Long Term Oxygen Therapy (LTOT)

History, Scientific Foundations, and Emerging Technologies

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6th Oxygen Consensus Conference Recommendations

National Lung Health Education Program

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Preface

Long term oxygen therapy (LTOT) is well established as the standard of care for many patients with chronic stable hypoxemia. Most studies have been done in Chronic Obstructive Pulmonary Disease (COPD), but patients with other causes of chronic hypoxemia and its consequences are also likely to benefit. Both the length and quality of life are improved with LTOT used inside and outside the home. It is believed that increased blood flow to central organs, made possible by increasing exercise with ambulatory oxygen, is the main reason for those benefits.

Industry has continued to produce new ultra-light weight oxygen systems, which can truly be called "ambulatory." Low weight oxygen concentrators are making oxygen travel more practical and realistic for patients who require oxygen around the clock. At the very time that these advances are occurring, third party payors, mainly Medicare, are continuing to plan reductions in reimbursement for newer systems. A realistic reimbursement system is critical to the future of LTOT, which, involves the lives of approximately 1.2 million Americans.

The original purpose of this monograph was to provide background for participants in the Sixth Oxygen Conference held in Denver, Colorado in August 2005. (2006 *RespCare* 51(5):519-525) The purpose of this booklet is to provide the important historical and scientific highlights for LTOT and to present a better understanding of the new life that occurs with LTOT.

This booklet briefly presents the history of LTOT and the state of our knowledge about the scientific basis for LTOT. Emerging technologies promise to make LTOT more available and effective for the growing number of patients with a medical necessity for LTOT. Increased mobility is key to improving quality of life.

1. Historical Highlights

History records that oxygen was first discovered by Joseph Priestley on August 1, 1774, when he obtained a colorless gas by heating red mercuric oxide. He recognized that the candle flame would burn brighter in what he had termed "dephlogisticated air." He captured the gas in an inverted bell, and he and two mice were the first to breathe this "pure air." He noted a "light and easy feeling" and remarked, "who can tell but that in time this pure air may become a fashionable article in luxury."[1,2] Carl Wilhelm Scheele, a Swedish chemist, also discovered oxygen, maybe as early as 1773.[3] Priestley's friend, Antoine Lavoisier, successfully repeated Priestley's original experiment and named the newly discovered gas oxygen. Oxygen was first used clinically in dental anesthesia as early as 1868.

The first recorded use of oxygen, during the treatment of acute bacterial pneumonia, was in York, Pennsylvania, on March 6, 1885. Dr. George Holtzapple produced oxygen from chlorate of potassium and black oxide of manganese by heating the chemicals in a large glass cylinder with a flame from a lamp. The resultant oxygen was delivered via rubber tubing to the face of a young man who was dying from pneumonia (presumably secondary to the consequences of his hypoxemia). After several hours the crisis passed and the young man recovered.[4]

The nasal catheter first came to be used as a conduit for oxygen therapy at around the turn of the century. Other oxygen delivery devices were soon to follow.[5]

Following John S. Haldane's expedition to Pike's Peak in 1913, he concluded in his landmark article in the *British Medical Journal* in 1919 that "partial anoxia means not a mere slowing down of life, but progressive, and perhaps irreparable damage to human structure."[6] Haldane predicted that oxygen would soon be used in hospitals.

Alvan Barach was the first to systematically employ oxygen for the treatment of bacterial pneumonia.[7] Barach modified an oxygen tent, originally invented by Leonard Hill.[7,8] Barach was also interested in the role of oxygen and relief of dyspnea during exercise. In 1958 he developed a small transfillable oxygen cylinder suitable for use during exercise (Figure 1). Cotes and Gilson also gave oxygen to ambulatory patients from small portable high-pressure cylinders in the United Kingdom (UK). Cotes reported on increased walking time and improved arterial oxygen saturation with the use of supplemental oxygen during exercise.[9] By 1955 approximately 30% of all "chemists" in Wales and Monmouthshire (population 2.6 million) were supplying oxygen by prescription, at that time, to an astonishing 860 patients. Oxygen cylinders were the only modality utilized for the delivery of oxygen therapy in that era. Apparently this practice did not continue in the UK, or else it is not recorded in the literature. Barach died in 1976, and had been an inspiration to many who began to learn the values of LTOT and develop innovative new oxygen systems.

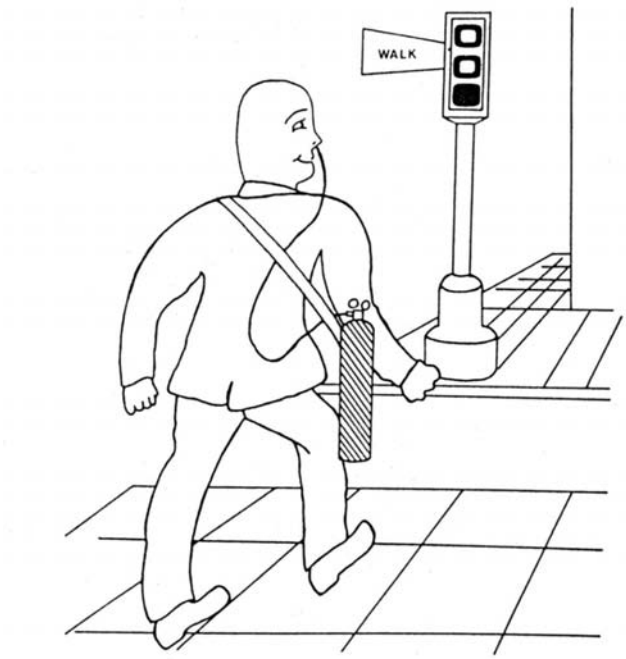

Figure 1. Cartoon diagram by Dr. Barach emphasizing the importance of walking with ambulatory oxygen.

2. Physiologic Responses to LTOT

The first liquid transfillable systems became available commercially from the Linde Corporation in 1965. The Denver Group enrolled 6 patients in a study to investigate the utility of supplemental oxygen on the basis of clinical evidence of severe pulmonary hypertension, erythrocytosis, hematocrit > 55%, and markedly reduced exercise tolerance.[10] These six patients were admitted to a clinical research unit for the purpose of stabilization for one month, when no oxygen was used. During stabilization, the administration of bronchodilators, diuretics, cardiac glycosides when indicated, and treatment of any evidence of infection was instituted and provided for clinical stabilization. Patients were encouraged to eat a high-calorie diet and exercised systematically each day to improve physical conditioning and to increase exercise capability. At the end of this control month, cardiac catheterization was done to measure pulmonary artery pressure, cardiac output, and pulmonary vascular resistance. Chromium-51-tagged red cell mass determinations were also made.[10] During the second month, the patients were maintained on the same diet and maintenance medications, and oxygen was administered by nasal canula at a flow sufficient to bring oxygen saturation above 90% during rest and exercise. In all patients, this required 1-3 L/min, averaging 2 L/min. At the end of one month, cardiac catheterization and red cell mass studies were repeated. Marked reductions in pulmonary artery pressure and pulmonary vascular resistance were observed in 4 of the 6 patients. The red cell mass improved in 4 of the six patients in whom both determinations could be accomplished. The most dramatic outcome was the markedly increased exercise tolerance in these patients (Figure 2).

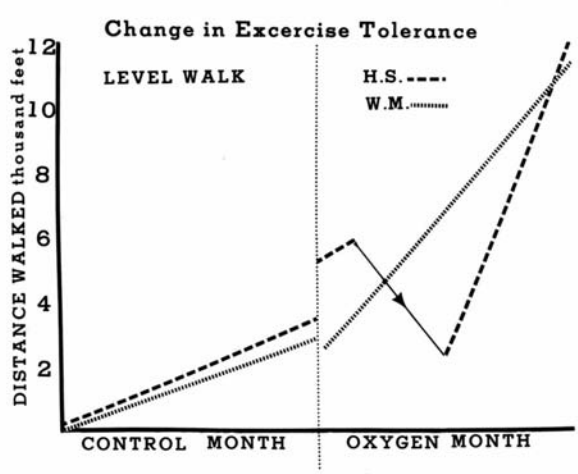

Figure 2. Improvement in exercise tolerance in two patients trained at level walk. Note the slow change during the control month, and the marked rapid rise in tolerance during the oxygen month. W.M. and H.S. are the patients' initials. Temporary decrease in H.S.'s exercise tolerance during the oxygen month was due to an episode of acute bronchitis.

The first of these oxygen study patients became our first home care patient in Denver. Pictures of his quality of life and home functioning have been reported on numerous occasions in previous writing by one of us (TLP).[11]

At approximately the same time, an almost identical study was done in Birmingham, England, which resulted in exactly the same conclusions about hemodynamic improvements and red cell mass in response to supplemental oxygen therapy.[12] Formal exercise studies were not conducted by the Birmingham group, largely because cumbersome high-pressure

2. Physiologic Responses to LTOT (Cont.)

cylinders were used. However, these were used with a "trolley," so some degree of ambulation was possible while pushing the oxygen cylinders. Although no accounts of exercise tolerance are reported, the authors remark, "Exercise tolerance increased remarkably . . . even though there was no specific program of training."

In 1968 we reported on 20 patients with advanced chronic obstructive pulmonary disease (COPD) who received continuous ambulatory oxygen therapy from a liquid oxygen portable system for up to 18 months.[13] In that article we showed crude anecdotal evidence of improvement in cor pulmonale, with evidence of improvement in electro-cardiograph tracings and in the cardiac silhouette, with resolution in right ventricular size as a result of 6 months of oxygen administration. This report also documented a progressive reduction in hematocrit and an increase in dry body weight over one year, which suggested some nutritional or metabolic benefit from LTOT. In this paper, we demonstrated a reduction in hospitalizations visually documented in one dramatic illustration showing the size of a patient's hospital record before and after oxygen, during an equal 18-month period (Figure 3).[13]

Figure 3. Size of a patient's hospital record before and after oxygen, during an equal 18-month period. (From

Following these original observations, other investigators in the UK focused on the daily requirements of oxygen required to reverse pulmonary hypertension in patients with COPD.[14,15] These studies gave evidence that oxygen delivered from a stationary source for as little as 15 hours per day resulted in an improvement in pulmonary hypertension in some, but not all, patients. There was even a suggestion that 12 hours of oxygen could be effective.[14,15]

In a later report, the Denver Group was able to show an improvement in survival in patients before and following oxygen administration with clinical evidence of cor pulmonale before and following response to supplemental oxygen administration, compared with historical controls from the Veterans Administration-Armed Forces study on course and prognosis in COPD.[16] A similar survival benefit was not found in patients who did not have clinical evidence of cor pulmonale.[16] It must be emphasized that all of these early studies were in small groups of patients without a contemporary cohort comparison group.

3. Two Major Randomized Clinical Trials

THE BRITISH MEDICAL RESEARCH COUNCIL CLINICAL TRIAL

Clinical investigators in the UK, led by the late David Flenley, asked an important question about the treatment of patients with COPD and chronic stable hypoxemia (arterial oxygen tension [P_aO_2] ≤ 55 mm Hg) and the effect of LTOT on survival. In a multicenter trial in the UK, the patients were randomized to receive either 15 hours of oxygen (including the hours of sleep) from a stationary system or no supplemental oxygen.[17] Figure 4 shows a survival curve from this study. It is interesting that improvement in survival in the supplemental oxygen group does not appear until after 500 days.

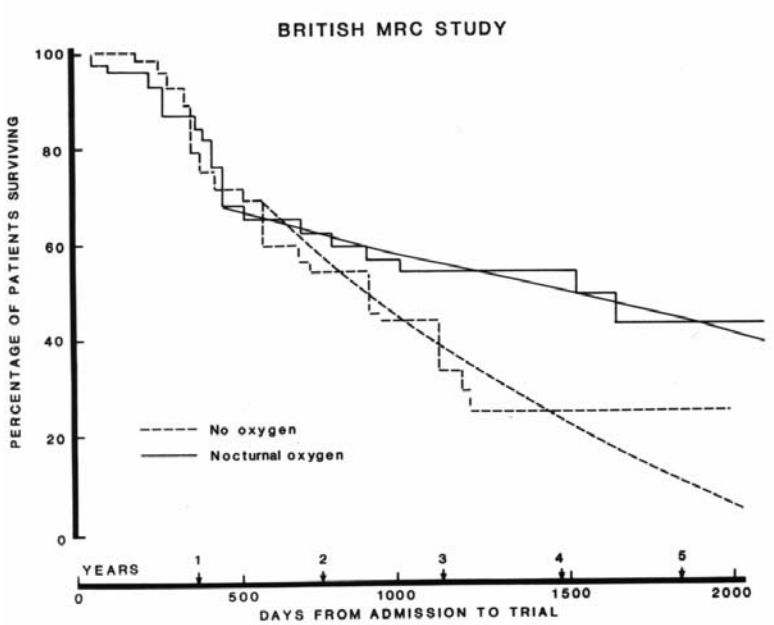

Figure 4. Survival in the British Medical Research Council study comparing oxygen for 15 hours a day from a stationary source, compared with no oxygen. (From reference 17, with permission)

THE NOCTURNAL OXYGEN THERAPY TRIAL (NOTT)

The NOTT enrolled 203 patients in 6 centers. The requirements for entry included P_aO_2 of ≤ 55 mm Hg in the 3-week stabilization period, during which bronchodilators and antimicrobials were used as indicated. Patients were exercised on a daily basis to improve physical conditioning during the stabilization period. At the end of this stabilization phase, the oxygen tension in 45 subjects improved while breathing room air to the extent that they no longer qualified for the study, (i.e., the oxygen tension had improved to 55 mm Hg during the stabilization period.[18]) A few patients with an oxygen tension of 55-59 mm Hg were also entered into the study because of clinical evidence of cor pulmonale based on electrocardiograph criteria and/or a hematocrit value of 55 or higher. In the NOTT only 4 patients were considered too ill to enter the stabilization period without oxygen.[19] Other exclusion criteria were the presence of serious comorbidity, refusal by the patient to follow a complex protocol that required two cardiac catheterizations, and residence too far from the testing center for the necessary close observations required by this study.[19]

Patients were randomized to receive either nocturnal oxygen therapy (NOT) using a stationary source or continuous oxygen therapy (COT). The randomization process resulted in patients who were excellently matched by age, gender, ethnic background, years of formal education, physiologic tests during rest and exercise, pulmonary pressure, and pulmonary vascular resistance. The survival outcome is presented in Figure 5. Significant survival differences between the groups were observed at 12, 24, and 36 months ($p < 0.01$).

Two Clinical Trials (cont.)

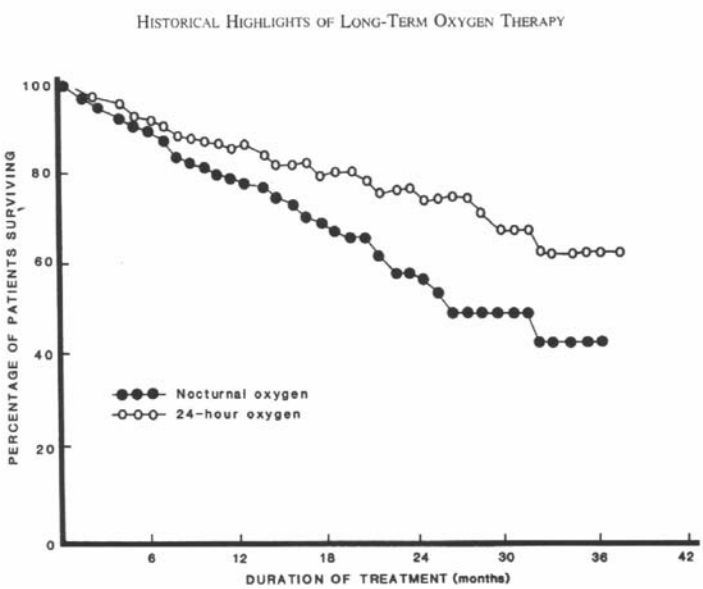

Figure 5. Survival in the Nocturnal Oxygen Therapy Trial where "24-hour oxygen" duration was actually 19.4 hours median and 17.7 hours mean. Nocturnal oxygen by diary was for 11.8 hours mean from a stationary system. (From Reference 18, with permission)

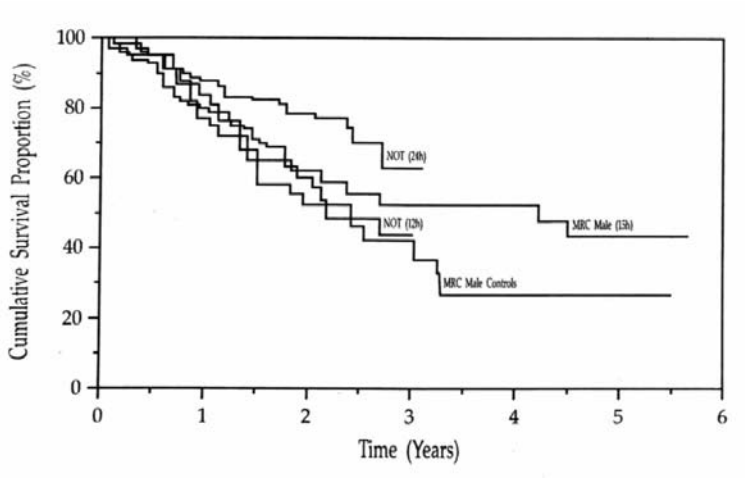

Figure 6. Combined data from the Nocturnal Oxygen Therapy (NOT) Trial of the National Institutes of Health (NIH) and the Medical Research Council (MRC) Study showing the improvement in survival proportional to the duration of oxygen therapy (h) each day. MRC controls received no oxygen. Note that the NOT (24 h) group also had access to ambulatory oxygen therapy. (Data from Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease. Ann Intern Med 1980. 93:391-398 and Medical Research Council Working Party. Long-term domicillary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Lancet 1981: (681-686.)

Since the demographics and disease severity of COPD patients in the MRC and the NOTT studies were quite similar, it is reasonable to compare the survival curves. This is done in Figure 6. In brief, this figure shows that survival in COPD with chronic stable hypoxemia is poor when supplemental oxygen is not given. Survival is better in patients who received 12 to 15 hours of oxygen therapy a day. Survival was best in patients who received nearly continuous oxygen from an ambulatory system. These differences in survival could have been related to the duration of oxygen therapy, the method, or both.

4. Other Benefits from Oxygen

In earlier studies, Krop et al found improved brain function in patients with advanced COPD as the result of breathing supplemental oxygen compared with room air.[20] Later in the NOTT study, Grant et al found significant impairment in brain function prior to receiving oxygen therapy in NOTT patients, compared with well-matched controls.[21] (See Re-Examination of the Nocturnal Oxygen Therapy Trial [Page 12] for details and Reference 30.) Patients who received both NOT and COT had improved brain function at the 6-month observation point. But only COT patients had continued improvement in brain function at the end of one year, with a slight decline in the NOT patients.[22]

Numerous methods were used to determine changes in the quality of life during the NOTT. Although global benefit was obvious to most observers, actual quantification of the quality of life by specific instruments was somewhat difficult. The best estimates were derived from the numerous neuropsychologic studies, results which have previously been reported.[22,23] These studies documented the profound effect of COPD and hypoxemia on various indices of brain function and showed that a small but significant improvement in brain function occurred with the use of oxygen therapy. It is difficult to separate the effects of oxygen therapy from pulmonary rehabilitation (i.e., exercise physical conditioning and nutritional repletion) in such studies.

5. Oxygen "Dosing" (Liter Flow)

The common practice of initiating the oxygen "dose" at 2 L/min by nasal cannulae is drawn from two studies done in the 1960s; one from Winnipeg, Canada[24] and the second from the Denver Group.[25] In each case a small number of patients (17 in each study), hospitalized for exacerbation of COPD received gradually increasing flows of supplemental oxygen under stable state conditions. These two articles alone form the foundation of initiating oxygen in COPD patients at 2 L/min! Figure 7 presents the data from the Denver study published in 1967.

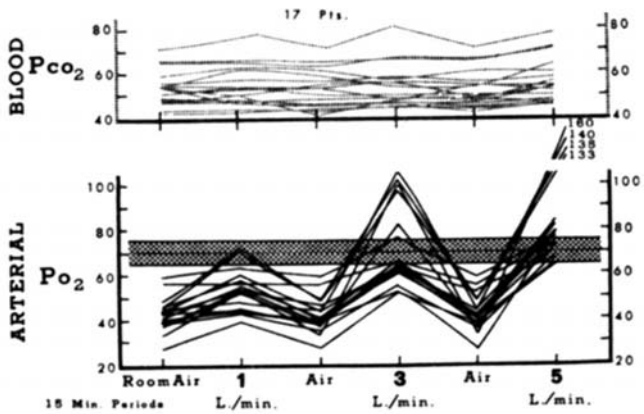

Figure 7. Arterial blood gas response in 17 patients with chronic airway obstruction in whom progressive PCO_2 rise did not develop while they were receiving low flow oxygen. (Cross-hatched area represents normal PaO_2 at Denver.)

5. Oxygen "Dosing" (cont.)

The Nocturnal Oxygen Therapy Trial (NOTT) established that the great majority of patients with advanced COPD and hypoxemia can be managed with oxygen delivered by nasal cannulae at 1 to 2 L/min. Measurements were made at rest by arterial blood gas analysis. Fewer than 10 percent of individuals with COPD required 3 L/min or more at rest to achieve adequate oxygenation in this study. Additional studies in conjunction with NOTT suggested adding an additional 1 L/min flow requirement during conditions of exercise and while sleeping.[18] Thus, this increased oxygen flow "requirement" is likely due to the increased metabolic demands of exercise and a modest degree of hypoventilation during sleep with or without an additional degree of oxygen transport abnormality during sleep or both. Thus, if the baseline liter flow at rest needed to bring the patient's oxygen tension to the range of 60 to 65 mm Hg or an oxygen saturation to between 90 to 94 percent saturation is 2 L/min, this same individual will require 3 L/min while exercising or during the hours of sleep. Whether or not these flows are actually required should be the subject of more extensive clinical research trials.

In practice, these liter flow rates are commonly employed today (with or without monitoring by pulse oximetry) to document the need. Fortunately, the advent of portable, accurate and inexpensive pulse oximeter devices, used to detect reflection of arterial oxygen by pulse sensing of the saturation (which reflects the amount of hemoglobin carrying oxygen expressed as a percent of the total hemoglobin [S_PO_2]) offers a new opportunity, indeed a new dimension, in patient monitoring under all conditions of daily living - including sleep.

The public and physician's expectations (that flow rates between 1 and 3 L/min or more are required in clinically stable patients), must be reconciled with the reality that the newest light weight oxygen concentrators and ultra-light weight liquid systems, using pulse delivery, actually provide less than 1 L/min total oxygen flow. The conserving systems, utilized with these devices, provide for more oxygen instillation during inhalation, but it must be appreciated that the nose and pharynx are a reservoir and accordingly, all of the oxygen flowing during the expiratory pause, or even during exhalation, is not wasted.[26]

6. Prescribing Criteria

All of these controlled clinical trials reviewed above that examined outcomes from the use of supplemental long term home oxygen have dealt only with patients faced with the problem of advanced COPD.

Guidelines for prescribing home oxygen in COPD, based on the Nocturnal Oxygen Therapy Trial (NOTT), are listed in Table 1. It was concluded that a significant level of hypoxemia must be documented prior to prescribing supplemental oxygen therapy. (For example, PaO_2 of 55 or less with SaO_2 of 88 percent or less for three weeks or more when the patient is in a clinical stable state - free from the exacerbations of bronchitis, heart failure, and so forth.) Several supplementary criteria were also used to justify inclusion of subjects in the NOTT trial: 1] when the PO_2 was between 55 and 59 while the patient was in a stable condition, entry into the study was allowed if there was evidence of pulmonary hypertension as judged by ECG criteria with a right axis and so-called "P pulmonale," (P waves in standard leads 2, 3, and a VF greater than 2.5 mm Hg); 2] when an enlarged pulmonary outflow tract and prominent major pulmonary arteries were observed, as judged from standard chest

6. Prescribing Criteria (cont.)

radiographs (posterior, anterior, and lateral), as additional clinical evidence for pulmonary hypertension; 3] a clinical evidence of right heart failure with elevated jugular venous pressure, judged by inspection, liver engorgement, and peripheral edema suggesting cor pulmonale; or 4] evidence of secondary polycythemia with a hematocrit 55 percent or more. These latter two clinical states, (cor pulmonale and secondary polycythemia), were accepted as signs of an end-organ response to the presence of clinically significant hypoxemia.

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Table 1. General Prescribing Guidelines for Home Oxygen for Patients with Advanced COPD

Patient Selection Criteria

- *Stable course of disease on optimum indicated medical therapy, (e.g., bronchodilator, antibiotics, corticosteroids)*
- *At least two arterial blood gas determinations while breathing room air for at least 20 minutes*
- *Room air PO_2 that is consistently 55 mm Hg, or consistently 55-59 mm Hg plus cor pulmonale clinically diagnosed, or hematocrit 55%.*
- *Normoxic patients in whom less dyspnea and increased exercise capacity is demonstrated with the use of supplemental oxygen.*

Oxygen Dose

- *Continuous flow by a double or single nasal cannulae*
- *By demand system with demonstration of adequate oxygen saturation*
- *Lowest liter flow to raise PO_2 to 60-65 mm Hg or oxygen saturation to 88-94%*
- *Increase baseline liter flow by 1 L during exercise and sleep*

7. Oxygen Toxicity

The issue of possible tissue oxygen toxicity as a result of LTOT was reviewed by one of us (TLP) early in the Denver experience.[27,28] We were able to find proliferative and fibrotic lung tissue changes in 6 of 12 autopsy cases suggesting oxygen toxicity in patients on LTOT who received oxygen for 7 to 61 months (average 26.7 months). Similar changes were not found in patients with like degrees of COPD who had not received continuous oxygen therapy. However, there was no evidence that these lesions caused harm by increasing morbidity or by hastening death. These lesions were found most frequently in those who survived the longest (32-month mean survival in those with possible oxygen toxicity, compared with 23-month survival in those with no histologic evidence of oxygen toxicity). A curious negative relationship was found between oxygen toxicity and the extent of emphysema.[27]

8. Oxygen Safety

Early in our experience with the use of LTOT, the Center on Pulmonary Rehabilitation of the American College of Chest Physicians conducted a nationwide survey to seek any information about the occurrence of major fires, facial burns, etc. as a result of oxygen use in the home. This survey did not show a significant number of severe fires related to oxygen and the Center issued a statement that "Home oxygen is a safe form of therapy." Decades of home oxygen use in patients with chronic obstructive pulmonary disease and other respiratory and cardiovascular diseases has proved this concept. This is largely attributable to the dedication of medical staff and home oxygen suppliers who spend time providing oxygen patients with proper instruction in safety measures to avoid hazards. During the early years of LTOT, a few burns were reported when patients ignited their nasal cannulae whether by accident or purposefully! More recently a burn unit has reported on a retrospective analysis of burns related to oxygen use. Only twenty-three patients, mostly with COPD, average age of 70, were treated for burns associated with supplemental oxygen use over a 12-year period, which required admission to a burn unit! Average burn size was 3.9% of total body size.[29] However, amended reports of some burns continue to be mentioned in reviews about LTOT. A central registry for the recording of oxygen burns and other accidents is badly needed.

A myth needs to be dispelled: Oxygen will not explode, and it in itself is not combustible. Oxygen does vigorously support and accelerate the combustion of flammable materials in a dose-dependent fashion.

9. A Re-Examination of the Nocturnal Oxygen Therapy Trial (NOTT)

The main purpose of this section on ambulatory oxygen is to offer a new analysis of the Nocturnal Oxygen Therapy Trial (NOTT) data in order to explore why continuous oxygen therapy (COT) was superior to nocturnal oxygen therapy (NOT). We aimed to determine if survival was related to the exercise capacities of the patients at the time of randomization to oxygen or if it was a function of the duration of oxygen administration.

In the brief review, the NOTT study collected extensive data from a well-defined population of patients with advanced chronic obstructive pulmonary disease (COPD), who were randomly assigned to receive either NOT for approximately 12 hours per day from a stationary source or ambulatory oxygen (i.e., COT that was intended to be used as close to 24 hours per day as possible). In the NOTT, extensive outcome data was obtained that can answer important questions about oxygen therapy and its effects on the outcomes of exercise capacity, survival, and hospitalization requirements in this well-defined population.

The details of the original NOTT study have been reported elsewhere.[18] Patients with chronic stable hypoxemia with partial pressure of oxygen PO_2 of ≤ 55 mm Hg (who had no significant co-morbidities and were willing to participate in an exercise-oriented rehabilitation program utilizing oxygen) were randomized to receive either NOT from a stationary oxygen system or COT from an ambulatory system.[18,19] The randomization process resulted in the enrollment of patients who were well-matched by age, gender, and indices of disease severity. After the NOTT report, the magnetic data tapes were placed in the public domain in hopes that further analyses would be made by other investigators.

A Re-Examination of the NOTT (Cont.)

The original NOTT data set was obtained from the National Heart, Lung, and Blood Institute in its original format and converted into an Access (Microsoft Corporation, Redmond, Washington) database. From this database, information was imported into Excel spreadsheets (Microsoft Corporation, Redmond, Washington) for matching and analysis.[30]

WALKING ABILITY

In the NOTT, each candidate for the study participated in a comprehensive pulmonary rehabilitation program, with exercise performed on a daily basis for 3 weeks prior to randomization to NOT or COT. Each patient was urged to walk as much as possible each day during the 3-week stabilization period, and each was given a pedometer to monitor the distance walked each day. The distance was recorded by a research nurse or technician. This 3-week period was intended to bring each patient to a functional optimum before randomization to NOT or COT. The average number of feet that each patient walked per day was calculated during the third week of the stabilization period. We called this factor "walking level." Pedometer data for the 3-week stabilization and optimization period was available for 157 of the 203 total patients. We had maximum oxygen consumption measurements for 106 of the 203 total patients enrolled in the NOTT. In our matched group of 80 subjects, we had maximum oxygen consumption measurements for 18 subjects with a low walking level (39 mL/min), and 24 subjects with a high walking level (59 mL/min (p= 0.007). Thus, the walking level can be taken as a surrogate indicator of the maximum oxygen consumption measurement in this analysis. Patient demographics are in Table 2.

We divided the patients into a low walking and a high walking group by separating them based on the median walking distance achieved at the end of 3 weeks.

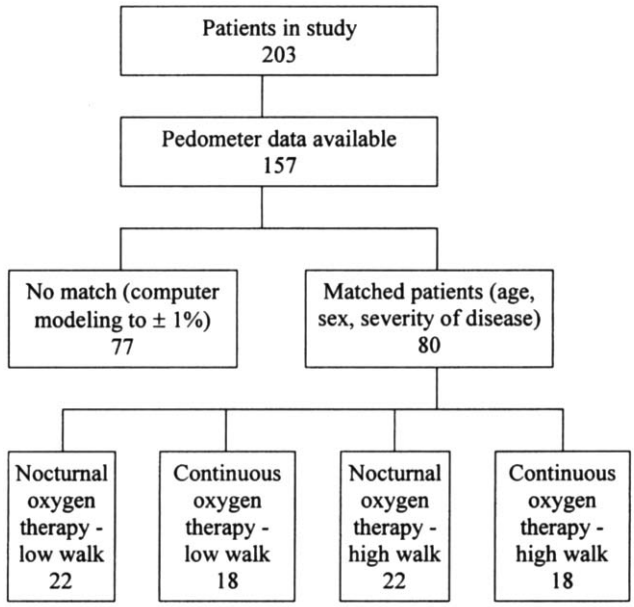

Figure 8. Re-Examiniation of the Nocturnal Oxygen Therapy Trial by pretreatment ambulation status. Origins of the 80 matched patients.

Figure 8 presents the origins of the 80 matched patients. The initial division of the patients by walking level at the median (3,590 ft/d) yielded groups that were not well matched by age. The low walking group was approximately 6 years older than the high walking group. To overcome this weakness, each low walking patient was manually matched with a high walking patient of similar age, treatment group (COT vs NOT), and percent of predicted forced expiratory volume in the first second (FEV_1). The resulting groups were 40 patients each in the low and high walking groups. These 80 patients were then further divided into COT and NOT groups. Table 2 shows that the results of this method lead to good matching of all parameters listed.

DATA ANALYSIS

The methods of Kaplan and Meier[31] were used to produce the survival function, using the product-limit estimate model. Statistical significance was tested using the method described by Cox.[32] Hospitalization data were analyzed by analysis of variance.

A Re-Examination of the NOTT (cont.)

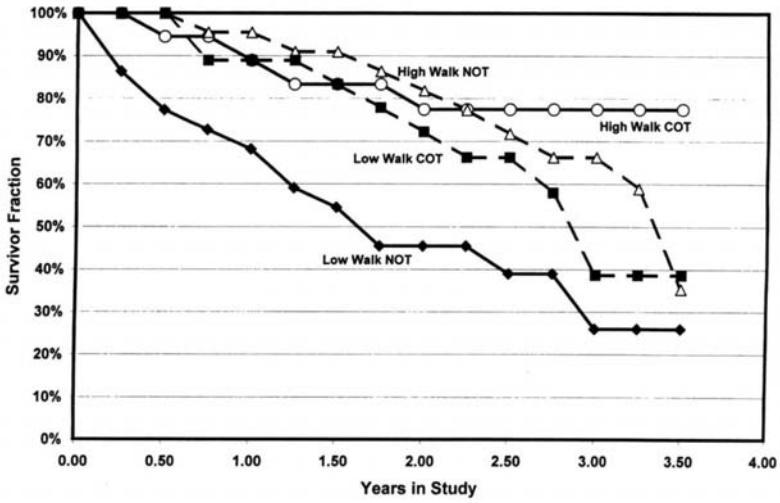

Figure 9. Survivorship vs walking level and oxygen therapy. Comparison of survivorship in high walk, high oxygen patients campared with low walk, low oxygen patients shows highly statistically significant differences. Low walk, high oxygen survival is better than low walk, low oxygen at 2.5 years, but not at 3.5 years. These differences are statistically significant (p = 0.01).

Figure 9 presents the survival of patients with low and high exercise capability who received low (NOT) versus high (COT) oxygen. Differences in survival between the low walkers on low oxygen and high walkers on high oxygen is statistically significant (p = 0.01). The difference is also significant between low walkers on low oxygen and low walkers on high oxygen (p = 0.01).

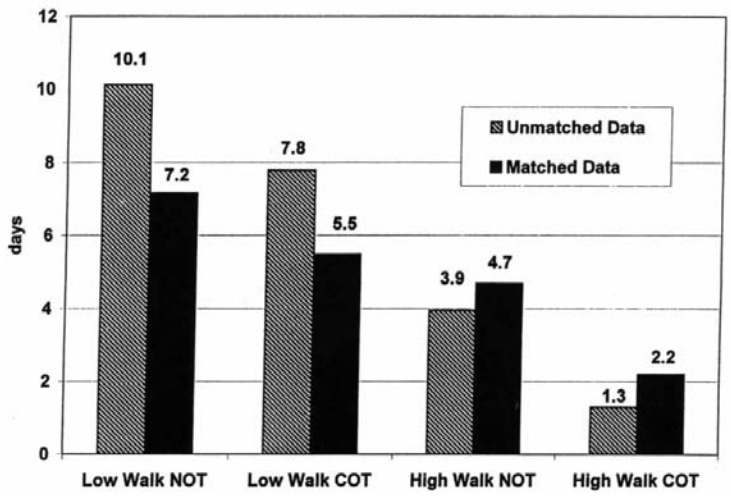

Figure 10. Hospital days per year in study. The lowest length of stay in admissions per year was in the high walk, high oxygen patients. (p = 0.05 and 0.01 respectively).
NOT = nocturnal oxygen therapy
COT = continuous oxygen therapy.

Figure 10 presents the hospitalization data in terms of the number of admissions per year and the average length of stay per admission for the 4 matched groups. A lower hospital utilization was observed in the high exercise groups versus the low exercise groups (p = 0.05). Using analysis of variance, the lowest hospital utilization was by the individuals with COT and high exercises. (high walk COT, p = 0.02)

*Table 2. Matching Data for Baseline Walking Comparison.**

Characteristic	Low Walk NOT	Low Walk COT	High Walk NOT	High Walk COT
n	22	18	22	18
Age, median, years	67.6	66.5	67.6	66.5
P_{O_2}, mm Hg	52.3	49.9	51.6	51.6
P_{CO_2}, mm Hg	45.7	42.6	42.4	43.2
pH	7.40	7.40	7.42	7.40
Heart rate, min^{-1}	92.6	95.2	85.9	95.8
Pulmonary artery mean pressure, mm Hg	31.6	29.1	26.9	30.1
Cardiac index, $L/min \cdot m^2$	2.76	2.88	2.62	3.04
Pulmonary vascular resistance, $dyn \cdot s \cdot cm^{-5}$	381	363	383	379
FEV_1, % of predicted pre-bronchodialator	25%	28%	25%	28%
FVC, % of predicted pre-bronchodialator	48%	51%	50%	49%

*Cardiac and blood gas data taken at rest with supplemental oxygen. All values are mean unless noted.
NOT = nocturnal oxygen therapy; COT = continuous oxygen therapy; FEV_1 = forced expiratory volume in the first second; FVC = forced vital capacity.

COMMENT

Improved survival in the NOTT study was in part related to reversibility of pulmonary hypertension.[33] Similar conclusions have been drawn by other investigators.[34-36] It is difficult to understand, however, how a modest reduction in mean pulmonary artery pressure (only 3-5 mm Hg), which causes only a slight decrease in the afterload of the right ventricle, could be the sole reason for the improved survival. In one study, improved survival was related to both a reduction in pulmonary pressure and an increase in maximum oxygen consumption.[34] In some patients who had a reduction in pulmonary artery pressure, there was an increase of left ventricular ejection fraction, which may be a reflection of improved global cardiac function because of relief of hypoxemia.[34]

Extensive exercise studies evaluating right ventricular function during exercise in COPD have shown that an increase in exercise tolerance is related to an increase in right ventricular function and increased oxygen consumption.[37,38] Increased exercise capacity in hypoxemic COPD patients often results from long term supplemental oxygen administration and is related to an improvement in right ventricular function.[37-39] Increased right ventricular function and oxygen consumption may occur in spite of increases in pulmonary artery pressure and pulmonary vascular resistance. The elevated pulmonary pressure and resistance are most likely due to fixed vascular changes in the pulmonary vascular bed, which are not reversible, even with long-term oxygen therapy (LTOT).[40] One study found a relationship between mixed venous oxygen tension and survival in patients who were candidates for LTOT.[39] The 5-year survival was better in patients with the highest mixed venous PO_2 and higher coefficient of oxygen extraction.[41] This study suggested that measures designed to increase cardiac output would be appropriate to improve tissue oxygen delivery.[41,42]

In other studies, patients who exhibited little or no ability to increase their cardiac output and systemic oxygen transport did not have increased exercise capacity.[37-39] These observations led to the conceptualization of the "right ventricular hypothesis."[41,43] The right ventricular hypothesis is based on the concept that limitation of right ventricular function limits systemic tissue organ transport. Before oxygen is given, ventricular function and oxygen transport may be limited by poor oxygenation of the myocardium. After oxygen is administered, right ventricular function can still be limited by structural damage of the right ventricle or by elevated right ventricular afterload from fixed pulmonary vascular changes. In any event, failure to improve right ventricular systolic function may limit tissue oxygen transport. By improving oxygen to the right ventricular myocardium, and by reducing right ventricular afterload, right ventricular function may improve. This, in turn, results in improved global cardiac function, increased tissue oxygen transport, and increased tissue energy production.

It is likely that tissue metabolic phenomena are responsible for improved survival. In the British Medical Research Council Study of LTOT in COPD, men who received oxygen versus men who did not receive oxygen, had an improvement in survival but this difference did not become apparent until after 500 days on LTOT.[17] In the NOTT study, improved survival did not become statistically significant until 18 months into LTOT.[18] These data suggest that the survival benefit from oxygen was a function of restorative metabolic changes in multiple organs, which occurred over months of LTOT.

The restorative value of oxygen on brain function has been previously reported.[22]

A Re-Examination of the NOTT (cont.)

Figure 11 shows an improvement in performance IQ, which was similar with both NOT and COT. However, with COT there was further improvement over the subsequent 6 months. Similarly, Figure 12 shows improvement in brain age quotient, with improvement in both NOT and COT patients after 6 months, but further improvement after 12 months with COT.[22] An improvement in brain function could reasonably be expected to require increased energy production. Such an increase in energy production would require increased systemic oxygen delivery. This has been demonstrated in patients who can increase their exercise tolerance with supplemental oxygen.[42,43] We believe that increased exercise tolerance and improved survival are a result of increased systemic oxygen delivery during supplemental oxygen administration.

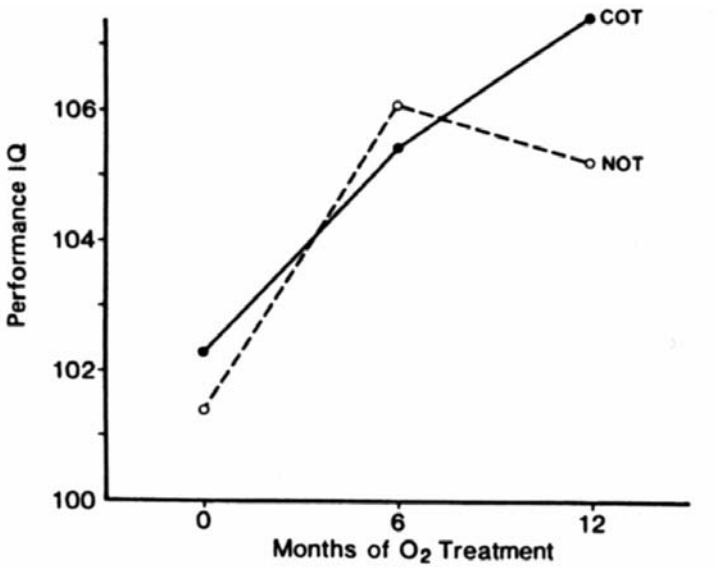

Fig. 11. Performance IQ from the Wechsler Adult Intelligence Scale in relation to duration of continuous (COT) versus nocturnal (NOT) oxygen therapy in COPD patients. (From Reference 22, with permission.)

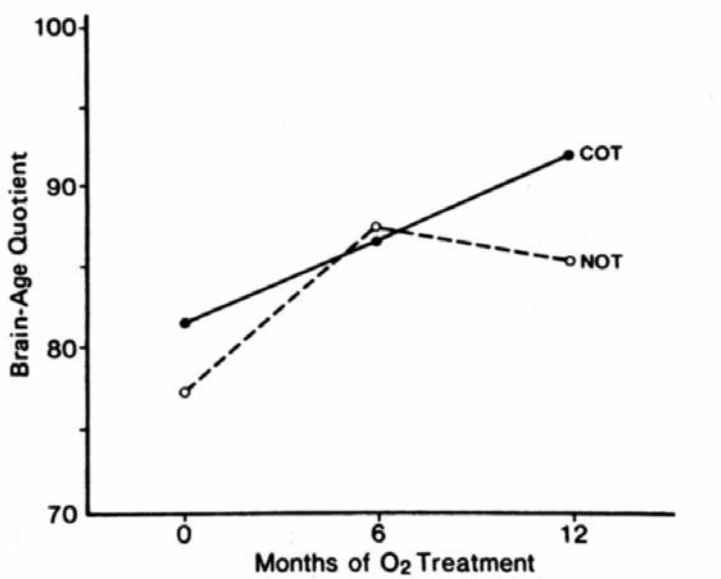

Fig. 12. Change in "fluid intelligence" (brain age quotient) in relation to continuous (COT) versus nocturnal (NOT) oxygen treatment in COPD patients. (From Reference 22, with permission.)

A restoration of arterial blood oxygenation while breathing room air has been reported following several months of LTOT.[44] This improvement in oxygen transfer across the lungs is believed to be due to improved ventilation-perfusion matching as a result of improved oxygenation, which is known to reduce pulmonary arteriolar constriction and bronchospasm. The long-term impact of LTOT on heart, brain, lung, and skeletal muscle function may also be due to a sustained increase in tissue oxygen transport and improved energy production in multiple organ systems.

A weakness of our study is that it is a retrospective analysis of a limited number of patients. But the NOTT study enrolled extremely well-characterized patients with respect to their exercise physiology and hospitalization outcomes. The present study suggests that improved tissue oxygen transport occurs in patients with relatively better exercise capacity who also receives more continuous

A Re-Examination of the NOTT (cont.)

ambulatory oxygen. Patients with lower levels of exercise capacity had better survival with oxygen delivered for a longer period of time.

This study suggests that new clinical trials are needed to compare outcomes in patients who utilize ambulatory oxygen for as many hours per day as possible, compared with stationary oxygen for an equivalent length of time. Such studies could answer the critical question about survival in relation to an ambulatory or stationary oxygen delivery sources, and address the question: does continuous ambulatory LTOT reduce hospitalizations?

COMMENT

The NOTT study showed improved survival in COT patients who received LTOT for longer periods (mean 17.7 h/d, median 19.4 h/d) from an ambulatory oxygen system, compared with the survival of NOT patients who received oxygen for a mean of 11.8 h/d from a stationary system. The differences in survival could have been due to the method or the duration of oxygen therapy, or both. An increase in cardiac output and increased oxygenation of the arterial blood (oxygen content) results in increased tissue oxygen transport. In addition, COT was associated with better survival and reduced hospitalizations, compared with NOT patients who were unable to increase their walking level.

10. Oxygen Technologies

Oxygen Therapy Devices

Long Term Oxygen Therapy (LTOT) devices are evolving to a new level of sophistication. Equipment used for home oxygen therapy is being developed with the patients' needs in mind, plus an appreciation for the costs associated with the service of LTOT equipment. This new breed of oxygen therapy equipment is arriving on the market at an opportune time, since a large number of "Baby Boomers" needing LTOT are just starting to receive prescriptions for home oxygen therapy.

Historical perspective

Not more than thirty years ago, a prescription for home oxygen therapy would require an industrial gas supplier to deliver several large (H size) cylinders to a patient's home. A large brass regulator would be put on the cylinder and a permanent humidifier attached for patient comfort. No portable systems were provided since oxygen therapy was prescribed at the end stage of the disease, and the patients were typically bed-bound. This therapy would most often be provided for less than a year and in many cases only a few weeks.

The late 1970's brought a new concept to home oxygen therapy. A device was developed that could generate oxygen in the home and never need to be refilled. Oxygen concentrators became popular since they provided a convenience to the provider and unlimited oxygen to the patient – barring mechanistic problems such as a loss of the energy source (i.e. electrical power failure) to run the concentrator. Portable oxygen was available as an emergency backup for the concentrator and could be used for short visits to the doctor or hospital. Patients were still not very ambulatory due to the progression of their disease and the lack of emphasis for activity. Liquid oxygen (LOX) for home application was available and popular for patients that wanted to be active, since the portable system was lighter in weight (compared to cylinders) and longer lasting (compared to cylinders). LOX continued to grow in popularity as patients, and physicians realized the advantages of these systems for optimizing use of LTOT during routine activities of daily living, exercise, and pulmonary rehabilitation.

Oxygen Technologies (cont.)

Two major changes have occurred over the past twenty years: 1) Patients are being prescribed oxygen earlier in their disease, often when they are younger and require LTOT to become more active. 2) Younger, active patients require an oxygen system that meets their needs for regular daily activity inside and outside their place of residence. Steel cylinders have evolved to aluminum, and sizes have been shrinking from E cylinders holding 680 liters to M cylinders holding 140 liters of gas. Oxygen conserving devices (OCD) have made the smaller cylinders more practical since the average 3:1 savings ratio allows for approximately 4 hours of mobility at a 2 L/min prescription.

OCDs have also helped LOX systems reduce size and last longer. The new 3 to 4 pound liquid oxygen portables can last from 6-8 hours at a 2 L/min setting. These new LOX portables have rejuvenated the home LOX industry, with several manufacturers introducing new small, lightweight portable systems.

Evolution of the technology

Cylinders are still being used during certain circumstances as portable oxygen systems. Patients may prefer an E cylinder as their portable since there is a safety factor of having enough oxygen available if the OCD should fail. And there is the option of using a wheeled cart to keep the weight of the portable off the patients' shoulders. Other patients like the M6 cylinder due to the small size and light weight. These systems can be placed in a case that hides the fact that the patient is using oxygen. A conserving device makes the small cylinders more practical, since there is a minimal operating time from these units versus using continuous flow.

LOX is the most efficient method of storing oxygen. With an 860:1 ratio of gas to liquid, a very small amount of liquid oxygen can expand to a large amount of gas. Early LOX portables held 1 liter of liquid. Expanding to 860 liters of gas, a 9-pound LOX portable could provide more gas than an E cylinder at less weight. OCD on a LOX portable can reduce the amount of oxygen needed to provide the desired operating time, which is why the new generation of LOX portables are smaller, lighter and longer lasting.[45]

LOX base units have improved to reduce the normal evaporation rate (NER), and several systems have telemetry to allow for monitoring of content and schedule delivery.

Concentrators have improved significantly in recent years. Systems currently on the market are more reliable at a lower cost and are the basis of most home oxygen therapy programs.

Concentrators that fill portable cylinders are new to the market. The ability to fill a cylinder in the patient's home gives patients freedom to refill the cylinders as often as their lifestyle permits, plus the provider does not need to deliver cylinders to patients' homes on a regular basis. Delivery of products to the home is one of the most expensive portions of a provider's cost of LTOT services. The continued reductions in reimbursement from CMS have driven manufacturers and providers to focus on ways to reduce delivery expenses.

The purchase price of the home-filling concentrator has been the barrier to providers to generally accept the system. A home-filling system can cost up to three times the purchase price of a standard concentrator. The economics of eliminating the delivery of cylinders, and the reduced inventory of cylinders and accessories to support LTOT has not been clearly documented by independent research. Other issues of concern related to the home filling concentrators are the additional cost of electricity that is the responsibility of the patient, plus the issue of 93% oxygen from a cylinder filled by a concentrator. Cylinders are typically used during exercise, and an OCD is

Oxygen Technologies (cont.)

utilized to extend operating time. The use of a combination of 93% oxygen, an OCD, and increased respiratory rate has not been proven by research studies to improve specific outcomes, but this approach might still have a positive impact on the patient's oxygen saturation.

Portable oxygen concentrators (POC) are new to the market. Featuring 9 pound weight, 1-8 hours of battery operating time and 93% oxygen purity, these devices utilize an OCD and have dose selection options. These units will have the same challenges to market entry as the home filling systems — higher cost and the issue of 93% oxygen delivered with an OCD to a patient with an increased respiratory rate. Clinicians have requested a portable oxygen concentrator for years and these new entries will start the process of refinement and improvement. Allowing one system to be both the base unit and portable will further reduce the cost of LTOT and provide the independence patients are looking for from their oxygen system.

Oxygen conserving devices are one of the fastest growing areas of LTOT. Frost and Sullivan have estimated that the total number of OCD sold in 2001 was 129,971, and sales were predicted to grow 15% annually.[46] In 1984 the first intermittent flow oxygen delivery device was introduced to the home care market. Appreciating the fact that oxygen delivered when the patient was exhaling was wasteful, this product sensed the patient's inspiratory effort and delivered a dose of oxygen only at the beginning of inhalation. This system eliminated the 2/3 of wasted oxygen that was being delivered during the patient's exhalation and pause between breaths. Eliminating waste improved operating times and has been the basis for most new oxygen systems used in the home. An OCD can reduce the scheduled delivery of oxygen via LOX and high pressure cylinder systems, and reduce associated costs. Newer portable concentrators and those developed in the future will depend on OCD technology to improve efficiency and minimize weight, making lightweight portable concentrators a more attractive and practical option for the delivery of LTOT possible.

Not all OCDs operate the same. The method of delivery for different systems has been described as a pulse delivery, demand delivery and hybrid.[46] The method of delivery impacts the volume of oxygen that is provided to the patient. The volume per breath determines the fraction of inspired oxygen (FIO2) the patient is receiving at each setting. The settings on each OCD are reference points and should not be considered the same FIO2 as continuous flow or other OCDs at the same setting. This misconception by patients, prescribers, and others involved in the care of LTOT patients was one of the reasons OCDs were not fully understood nor used optimally in the past – due to poor patient oxygenation at a certain settings. Most patients can be oxygenated with an OCD if the setting is changed to meet their oxygen dose requirement. This essentially equates to the need for oxygen titration at rest and during usual activities of daily living on an individualized basis – using the device(s) that the LTOT patient will be utilizing in the home and during ambulation and activity.

"Saving ratio" has been a claim of several manufacturers that feel their device performs better than others. The goal of oxygen therapy is to correct the patient's hypoxemia. Once that goal is reached, the amount of oxygen saving can be a value. Withholding needed oxygen from a patient to improve saving ratio is illogical and dangerous. Most consensus conferences on LTOT recommend that a patient is tested on an OCD at each activity level and the appropriate setting selected to maintain oxygenation. This concept applies to all oxygen therapy not just for conserving devices.

Oxygen Technologies (cont.)

Table 3. To calculate saving ratio, the following breathing patterns are used to simulate a patient breath pattern.

Pattern	Resistance	Compliance	Rate	Amplitude	Slope	% Inhale	V_T
1	20	30	15	20	40	34	~500
2	20	30	20	22.5	40	34	~500
3	20	30	25	26.5	40	34	~500
4	20	30	30	29	40	34	~500

Calculated Savings Ratios (CSR)

FIO_2 values resulting from continuous flow oxygen are recorded for each of the four breathing patterns used in Table 3. Results are placed into a graph from which best-fit lines are calculated. Results of FIO_2 values from continuous flow oxygen (CFO) are shown in Table 4 and graphed in Figure 13.

Table 4.

		FIO2			
		Pattern 1	Pattern 2	Pattern 3	Pattern 4
	1	27.2	24.4	23.5	23.0
	2	32.4	27.9	25.9	25.2
	3	36.2	31.1	28.3	27.4
	4	39.2	34.3	30.7	29.5
	5	42.0	37.2	33.3	31.6
	6	45.1	40.0	35.8	33.8

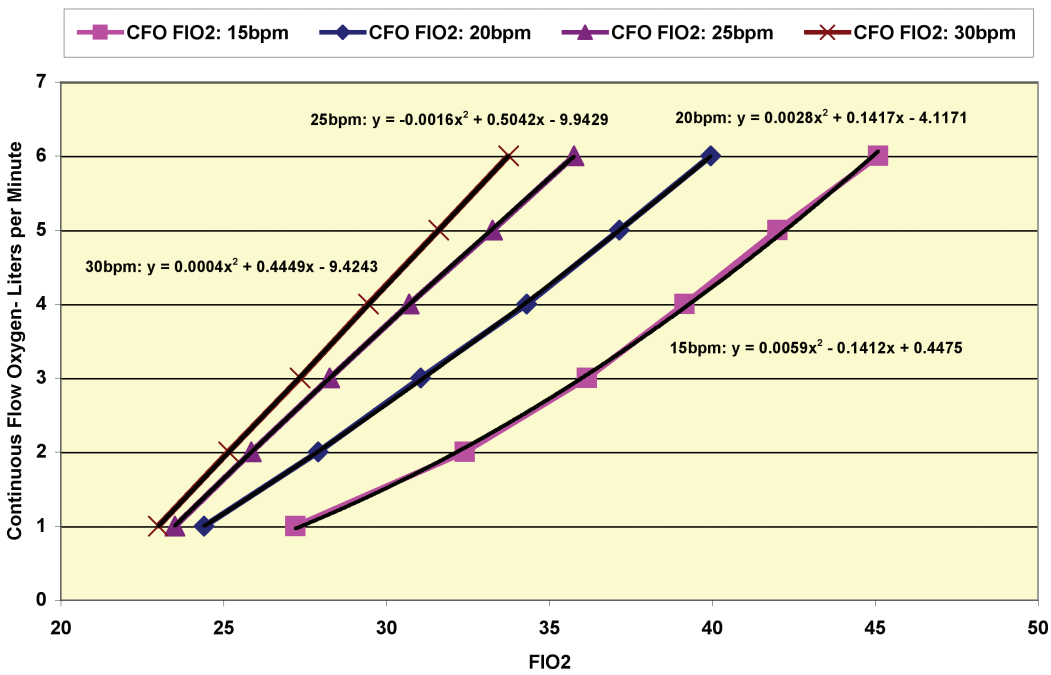

Figure 13. This chart shows resulting FIO_2 values from Continuous Flow Oxygen at various settings and breath rates. Best-fit lines are calculated from the resultant FIO_2 values at a given breath rate. These equations can be used to calculate an equivalent-to-Continuous Flow Oxygen value given a specific FIO_2 value.

Oxygen Technologies (cont.)

Using the FIO_2 values found when testing a given device and substituting those values into the best fit line equation, an 'Equivalent CFO' value is calculated.

Below is an example taken from the FIO_2 values recorded from an OCD device on Pattern 2, along with the resulting calculated equivalent to CFO.

Setting	%02	EqCFO
1	24.8	1.1
2	28.4	2.2
3	32.0	3.3

To determine the Calculated Savings Ratio for a given device setting and breath rate, take the Equivalent CFO value and divide by the total oxygen volume delivered (in liters) multiplied by the breath rate. Below is an example of the resulting CSR values from the same OCD device tested on Pattern 2.

Setting	EqCFO	V_{O2}	CSR
1	1.1	16.4	3.4
2	2.2	31.9	3.4
3	3.3	47.3	3.5

Thus, at Setting 1 and a breath rate of 20bpm, the total volume delivered was 16.4mL, or .0164L. The CSR calculation is 1.1 / (.0164 x 20), which results in a CSR value of 3.4.

There are several methods of oxygen conservation. The most popular is intermittent oxygen delivery systems. Early generations of OCDs offered the conserving unit separate from the oxygen regulator. The first major breakthrough in the technology was a system that integrated the regulator with the conserving unit. This "donut" style system has a cleaner presentation and convenience for the patient and requires changing the regulator when a cylinder is empty. The next breakthrough was the introduction of a pneumatic OCD. This simplified the system by eliminating the need to check and change batteries. The first pneumatic systems required a dual lumen cannula to operate the device. These cannulas were a little more costly to the provider and heavier than basic cannulas for the patient. Cost and comfort have improved with new dual lumen cannulas. Single lumen pneumatic conserving devices are an option. A competitive market and research has stimulated the investigation of new and better ways to conserve oxygen. Again, even with all the new technology being introduced, the first objective of oxygen therapy is to correct hypoxemia. The increased demand for effective, efficient LTOT devices will drive new products into the market. It will be the responsibility of the clinician to use these devices appropriately.

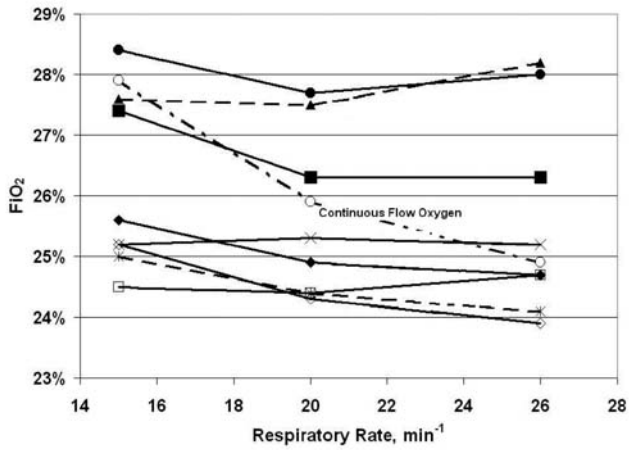

Figure 14. Graphic of eight conserving devices set at 2 L/min. With increased respiratory rate, FiO_2 varied between devices and continuous flow. Oxygen equivalency is a fallacy between continuous flow and different conserving devices.

Oxygen Technologies (cont.)

Conclusion

There are new lightweight oxygen systems enteringthe market and new oxygen conserving devicesintroduced almost every year. Options for reducing delivery costs associated with packaged oxygen are being developed which include:

- Portable Oxygen Concentrators (POC)
- Concentrators that fill cylinders in the home
- Concentrators that fill LOX portables in the home
- LOX base units with conserving devices

"Baby boomers" are hitting the age and health status where there will be the largest number of patients in that age bracket then has ever been experienced in the past. This group of patients will have specific healthcare needs and a large number will be prescribed LTOT. A new breed of 'healthcare savvy' patients is emerging – ones that know what they want and seek solutions to their health care needs – including optimal LTOT devices and accessories. The oxygen device market is primed for growth and the quality of care for LTOT patients should be the best it has ever been with innovative technology and appropriate services.

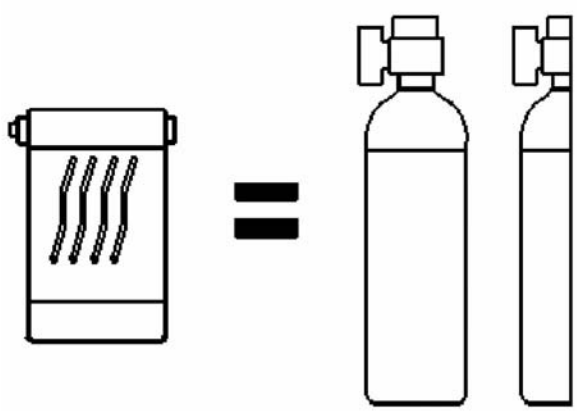

Figure 15. A one liter LOX is equal to approximately 1.5 E cylinders.

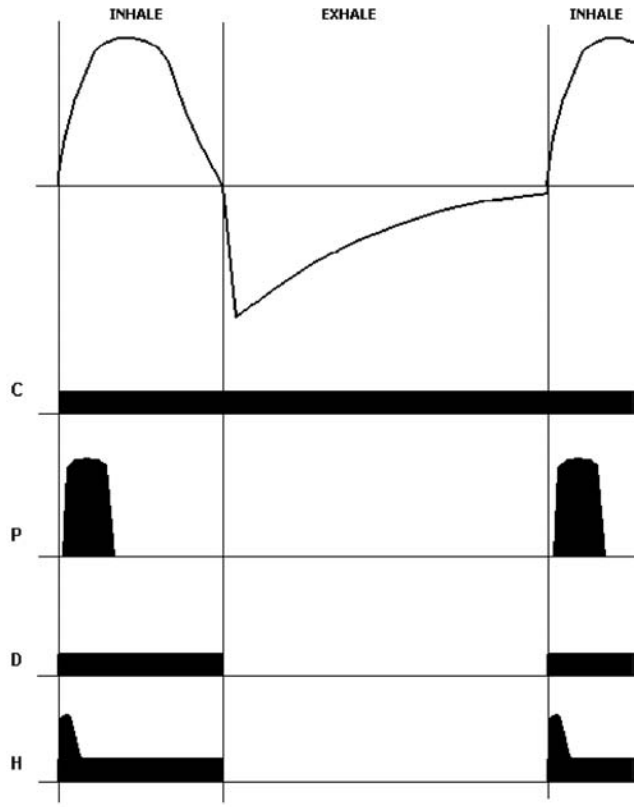

Figure 16. The top flow pattern represents a normal inspiratory/expiratory pattern. C represents continuous flow oxygen delivery. P represents a pulse flow that is not delivered through the entire inspiratory time. D represents demand flow that is on for the entire inspiratory cycle. H represents a hybrid with a higher peak flow (and volume) at the beginning of the inspiratory cycle, yet returns to a lower flow for the remainder of the inspiratory cycle.

11. Cost Effectiveness of LTOT

When the original NOTT Study was published, a theoretic consideration of LTOT cost effectiveness was published in an accompanying editorial.[47] The NOTT concluded that survival was improved by nearly continuous ambulatory oxygen, compared with nocturnal oxygen from a stationary source. The cost of increased life was also a consideration, as well as the cost of the associated morbidity due to increased longevity (i.e., drugs, doctors' visits, hospitalizations). In our re-analysis of the original NOTT data and the finding of reduced hospitalizations in ambulatory patients with preserved walk tolerance, it can be argued that ambulatory oxygen in functional patients can actually reduce costs even more than initially thought by reducing hospitalizations.

LTOT is not expensive when compared with other treatments for serious and life threatening illness. In 2006 ambulatory systems are reimbursed at approximately $225 per month, or $2700 per year. Stationary systems are reimbursed at a slightly lower level of $200 per month, or $2400 per year. This is far less than the annual cost for outpatient home hemodialysis (which costs $51,252 [USD] per year) or for home peritoneal dialysis ($29,965[48] [USD] per year). The reimbursement structure for the costs associated with the chronic management of end stage kidney dialysis has been mandated by Congress since 1972!

Based on data generated from the recently completed National Emphysema Treatment Trial (NETT), direct medical costs for lung volume reduction surgery (LVRS) are $71,515 compared with $23,271 for medical therapy for COPD patients in the first 12 months following randomization.[49] Direct medical costs in the following two years for patients having undergone LVRS and medical therapy were not significantly different.[49] Today LVRS is approved by Medicare. Quality of life improvement is considered a reasonable outcome by Medicare. Cancer chemotherapy and AIDS medications often cost $10,000 to $15,000 per month, or $120,000 to $180,000 per year.

Today LTOT is reimbursed at a flat rate, no matter what modality is prescribed or necessary for the patient. This is the so called "modality neutral" principle, which does not make sense. This policy also invites abuse, since some suppliers may choose to provide the least expensive technology, in spite of what is appropriate for the patient. Also, some who prescribe LTOT are not aware of all the devices available to deliver oxygen. This policy must change. If prospective controlled clinical trials prove the medical superiority of ambulatory oxygen worn by the patient (to allow for increased activities of daily living and restoration of organ system functions), and if the use of ambulatory oxygen also reduces hospitalizations, (as suggested in Figure 10), ambulatory oxygen may prove to be the most cost-effective modality. With emerging technologies, it is possible for suppliers to provide a wearable system for all appropriate patients. Both refillable low weight cylinders and home generation of liquid oxygen to fill ultra light weight wearable devices, are now approved by the FDA and are becoming more generally available. Oxygen reimbursement should be approved by Medicare to provide an appropriate ambulatory system for all patients who have the ability to benefit from these "wearable" systems (i.e. a device(s) and accessories that adequately oxygenate the patient in need of LTOT at rest and during usual activities of daily living inside and outside their place of residence). It is self-evident that current policies for LTOT reimbursement must be re-evaluated to be consistent with other reimbursement precedents already existing in the U.S. healthcare system to insure the principle of distributive justice.

LTOT is a bargain when compared with other technologies and surgeries used to extend life or to improve the quality of life. This fact should be respected: LTOT needs appropriate reimbursement!

12. The National Lung Health Education Program (NLHEP)

Many organizations – professional societies, device and pharmaceutical companies, LTOT patients, their caregivers and payers, patient advocacy groups, physicians, nurses, respiratory therapists and other respiratory care professionals, governmental and other regulatory agencies, as well as LTOT manufacturers, and providers – have worked laboriously over the years on the issues surrounding optimal and cost-effective use of LTOT by patients in need. Representatives from most of these organizations participated in the 6th Oxygen Consensus Conference held in Denver, CO, August 25-28, 2005. One of these organizations, the NLHEP, has been active for years in these pursuits. The NLHEP celebrates its 10th anniversary in 2006. The rich history of the NLHEP has been previously recorded.[50] The mission of the NLHEP is to reduce the impact and enhance the earlier detection of COPD, and initiate appropriate therapies for COPD and related disorders. Ensuring optimal and cost-effective use of LTOT is a high priority of the NLHEP.

The National Lung Health Education Program (NLHEP) is designed to identify and treat those in the early stages of COPD (emphysema and related chronic bronchitis). The NLHEP was actually 'conceived' at the 37th Aspen Lung Conference which led to: 1) a planning conference in 1994; 2)a second and more comprehensive workshop in Bethesda, MD, on August 29-31, 1995, chaired by one of us (TLP); 3)the launch of a new initiative "Building a National Strategy for the Prevention and Management of and Research in COPD" (JAMA 1997; 277:246-253)[51]; and 4) the 'birth' in 1996 of the NLHEP. The NLHEP executive committee meets semi-annually and is comprised of representatives from numerous collaborating professional, patient, and government groups. Members include the ACCP, ATS, ACP, AACVPR, AARC, ACAAI, AAPA, SIGM, NEF, and governmental liaisons from NCI, NHLBI, and NIOSH. NLHEP is supportive of and complementary to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), the US COPD Coalition, and the International COPD Coalition. The NLHEP's missions are: 1) to reduce the impact of COPD and related disorders by raising awareness of these diseases by the public, primary care clinicians, healthcare agencies, and policy makers, and 2) to establish that COPD is a major health problem and that the earlier detection and treatment of COPD will improve quality of life, minimize premature deaths, and reduce the cost of this disease and its related disorders. It is known that at least 50% (12 to 15 million) of people with COPD are not diagnosed or treated, despite their being symptomatic, and during the later stages of COPD, LTOT is required by some.[52]

The original NLHEP logo, and its recently modified logo which retains its original message, symbolize the lungs and the need for earlier identification of lung diseases.

A DECADE OF DEDICATION (1996 – 2006)

NLHEP Celebrates Its 10TH Birthday

"Test Your Lungs–Know Your Numbers." This became the NLHEP motto, and indeed our call to arms. We have had some major successes, including an often quoted consensus recommendation supporting the use of simple office spirometry as an early detection method to determine the presence of airflow obstruction in all smokers age 45 and older, and recent former smokers, and in anyone of any age with chronic cough, dyspnea on exertion, mucus hypersecretion and/or wheeze.[53] The NLHEP has encouraged industry to develop new, accurate, but inexpensive

The NLHEP (cont.)

spirometers, suitable for office and clinic use in the primary care setting.[54] Only the FEV_1 and FVC, or FEV_6 (as a surrogate for FVC), and the ratio of these two values are advised for use by primary care physicians for an earlier detection of COPD.

In 2000, a NLHEP spirometry sub-committee published a widely referenced consensus statement that reinforces the importance and need for earlier diagnosis and monitoring of COPD via the use of spirometry in primary care offices (Chest 117:1146-61).[53] This report established criteria for identifying those at risk for COPD and led to the 'Spirometry Review Process' that evaluates the utility and quality of commercial 'office spirometers' (see Resource section of www.nlhep.org).

NLHEP has awarded seed grants to support research efforts in COPD, and has sponsored COPD demonstration projects in community hospitals, These pilot projects, based on the NLHEP concept, have been established (for early identification and treatment of COPD) in various communities such as in Hanover, PA. These and other NLHEP-sponsored programs have made major progress to raise awareness and promote earlier detection of this disease- the first steps in controlling the increased morbidity and mortality associated with COPD.[52]

The Saturday AM CME symposia educational materials for primary care COPD education were developed, and following a successfully updated seminar, the first one in the modern series was launched in Tulsa, OK in February, 2002. James Seebass, Dennis E. Doherty and Thomas Petty led this seminar. This model proved successful and has been repeated on many occasions. A "Train the Trainer" workshop for young pulmonologists was held in Dallas, TX, to provide them with COPD information and educational instruments for future regional CME programs. "Trainers" are the "Disciples" of the NLHEP who can also carry the message to the grass roots of the nation.

In 2000, the NLHEP developed a strategic partnership with the AARC for COPD educational programs. Educational materials developed by the NLHEP include an informational brochure that established the NHLEP motto "Test Your Lungs–Know Your Numbers" (and containing answers to 20 commonly asked questions by COPD patients); the development of a user-friendly educational web site for patients and clinicians (www.nlhep.org), publication of numerous articles on COPD, COPD and spirometry education booklets, and a 6 year national media campaign to raise public awareness of COPD. We (TLP, DED) authored three booklets: "Prevent COPD Now" and "The Early Recognition and Management of COPD" for primary care physicians to encourage their search for asymptomatic COPD patients in their practices, and a booklet "Save Your Breath America! Prevent Emphysema Now," which contains information written in lay language for patients who may have or be developing COPD. Many thousands of these booklets have been distributed by the NLHEP and the AARC.

In 2004, the administrative functions of the NLHEP were transferred to Irving, Texas, where office space is being graciously provided by the AARC. Dennis E. Doherty assumed the role of Chairman, following his yeoman service as co-chairman for three previous years. Tom Petty and his associate, Louise Nett RN, RRT, remain emeritus members and consultants.

It is hoped that the current and future success of the NLHEP will ultimately lead to the earlier diagnosis, treatment, stabilization, and rehabilitation of patients in early symptomatic or incipient stages of disease in the future.

Appendix

Recommendations of the Sixth Oxygen Consensus Conference. *2006* [55]

Recommendation 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.

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

- Details of competitive bidding with quality standards (supplier selection process)

- Self-monitoring (e.g., spirometry, oxygen liter flow, and oxygen saturation)

- Reimbursement (understand 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 (e.g., loss of electrical power or malfunction of stationary/portable delivery device such as liquid-oxygen source equipment)

Recommendation 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, including RTs, 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, including RTs, following that patient's LTOT.

Recommendation 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 providing LTOT care. The pediatric patient should also be considered in the development of these standards. These standards, for example, could include, but not be limited to, indications for LTOT, patient education, matching the proper LTOT delivery device and accessories to patient 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.

Recommendation 5:
All patients who are provided an intermittent-flow device (which is one category of oxygen-conserving device) 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.

Recommendation 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.

Recommendation 7:
Evidence-based criteria are needed to define ambulatory/portable/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.

Recommendation 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 involved in the care of the LTOT patient 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 M.D. or D.O.

Recommendation 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.

Recommendation 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.

Recommendation 11:
Funding should be provided for research that evaluates the outcome 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.

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

Recommendation 13:
We recommend development of a demonstration project(s) to evaluate the utilization of resources for LTOT and incorporate compliance data into a re-certification process(es) when oxygen is prescribed in acute situations. An example might be establishment of a regional facility for conduct of re-certification 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 to conduct 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.

Recommendations of the Fifth Oxygen Consensus Conference. *1999* [56]

Recommendation 1:
Respiratory Home Care Services are endorsed as essential in LTOT. We recommend that LTOT should be viewed as a compendium of therapeutic services including educating patients, assessing patients, monitoring therapeutic benefits, evaluating patient compliance, communicating with primary care physicians, and providing and maintaining the necessary technology. Establish minimum service standards with respect to supplying oxygen services for homecare providers. (e.g. respiratory srofessionals, fafety, 24-hr access….)

Recommendation 2:
The NIH should fund a scientific study to determine the benefits of truly portable O_2 therapy in terms of survival, quality of life, healthcare utilization and physiological outcomes.

Recommendation 3:
The evolution of our healthcare system has resulted in the discharge of patients from hospital based care into the home setting at a higher acuity level and the management of more acutely ill patients in the outpatient setting. It is recommended that patients being diagnosed with unstable respiratory disease with prescribed oxygen therapy be re-certified after the initial 90 days of therapy for long-term oxygen therapy. Once the need for long-term oxygen therapy is established, repeat measurement of arterial blood gases or saturation is not necessary or justifiable for re-certification. These measurements are medically necessary and justifiable for the physician to evaluate the course of the disease and to make adjustments in oxygen flow rate.

Recommendation 4:
Standardized education of patients, caregivers and medical professionals is of prime importance, utilizing existing materials. An Education Consensus Conference is recommended for the evaluation of current literature and to define tools to be used to educate patients, caregivers and others. Enhance education with a national oxygen awareness and lobbying effort. Employ national groups such as NHOPA, ACCP, ATS, AARC, NAMES, AACVPR, NAMDRC, PERF, VA and a manufacturer's coalition.

Recommendation 5:
Provision for ambulation oxygen portable must be defined and reimbursed accordingly. "Ambulatory" to mean availability for daily use, carried by the patient, weighing less than 10 pounds, minimum oxygen duration of at least 4-6 hours at 2 L/min continuous flow or equivalent. Redefine portable O_2 as equipment that can be carried by most patients on their person during ADL, weighing 10 pounds or less, 2 L/min. System must be selected for the needs of a specific patient. Consider portability (weight), duration, and frequency of use. We recommend that technology development focus on technologies that are more compatible with patients' lifestyles such as lightweight, portable oxygen systems.

Recommendation 6:
To assure patients rights and an informed choice of LTOT that meets their medical needs,

an accepted definition of *access* must be developed by clinicians, which addresses issues such as access to medical care, pulmonary rehabilitation, service, equipment, and supplies. Once the definition is established, it must be presented to HCFA and other third party payers. Re-define "access to care" to facilitate provision of truly portable oxygen.

Recommendation 7:
Support O_2 patients in their need for airline travel. DOT / Coast Guard criteria to be adapted by FAA/ Airlines. Patients have a right to medically necessary oxygen therapy during all phases of air travel. Acceptable airline service must include the establishment of consistent policies and the provision of appropriate *and* sufficient oxygen, equipment and supplies (e.g. adjustable flow meters) that will meet the patient's prescribed oxygen order.

Recommendation 8:
It is recommended that upon initial setup and periodically thereafter, that all O_2 therapy devices, particularly OCD, that patients be titrated to the proper flow rate at rest, exercise, and sleep, to achieve maximum benefit. The AARC and/or AACVPR should create clinical practice guidelines for the evaluation and monitoring of LTOT. This should include both short and long term plans.

Recommendation 9:
Patient compliance is essential to the efficiency of LTOT and can be improved though initial and on-going patient education and intervention with access to appropriate services and oxygen systems. Compliance will be enhanced by optimized reimbursement and empowering the patient with choices to best meet their medical needs. Health care professionals should continue efforts to assure compliance to M.D. prescription.

Recommendation 10:
An oxygen patients Bill of Rights should be developed to assure a standardized and appropriate level of patient care that will be used by all patients and health care providers. Supporting documents should include education checklists, defined patient responsibilities, and a defined role of the RCP in the care of LTOT patients.

Recommendation 11:
A system of patient advocacy should be developed to represent LTOT users and providers. The system should include a mechanism to resolve complaints and concerns, which would improve patient compliance and satisfaction. Tell HCFA about it.

Recommendation 12:
Encourage scientific investigations to explore further indications for oxygen therapy. e.g. exercise, sleep with daytime normoxia.

Recommendation 13:
Acknowledge the electrical power costs of O_2 equipment device usage, as well as other hidden costs.

Recommendation 14:
Adequate reimbursement for medically necessary and technology appropriate oxygen delivery systems (e.g. ambulatory oxygen, conserving devices and transtracheal oxygen) will improve patient compliance and optimize clinical outcomes.

Further Recommendations for Prescribing, Reimbursement, Technology Development, and Research in Long-term Oxygen Therapy. *1993* [57]

Recommendation 1:
The Certification of Medical Necessity (CMN) for prescribing LTOT, HCFA From 484 is acceptable but still complex and difficult for

primary care physicians to complete. Further simplification is needed. There is *no* need for any additional treatment form or orders by the physicians in prescribing LTOT.

Recommendation 2:
Continued efforts are essential to educate physicians, particularly primary care physicians, on the indications for LTOT and how it should be prescribed. Major organizations such as the American College of Physicians (ACP), the American Academy of Family Practice (AAFP), and the American College of Family Physicians – Osteopathic (ACFP) should provide regular education workshops for primary care physicians on prescribing LTOT. Principles of prescribing LTOT should be taught in all medical schools, both for M.D. and Osteopathic degrees.

Recommendation 3:
To improve communications and "standardize" LTOT terminology, especially for use in the CMN and for medical reimbursement policy, the following definitions are suggested: (1) Stationary oxygen equipment – a large reservoir of oxygen or oxygen producing device that cannot be easily moved or carried by the patient. Examples: H or K cylinder with compressed oxygen; stationary home oxygen concentrator; or liquid oxygen reservoir. (2) Portable oxygen equipment that can be moved or transported by patients, but not "on their person" during daily activities. This equipment usually weighs more than 10 lbs. Examples: E cylinder and regulator mounted on a cart or stroller or suitcase-sized battery operated oxygen concentrator. (3) Ambulatory oxygen – any oxygen equipment that can be carried by most adults "on their person" during activities of daily living, weighing 10 lbs or less. Additionally, the oxygen supply must last at least 4-6 hr at 2 L/min or the physiologic equivalent. Examples: small liquid oxygen canister or small lightweight high-pressure cylinder and regulator.

Recommendation 4:
New or revised LTOT orders should include the oxygen flow necessary to correct hypoxemia, both at rest and during usual exercise. The physician or qualified laboratory personnel under medical supervision are responsible for making or supervising these measurements, utilizing arterial oxygen saturation or tension monitoring.

Recommendation 5:
Because supplying ambulatory oxygen has a higher cost than portable oxygen for both equipment and service, it is recommended that these facts be taken into consideration in setting oxygen reimbursement policy. Specifically a higher reimbursement category is recommended for ambulatory oxygen in excess of that currently allowed for portable systems.

Recommendation 6:
A prospective longitudinal multicenter study is needed to evaluate the medical efficiency of ambulatory oxygen systems versus stationary oxygen delivery systems in hypoxemic patients with COPD. Some objectives of the study would include (1) patient compliance, (2) quality of life, (3) exercise tolerance, and (4) survival. The Veterans Administration Medical Centers would appear to be ideal sites for such a study. Since many of these centers currently have contacts with home oxygen suppliers that provide only stationary oxygen systems with portable, but not ambulatory, capability; the provision of ambulatory equipment for a group of study patients would not compromise the care that currently exists. The VA Medical Centers also serve a large population of patients with COPD.

Recommendation 7:
A prospective study in patients with COPD without daytime hypoxemia should be undertaken with the primary goal of examining the effect of oxygen therapy during sleep on mortality. Additional goals should be to follow a

noninvasive measure of cardiopulmonary function and to determine a cost outcome in terms of the number of hospitalization days, clinic visits, etc. This investigation should be prospective, multicentered, double-blind, and include appropriate sham-treated desaturators and nondesaturator controls. It could be carried out best in centers with broad populations of COPD patients and with existing sleep laboratories to identify potential subjects. The final design could be similar to, and incorporate many of the techniques used in, the NOT study (4).

Recommendation 8:
It is recognized that current scientific data appear insufficient to make solid conclusions about the efficiency of nocturnal supplemental oxygen in patients who are not hypoxemic (PaO_2 > 60mmHG) while awake. The committee recommends that current prescribing practices in this setting be determined by individual practitioners within the framework of HCFA guidelines, based upon their experience and the facilities available for detecting NOD. At the same time, it should be realized that future prescribing practices may need to be modified as scientific data becomes available to support or refute them.

New Problems in Supply, Reimbursement, and Certification of Medical Necessity for Long-Term Oxygen Therapy. *1990* [58]

Recommendation 1:
A new policy for oxygen reimbursement is necessary. It is illogical and detrimental to patient care to base reimbursement of home oxygen therapy on flow rate and ignore the source of oxygen and the variable costs involved in providing oxygen from different devices and in different forms (liquid vs. gaseous). Reimbursement should be based on the DME provider's reasonable costs for supplying these different modalities of oxygen therapy. The geographic discrepancies in reimbursement for oxygen therapy must also be addressed. Rural areas should be considered as high cost areas when liquid oxygen systems are being provided because of the low population density and the greater distances involved in providing systems. It should also be recognized by HCFA that portable oxygen and ambulatory oxygen are not synonymous. Portable systems, such as cylinders or strollers, are cumbersome and impede full activity. Ambulatory systems can be carried easily by patients and are designed to allow and encourage full mobility. Ambulatory systems, e.g., liquid ambulatory units, allow daily exercise, which is key to pulmonary rehabilitation.

Recommendation 2:
In redesigning the reimbursement system, the development and use of oxygen-conserving devices and techniques should be encouraged and not discouraged by reimbursement policy. Cost savings that can be achieved through oxygen conservation must be viewed in the context that oxygen is the least expensive component in oxygen therapy. The real benefit from oxygen-conserving technology is improved patient care and better compliance with therapy because of smaller, lightweight ambulatory oxygen units that allow greater mobility and improved quality of life. The increased costs of new oxygen delivery equipment and technology can be balanced to some degree by the modest reduction in the cost of supplying oxygen, but the cost savings for the DME provider are likely to be small.

Recommendation 3:
Until reimbursement policy can be changed, it is recommended that all oxygen be reimbursed at the flow rate necessary to achieve correction of hypoxemia using flow through a nasal cannula as a uniform standard and that the "dual reporting" of flow rate and amount of oxygen delivered be eliminated.

Recommendation 4:
It is recommended that patients with unstable respiratory disease, such as those leaving an acute care hospital, who have not previously qualified for long-term oxygen therapy and who at the time of discharge qualify for home oxygen therapy under currently established criteria, be issued a CMN for short-term oxygen therapy. Recertification for long-term oxygen therapy would be necessary in 30 to 90 days when the patient is judged by the physician to be clinically stable and receiving optimal therapy. Once the need for long-term oxygen therapy is established, repeat measurement of arterial blood gases or oxygen saturation is not medically necessary or justifiable for the physician to evaluate the course of the disease and to make adjustments in oxygen flow rates.

Recommendation 5:
The previous recommendation has a great potential for cost savings and can improve quality of care by eliminating unnecessary oxygen therapy. Some of the cost savings achieved in this area should be applied to correction of the inequalities that exist in the current reimbursement system. Consideration should also be given to reimbursement of short-term oxygen therapy at a higher rate because the initial delivery, setup, and educational costs must be amortized over a shorter time period and the maintenance and storage costs will increase.

Recommendation 6:
It is recommended that the CMN form be a one-page document with the information necessary for certification on one side and instructions for completion on the reverse side. The physician should continue to provide the documentation of medical necessity and prescribe the oxygen delivery system that is medically indicated for the patient as well as the appropriate oxygen flow rates that may vary between rest, activities of daily living, and sleep. Many items can be more quickly and efficiently completed by a check list format. The DME provider should be able to fill in portions of the certificate that do not change the prescription.

Recommendation 7:
It is recommended that when home oxygen is prescribed in the hospital, the CMN form should be completed before discharge and the DME supplier notified in ample time to provide the equipment and instructions necessary for appropriate therapy. Physicians recognize that other medications cannot be dispensed until the discharge prescription is completed. Each hospital should be responsible for compliance with this policy and this should become an area of review by the Joint Commission on Accreditation of Healthcare Organizations. The CMN forms must be readily available in all acute medical facilities where patients are likely to be discharged with home oxygen therapy.

Recommendation 8:
A program must be established to educate primary care physicians who are responsible for ordering home oxygen therapy. The CMN form is now and will continue to be one of the most complex prescriptions that physicians are required to complete. The prescribing physician not only must understand the indications for short-term and long-term oxygen therapy but also must be familiar with the various systems for supply and delivery of oxygen and know which best meets the needs of each patient. At the present time, there are striking variations in Medicare carrier policies for documentation, certification and reimbursement of home oxygen therapy. Education of carrier medical directors, who usually are not specialists in respiratory disease, would help alleviate most of these discrepancies. Other health care providers who are involved in home oxygen therapy would also benefit from a comprehensive education program.

Further Recommendations for Prescribing and Supplying Long-Term Oxygen Therapy. *1987* [59]

Recommendation 1:
For the purposes of LTOT, the definition of the term "ambulation" should be expanded to include all activities requiring mobility beyond the delivery range of a stationary oxygen source (up to 50 feet of oxygen tubing).

Recommendation 2:
The medical standard for LTOT should be continuous administration (24 h/day) with ambulatory capability.

Recommendation 3:
Exceptions to continuous administration with ambulatory capability (e.g. a portable oxygen source) should be specified and would be expected to include (1) patients who are not capable or desirous of activity beyond the delivery range of a stationary oxygen source; (2) patients requiring oxygen only during sleep; (3) patients requiring oxygen only during ambulation; (4) patients who prove to be noncompliant with prescribed therapy and in whom it is demonstrated repeatedly that the portable oxygen source is not being used.

Recommendation 4:
Initial documentation of the medical necessity for LTOT should consist of an arterial blood gas measurement performed when the patient is stable and receiving optimal medical management and analyzed by a duly approved laboratory (e.g. American Thoracic Society, College of American Pathologists, Joint Committee on Accreditation of Healthcare Organizations, etc). Oximetry is recognized as an appropriate and acceptable methodology for documenting hypoxemia during activity and sleep. It is also an acceptable follow-up methodology for evaluating and monitoring LTOT. The need for continued use of LTOT should be verified on an annual basis by the patient's physician.

Recommendation 5:
The physician should prescribe the oxygen source (such as compressed gas, liquid oxygen, or concentrators) and must also prescribe the delivery device (such as continuous nasal cannula, transtracheal administration, reservoir nasal cannulas, pulse-dose oxygen administration and demand valve) based on the most appropriate therapeutic regimen for each individual patient. The liter flow to correct hypoxemia must be specified by the physician.

Recommendation 6:
Once a hospitalized patient is identified as needing home oxygen therapy, transfer to the home setting should include, but not be limited to (1) whether the patient should be given oxygen en route from hospital to home (to be determined by the physician), and (2) adequate instruction and familiarization of the patient (and his/her family) with the oxygen equipment prior to discharge and upon arrival home.

Recommendation 7:
Equipment maintenance is best handled by close adherence to the manufacturer's recommendations for each specific item of equipment. Therefore, it is important that (1) manufacturers always provide, coincident with the market introduction of any new equipment, comprehensive maintenance and repair instructions appropriate to the nature and anticipated level of field service of the equipment, and (2) such instructions are to be kept up to date as design modifications are made.

Recommendation 8:
Clinical evaluation should include regular assessments of patient compliance with prescribed therapy, potential complications, potential hazards, and the need for continued education. Patients receiving LTOT share

responsibility with the prescribing physicians for remaining in communication with their physician or designate in order to assure continued appropriate care for their condition.

Recommendation 9:
For patients receiving LTOT, routine measurement of their arterial blood gases or oxygen saturation in the home environment is not necessary; however, such measurements may be useful in patients found to be clinically unstable. Furthermore, the physician continues to have the responsibility of documenting the efficiency and safety of the LTOT in correcting the patient's hypoxemia and its clinical consequences after the initiation of home oxygen therapy.

Recommendation 10:
The development of quality assurance standards for continuing medical management of the home oxygen patient is beyond the scope of the current committee. It is recommended, however, that a conference of appropriate healthcare providers (physicians, respiratory care practitioners, respiratory nurses, durable medical equipment (DME) providers, etc.) should develop a set of guidelines for appropriate medical followup.

Recommendation 11:
In view of the need for education of physicians concerning the indications, means of administration and complications of LTOT, it is recommended that the appropriate professional societies set up continuing medical education courses leading to certification in long-term oxygen treatment. The certification should only be awarded after competence is shown by an objective evaluation and should be for a defined period of time. The necessary continuing medical education and certification should be made available to all practicing physicians who seek certification of competence in LTOT.

Recommendation 12:
Reimbursement must be based on: (1) patient's continuous oxygen flow requirements regardless of the oxygen source or delivery device employed; (2) whether or not the patient is ambulatory in accordance with recommendations 1 through 3; (3) the technological and professional components necessary to meet the therapeutic requirements.

Problems in Prescribing and Supplying Oxygen for Medicare Patients. *1986* [60]

Recommendation 1:
There is *no substitute* for oxygen therapy. It is appropriate that each patient should receive optimum therapy *before* long term oxygen therapy is ordered. The term "optimum therapy" will depend on the overall condition of the patient as viewed by the prescribing physician. Furthermore, "optimum therapy" will remain a part of the patient's total treatment even while receiving oxygen therapy.

Recommendation 2:
In patients with arterial PO_2's of 55 at rest, it is deemed medically necessary that a portable system be provided to facilitate ambulation in addition to a stationary oxygen delivery system. Similarly, in patients demonstrated to develop hypoxemia (PaO_2 = 55 mmHg) only during exertion, a portable system should be approved for ambulation.

Recommendation 3:
The requirement to demonstrate "clinical improvement" in the patient's condition, as evidenced by an *increase* in the patient's ability to exercise or perform various activities should be removed. That exertion induced hypoxemia occurs is sufficient evidence of the need for oxygen therapy during exercise. Data from carefully conducted clinical trials clearly documents the long-term benefits of oxygen

therapy in hypoxemic chronic lung disease patients.

Recommendation 4:
It should be recognized that the cost of various systems and accompanying support services may vary considerably. The physicians' considered judgement regarding the type of system to be provided is based on physical, psychological, social, and regional factors as well as cost. Therefore, cost considerations should not be used to overrule the medical necessity of a particular method of providing oxygen.

Recommendation 5:
When ambulation in and outside of the home is judged to be part of the therapeutic regimen, a portable system will be necessary. When oxygen concentrators are provided as the sole means of oxygen delivery, a supplemental oxygen system is medically necessary because of unpredictable power failures or electrical malfunctions. The current regulations require that the physician indicate the concentration of oxygen to be used. If the delivery system provides greater than 85% oxygen at the liter flow prescribed, then the requirement for a statement of the concentration is unnecessary. For purposes of these regulations, oxygen levels of 85% percent or greater are therapeutically equivalent to 100% oxygen.

Recommendation 6:
Consideration should be given to developing a standardized prescription form for use by suppliers and carriers. Such a form would facilitate compliance by physicians in providing the data required by the regulations.

Recommendation 7:
HCFA should urge carriers to obtain consultants who are experts in the nuances of oxygen therapy to advise them on unusual prescriptions for home oxygen therapy, as set forth in regulations 4 and 5, Page 13746, Federal Register. In addition, HCFA itself should solicit the comments of experts in the field as part of the policy-making process.

Recommendation 8:
It is not possible to offer a recommendation at present concerning the clinical use of oxygen conserving devices. Long-term studies are sorely needed.

Recommendation 9:
An educational effort needs to be mounted to better educate the profession in the principles and practice of home and ambulatory oxygen therapy. The appropriate professional bodies should be contacted to begin planning such an effort.

Recommendation 10:
A small workshop of 20-30 persons should be convened to explore areas of concern between suppliers and carriers, with representatives of HCFA and the medical profession serving as resource personnel. The emphasis in this workshop should be on making recommendations for resolving differences and establishing open lines of communication between carriers and suppliers. Ideally, this workshop should be convened under the auspices of the Department of Health and Human Services, and with co-sponsorship by professional organizations such as the American Thoracic Society, the American Association for Respiratory Care and other interested organizations.

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Notes:

The New Era

The prevention of lung disease and the promotion of lung health is the goal of the National Lung Health Education Program (NLHEP), conducted in collaboration with government, medical and other health professional organizations. Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in the United States. Because of this, the NLHEP was implemented to develop and promote a nationwide education program designed to identify COPD in its early stages. One objective is to promote a program of intervention to slow the progression of COPD before development of clinical symptoms of chronic cough, excess mucus and shortness of breath, which are early signs of risk leading to disabling forms of this chronic lung disease. The spirometer can be used to identify early stages of COPD and can also identify people at risk of death from lung cancer, heart attack, and stroke. Indeed, preservation of lung health is the key to good health in general.

NLHEP

www.nlhep.org

Test Your Lungs – Know Your Numbers

National Lung Health Education Program

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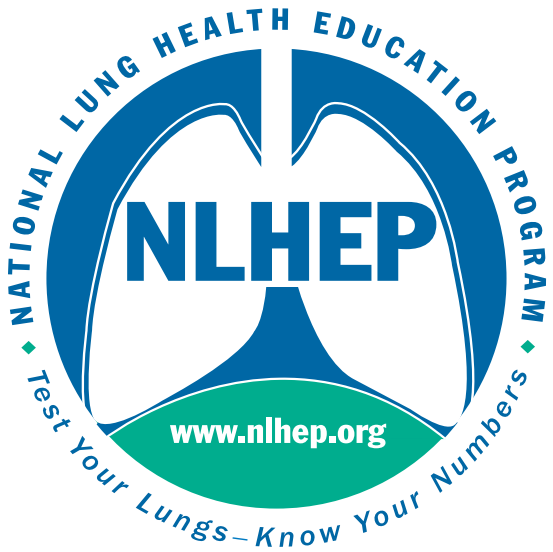

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