

Recommendations of the 6th Long-Term Oxygen Therapy Consensus Conference

Dennis E Doherty MD and Thomas L Petty MD
for the Writing and Organizing Committees

Introduction

In 1986, the first of the series of long-term oxygen therapy (LTOT) consensus conferences was held in Denver, Colorado. Its aim and the aim of those that followed was to consider emerging issues and problems in LTOT prescribing, reimbursement, and access, as well as education and research challenges. Subsequent conferences were held in 1987, 1990, 1993, and 1999. The reports of these were published.¹⁻⁵ These conferences helped to create and pave the way for advances in prescribing LTOT, such as the Certificate of Medical Necessity for LTOT (ie, the oxygen prescription and reimbursement criteria). These conferences also stressed the challenges for the education of physicians and other respiratory professionals involved in the care of LTOT patients, and the need for technological standards.

Each conference used a modification of the Delbecq nominal-group interactive method.⁶ This method assures that all participants' issues are aired in an anonymous and/or open-forum fashion, and that all thoughts are considered in small breakout groups and then again in a final

session where consensus recommendations are finalized by all participants.

It was important for all participants to understand that the development of consensus is a group process, and not an individual dominance, a majority rule, nor a "voting" method. This process was first used in America by the Quakers, who needed a nonconfrontational "common sense" (consensus) method in dealing with contentious issues. In the consensus-development method, no votes are taken. This method avoids dualism. This is intended to be a rational way of seeking general agreement. Consensus does not mean unanimity. Those who participate in consensus development do not always get their way; they agree with the group that moving forward in areas of minor disagreement, as well as in areas of agreement, is better than strife over individual issues. This was the concept that the organizers put forth and the participants of the 6th LTOT Consensus Conference followed.

The first day and a half of the conference provided state-of-the-art lectures and discussions by experts in subjects of relevance in LTOT, from "History" to "Current Evidence" to "Current Practical Aspects" to "Needed Research" in the LTOT arena. On the afternoon of the second

Dennis E Doherty MD is affiliated with the Division of Pulmonary, Critical Care, and Sleep Medicine, University of Kentucky, Lexington, Kentucky and is Chairman of the National Lung Health Education Program. Thomas L Petty MD is affiliated with the Department of Medicine, University of Colorado Health Sciences Center, and the National Lung Health Education Program, Denver, Colorado.

The 6th Long-Term Oxygen Therapy (LTOT) Consensus Conference was held in Denver, Colorado, August 25-28, 2005. LTOT stakeholders in attendance included LTOT patients, patient groups, physicians, nurses, respiratory therapists and other respiratory-care professionals, governmental and other regulatory agencies, LTOT payers, manufacturers, and providers (see the appendix for the full list of participants). The recommendations and opinions presented in this report do not necessarily represent the thoughts or opinions of the organizations the participants represented, but rather represent a consensus of the entire group of participants. All attendees filled out and signed a disclosure form identifying any potential conflicts of interest before they were allowed to participate in the consensus process.

All participants and/or organizations that they represented financed their own travel to and expenses at the conference, with the exception of some patients and physicians whose expenses were covered in part or in whole

by conference funds. All funds generated by the conference from the sponsors listed below were expended on the above costs, conference facilities, and other usual costs of running a conference. Funds left over will be expended on the publication of a manual, "The History of Oxygen," co-authored by the co-chairs of this conference.

Sponsors (in alphabetical order): AirSep; Chart BioMedical (Caire); Cardinal Health Respiratory; CHAD Therapeutics; COPD Partners; DeVilbiss (Sunrise Medical); Inogen; Invacare; Lincare; Luxfer Gas Cylinders; The Med Group; Nonin Medical; OxyTec Medical; Tyco Healthcare/Puritan Bennett; Precision Medical; Respiroics; SeQual Technologies; Transtrachael Systems; VGM and Associates. No one sponsor contributed more than 9% of the total funds donated.

Correspondence: Dennis E Doherty MD, Division of Pulmonary, Critical Care, and Sleep Medicine, Department of Internal Medicine, College of Medicine, University of Kentucky, 740 S Limestone, Room K-528, Lexington KY 40536-0284.

day, 5 smaller breakout consensus-development groups were assigned to consider the following areas: (1) clinical issues, (2) manufacturer issues, (3) home-medical-equipment suppliers issues, (4) patient issues, and (5) research.

The last day of the conference, when all participants reconvened and the chairs/co-chairs of the breakout groups reported on their respective breakout group's conclusions, led to vigorous and very productive discussions about certain features of LTOT technology. One subject that generated healthy discussion, upon which a full consensus was not reached, was what defines systems that are basically "stationary" versus "portable" versus "wearable." Although everyone agreed that many of the newer LTOT devices that are available may fit into the categories "stationary," "portable," or "wearable," no general agreement could be reached about the specifications of such devices. That is, it was agreed that a "portable" or "wearable" device should be a size and weight that allows the patient to do activities of daily living suitable to his or her own lifestyle while maintaining proper oxygen saturation, but the group could not come to a consensus with regard to the specific weight or configuration of these devices. It was agreed that specific recommendations for these variables may be possible in the future if appropriate research studies are designed and performed.

The only other subject of substantial controversy, upon which consensus could not be reached, was the issue of the necessity for recertification of the LTOT prescription, particularly when LTOT is initiated for chronic stable patients with hypoxemia (see Recommendation #13 regarding recertification when LTOT is initially prescribed for an exacerbation of COPD). This topic received liberal discussion. No firm recommendations were made. Of interest, these 2 controversial issues were also vigorously considered at the 5th LTOT consensus conference.⁵ Other less contentious issues were also discussed by all participants, and consensus was strongly reached, as outlined below.

Today approximately one million Americans receive LTOT, at a cost of over 2 billion dollars per year. The recent emergence of new technologies, as well as the definite need for additional evidence-based scientific research to understand the needs and benefits of LTOT, dictated that this 6th LTOT conference be convened. It is wholeheartedly hoped by the organizers and participants of this well-attended 6th LTOT Conference that the following recommendations will help to facilitate not only an improved recognition of the needs and benefits of LTOT, but also to stimulate the design and funding of focused research that will further establish the benefits of LTOT. In the end, this will lead to the unanimous goal of all participants, to help those who are the focus of this conference: the LTOT patients.

Recommendations From the 6th LTOT Consensus Conference

1. In order to assure quality LTOT patient care, we recommend comprehensive education for patients, prescribing primary-care and specialist physicians, respiratory therapists (RTs) and other respiratory professionals, regulatory agencies, payers, families, caregivers, and the public. Easy-to-use, understandable, and readily available educational resources should be further developed to meet these needs, including printed and audiovisual materials, as well as Internet resources. LTOT education should also be incorporated into the curriculum of health-professional training programs for those who will provide care to LTOT patients. Consensus was not reached with regard to the practicality and requirement for credentialed educators to initiate and follow LTOT delivery to patients. However, it was agreed that such programs of education and/or certification should be developed and implemented to meet these potential needs in the future.

2. Clinical educational materials should be developed and provided to the patient and LTOT caregiver/provider, including but not limited to the following topics:

- Details of competitive bidding, with quality standards (supplier selection process)
- Self-monitoring (eg, spirometry, oxygen liter flow, and oxygen saturation)
- Reimbursement (eg, the criteria of the Centers for Medicare and Medicaid Services [CMS] and other 3rd-party payers, including managed-care organizations)
- Compliance and adherence to the LTOT prescription
- Benefits and availability of pulmonary rehabilitation
- What to do in emergency situations (eg, loss of electrical power or malfunction of stationary/portable delivery devices, such as liquid-oxygen source equipment)

3. All patients of all groups should have access to the appropriate LTOT delivery systems and accessories, to optimize maximal medical compliance, activities of daily living inside and outside the home, and travel (planes, trains, automobiles, and cruise ships). Patients should have access to respiratory-care professionals adequately trained in LTOT, on an intermittent basis, in the home/place-of-residence or the clinic, depending on the patient's degree of mobility, as deemed appropriate by the physician or physician-designated respiratory-care professional following that patient's LTOT.

4. Standards for LTOT should be further developed that would provide clinical practice guidelines that, whenever possible, are evidence-based and/or supplemented by expert opinion. These standards should be interdisciplinary and address the role of not only physicians, but also of RTs and other allied health and respiratory professionals pro-

viding LTOT care. The pediatric patient should also be considered in the development of these standards. These standards, for example, could include, but should not be limited to, indications for LTOT, patient education, matching the proper LTOT delivery device and accessories to the patient's needs and abilities, appropriate monitoring, the role of pulmonary rehabilitation, and current policies and procedures for travel with supplemental oxygen therapy. Performance measures should be established to evaluate quality of care.

5. All patients who are provided an intermittent-flow device (which is one category of oxygen-conserving devices) must be clinically evaluated and titrated to the intermittent flow required by the specific device being employed, in order to ensure optimal oxygen delivery for that individual patient during rest and during routine activities of daily living.

6. Consideration should be encouraged for improving all of the processes involved in the delivery of LTOT. This would include education for physicians, case managers, discharge planners, home-medical-equipment providers, RTs, and other professionals involved in the management of LTOT patients.

7. Evidence-based criteria are needed to define "ambulatory," "portable," and "wearable" oxygen technologies as they apply to each specific patient's clinical and lifestyle needs, on an individualized basis. Until such evidence exists, the physician, patient, and home-medical-equipment provider must effectively collaborate, using their best efforts and state-of-the-art knowledge in that time frame to ensure that all LTOT users have access to the best and most appropriate technologies that fit their clinical and lifestyle needs.

8. 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. Reimbursement obstacles to providing quality LTOT in the patient's home or other place of residence by RTs or other respiratory-care professionals should be resolved, as well as obstacles to providing comprehensive pulmonary rehabilitation. Reimbursement should be based on the LTOT device that is "best for the patient," as prescribed by an MD or DO.

9. CMS and other payer organizations should be encouraged to support appropriate reimbursement that will ensure access to innovative technologies that are appropriate for the individual patient's clinical and daily lifestyle needs.

10. LTOT should be incorporated into the disease-management/health-maintenance approach to the comprehensive care of patients with chronic lung and/or cardiac disease. This recognizes the importance of providing an interdisciplinary continuum of care across all sites, including, but not limited to, facilitating access to pulmonary

rehabilitation by adequate reimbursement. The benefits of such disease management should be evaluated on an ongoing basis by appropriate outcome evaluations and performance-improvement measures.

11. Funding should be provided for research to evaluate the outcomes and cost-effectiveness of LTOT, including, but not limited to, research on the safety and efficacy of established as well as new oxygen-delivery devices, and research on other indications for LTOT, such as enhancing quality of life and reduction of symptoms. This might be accomplished by joint projects with CMS and other payers and research organizations, and by helping to recruit patients needed for ongoing and future research studies.

12. All professional and lay organizations and societies should incorporate LTOT patients into their advocacy efforts for LTOT.

13. We recommend development of a demonstration project(s) to evaluate the utilization of resources for LTOT and to incorporate compliance data into a recertification process(es) when oxygen is prescribed in acute situations. An example might be establishment of a regional facility for conduct of recertification examinations. Such a center would be capable of evaluating LTOT prescription at rest, during exercise, and during sleep. Studies should utilize the equipment modality that the patient is currently using or will be using in the near future. Recommendations might also be made as to the LTOT modality that would provide greatest benefit for the patient, based on his or her individualized activities of daily living and lifestyle (at rest and during usual daily activity). This would relieve the prescribing primary-care physician, pulmonologist, RT, or home-medical-equipment provider from the responsibility of conducting these examinations. Feedback should be provided to the physician/clinician and home-medical-equipment provider. A study to evaluate the need for an initial LTOT prescription following an exacerbation of COPD and for the need to continue LTOT after recovery and stabilization is recommended.

Writing Committee

Dennis E Doherty MD (Co-Chair)

Thomas L Petty MD (Co-Chair)

William Bailey MD

Brian Carlin MD

Richard Cassaburi MD

Kent Christopher MD

Paul Kvale MD

Barry Make MD

Douglas Mapel MD

Paul Selecky MD

Jon Tiger

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Appendix
Sixth Oxygen Consensus Conference
August 25-28, 2005
Final Attendee Roster

Peter Almenoff MD
VHA National Program
Department of Veterans Affairs
Kansas City, Missouri

Charlie Atlas
OxyTec Medical Corporation
Anaheim Hills, California

William Bailey MD
University of Alabama Lung Health
Center
Birmingham, Alabama

Gary Bain
Emphysema Foundation For Our Right
to Survive (EFFORTS)
Claycomo, Missouri

Peter Bliss
OxyTec Medical Corporation
Prior Lake, Minnesota

Tim Buckley RRT
Walgreen's DME/Homecare Division
Deerfield, Illinois
(Representing American Association for
Respiratory Care)

Mary Burns RN
Pulmonary Education/Research
Foundation
Lomita, California

Vicky Butler
Luxfer Gas Cylinders
Nottingham, England

Jim Byington
Mountain Aire Medical
Colorado Springs, Colorado

Brian Carlin MD
Allegheny General Hospital
Pittsburgh, Pennsylvania
(Representing American Association for
Cardiovascular and Pulmonary
Rehabilitation)

Richard Casaburi MD
Harbor-UCLA Medical Center
Torrance, California

Geralyn Chin
Tyco Healthcare/Puritan Bennett
Pleasanton, California

Kent Christopher MD
Pulmonary Division
University of Colorado Health Sciences
Center
Denver, Colorado

Lyn Cole
LTOT Patient
Littleton Colorado

Ronald Cook
Emphysema Foundation For Our Right
to Survive (EFFORTS)
Morrow, Georgia

Terry deBruyn RRT
Nonin Medical.
Plymouth, Minnesota

Dennis E Doherty MD (Co-Chair)
Division of Pulmonary, Critical Care,
and Sleep Medicine,
University of Kentucky
and
National Lung Health Education
Program (NLHEP)
Lexington, Kentucky

Patrick Dunne RRT
Healthcare Productions
Fullerton, California
(Representing American Association for
Respiratory Care)

Dan Easley
COPD Partners
Longmont Colorado

Gerard Ely
Linde Gas Therapeutics
Rueil Malmaison France

Bob Fary RRT
Inogen
Goleta, California

Edna Fiore
NE California Patient/Family Advisory
Council
and
COPD Connection newsletter
Littleton, Colorado

Dennis Fitzgerald RRT
AirSep Corporation
Buffalo, New York

John Frank
Respironics
Murrysville, Pennsylvania

Mary Gilmartin RN
National Jewish Hospital
Denver, Colorado

Len Godfrey
Cardinal Health Respiratory
McGaw Park, Illinois

John Goodman RRT
Transtrachael Systems
Englewood, Colorado

Laura Havrilla
Respironics
Murrysville, Pennsylvania

Jeff Hennelly
Chart Industries (Caire)
Burnsville, Minnesota

Mark Higley
VGM and Associates
Waterloo, Iowa

Mary Hirsh-Erslon RN
Tyco Healthcare/Puritan Bennett
Pleasanton, California

John Hiser RRT
Respiratory Care Program
Tarrant County College
Hurst, Texas

Robert Hoover Jr MD
Sunrise Medical
Nashville, Tennessee

RECOMMENDATIONS OF THE 6TH LONG-TERM OXYGEN THERAPY CONSENSUS CONFERENCE

Eulia Hudson LTOT Patient Denver, Colorado	Barry Make MD Emphysema/Rehab National Jewish Medical/Research Center Denver, Colorado	Jenna Pedersen RRT Lincare Clearwater, Florida
Pamela Jackson SeQual Technologies. San Diego, California	Douglas Mapel MD Lovelace Clinic Foundation Albuquerque, New Mexico	Vernon Pertelle RRT Alexandria, Virginia (Representing American Association for Home Care)
Stephen Krentler Precision Medical Northampton, Pennsylvania	Jacquelyn McClure RRT National Respiratory Network and The Med Group Pittsburgh, Pennsylvania	Thomas L Petty MD (Co-Chair) Department of Medicine University of Colorado and National Lung Health Education Program Denver, Colorado
Paul Kvale MD American College of Chest Physicians and Henry Ford Health System Detroit, Michigan	Robert McCoy RRT Valley Inspired Products Apple Valley, Minnesota	Tom Pontzius VGM and Associates/Nationwide Respiratory Waterloo, Iowa
Marty Lannon LTOT Patient Prior Lake, Minnesota	Jon McLellan RRT Respironics Murrysville, Pennsylvania	Phillip Porte National Association for Medical Direction of Respiratory Care Vienna, Virginia
Frank Lazzaro Respironics Murrysville, Pennsylvania	Carolyn McMahon Cardinal Health Respiratory McGaw Park, Illinois	Terry Preston Chad Therapeutics Leawood, Kansas
John Ledek Invacare Corporation North Ridgeville, Ohio	France Meder Luxfer Gas Cylinders Riverside, California	Ed Radtke SeQual Technologies San Diego, California
Joe Lewarski RRT Inogen Goleta, Georgia	Bob Messenger RRT Invacare Elyria, Ohio	J Daryl Risinger Inogen Goleta, California
Angelo Libertore AirSep Corporation Buffalo, New York	Bob Mogue OxyTec Medical Corporation Anaheim Hills, California	Barbara Rogers National Emphysema/COPD Association New York, New York
Michael Littner MD Pulmonary, Critical Care and Sleep Medicine Virginia Greater Los Angeles Healthcare System Sepulveda California (Representing Department of Veterans Affairs)	Peter Mosby Lincare Indianapolis, Indianapolis	Raj Roychoudhury Tyco Healthcare/Puritan Bennett Pleasanton, California
Holly Lockwood LTOT Patient Grand Junction, Colorado	Louise Nett RRT National Lung Health Education Program Denver, Colorado	Vlady Rozenbaum COPD-AlabamaERT Silver Springs, Maryland
Karen Lui RN Southwest Florida Heart Group Fort Meyers, Florida	Marcia Nusgart, RPh Coalition of Respiratory Care Manufacturers Bethesda, Maryland	Shino Sakai Teijin Pharma Limited Tokyo, Japan
	Adrian Oleck MD AdminaStar Federal Indianapolis, Indiana	

RECOMMENDATIONS OF THE 6TH LONG-TERM OXYGEN THERAPY CONSENSUS CONFERENCE

Robert Sandhaus MD
Alpha-1 Foundation
and
National Jewish Hospital
Denver, Colorado

Cheryl Sasse
Minnesota Lung Association
St Paul, Minnesota

Paul Selecky MD
Hoag Hospital
Newport Beach, California
(Representing American College of
Chest Physicians)

Len Serafino
Chad Therapeutics
Chatsworth, California

Steve Shaw
Chart BioMedical (Caire)
Marietta, Georgia

Clyde Shuman
Precision Medical
Northampton, Pennsylvania

Rem Siekmann
Sunrise Medical - Respiratory Product
Division
Somerset, Pennsylvania

Joseph Smith RRT
Invacare Corporation
Elyria, Ohio

Joseph Sokolowski Jr MD
National Association for Medical
Direction of Respiratory Care
Medford Lakes, New Jersey

Patrick Strollo Jr MD
UPMC Sleep Medicine Center
Montefiore University Hospital
Pittsburgh, Pennsylvania

Patricia Tanquary PhD
Contra Costa Healthcare
Martinez, California

Brian Tiep MD
Respiratory Disease Management
Institute
Irwindale, California
(Representing American Thoracic
Society)

Jon Tiger
National Home Oxygen Patients
Association
Wichita, Kansas

John Tooker MD
American College of Physicians
Philadelphia, Pennsylvania

Jun Ueki MD
School of Health Care and Nursing
Department of Respiratory Medicine
Juntendo University
Tokyo, Japan

Peter Wagner MD
American Thoracic Society
and
University of California, San Diego
La Jolla, California

Scott Wilkinson
Invacare Corporation
Elyria, Ohio

Thomas Williams
Inogen
Scottsdale, Arizona

Jeff Wills
HME/RT Advisory Council
CV Medical Solutions
Oklahoma City, Oklahoma

Peter Wilson
PortableOxygen.org
Spotsylvania, Virginia

Monika Worlin
Cardinal Health Respiratory
McGaw Park, Illinois

David M Young
Cardinal Health Respiratory
McGaw Park, Illinois

Writing Committee

Dennis E Doherty MD (Co-Chair)
Division of Pulmonary, Critical Care,
and Sleep Medicine
University of Kentucky
and
National Lung Health Education
Program
Lexington, Kentucky

Thomas L Petty MD (Co-Chair)
Department of Medicine
University of Colorado
and
National Lung Health Education
Program
Denver, Colorado

William Bailey MD
UAB Lung Health Center
Birmingham, Alabama

Brian Carlin MD
Allegheny General Hospital
Pittsburgh, Pennsylvania
(Representing American Association for
Cardiovascular and Pulmonary
Rehabilitation)

Richard Casaburi MD
Harbor-UCLA Medical Center
Torrance, California

Kent Christopher MD
Denver, Colorado

Paul Kvale MD
American College of Chest Physicians
Henry Ford Health System
Detroit, Michigan

Barry Make MD
National Jewish Medical/Research
Center
Denver, Colorado

Douglas Mapel MD
Lovelace Clinic Foundation
Albuquerque, New Mexico

Paul Selecky MD
Hoag Hospital
Newport Beach, California
(Representing American College of
Chest Physicians)

Jon Tiger
National Home Oxygen Patients
Association
Wichita, Kansas