PH = pulmonary hypertension.

*See online supplement for full comments.

to provide expert presentations in key areas: the patient perspective (M.H.), the impact of relevant historical oxygen study results (R.C.), an overview of the CMS oxygen coverage guidelines, and the CMS DME quality standards (T.D.) (21, 22), an update on available ATS Patient Supplemental Oxygen Survey data (S.S.J.), and a panel presentation from three members with expertise in oxygen-related patient advocacy (J.L.S.), lobbying (P.P.), and ATS governmental relations (G.W.E.). After these presentations, the patient, clinician, DME, and payer subgroups presented their summaries.

The second half of the workshop consisted of an interactive discussion of the entire group to flesh out additional issues, followed by “mixed” subgroup discussions to focus on strategies and solutions, which were presented to the entire group. A summary of action items with timelines ended the workshop.

After the workshop, the subgroup chairs and workshop presenters submitted their written summaries to the co-chairs to incorporate into one manuscript. Additional references were added that were either missed or not available at the time of the workshop. The draft manuscript was reviewed and edited on multiple occasions by the full committee.

Results

Background and Existing Evidence Related to Home Oxygen Therapy

Influence and results of previous investigations or workshops.

UPDATE ON ATS NURSING ASSEMBLY PATIENT SUPPLEMENTAL OXYGEN SURVEY DATA. S.S.J. presented data from the Nursing Assembly online survey (17) that included responses from 1,926 adult supplemental oxygen users in the United States. One-half of the respondents reported having “problems” with their oxygen, including equipment malfunction, lack of portable options (especially for travel), and lack of physically manageable and high-flow options. Seventy percent of respondents reported that they had no more than 4 hours of portable oxygen supply, yet 81% of respondents reported that they desired more than five. Respondents reporting oxygen problems more frequently had an emergency room visit or hospitalization during the previous year and were less likely than other

respondents to have received oxygen education from a health care professional (17). Qualitative data from write-in responses revealed consistent themes of anxiety and worry related to inadequate systems often leading to social isolation (18). These findings indicate inadequate compliance by DME companies with existing CMS quality and beneficiary protection standards.

EXISTING EVIDENCE FOR LONG-TERM OXYGEN THERAPY. R.C. presented an overview of key investigations related to oxygen therapy in patients with COPD, emphasizing that the underlying rationale is not simply to obtain satisfactory oxygen saturations, improve symptoms, or enhance exercise tolerance, but to improve survival. The Nocturnal Oxygen Therapy Trial Group (2) and the Medical Research Council Working Party (3) published the results of multicenter randomized clinical trials of oxygen in 1980 and 1981, respectively, and the role of LTOT in patients with COPD and severe resting

room air hypoxemia. Results of the two COPD oxygen trials indicated that LTOT reduced mortality in an apparent dose-dependent manner. These results from the Nocturnal Oxygen Therapy Trial and Medical Research Council studies form the key evidence for our practice today.

Two previous multidisciplinary Oxygen Consensus Conferences in 2000 (23) and 2006 (1) identified research priorities for investigating the efficacy of LTOT in patients with COPD with resting, exertional, and nocturnal hypoxemia. They concluded that additional investigations were warranted to examine and compare outcomes of oxygen use versus no oxygen use in patients with mild resting hypoxemia, nighttime-only hypoxemia, exertion-only hypoxemia, or hypoxemia both during rest and during exercise.

The 2016 randomized Long-Term Oxygen Therapy Trial (24) examined the long-term benefit of oxygen on all-cause mortality or hospitalization in patients with

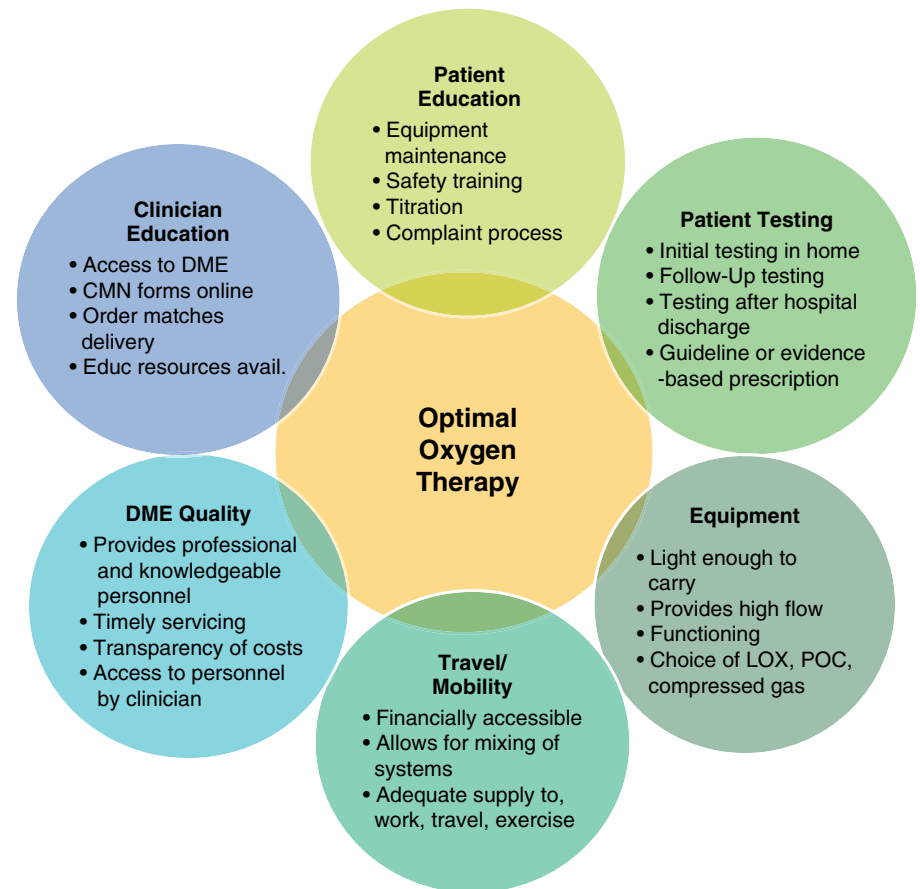


Figure 1. Conceptual model of optimal oxygen therapy. CMN = Certificate of Medical Necessity; DME = durable medical equipment; LOX = liquid oxygen; POC = portable oxygen concentrator.

COPD with moderate resting (89–93%) or isolated exertional desaturation not exceeding 90%. The control group received no oxygen therapy and the treatment group received both stationary and ambulatory oxygen systems. Results confirmed that, in this cohort of patients with COPD, there was no benefit of oxygen supplementation on the primary outcome (first hospitalization or death) or secondary outcomes of quality of life, depression, anxiety, or functional exercise performance (24).

There are minimal data on adherence in LTOT users or on the effect of LTOT on activity levels in everyday life (25). Entirely unknown is whether or not existing patients receiving LTOT meet prescribing criteria. In a sample of 50 patients with COPD who were receiving oxygen, 38% did not meet blood gas oxygen criteria (26), and in another study, 41% of 237 participants did not meet the criteria for home oxygen (27).

In summary, these findings confirmed that oxygen prolongs survival in patients with COPD who are severely hypoxemic at rest, but additional research is needed to determine whether supplemental oxygen improves other outcomes meaningful to patients with COPD or other chronic respiratory conditions. It may be considered that, by restricting the provision of supplemental oxygen to only those who meet prescribing criteria, resources can be freed to provide optimal therapy to those who will benefit. Therefore, the need for evidence or guideline-based recommendations to identify which patients most benefit from supplemental oxygen therapy is a concurrent issue to address.

Key points on Centers for Medicare and Medicaid Services: T.D. described how the role of the CAO is to resolve complex

concerns and to provide education about the CB program. Clinician providers also have available the Competitive Bidding Implementation Contractor to assist them or their patients in finding suppliers and reporting complaints for further investigation. After this workshop, new initiatives to improve the ordering process to eliminate denials of claims have been established, including the development of templates to give improved guidance on what is needed to show medical necessity in the ordering process.

T.D. provided information on the complaint process that is a critical component for CMS to document and resolve concerns. In addition, the “Medicare Coverage of Home Oxygen Therapy” (21) and “CMS DMEPOS Quality Standards” (22) were reviewed, highlighting the CMS guidelines for oxygen eligibility, required documentation, and criteria to receive oxygen items and equipment for home use. Additional CMS points are presented in Table 1.

During the subsequent discussion, workshop attendees described their experiences with current practice, which was not always in accordance with these guidelines. Attendees identified problems such as required equipment maintenance not being performed, delivered equipment not matching clinician orders, and the paucity of education patients received on how to operate their equipment or troubleshoot problems as they arise. It was unanimously agreed that identifying an effective and user-friendly mechanism by which clinicians and patients can provide the CMS with feedback is a priority. Patients reported that they were either unaware of the CMS 1-800-MEDICARE number, experienced prolonged wait times, or had

difficulty getting connected to an advocate. Data collected from the 1-800-MEDICARE number are collated by CMS and provided to Congress as needed to propose changes, but patients and health care providers do not have access to this information.

Current advocacy and lobbying efforts. Select comments on advocacy efforts and concerns discussed at the workshop are shown in Table 2, with the full summary in Table E2 in the online supplement.

Consensus Definition of Optimal Home Oxygen Therapy

The workshop members came to consensus on the definition of optimal oxygen therapy (Figure 1, Box 1, and Table E2).

Barriers to Optimal Home Oxygen Therapy: Key Findings of Stakeholder Groups

Barriers to optimal home oxygen therapy, by stakeholder group, are presented in Table 3.

The patient’s perspective. The patient subgroup noted barriers to optimal oxygen that included confusion and lack of awareness of available oxygen delivery systems and devices, lack of a “patient-centric” approach to oxygen, and the general “alarm” over the past 3–4 years experienced by advocacy foundations that have received an increase in requests for assistance from their patients to resolve their oxygen problems.

There are few published patient-reported data regarding oxygen problems. The ATS Nursing Assembly Patient Supplemental Oxygen Survey noted that the most frequent problems reported by patients were equipment malfunction, lack of portability (too heavy to manage), reduced availability of liquid oxygen systems (that provide high flow and portability), and

Box 1. Definition of optimal home oxygen therapy.

Optimal oxygen therapy prioritizes maximizing each individual patient’s quality-of-life and health outcomes with a goal to minimize the burden on patients, their families, providers, payers, and oxygen suppliers.

Key Principles:

- *Optimal oxygen therapy requires an effective and transparent interface between patients, caregivers, clinicians, durable medical equipment (DME) companies, and payers to ensure patient-centered, long-term management of hypoxemia.*
- *A qualified clinician provides initial and ongoing assessment of hypoxemia, and establishes a guideline or evidence-based oxygen prescription during rest, exertion, and sleep (and high altitude as needed) and ensures an individualized action plan and therapeutic oxygen patient education program.*
- *The collaborative efforts of the clinician and DME company provide patient-centered oxygen systems that are clinically effective and safe, support maximal long-term mobility and management of hypoxemia, and address comorbidities including frailty, cognitive and/or physical impairments, as well as patient financial constraints.*

Table 3. Barriers to optimal home oxygen therapy by stakeholder group

Stakeholder Group	Identified Barriers
The patient	<ul style="list-style-type: none"> ● Variation in, or lack of, oxygen saturation testing practices ● Inadequate patient education on use of oxygen (“drop-shipping” of equipment, use of voluminous technical equipment manuals) ● Wide variety of oxygen equipment and patient unawareness of their choices ● Absence of safeguards to protect the patient if their DME goes out of business—including short notice, no written notice, no assistance from the closing DME ● Malfunctioning equipment combined with a lack of DME company regulation of equipment maintenance ● Testing or requalification in the outpatient setting on different oxygen devices than the patient uses at home ● No reimbursement combined with extremely challenging processes to arrange for air travel, or oxygen set up at a travel destination
The clinician	<ul style="list-style-type: none"> ● Unawareness of the rights of oxygen users and the processes by which to report problems ● Lack of collaborative clinical guidelines that elucidate the elements of an optimal prescription causing delivery delays, or finding that the prescribed oxygen system is not available ● Unsafe and problematic direct marketing from oxygen companies to patients and families without clinician input or local equipment service and support ● Difficult and time-consuming process for clinician access to compare and evaluate information on available oxygen delivery systems and devices ● Inability of the clinician to speak directly to the DME providers at the time of oxygen ordering ● Patients not receiving an initial global evaluation, including the impact of their disease trajectory, changing oxygen needs, and/or removal of oxygen when no longer needed due to resolution of hypoxemia ● Absence of outcome measures for oxygen therapy such as survival, quality of oxygen supplier services, and patient adherence to oxygen therapy ● Limited use of therapeutic patient education: providing information alone is not sufficient ● Clarity on the part of the ordering clinician as to what role CMS and CB play when few or restricted portable systems are available and what appeal process is available
The DME oxygen supplier	<ul style="list-style-type: none"> ● Imprecise, poorly written and documented oxygen prescriptions and recertifications that need to be reworked multiple times and result in delayed delivery of oxygen to the patient, frustration for all concerned, and jeopardization of DME reimbursement ● Referring health care providers’ lack of knowledge regarding qualifying criteria for supplemental oxygen, the various equipment and accessories, and required documentation ● A paucity of knowledgeable personnel at the DME offices with whom to confer ● An ineffective working interface between health care providers and DME suppliers including the use of paper forms requiring hard copy signatures ● No standardization of qualifying testing; health care providers cannot test patients on all equipment and accessories in the office—most medical offices have, at best, E-type cylinders equipped with continuous flow regulators ● No awareness by health care providers in the hospital or in offices of the limitations of the individual patient’s home environment and lifestyle ● Diminished role of professional respiratory therapists (RTs) in the home setting. RTs in the home setting could improve the efficacy and efficiency of the system by assessing both the initial and ongoing need for oxygen, ensuring appropriateness of equipment, educating patients and families about proper oxygen use, assessing functionality of equipment, etc. ● DME companies’ reliance on their delivery drivers to be the eyes and ears in the home; the education and training of DME drivers is unclear ● Various government cost containment initiatives over the past two decades have resulted in industry revenue losses, particularly from the 2011 Competitive Bidding Program ● DME companies today in rural areas receive approximately one-half the reimbursement they received in 2015 for a typical home oxygen setup (AAHC data presented in workshop)
The payer	<ul style="list-style-type: none"> ● Lack of communication and coordination with DMEs impacts patients, clinicians, and clinical outcomes ● DMEs often underutilize RTs to provide home oxygen assessment, setup, monitoring, and patient/caregiver training. This increases the potential for poor quality, and inadequate effectiveness and safety ● Patients often cannot access appropriate light-weight portable and/or transfilling systems, POCs, high-flow systems including liquid oxygen, and transtracheal oxygen catheters, further limiting clinical effectiveness and independence ● DMEs often advise patients and clinicians that these systems are not available or provided by the DME, despite CMS rules ● Patient and clinician questions, advice, and concerns are managed by DMEs that have a vested and potentially biased interest in their response to these queries ● Oxygen equipment technology has greatly improved over the past 20 yr to more effectively meet the needs of hypoxemic patients, yet systems currently used employ outdated technology from the twentieth century ● Legislative statutes related to oxygen reimbursement are outdated, with reimbursement tied to a 2-L/min flow rate and no reimbursable service component. Clinical effectiveness is not a measured outcome under the current structure. The existing framework ignores variability of patient oxygen requirements, response, and adherence with missed opportunities for clinical effectiveness and adherence ● Finally, DMEs are reimbursed at a 45% lower rate compared with precompetitive bidding levels, with DMEs incentivized to bid low to be awarded contracts. This saves CMS money, but has resulted in a decline in service, clinical effectiveness, adequate equipment options, potential lack of patient mobility and its related consequences, and the vital role of the DME home respiratory therapist

Definition of abbreviations: AAHC = American Association for Homecare; CB = competitive bidding; CMS = Centers for Medicare and Medicaid Services; DME = durable medical equipment; POCs = portable oxygen concentrators; RTs = respiratory therapists.

Table 4. Key themes and strategies identified to address barriers and gaps

Feature/Goal	Elements
Meet educational needs of patients	<ol style="list-style-type: none"> 1. Incorporate patient preference as to whether they want to use supplemental oxygen after a discussion with their health care providers and being presented expected benefit of use, risk of nonuse, and explanation of medical need 2. Mandate patient education be provided to meet FDA 483 and CMS statutes 3. Revise instruction to “titrate as they migrate” (implementation of home oximetry for self-titration of LTOT flow rate) concept 4. Provide every patient with a: <ol style="list-style-type: none"> a. “Bill of Rights” for supplemental oxygen users (CMS has one) b. Clear, effective, and user-friendly process for reporting unresolved oxygen problems to CMS provided by DME at time of equipment delivery c. “FAQ” sheet, “Oxygen Start Sheet” d. “YouTube”-type video instruction e. “Oxygen Action Plan”—part of global assessment 5. Establish a national consumer mechanism to access clinician and patient feedback on all DMEs; have these data available to patients, clinicians, and CMS. Use model similar to Medicare’s “Nursing Home Compare” (https://www.medicare.gov/NursingHomeCompare/search.html), or Joint Commission on Accreditation (JCAH; https://www.jointcommission.org) 6. Emphasize potential role of DMEs in keeping patients out of the hospital 7. Tailor education on equipment choices by diagnosis, e.g., COPD low flow and long term, vs. ILD high flow and shorter term 8. Establish mandated, minimum required patient oxygen educational content and provide through novel approaches in clinics, pulmonary rehabilitation programs, and online programs 9. Ideas discussed included: “Oxygen Management Program,” “Oxygen Center,” “Oxygen Clinics,” “Oxygen Navigator,” “Oxygen Kiosks,” “Certified Oxygen Educators,” and include family/caregivers and trained peer educators 10. Create standardized oxygen education content in pulmonary rehabilitation programs to address the problems documented in recent patient surveys (17–19) 11. Explore telemedicine to monitor adherence, efficacy, and ongoing need 12. Create separate education and monitoring pathways for hospital discharge vs. home oxygen setups as the patient needs; follow-up differs for these two groups
Meet educational needs of clinicians	<ol style="list-style-type: none"> 1. Disseminate existing CMS oxygen-prescribing resources 2. Create an ATS Oxygen website with separate tabs for clinicians and patients for rapid access to prescribing guidelines 3. Collaborate with CMS to allow electronic provider signature on the Certificate of Medical Necessity (CMN) forms to avoid delays in delivery 4. Develop universal online DME prescription and testing forms to avoid delays in delivery 5. Incorporate oxygen education for MDs (pulmonologists and PCPs), APPs, RNs, RTs, home health aides, etc., in board questions and in professional and vocational training content 6. Collaborate with multidisciplinary groups to establish Supplemental Oxygen Therapy Guidelines specific to each lung disease
Provide ongoing monitoring and reassessment of supplemental oxygen users’ needs	<ol style="list-style-type: none"> 1. Recently discharged and newly prescribed patients require follow-up oxygen testing to assess effectiveness and adherence, and discontinuation of equipment for patients who no longer meet predefined criteria. The optimal follow-up interval needs to be defined yet the current 1-yr reevaluation requirement likely contributes to inadequacies in effectiveness and adherence 2. Assess the impact of RTs in the home setting on decreasing CMS costs by identifying oxygen users who no longer meet its prescribing criteria, providing preventive education, maintaining equipment, and improving adherence 3. Create a billable CMS code for DME services (not just products), including RT visits for assessing the adequacy of the current oxygen prescription and providing self-management education, both in-home or within a physician practice setting during a “face-to-face” follow-up appointment 4. Create billable CMS codes for oxygen supplies, including transtracheal oxygen (TTO) 5. Create telemedicine strategies to track patient adherence to their oxygen therapy prescription. Provide this feedback to the prescribing physician so as to inform their discussions with patients 6. Discharge nonadherent patients. Use RTs in-home to assess
Assess objective measures of DME service quality	<ol style="list-style-type: none"> 1. Create interface between CMS and DMEs to monitor and quantify DME outcomes to ensure CMS rules are followed 2. Improve clinician utilization of available CMS education, resources, and established feedback mechanisms so that payers can track and analyze patterns and trends in DME and oxygen utilization, access, and customer service 3. Describe performance metrics, oxygen delivery personnel training, audit procedures, and quality benchmarks for DMEs; make results available to patients and clinicians

(Continued)

Table 4. (Continued)

Feature/Goal	Elements
Provide and improve access to oxygen equipment to optimize mobility	<ol style="list-style-type: none"> 1. Fund technology research <ol style="list-style-type: none"> a. Remote control, wireless technology for patients to change liter flow without desaturating while they walk to their stationary concentrator, which may be on another level or room within their home (e.g., used for sleep in an upstairs bedroom) b. Improved POC battery life, weight, and size (e.g., engaging automotive and space technology [e.g., NASA]) c. High-flow technology—need more powerful, compact, lightweight POCs d. Improved pulse oximeter performance (reliability during movement, sensitivity in patients with peripheral circulation issues) e. Predictive/precision interactive technology that adjusts oxygen flow using oxygen saturation feedback f. Online CMN completion to streamline and standardize the oxygen prescription process, reduce errors, and expedite setup. Use online repository 2. Revise reimbursement practices <ol style="list-style-type: none"> a. Assess the impact of current reimbursement methodologies b. Reimburse by prescribed oxygen flow rate; the current system is based on 2 L/min c. Revise reimbursement criteria to address high-flow users' need for liquid or TTO, working patients' need for additional systems/mixing of systems d. Change the oxygen benefit to provide a DME service component reimbursement; currently only equipment is reimbursed e. Collaborate with national organizations such as AARC and AAHC and patient groups to collect data on patient oxygen issues related to reimbursement 3. Provide portable equipment to allow unrestricted mobility and employment outside of the home 4. Perform time-of-delivery (or preassessment in clinic), in-home patient assessment to determine patients' size/weight/strength, presence of stairs, driving, exercise, use of assistive devices, travel, etc., in order to deliver appropriate equipment 5. Investigate the CMS QA process and data collection/analysis/conclusions on patient-reported problems 6. Create interactive CMS website with oxygen use and problem-solving toolkits for patients and providers 7. Remove oxygen from DME or create separate category (do not include with wheelchairs, beds, etc.)

Definition of abbreviations: AAHC = American Association for Homecare; AARC = American Association for Respiratory Care; APP = advanced practice provider; CMN = Certificate of Medical Necessity; CMS = Centers for Medicare and Medicaid Services; COPD = chronic obstructive pulmonary disease; DME = durable medical equipment; FAQ = frequently asked questions; FDA = Food and Drug Administration; ILD = interstitial lung disease; LTOT = long-term oxygen therapy; MDs = doctors of medicine; NASA = National Aeronautics and Space Administration; PCP = primary care practitioner; POC = portable oxygen concentrator; QA = quality assurance; RN = registered nurse; RT = respiratory therapist; TTO = transtracheal oxygen.

the lack of portable oxygen concentrators (POCs) that deliver continuous, high-flow oxygen (17). They also encountered issues with access to oxygen, inadequate insurance coverage, and equipment/information/service that did not meet their needs. The combination of needing oxygen and these other issues led to anxiety/concern/worry, resulting in impaired quality of life and social isolation (18). After this workshop, additional survey data supported these findings. Dobson DaVanzo & Associates were commissioned by the American Association for Home Care to survey beneficiaries, case managers, and DME suppliers on the effects of the Competitive Bidding Program. Similar to results from the ATS Nursing Assembly's survey, this group found that 56.9% of home oxygen users reported problems accessing DME suppliers and/or services (19).

The clinician's perspective. From the clinician's perspective, the primary barriers to optimal supplemental oxygen therapy include the lack of clinical guidelines, limitations of current equipment (high flow and portability), equipment not matched to meet each patient's supplemental oxygen

needs, the current reimbursement structure, and other concerns listed in Table 3. Durable Medical Equipment, Prosthetic, Orthotic, and Supplies (DMEPOS) guidelines currently address actions that should be undertaken by suppliers and clinicians in cases of noncompliance, but it is unclear who is accountable for assessing and reporting compliance problems. Clinical guidelines are needed that define health care team members' roles, address the essential elements of an oxygen prescription, specify which patients it should be prescribed for, describe who will educate patients about oxygen therapy, and explain the competitive bidding process (1, 28–31).

Inconsistent instruction and education to patients, families, and caregivers on the use and care of equipment can undermine adherence and safety. Two factors that impact patient adherence with oxygen therapy as prescribed are regular follow-up and communication between health care providers and patients as well as the use of portable devices (7). Innovative approaches to patient education, such as regional or mobile clinics and telemedicine (remote monitoring),

would likely improve the current state of absent or fragmented communication and follow-up. For example, in addition to the initial test for a patient to qualify for supplemental oxygen, periodic retesting is important to document the ongoing need, remove patients from the risk of therapy (fire, tripping hazards) who no longer qualify, adjust settings, and further individualize oxygen delivery devices and systems.

The DME oxygen supplier's perspective. The DME subgroup identified three key areas of concern: 1) clinicians' lack of oxygen equipment knowledge and the qualifying ordering process related to the CMS Certificate of Medical Necessity; 2) the lack of evidence and consensus around the optimal assessment and reassessment of oxygen need, including the qualification of DME personnel as educators; and 3) the impact of government reimbursement initiatives on DME revenue.

Competitive bid pricing has forced DME companies to find less expensive ways to do business, including eliminating products and services, decreasing staff, and closing offices. According to the American

Association for Home Care, the total number of DME companies in the United States has dropped from 10,465 in July 2013 to 6,181 as of April 2017 (9). Because of its cost, liquid oxygen equipment, once the staple for oxygen users needing high flow or for those needing lightweight, long-lasting portability, has been significantly reduced since competitive bid pricing went into effect. In fact, many smaller DME companies in rural areas report that, to stay afloat, they have had to switch their entire business to a “nondelivery” model of home-fill units and portable oxygen concentrators. The combination of limited equipment choices and fewer DME companies creates poor access and both scarcer and lower quality services for patients. After this workshop, input was solicited from a rural

DME supplier as none was represented within the workshop group (see the online supplement). Solicitation revealed additional barriers unique to rural communities.

The consequences to patients of poor reimbursement to DME companies are recognized (2, 3). CMS and other payer organizations should be encouraged to reimburse at levels that will ensure patients have access to basic services “appropriate for the individual patient’s clinical and daily lifestyle needs” and “LTOT should be reimbursed adequately for the LTOT delivery device, accessories, and associated LTOT services provided, linked to approved standards of care when available, and wherever possible based on clinical outcomes research” (1). CMS’s own

“DMEPOS Quality Standards” specify that “the supplier shall govern its business so that it obtains and provides appropriate quality equipment, item(s), and services(s) to beneficiaries” (22), yet this appears to be impossible under the current reimbursement structure.

The payer’s perspective. From the payer’s perspective, many of the challenges influencing optimal oxygen provision and use were similar to those of other stakeholders. Specific to this group’s perspective was a focus on outdated legislative statutes and a payer system that does not promote clinical effectiveness. The current framework for managing outpatient hypoxemia uses oxygen delivery systems that are often inappropriate, inadequate, and at times unsafe for ambulation. Patients

Table 5. Potential research questions to address gaps and barriers of optimal oxygen therapy

Area of Research	Questions for Investigation
Technology	<ol style="list-style-type: none"> 1. What other oxygen delivery device options could be developed to raise inspired oxygen in addition to the existing Oxymizer pendant and Oxymizer mustache cannulas? 2. What cloud-based technology will measure effectiveness of oxygen therapy, patient activity levels, and adherence? 3. Can a uniform CMN electronic platform be developed to streamline qualifying for, ordering, and documentation of oxygen coverage? 4. Can technology research develop remote control, wireless, predictive/precision interactive technology to adjust oxygen flow remotely, or use oxygen saturation feedback to do so? 5. Is there technology to allow for an increase in the concentrating ability of POCs to allow higher continuous flow settings? 6. Can collaboration with industry research and development companies identify a longer-lasting, smaller, and lighter POC battery?
Health care resource utilization	<ol style="list-style-type: none"> 1. Can access to CMS data from the CMN form provide outcome data and trends of health care utilization and survival based on diagnosis/ICD10 code, type of oxygen system used, and flow rate prescription? 2. What interventions would reduce overuse, underuse, and misuse of supplemental oxygen, and reduce the rates of emergency room visits and/or hospital admissions? 3. Does use of a respiratory health care professional to monitor ongoing home supplemental oxygen use and qualification decrease health care resource utilization by discontinuing service to those patients who no longer qualify?
Education	<ol style="list-style-type: none"> 1. Can tools for patients and clinicians to understand and interface with CMS and DMEs decrease clinician time, improve time to set up for oxygen patients, and improve adherence to prescribed oxygen therapy? 2. How can the existing CMS clinician oxygen educational resources be more accessible to clinicians in their work settings? 3. What are the essential components or minimal requirements for supplemental oxygen patient education and assessment? 4. What modality best provides oxygen education? (PR, kiosks, oxygen clinics, written, face-to-face, etc.) 5. How can we increase utilization of PR programs as one option to improve patient oxygen education?
Reimbursement	<ol style="list-style-type: none"> 1. How can ATS collaborate with advocacy and governmental organizations to change existing statutes that ignore service quality, clinical outcomes, and high flow rates? 2. Would a payment system based on DME quality metrics, results, and patient feedback improve DME oxygen services?
Risk factors for nonadherence	<ol style="list-style-type: none"> 1. How is successful oxygen adherence defined? 2. What are the risk factors that predict a patient’s nonadherence to their oxygen prescription? 3. What system-, provider-, and patient-level interventions can be implemented to promote appropriate use of supplemental oxygen?
Criteria for oxygen in non-COPD populations	<ol style="list-style-type: none"> 1. Investigate factors that determine which patients benefit from supplemental oxygen therapy

Definition of abbreviations: CMN = Certificate of Medical Necessity; CMS = Centers for Medicare and Medicaid Services; COPD = chronic obstructive pulmonary disease; DME = durable medical equipment; ICD10 = *International Classification of Diseases, 10th Revision*; POC = portable oxygen concentrator; PR = pulmonary rehabilitation.

with severe hypoxemia have particularly few options. Appropriate patient assessment and training by clinicians competent in the management of hypoxemia may be lacking. An individualized approach is needed to address specific challenges for patients who may be cognitively impaired, have very severe hypoxemia, live in a home with numerous potential physical obstacles (e.g., pets, furniture, stairs), work outside the home, have small children, or are caregivers themselves.

Key Themes and Strategies Identified to Address Barriers and Gaps

This workshop was the first gathering of its kind to amass input from all stakeholders to address the multiple concerns around supplemental oxygen being reported nationally by patients and clinicians. The overwhelming consensus of workshop participants was that a call to action is urgently needed to develop a universally accepted, adequately funded, comprehensive oxygen program, which should include a process for identifying which patients most benefit from supplemental oxygen. Key features of such a program identified by the multidisciplinary workshop groups are shown in Table 4 and include a major focus to better meet the educational needs of patients and their caregivers regarding expectations for the benefits of oxygen, written and verbal instructions on the safe use of their equipment, and effective mechanisms to report and resolve problems. Improving clinician education will likely yield more timely delivery of oxygen equipment to patients and can be facilitated by web-based oxygen ordering and information on matching equipment to patients' needs. Evidence-based clinical guidelines and research should help identify which patients most benefit from supplemental oxygen. Quality measures are needed not only to identify benchmarks for DMEs to meet, but also to measure outcomes of patients using oxygen.

Areas of Future Research

The research questions for future investigation should focus on 1) technology for remote control or feedback oxygen devices, and for high-flow portable devices, 2) health care resource utilization including retesting and integration of CMS oxygen data, 3) establishment of required patient oxygen education, 4) reimbursement system revisions to incorporate quality

metrics and oxygen system requirements, 5) assessment and predictors of adherence, and 6) establishment of evidence or guideline-based therapy (including use in non-COPD populations), incorporating health care outcomes of economics, quality of life, dyspnea, and mobility (Table 5).

Conclusions

Findings of this workshop confirm the existence of significant barriers to optimal supplemental oxygen therapy from all stakeholders' perspectives, which have been validated by subsequent publications (17, 19, 32, 33). The successful implementation of the proposed strategies will require strong interdisciplinary partnerships and integration of data to change policy, enhance care quality, and improve patient outcomes. The workshop goal of lessening gaps in clinician knowledge and evidence-based practice is being addressed by the May 2018 ATS-funded Oxygen Clinical Practice Guidelines project, as well as by oxygen-related programming submissions for the ATS International conference in 2019. Advocacy for policy and payer changes occurred with ATS Patient Supplemental Oxygen Survey data presentations at Capitol Hill briefings and the formation of "Oxygen Coalitions" to target policy changes. From the patient stakeholder group's perspective, advances in oxygen device technology are long overdue and were addressed through a patient-driven process to fund research to develop a remote control oxygen device (34).

This ATS workshop confirmed a definable crisis in supplemental oxygen delivery in the United States and identified key strategies to mobilize urgent attention and intervention. ■

This workshop report was prepared by an *ad hoc* subcommittee of the ATS Assemblies on Nursing, Clinical Problems, and Behavioral Science and Health Services Research.

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