Abstract Submissions

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Table of Contents

ACCORD COPD I: Efficacy and safety of twice-daily aclidinium bromide in COPD patients ......................... 4
ACCORD COPD I: Nighttime symptoms and rescue medication use with twice-daily aclidinium bromide in COPD patients .................................................................................................................. 5
Improving Compliance for Spontaneous Breathing Trials in the MSICU ......................................................... 6
Discovering Alpha-1 in COPD Patients Via Outpatient PFT ................................................................................ 7
Instituting Focused Care: Creating a Pulmonary Mobility Unit .......................................................................... 8
Sex Differences in Ventilatory Mechanics of Emphysema Patients ................................................................. 9
Dr. Thomas L. Petty’s Legacy: Snowdrift Pulmonary Conference and the Colorado COPD Connection ....... 10
A Bench Study to Compare Portable Therapies for Respiratory Insufficiency: Continuous Flow Oxygen (CF), Intermittent Flow Oxygen (IF), and Non-Invasive Open Ventilation (NIOV) .......................................................... 11
Performance of Activities of Daily Living as a Predictor of Rehospitalization for Patients with COPD Exacerbations .............................................................................................................. 12
Reducing Total Costs of Aerosolized Medication Delivery Using the AeroEclipse II Breath Actuated Nebulizer ................................................................................................................................................ 13
Prevalence and Impact of Nighttime Symptoms of COPD in a Clinical Trial Population ............................. 14
Results from Qualitative Research on Patients’ Experience of Nighttime COPD Symptoms .................... 15
Pre-Diagnostic Exacerbations of COPD: A Potential Screening Criteria ..................................................... 17
The Medical Burden of COPD .......................................................................................................................... 18
The Disability Burden of COPD ........................................................................................................................ 19
Augmented Ventilation Assistance to Improve Activities of Daily Living ..................................................... 20
Medication Usage for Patients with COPD Who Were Readmitted Within 30 Days Following Hospital Discharge for an Exacerbation ........................................................................................................ 21
Non-Invasive Assessment of Ventilatory Mechanics Before and After Lung Volume Reduction Surgery: a Case Series .............................................................................................................................................. 22
Comparative Efficacy of Once-Daily Indacaterol 75µg in COPD in Terms of Forced Expiratory Volume: A Patient Level Network Meta-Analysis ........................................................................................................ 24
Medication Usage for Patients with COPD Following Hospital Discharge Following an Exacerbation ...... 25
Rehospitalization Rates for Patients with COPD Who Require Supplemental Oxygen Therapy Following a Hospitalization for an Exacerbation [Refusal of Patients to Continue Program] ........................................ 27
Patient Satisfaction Following a Transition of Care COPD Management Program in the Home ............... 28
How to Start a Pulmonary-Cardiac Rehabilitation Program in Under 90 Days .............................................. 29
Efficacy and Safety of Indacaterol 75 µg Once Daily In Patients With Moderate-to-severe COPD ............ 30
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy of Roflumilast in Elderly Patients with Chronic Obstructive Pulmonary Disease</td>
<td>32</td>
</tr>
<tr>
<td>EFFORTS: COPD Advocacy From the Ground Up</td>
<td>33</td>
</tr>
<tr>
<td>Reduction in the Risk of Initial and Subsequent Exacerbations Following Roflumilast Treatment: Pooled Results from Two Pivotal Trials</td>
<td>35</td>
</tr>
<tr>
<td>Transition of Care Program and Rehospitalization Rates for Patients with COPD Who Require Home Oxygen Therapy Following an Exacerbation: An Update</td>
<td>36</td>
</tr>
<tr>
<td>The Role of Imaging in Phenotyping Chronic Obstructive Pulmonary Disease Compared with Lung Function Testing</td>
<td>37</td>
</tr>
<tr>
<td>Smart Nasal Cannula: Clinical Utility Study on LTOT Patients</td>
<td>38</td>
</tr>
<tr>
<td>Background of Illinois COPD Coalition and Midwest COPD Network convened by Respiratory Health Association</td>
<td>39</td>
</tr>
<tr>
<td>Smooth Sailing for Respiratory Patients: Rehabilitation on the High Seas</td>
<td>40</td>
</tr>
<tr>
<td>Breathe New Hampshire’s COPD Awareness Team: Breathe, Engage, Unite</td>
<td>41</td>
</tr>
<tr>
<td>Reversibility of obstruction, significant bronchodilator responsiveness, and mortality in the Lung Health Study</td>
<td>42</td>
</tr>
<tr>
<td>Chronic Respiratory Disease, Comorbid Cardiovascular Disease, and Mortality in a Representative U.S. Cohort</td>
<td>43</td>
</tr>
<tr>
<td>The Bronchiectasis Research Registry</td>
<td>45</td>
</tr>
<tr>
<td>Effect of Upper Extremity Exercise on Dyspnea and Fatigue in COPD Patients</td>
<td>46</td>
</tr>
<tr>
<td>The Mid-Atlantic Regional COPD Center and the Corporate Education and Awareness Toolkit</td>
<td>47</td>
</tr>
</tbody>
</table>
ACCORD COPD I: Efficacy and safety of twice-daily aclidinium bromide in COPD patients

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Introduction: Aclidinium bromide is a novel, long-acting muscarinic antagonist developed for the treatment of chronic obstructive pulmonary disease (COPD). Previous clinical trials have shown that treatment with aclidinium resulted in sustained bronchodilation and a favorable safety profile in patients with moderate-to-severe COPD. This Phase III study evaluated the efficacy and safety of 2 doses of aclidinium bromide (200 µg and 400 µg) administered twice daily versus placebo.

Methods: In this 12-week, double-blind, multicenter, placebo-controlled trial, moderate-to-severe COPD patients were randomized (1:1:1) to either twice-daily aclidinium (200 µg or 400 µg) or placebo. The primary and secondary efficacy endpoints were adjusted mean change from baseline in morning pre-dose (trough) and peak FEV1 at Week 12, respectively. Additional measures included St George’s Respiratory Questionnaire (SGRQ) and the Transitional Dyspnea Index (TDI). Safety assessments included adverse events (AEs), clinical laboratory measures, vital signs, and ECGs.

Results: A total of 561 patients were randomized and 467 (83%) completed the study. At Week 12, both doses of aclidinium showed a statistically significantly greater improvement in the placebo-corrected, adjusted mean change from baseline (±SE) in trough FEV1 (86±21 mL, 200 µg and 124±21 mL, 400 µg; p<0.0001 for both). Adjusted mean change from baseline in peak FEV1 was also statistically significantly improved for both aclidinium 200 µg and 400 µg over placebo at Week 12 (146±23 mL and 192±22 mL, respectively; p<0.0001 for both). Both doses of aclidinium showed statistically significant improvements from baseline in placebo-corrected SGRQ total score at Week 12 (-2.73±1.1, 200 µg and -2.54±1.1, 400 µg; p<0.02 for both) as well as TDI focal score (200 µg, 0.9±0.3; 400 µg, 1.0±0.3; p<0.01 for both). The only treatment-emergent adverse event (AE) reported by >5% of patients was COPD exacerbation (9.2%, 200 µg; 7.4%, 400 µg; 12.4%, placebo). The incidence of all other AEs was <4% and was comparable across groups. Treatment with either dose of aclidinium resulted in an incidence of systemic anticholinergic events that was low and similar to placebo.

Conclusions: Aclidinium 200 µg and 400 µg twice daily significantly improved lung function, dyspnea, and health status in patients with moderate-to-severe COPD. Both doses of aclidinium were well tolerated throughout this study with an incidence of systemic anticholinergic events that was similar to placebo.

*This study was supported by Forest Research Institute, Inc., a wholly owned subsidiary of Forest Laboratories, Inc., and by Almirall S.A.
**ACCORD COPD I: Nighttime symptoms and rescue medication use with twice-daily aclidinium bromide in COPD patients**

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**Introduction:** Patients with chronic obstructive pulmonary disease (COPD) often experience nighttime symptoms and sleep difficulties, which may reduce their quality of life. Little has been published about the effects of currently available COPD medications on nighttime symptoms. In this Phase III study, nighttime symptoms and rescue medication use were assessed with twice-daily treatment with aclidinium bromide in patients with moderate-to-severe COPD.

**Methods:** In this 12-week, double-blind study, COPD patients with FEV₁/FVC <70% were randomized (1:1:1) to aclidinium 200 µg, 400 µg, or placebo. Nighttime symptoms were reported daily using electronic diaries containing a COPD Nighttime Symptoms Questionnaire, which assessed symptom frequency and its effect on morning activities, and measured breathlessness and sputum production. Sleep diary entries and rescue medication use were also assessed.

**Results:** A total of 561 patients were randomized and 467 (83%) completed the study. Mean (SD) postbronchodilator percent predicted FEV₁ at screening was 53.9 (13.3) %. At Week 12, aclidinium 200 µg and 400 µg significantly reduced nighttime COPD symptom frequency compared with placebo (p<0.05 and p<0.005, respectively). Both doses of aclidinium also significantly reduced the severity and impact of nighttime breathlessness and cough on morning activities versus placebo (p<0.01 and p<0.05, respectively). The severity of early morning breathlessness and restriction of activities due to breathlessness were also reduced with aclidinium 200 µg (p<0.01) and 400 µg (p<0.001) versus placebo. Compared with placebo, the self-reported amount of sputum produced over 24 hours was significantly reduced with aclidinium 200 µg (p<0.05) and 400 µg (p<0.01) at Week 12 while that produced during sleeping hours was not significantly reduced with either dose. Over the 12-week period, treatment with aclidinium 400 µg resulted in a significantly greater improvement in both frequency of sputum production at night and activities restricted by morning breathlessness (p<0.01 and 0.05, respectively) versus the 200 µg dose. Aclidinium 400 µg significantly improved the severity and impact of breathing symptoms on sleep versus placebo at 12 weeks (p<0.01). The frequency of nighttime awakenings and ability to fall back asleep were significantly improved at Week 12 with aclidinium 400 µg versus placebo (p<0.05). All other sleep diary measures were not significantly different between aclidinium and placebo. Both aclidinium 200 µg and 400 µg reduced total daily rescue medication use versus placebo by 0.7 (p=0.0010) and 0.9 (p<0.0001) puffs per day, respectively.

**Conclusions:**
Twice-daily aclidinium 200 µg and 400 µg reduced the frequency, severity and impact of nighttime/early morning symptoms as well as daily rescue medication use. Treatment with aclidinium may increase the health status of patients with COPD.

*This study was supported by Forest Research Institute, Inc., a wholly owned subsidiary of Forest Laboratories, Inc., and by Almirall S.A.*
Improving Compliance for Spontaneous Breathing Trials in the MSICU

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Problem: A major component of the Institute for Healthcare Improvement (IHI) Ventilator Bundle is to assess the patient’s readiness to extubate on a daily basis. An internal audit examining this intervention in the Medical Surgical Intensive Care Unit (MSICU) in March 2011 revealed a 31% adoption level. Upon further investigation, it was noted that performance of daily Spontaneous Breathing Trials (SBT) varied among respiratory care practitioners (RCP), and was not well coordinated with the sedation holiday procedure performed by RNs for patients on the same unit. Therefore, the aim of the project was to improve compliance with the performance of the SBT protocol.

Evidence: One of the main elements of the IHI Ventilator Bundle is to conduct a daily assessment of the patient’s readiness to extubate after the lightening of sedation. This ensures the patient is awake and able to participate in weaning and assist with coughing and clearing secretions. Evidence supports that this pairing of interventions will decrease the length of time on the ventilator, incidence of ventilator acquired pneumonia, and the patient’s overall length of hospital stay.

Implementation: The IHI Critical Care Workstream team (a multidisciplinary group focused on performance improvement in the MSICU) developed a plan to improve hand-off in care among the RCP and RN in the unit with a focus on the SBT process. Exclusion and performance criteria for how to conduct the SBT were reviewed and clarified by the physician and RCP of the team. A process for identifying eligible patients and a supportive flow diagram were introduced to the RCP staff to improve consistency in care. A visual cue was placed on the door of the patient’s room during RCP morning rounds. Feedback on the process was solicited from all staff and suggestions for improvements implemented quickly using a rapid-cycle “Plan, Do, Study, Act” (PDSA) method.

Outcomes: Compliance was measured based on whether all eligible patients were identified and if the procedure was then carried out as specified in the protocol. 90 days after implementation, 100% of eligible patients were identified correctly and 70% had the SBT completed correctly. Number of ventilator days per patient was reduced from 2.79 to 1.75. Overall length of stay for ventilated patients was reduced from 3.73 to 2.19 days. VAP rates continue to remain at zero with this intervention.

Implications: Patient outcome has been improved and cost of care reduced through active implementation of this program. Feedback from staff suggests that communication in care improved after implementing RCP bedside rounds and providing a visual cue as a reminder to all staff of the plan to conduct the SBT that day. SBT compliance and coordination of care improved with implementation of this IHI ventilator bundle initiative in the MSICU.
Discovering Alpha-1 in COPD Patients Via Outpatient PFT

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**Background:** An estimated 100,000 individuals in the United States have Alpha-1 Antitrypsin Deficiency (A-1), but less than 10% have been diagnosed. The American Thoracic Society/European Respiratory Society (ATS/ERS) Statement on the Diagnosis and Management of individuals with A-1 recommends routine testing for individuals with Chronic Obstructive Pulmonary Disease (COPD), asthma with incomplete reversibility and patients with A-1 symptoms. The objective of this study was to validate routine screening for A-1 in patients referred for outpatient pulmonary function test (PFT) based on their PFT results and A-1 related symptoms.

**Methods:** 165 individuals were selected for A-1 testing based on PFT results of less than 80% of predicted for: forced expiratory volume in 1 second (FEV1), forced expiratory volume in 25-75 seconds (FEV25-75), forced vital capacity (FVC), FEV1/FVC, and diffusion capacity (DLCO). Additional considerations were obstructive flow-volume curve patterns and minimal bronchodilator reversibility. Patients were questioned regarding symptoms related to A-1 and their smoking history.

**Results:** 18 (11%) of the individuals tested for A-1 were positive, including MS genotype individuals (carriers). Genotypes consisted of one ZZ patient, two SZ patients, four MZ patients, and eleven MS patients. Of the 18 patients containing altered A-1 genes, 11 had COPD (60%), 3 had asthma (16%), 3 had sarcoidosis (16%), 1 had bronchiectasis (4%), and 1 had abnormal chest x-ray (4%). More than 11 subjects (56%) had less than 80% of predicted in the following PFT parameters: FEV1, FEF25-75 and DLCO. 15 subjects (83%) had minimal post-bronchodilator reversibility. 13 patients (72%) had obstructive flow-volume curve patterns and 11 patients (61%) had a smoking history.

**Conclusions:** 11% of the 165 patients tested for A-1 had an altered gene, which is slightly greater than the less than 10% patient population predicted to be A-1. Basing A-1 testing criteria on diagnosis, PFT parameters less than 80% of predicted for FEV1, FEF25-75, and DLCO, absence of post-bronchodilator reversibility, and obstructive flow-volume curve pattern could further predict identification of an A-1 individual. Screening and testing for A-1 in patients referred for outpatient PFT could potentially identify a larger number of undiagnosed A-1 individuals.
Instituting Focused Care: Creating a Pulmonary Mobility Unit

*Elise Fodor, RN, BSN and Mary Spanke, RN, MSN*

**Aim:** Our goals were to improve care of patients admitted to the hospital for COPD exacerbations and improve outcomes for COPD patients.

**Methods:** We created a Pulmonary Mobility Unit (PMU) that specializes in care of the COPD acute exacerbation patient. Patients admitted to this unit are evaluated and treated by physical and occupational therapy on the morning of their second day in the hospital and then daily until their discharge. Exercise goals with the patients focus on decreasing symptoms, improving quality of life, increasing exercise tolerance, and maintaining and/or improving independence with activities of daily living. A mobility team (consisting of a specially trained nursing assistant, physical therapy aide, and a respiratory therapist) rounds on the patients each afternoon to provide ambulation and document their progress. Education about medications is provided to each patient at their bedside by a pharmacist. Respiratory therapists teach patients breathing techniques and how to use their inhalers and nebulizers properly. Dieticians are available for patients that require extra assistance with meal planning, weight loss or gaining strategies, and resources. Nurse Clinicians round daily on the patients to provide teaching about their disease, assess their progress, address smoking cessation, provide community resources, and facilitate referrals to out patient pulmonary rehabilitation. The Nurse Clinicians call the patients after discharge to answer questions, encourage medication adherence and attendance at follow up appointments and inquire about their hospital stay.

**Findings:** A comparison of the data from the Pulmonary Mobility Unit and patients that met the same criteria but were cared for on other units with the same acuity level was analyzed. It was determined that between the months of May to September 2010 length of stay for patients that stayed on the Pulmonary Mobility Unit was decreased by greater than 0.5 days. Other outcome measurements are currently being explored including patient satisfaction scores and 30 day readmission rates.

**Conclusions:** By instituting this focused care approach patients express greater satisfaction with their hospital stay, increased knowledge about their disease process and shorter lengths of stay in the hospital.
Sex Differences in Ventilatory Mechanics of Emphysema Patients

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**Aim:** Even though sex differences in ventilatory mechanics have been demonstrated in healthy populations, this has not been evaluated in individuals with emphysema. Studies of men with severe emphysema (EM) demonstrated paradoxing of the abdominal ribcage compartment (RCa) and a greater volume change in the abdominal compartment (Ab) than the pulmonary ribcage compartment (R Cp). The purpose of this study was to determine if women with severe emphysema (EW) had similar ventilatory mechanics and if sex differences in the volume change to total tidal volume in the pulmonary ribcage (ΔVRCp), abdominal ribcage (ΔVRCa) and abdominal compartment (ΔVAb) exist between EW and EM.

**Methods:** 11 consecutive patients (5 EW, age 60 ± 7yrs, FEV₁/FVC: 27 ± 6), (6 EM, age 63 ± 7yrs, FEV₁/FVC: 28 ± 5) undergoing a cardiopulmonary exercise test (CPET) for lung volume reduction surgery (LVRS) evaluation were recruited to also participate in simultaneous optoelectronic plethysmography (OEP) testing before and after exercise and during a maximal voluntary ventilation (MVV) maneuver. An independent samples t-test compared ΔVRCp, ΔVRCa, and ΔVAb between groups for each condition, significance set at p<0.05.

**Findings (mean ± standard deviation):** Preliminary results demonstrated no significant differences between the EW and EM baseline forced expiratory flow one second / forced vital capacity ratio (FEV₁/FVC), diffusion capacity, total lung capacity (TLC) and TLC/residual volume (RV). Men had significantly greater %RV (246% ± 43 vs. 179% ± 23, p=0.008).

Before CPET: ΔVRCp: EW 44% ± 7 vs. EM 32% ± 6, p=0.018; ΔVRCa: EW 17% ± 6 vs. EM 9% ± 11, NS; ΔVAb: EW 39% ± 5 vs. EM 59% ± 14, p=0.016.

Directly after CPET: ΔVRCp: EW 45% ± 2 vs. EM 30% ± 8, p=0.007; ΔVRCa: EW 23% ± 8 vs. EM 7% ± 10, p=0.028; ΔVAb: EW 33% ± 9 vs. EM 62% ± 17, p=0.006.

MVV: ΔVRCp: EW 41% ± 19 vs. EM 29% ± 20, NS; ΔVRCa: EW 20% ± 7 vs. EM 7% ± 14, p=0.074; ΔVAb: EW 38% ± 16 vs. EM 64% ± 19, p=0.041.

**Conclusion:** This study observed EW had different ventilatory mechanics than EM, confirming sex differences in the ventilatory mechanics of emphysema patients. Similar to past studies, men with emphysema continued to demonstrate a paradoxing of the RCa thus causing a decrease in ΔVRCa and increase in ΔVAb when compared to other compartments. Women with emphysema did not demonstrate a paradoxing of RCa and show generally greater ΔVRCp and ΔVRCa and less ΔVAb than men despite similar upper lobe predominant disease and physiologic severity of expiratory airflow obstruction. These results suggest a possible mechanical breathing advantage in women with emphysema, with greater ability to displace the pulmonary ribcage and abdominal ribcage volume both at rest and with exercise and maximal ventilatory effort, in the setting of lung hyperinflation.
Dr. Thomas L. Petty’s Legacy: Snowdrift Pulmonary Conference and the Colorado COPD Connection

Edna Fiore, Louise Nett, RN

The Snowdrift Pulmonary Conference, a New Jersey Nonprofit Corporation, was formed in July 1994 by Dr. Thomas L. Petty and several others for the purpose of education in the field of pulmonary medicine. The mission of the Snowdrift Pulmonary Conference is:

- Continuing and current education programs for primary care physicians and pulmonary patients on pulmonary topics.
- Expand continuing medical education to include students, residents, fellow, and other allied medical professionals on pulmonary and cardiopulmonary topics.
- Support continuing medical education for allied health medical groups
- Maintain the dtompetty.org (Thomas L. Petty, M.D.) web site

The most significant educational endeavor of Snowdrift has been the writing and publication of numerous monographs on Chronic Obstructive Pulmonary Disease. The authors have broad experience in both academic and clinical medicine. The most popular monograph was written for patients, entitled Frontline Advice for COPD Patients. Snowdrift Pulmonary Conference participates in education of patient support groups in Colorado and elsewhere. In the spring of 2004, inspired by the impetus of the fist US COPD Coalition, Dr. Petty brought together a committee consisting of patients and professionals from the University of Colorado, National Jewish Health, the American Lung Association of Colorado, other healthcare institutions and medical equipment providers. This committee that is now known as the Colorado COPDConnection (www.copdconnectco.org) has planned and presented a day of Education featuring well known speakers in the fields of pulmonology, Long term Oxygen Therapy and equipment along with other topics of interest to the Lung Health Community in the fall of the past eight years.

In 2006 members of the Colorado COPD Connection and the Colorado Department of Health established the first State COPD Coalition. The Colorado COPD State Plan and Surveillance Report has served as a prototype for many of the other State COPD Coalitions. In 2009 the annual Conference was officially designated “Thomas L. Petty MD Moving Mountains Lung Health Conference”. In 2012 the Colorado COPD Connection will carry out another of Dr. Petty’s visions with the planning and presentation of a Moving Mountains Conference in Grand Junction on Colorado’s western slope.
A Bench Study to Compare Portable Therapies for Respiratory Insufficiency: Continuous Flow Oxygen (CF), Intermittent Flow Oxygen (IF), and Non-Invasive Open Ventilation (NIOV)

Robert McCoy, RT, Valley Inspired Products

Background: Respiratory insufficiency affects both ventilation and oxygenation for a multitude of diseases. CF oxygen therapy has been the standard treatment for improving oxygenation, with IF oxygen therapy recently becoming popular due to improved efficiency of delivery. Augmented ventilation with oxygen therapy is used in the hospital to treat respiratory insufficiency, yet mobility has not been possible. A new Non-Invasive Open Ventilation system (Breathe Technologies, San Ramon, CA) is available to augment ventilation and provide supplemental oxygen therapy while a patient is ambulatory. This simple bench comparison is intended to differentiate assorted performance characteristics of CF, IF and NIOV.

Method: A lung simulator (Hans Rudolph, Shawnee, KS) was equipped with a simulated nose and programmed to breathe a sinusoidal-type waveform at 20 BPM with 600 Vt, and 1:2 I:E ratio. CF O₂ was delivered to the lung via nasal cannula at various liter flows (2, 4, 6 LPM); IF O₂ delivery was via an OCD (DeVilbiss Healthcare, Somerset PA) at various settings (2, 4, 6); NIOV was delivered via proprietary pillows cannula at mL delivery settings of 150 and 250. Measured characteristics for each therapy included Vt, FiO2, volume flow, and airway pressure.

Results: Tidal volume was 679/934 for 150/250 mL NIOV; 608 for 2/4/6 LPM CF; 606 for IF at 2/4/6. FiO2% was 37.6/39.6 for 150/250 mL NIOV; 27.3/31.2/35.3 for 2/4/6 LPM CF; 26.2/30.9/31.7 for IF at settings 2/4/6. NIOV significantly increased both peak flow and volume at 150/250 mL settings; CF and IF at all settings tested did not. Peak pressures during inhalation were: NIOV 150/250- 2.3/5.0cmH2O; CF and IF at all settings showed no significant change from 0cmH2O. NIOV at the two settings tested provided supplemental volume and some pressure support during inhalation not possible with CF/IF at standard settings.

Conclusion: Oxygen delivery characteristics and outcomes differed between therapy modes. NIOV was able to provide higher tidal volume, FiO2, peak flow and peak inspiratory pressure than both CF and IF in this comparison. NIOV was able to provide supplemental volume to augment ventilation and pressure support to help keep the airways open during inhalation. Bench testing suggests that NIOV may be able to provide sufficient oxygen and respiratory support for patients with respiratory insufficiency. Further study is recommended.
Performance of Activities of Daily Living as a Predictor of Rehospitalization for Patients with COPD Exacerbations

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Background: A significant number of patients with COPD who are hospitalized with an exacerbation are readmitted to the hospital within a 30 day period following discharge. Predictors for such rehospitalization risk have yet to be identified.

Purpose: To evaluate the rehospitalization rates for patients with COPD using performance of activities of daily living as a metric marker.

Method: The Discharge, Assessment, and Summary @ Home (D.A.S.H., Klingensmith HealthCare, Ford City, Pennsylvania) program is a respiratory therapist driven home care based program for patients with COPD who are using supplemental oxygen following discharge from the hospital. As part of the program the measurement of activities of daily living is made on the day #1, day #7, and day #30 post-hospitalization. A series of four patient selected ADLs is performed at each visit (e.g. walking the four points of the home, loading the dishwasher). Oxygen saturations are maintained above 90% using a SmartDose Oxygen delivery system. Each ADL is performed and measured as either completed or not completed based upon the actual task at hand.

Results: A total of 229 patients were entered into the study and had four ADLs performed at each of the three visits. 23/229 (9%) patients were readmitted to the hospital within a 30 day period. 8 (3.5%) were readmitted with a COPD exacerbation and the remaining 15 (6.6%) were readmitted for other reasons. For those patients (n=42) who performed 1 or less of 4 ADLs to completion by day #7 of the program, there were 8 (19%) readmitted. For those patients who could perform 2 or more ADLs to completion there were 15/187 (8%) readmitted.

Conclusions: Those patients with COPD who were oxygen dependent following hospital discharge for an exacerbation who could perform one or less ADLs to completion by 7 days following discharge have a higher 30 day readmission rate to the hospital. Performance of ADLs may be a helpful marker to determine risk for rehospitalization and should be considered to be performed in the home environment following discharge.
Reducing Total Costs of Aerosolized Medication Delivery Using the AeroEclipse II Breath Actuated Nebulizer

John Wilson, RT

**Methods:** We transitioned a 38 bed pulmonary unit from traditional jet nebulizers to BAN nebulizers and developed a medication dosing and frequency protocol. Albuterol was converted to 0.5 ml of a 0.5% solution with 1ml normal saline. Atrovent was converted to one half unit dose. The breath actuated mode via mouthpiece or mask interface with normal saline increased to 2 ml and continuous mode was used. Frequencies were changed from Q4 to Q6 and QID to TID. BANs were changed weekly versus daily with traditional nebulizers. Average hourly rate, treatment time, drug costs, and device costs for June through November 2008 were compared to 2007. To ensure effectiveness of therapy we compared the average number of both scheduled and PRN treatments per patient per day. Subsequently, we utilized this model to convert all impatient beds to BAN in June 2010 and compared data to a similar time period in 2009.

**Results:** Our initial 2008 conversion resulted in a 20% decrease in total costs with an annualized savings of $52,360. Additionally a 31% decrease in minutes per day in therapist time to administer medications and 21% increase in duration between treatments was realized. The average number of scheduled treatments per patient per day was 3.4 and 2.8 in 2007 and 2008 respectively while the average number of PRN treatments was 0.16 and 0.15 in 2007 and 2008 respectively. In the 2010 analysis BAN nebulizers account for an 18% decrease in total costs, and a 19% decrease in total treatment time. Use of BAN nebulizers resulted in an annual savings at Forsyth Medical Center of $186,789 and estimated savings of $475,411 across Novant Health facilities. Average number of scheduled treatments per patient per day was 3.3 and 3.1 in 2009 and 2010 respectively while the average number of PRN treatments was 0.24 and 0.27 in 2007 and 2008 respectively. Additionally, we compared 2010 data from the units in our initial 2008 group to ensure the improvement reported was maintained in that area.

**Conclusions:** We hypothesized the AeroEclipse II breath actuated nebulizer combined with an aggressive dosing and frequency protocol would result in cost savings.

Using the AeroEclipse II breath actuated nebulizer in conjunction with an aggressive medication dosing and frequency reduction protocol provides significant savings. Greater gains have been realized for the pulmonary specific unit which treats patients with more severe pulmonary conditions.
Prevalence and Impact of Nighttime Symptoms of COPD in a Clinical Trial Population

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**Introduction:** Nighttime symptoms are commonly discussed in asthma literature, however, very little is known about nighttime symptoms in patients with chronic obstructive pulmonary disease (COPD). This post hoc analysis was performed in order to determine the prevalence of nighttime symptoms of COPD in a clinical trial population and examine the effects of these symptoms on sleep.

**Methods:** Baseline data were collected as part of a Phase III, randomized, double-blind, placebo-controlled, multicenter trial with the novel, long-acting muscarinic antagonist, aclidinium bromide, administered twice-daily (LAS-MD-33) among patients with moderate-to-severe COPD. At screening, patients received an eDiary containing questionnaires that were self-administered every morning during the 2-week run-in period and throughout the study. Questionnaire items assessed the frequency of cough, feeling out of breath, wheezing while breathing, and sputum production during the previous night. Patients were also asked about their use of rescue medication at night and the impact of symptoms on sleep. Analyses were conducted using data from the week prior to the baseline visit, among all patients with more than 3 eDiary assessments during the baseline week (n=535).

**Results:** Nighttime symptoms were experienced by 97% of the total study population at least once during the baseline week. Most patients reported experiencing coughing on at least one night (91%), followed by feeling out of breath (85%), sputum production (75%), and wheezing while breathing (74%). Multiple episodes of nighttime symptoms during a given night were also common. For instance, more than half of patients (58%) reported at least one night where they coughed ≥3 times. Similar results were seen for ≥3 episodes of shortness of breath (45%), wheezing (49%), and sputum production (43%). Patients indicated that COPD breathing symptoms impacted their sleep, with 79% noting that their COPD breathing symptoms resulted in either nighttime awakenings or early awakenings at least once. Severe sleep disturbance was also prevalent, with 20% of the study sample indicating that they were awake for most of the night or could not sleep at all due to COPD breathing symptoms on at least one night. In spite of the high prevalence of reported nighttime symptoms, only 40% of patients indicated they had used rescue medication at night during the previous week.

**Conclusion:** Nighttime symptoms were found to be common and disruptive to sleep in this clinical trial sample of moderate to severe COPD patients. These analyses were conducted in a clinical trial population with no symptomatic criteria for entry; thus, generalizability of these results to the overall COPD population is unknown. Additional studies examining the effects of nighttime symptoms on COPD patients are necessary. The results of this analysis suggest that clinicians should consider nighttime symptoms when treating COPD patients.

*Juliana Setyawan worked for the Forest Research Institute while performing this analysis but is currently employed by Shire Pharmaceuticals. Shire Pharmaceuticals was not in any way associated with this study.

*This study was supported by Forest Research Institute, Inc., a wholly owned subsidiary of Forest Laboratories, Inc. and by Almirall S.A.
Results from Qualitative Research on Patients’ Experience of Nighttime COPD Symptoms

Michael Schaefer,1 Andrew Palsgrove,1 Asha Hareendran,2 Katherine Houghton,2* Michelle Mocarski,3 Robyn Carson,3 Juliana Setyawar,3* Barry Make4

1United BioSource Corporation, Bethesda, MD, USA; 2United BioSource Corporation, London, UK; 3Forest Research Institute, Jersey City, NJ, USA; 4National Jewish Health, Denver, CO, USA

Introduction: Previous studies have shown that patients with COPD experience symptoms at night and this may be associated with sleep disturbance and general fatigue. Very little is currently known about how nighttime symptoms impact patients’ lives. The objective of this study was to explore patients’ experience of COPD nighttime symptoms and their impact using descriptions obtained directly from the patient perspective.

Methods: A total of 27 COPD patients participated in one of four focus groups conducted in four cities in North America. Participants with a full range of COPD severities (GOLD Stages I to IV) who experienced COPD symptoms at night or in the early morning were recruited. Information about patient experiences was elicited through open-ended discussions conducted by trained interviewers, using a semi-structured interview guide. Subjects completed socio-demographic and clinical questionnaires, including the St. George’s Respiratory Questionnaire for COPD (SQRQ-C). The discussions were audio recorded and transcripts were systematically analyzed. Qualitative analysis software (ATLAS.ti, version 5.0) was employed to identify emergent concepts to facilitate a greater understanding of patients’ experience of nighttime COPD symptoms.

Results: Analyses of qualitative data revealed that 88.8% (N=24) of participants experienced COPD symptoms at night. Forty-eight percent (N=13) of all patients interviewed reported experiencing nighttime awakenings. Patients who reported awakening at night attributed their awakening to: cough (46.2%), shortness of breath (23.1%), and wheezing (7.7%), while 53.8% were unable to make a specific attribution. A total of 16.7% of patients also reported rescue medication use at night. Data from the 24 patients who reported experiencing nighttime symptoms indicated that the most common symptom was shortness of breath (n=17, 70.8%), followed by cough (n=15, 62.5%), difficulty with mucus/phlegm (n=14, 58.3%), wheezing (n=11, 45.8%), tightness in chest (n=4, 16.7%), and chest congestion (n=2, 8.3%). Of the patients who reported experiencing nighttime symptoms, 67% reported that they were not completely satisfied with their sleep. Patients attributed dissatisfaction with sleep to cough (31.3%), dry mouth (25%), difficulty with sputum (18.8%), and anxiety (12.5%). In addition to awakenings at night, the impact of nighttime symptoms was reported in terms of difficulty falling asleep (33.3%) and not feeling rested the next day (25%). Other reported impacts of nighttime COPD symptoms were inability to lay flat (37.5%) and anxiety (12.5%). Results for SQRQ subscale scores ranged from 32.1 to 64.6.

Conclusions: Results from these focus group discussions indicate that COPD patients experience COPD symptoms at night such as shortness of breath, cough, and wheezing. Nighttime symptoms of COPD were reported to cause a notable impact on patients’ lives in terms of nighttime awakenings. Symptoms at night were also associated with difficulty falling asleep, inability to lie flat in bed, anxiety, and not feeling rested the next day. Nighttime symptoms should be considered in the evaluation and treatment of patients with COPD.
*Katherine Houghton was employed by United BioSource Corporation during the conduct of the analysis, but is currently employed by RTI Health Solutions. Juliana Setyawan worked for the Forest Research Institute while performing this analysis but is currently employed by Shire Pharmaceuticals. Neither RTI Health Solutions nor Shire Pharmaceuticals were in any way associated with this study.

This study was supported by Forest Research Institute, Inc., a wholly owned subsidiary of Forest Laboratories, Inc.

References
Pre-Diagnostic Exacerbations of COPD: A Potential Screening Criteria

Barbara P. Yawn, MD, Matthew Rank, MD and Peter C. Wollan, PhD

Abstract: COPD is usually recognized in its later stages, delaying opportunities for therapies that could improve patients’ quality of life and functional capacity. Current COPD screening questionnaires have only moderate levels of sensitivity and specificity (ranges of 68 to 80%). An additional question related to respiratory events in the past two years might improve the these levels of sensitivity and specificity rates. This study is designed to assess the level of respiratory events in the two years before first COPD diagnosis to evaluate the feasibility of using respiratory events as an additional screening criteria for COPD.

Methods: This is a retrospective study using true population based administrative data. All residents of Olmsted County, MN who had a first diagnosis of COPD between 2005 and 2007 were identified using codes for COPD and chronic bronchitis in adults 45 years of age and older. The same administrative data set was used to determine the number of visits with respiratory diagnostic codes in the 24 months prior to the first COPD diagnosis and the 24 months after the first COPD diagnosis. The use of oral steroids in any of the respiratory visits was also identified. Any non-index visits that were coded as a COPD exacerbation, pneumonia or bronchitis treated in the office with oral steroids or coded during an emergency room visit or hospitalization were considered as a definite COPD exacerbations. Those codes such as URI or wheezing without oral steroids being prescribed were considered possible COPD exacerbations.

Results: A total of 682 patients were identified with new diagnoses of COPD: 347 women and 335 men (mean ages 65.7 and 67.6). An additional group of 249 people had a single diagnostic code for COPD with no respiratory related codes in the previous or following 2 years. These patients were not included in further analysis since it seems unlikely they actually have COPD.

In the two years prior to diagnosis the subjects experienced a range of 0 to 25 respiratory events that were definitely consistent with COPD exacerbations [mean 2.5/2 years, s.d. 3.85 (mean 2.81 and 2.21 for women and men., respectively). In addition, they had a mean of 0.99/2 years (1.11 for women and 0.86 for men) events that were possible COPD exacerbations with diagnostic codes such as URI.

In the two years after the diagnosis, this same group of individuals experienced a range of 0 to 23 respiratory events that were definitely consistent with COPD exacerbations [mean 0.96/2 years, s.d. = 1.32 (mean 1.07 and 0.85 for women and men, respectively). They experienced an additional 1.5 events in the 2 years (1.51 in women and 1.45 in men) that were possible COPD exacerbations. The rate of COPD exacerbations and possible exacerbations tended to be higher in the 2 years prior to the COPD diagnosis compared to the two years after (p >0.07). Overall, 230 subjects (33.7%) had four or more respiratory events consistent with definite COPD exacerbations in the two years prior to their COPD diagnosis (137 women, 55.0%, and 93 men, 27.8%, p = .002).

Conclusions: Both men and women experience significant rates of respiratory events in the two years prior to their initial COPD diagnoses. Next steps in this research including comparing our results with assessment from a group age and gender matched smokers without COPD diagnoses. If these rates are higher as we anticipate, then the final portion of this work would be to assess the added value of including a question regarding the number of respiratory events in the previous two years to current COPD screening questionnaires.
The Medical Burden of COPD

Julia Thornton Snider, PhD; John A Romley, PhD; Ken S Wong, PharmD; Jie Zhang, PhD; Michael Eber, BSE; Dana P Goldman, PhD

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Background: Affecting an estimated 12.6 million and causing over 100,000 deaths per year, chronic obstructive pulmonary disease (COPD) exacts a heavy burden on American society.

Methods: We quantify the direct (medical) economic burden of COPD through the use of two major data sources: the Ingenix claims database of privately-insured Americans and the Medical Expenditure Panel Survey (MEPS). The Ingenix data features 213,050 unique beneficiaries with COPD between the years of 2004 and 2009. In the Ingenix data, we examined the average medical costs of beneficiaries with COPD, and how costs varied by patient characteristics. To estimate the contribution of COPD to the medical costs in a nationally representative population, we linked the MEPS, with its detailed expenditure information, to the National Health Interview Survey (NHIS), to take advantage of the latter survey’s nationally standard measurement of disease prevalence. We performed hedonic regression analysis to estimate the contribution of COPD to an individual’s medical costs, adjusting for an extensive set of demographic and socioeconomic controls, as well as comorbid conditions.

Findings: In the privately-insured (Ingenix) population, the average person with COPD incurred total medical costs of $23,988 (2010 dollars), of which nearly 23 percent was paid out of pocket. Medical costs were lower for patients on bronchodilators and inhaled corticosteroids, and highest for patients on oxygen therapy. Medical costs increased substantially with disease severity, with the mildest patients incurring about 63 percent of average costs, while the most severe incurred about 234 percent. Using the nationally representative (MEPS) sample, we found that COPD adds between $3,613 and $5,107 in attributable medical expenditures per diagnosed person per year. This adds up to a nationwide excess spending burden between $45.2 and $63.8 billion annually, or about 3 percent of total U.S. medical spending.

Conclusion: Our results suggest that COPD imposes a substantial burden on the American healthcare system.
The Disability Burden of COPD

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Background: Affecting an estimated 12.6 million and causing over 100,000 deaths per year, chronic obstructive pulmonary disease (COPD) exacts a heavy burden on American society.

Methods: We quantify the impact of COPD on Americans aged 51 and older — in particular, their employment prospects and their likelihood of collecting federal disability benefits — by conducting longitudinal regression analysis using the Health and Retirement Study.

Findings: After controlling for initial health status and a variety of sociodemographic factors, we find that COPD decreases the likelihood of employment 8 percentage points, or 22 percent in relative terms. This effect is larger than those for heart disease, stroke, cancer, hypertension, and diabetes. Furthermore, COPD is associated with a 4.8 percentage point, or 135 percent, increase in the likelihood of collecting Social Security Disability Insurance (SSDI), as well as a 3.1 percentage point, or 133 percent, increase in the likelihood of collecting Supplemental Security Income (SSI). These effects are again the largest of any of the conditions studied.

Conclusion: Our results suggest that COPD imposes a substantial burden on American society by inhibiting employment and creating disability.
Augmented Ventilation Assistance to Improve Activities of Daily Living

Robert McCoy, RT, Brian Carline MD, Kim Wiles, RRT

Overview: Respiratory insufficiency is a limiting factor for patients with chronic lung disease that wish to do activities of daily living (ADL). Many factors can contribute to respiratory insufficiency including hypoventilation, perfusion or conditioning and can combine to prevent patients from exercise or routine activities that could reduce complications and exacerbations. A new augmented open ventilation system (Breathe Technologies) has been developed and cleared for use by the FDA that provides both oxygen therapy and ventilation. The system is light enough to be carried by the patient (1 Lb) and has a unique interface that can be worn with comfort and cosmetics that are necessary to gain patient compliance for public use.

Patient Study: We evaluated a sever COPD and respiratory insufficiency patient on the new augmented ventilator. The severity of the disease has limited the patient’s ability to travel outside his house without dyspnea, fatigue and fear of a medical event. The patient’s physician wrote a prescription for the evaluation of the augmented ventilation system on his patient to determine if the patient would tolerate the device and gain any benefits.

The patient was educated on the augmented ventilation system and was allowed to wear the ventilator for 30 minutes to acclimate and ask questions.

Oxygen saturation and heart rate was collected every 30 seconds during in house ADLs for both current and augmented ventilation device. Borg, Comfort rating system (CRS) and Fatigue rating system (FRS) was collected at the beginning, middle and end of the ADL exercise. The patient was severely limited on their current oxygen system with minimal activity within his home. The patient tolerated the ventilation system and was able to complete the same ADL within his home without desaturation or discomfort.

Discussion: Even though this was a very limited experience with this new device it addressed several questions that may be asked since there is no competitive product that meets this clinical application.

- The nasal interface was comfortable and well tolerated by the patient
- The positive pressure from the ventilator did not interfere with the patient’s normal ventilation and did not impact the patient’s normal breathing (patient comment “it felt smooth”)
- The device reduced the patients feeling of dyspnea and reduced the fear of trying to do more exercise (patient comment “I’m good to go again”)
- The device maintained oxygenation better than the patients existing oxygen system.
- The patient was able to move about their home with the ventilator allowing for use with ADLs
- The patient would not be hesitant to use the product in public (patient comment “I would walk the Mall”)

Conclusion: Augmented ventilation for home therapy may provide the necessary ventilator assistance to allow patients to participate in pulmonary rehabilitation programs and do ADLs in their home to improve conditioning and prevent complications associated with sedentary lifestyle caused by respiratory insufficiency.
Medication Usage for Patients with COPD Who Were Readmitted Within 30 Days Following Hospital Discharge for an Exacerbation

Carlin, Brian W.1; Wiles, Kim2; Easley, Dan2; Rees, Nan3

1. Allegheny General Hospital, Pittsburgh, PA, United States. 2. Klingensmith HealthCare, Ford City, PA, United States.3. St. Clair Hospital, Pittsburgh, PA, United States.

Background: Appropriate medication use is an important component in the management of a patient with COPD following a hospitalization for an exacerbation. Readmission rates may depend upon the actual medications being used.

Objective: To evaluate the medication usage in patients with COPD who were readmitted to the hospital following discharge for treatment of an exacerbation.

Method: The Discharge, Assessment and Summary @ Home (D.A.S.H., Klingensmith HealthCare) program was implemented for patients who require supplemental oxygen use following hospital admission and has been previously described in detail. For those patients who were readmitted to the hospital within the first 30 days following discharge, analysis of the respiratory medications being used was done. Medication usage was obtained directly from the patient by the respiratory therapist who was visiting the patient in the home on the day following hospital discharge. Medications were classified based upon the following: metered dose inhaler (MDI), long acting beta agonist (LABA), long acting muscarinic agent (LAMA), inhaled corticosteroid (ICS), oral corticosteroid (OCS), antibiotic (ATB), aerosol (beta agonist and/or muscarinic), or leukotriene modifier (LTM). Three hundred and one patients with COPD from 23 different hospitals were studied.

Results: 14 of the 301 (5%) patients in the DASH program were readmitted within the first 30 days following discharge. The following medications/combinations were being used. 4/14 (28%) were receiving an MDI or ICS only of which two patients were on no therapy. Only 1/14 (7%) was receiving an oral corticosteroid and 0/14 (0%) were receiving an antibiotic. 8/14 (57%) patients were on a combination that included LAMA and/or LABA, and an ICS and/or OCS. 2/14 (14%) were on a LAMA alone.

Conclusions: In this COPD patient population who required rehospitalization within 30 days of hospital discharge, 28% of patients failed to be prescribed therapy that has been shown to reduce exacerbations. Variable usage patterns in this patient population exist. More well-defined guidelines regarding such therapy should be developed and implementation encouraged.
Non-Invasive Assessment of Ventilatory Mechanics Before and After Lung Volume Reduction Surgery: a Case Series

Moran SL, Layton AM, Basner RC, Thomashow BM, Jellen P and Bartels MN

Aim: Lung volume reduction surgery (LVRS) confers a mortality and functional advantage to a select group of patients with severe emphysema. This benefit in part, has been attributed to a reduction in residual volume (RV). However, questions remain as to the exact mechanism through which this benefit is attained. We therefore measured respiratory mechanics in 3 patients before and after LVRS using optoelectronic plethysmography (OEP), a non-invasive breath-by-breath assessment of thoraco-abdominal volume changes.

Methods: 3 consecutive patients (2 female, 1 male; average FEV1/FVC 23%, average RV/TLC 51%) undergoing cardiopulmonary exercise testing (CPET) before and after LVRS were studied. All subjects had upper-lobe predominant emphysema, the male subject had high exercise capacity (75 Watts), and the females had low exercise capacity (both 25 Watts). OEP during quiet breathing (QB) and maximum voluntary ventilation (MVV) maneuver was performed immediately prior to and following CPET. Ventilatory mechanics were measured with OEP evaluating absolute thoraco-abdominal volume changes, along with individual chest wall components: pulmonary rib cage (RCp), abdominal rib cage (RCa), and abdomen (Ab). With OEP the percent contribution of each chest wall component to the tidal volume (Vt) was determined, along with end-expiratory lung volumes before and after exercise, to assess dynamic hyperinflation (DH).

Findings: Subject 1 (F, 61 years) had no functional improvement after LVRS, by CPET or Pulmonary Function Test (PFT). There was no DH following exercise, before or after LVRS. In 3 of 4 test conditions the percent contribution from the Ab increased, and the percent contribution from RCa decreased following LVRS. (Percent contributions abbreviated %RCp-%RCa-%Ab)

QB: pre-LVRS pre-CPET 41-14-44; post-LVRS pre-CPET 40-15-44
QB: pre-LVRS post-CPET 45-18-37; post-LVRS post-CPET 47-10-41
MVV: pre-LVRS pre-CPET 55-13-32; post-LVRS pre-CPET 45-3-50
MVV: pre-LVRS post-CPET 45-19-35; post-LVRS post-CPET 44-9-47

Subject 2 (M, 54 years) demonstrated marked improvement in CPET and PFT following LVRS. There was DH with exercise before LVRS, but not after LVRS, mainly due to a decrease in RCp volume. In 3 of 4 test conditions, %Ab increased following LVRS.

QB: pre-LVRS pre-CPET 40-20-39; post-LVRS pre-CPET 29-13-56
QB: pre-LVRS post-CPET 45-17-38; post-LVRS post-CPET 36-17-50
MVV: pre-LVRS pre-CPET 34-26-39; post-LVRS pre-CPET 38-14-48
MVV: pre-LVRS post-CPET 33-24-43; post-LVRS post-CPET 50-13-36

Subject 3 (F, 51 years) showed mild improvement in PFT, but not CPET, following LVRS. There was no DH following exercise, either before or after LVRS. During all test conditions %Ab increased, with a comparable decrease in %RCp, after LVRS.

QB: pre-LVRS pre-CPET 48-17-35; post-LVRS pre-CPET 40-18-45
QB: pre-LVRS post-CPET 46-17-37; post-LVRS post-CPET 35-15-50
MVV: pre-LVRS pre-CPET 41-22-36; post-LVRS pre-CPET 27-19-53
Conclusions: These 3 subjects had varying functional responses to LVRS. In the case of subject 2, who showed marked improvement, OEP showed an attenuation of DH following exercise after LVRS. All subjects showed an increase in the Ab compartment contribution to $V_t$ after LVRS, although to varying extents. Whether this reflects a mechanical breathing advantage following LVRS remains to be investigated.
Comparative Efficacy of Once-Daily Indacaterol 75µg in COPD in Terms of Forced Expiratory Volume: A Patient Level Network Meta-Analysis

Shannon Cope, Jie Zhang, Swetha Raparla, James Williams, Jeroen P Jansen

Objective: To evaluate the comparative efficacy of indacaterol 75µg once-daily (OD) compared to tiotropium, salmeterol, and formoterol by combining data from the indacaterol trial program using indirect comparison and meta-analysis techniques.

Methods: Individual patient data (IPD) were available from six randomized controlled trials (RCTs) comparing indacaterol 75µg to placebo (B2354 and B2355), indacaterol 150µg to placebo (INLIGHT-1 and 2, and INHANCE), salmeterol 50µg (INLIGHT-2), and tiotropium 18µg open label (INHANCE), and indacaterol 300µg to formoterol 12µg (INVOLVE). Results from these RCTs were synthesised simultaneously by means of a Bayesian network meta-analysis using IPD. As a result, relative efficacy estimates between all regimens were obtained. The endpoint of interest was trough forced expiratory volume in 1 second (FEV1) at 12 weeks. In order to minimize confounding bias, treatment by covariate interactions were incorporated in the models for baseline FEV1, current smokers (yes/no), and reversibility to short-acting β2-agonists (yes/no) and short-acting anticholinergics (yes/no).

Results: The RCTs had similar study designs and inclusion criteria. Results with and without treatment*covariate interactions were consistent and the adjusted results are presented for FEV1 at 12 weeks. All interventions were more efficacious than placebo. Indacaterol 75µg resulted in a higher FEV1 compared to formoterol 12µg (70 mL difference; 95% Credible Interval [CrI] 20 to 110 mL). Indacaterol 75µg resulted in similar FEV1 improvements compared to tiotropium (0 mL; 95% CrI -50 to 40 mL) and salmeterol 50µg (20 mL; 95% CrI -30 to 70 mL).

Conclusion: The IPD network meta-analysis of six RCTs suggested that indacaterol 75µg OD is at least as efficacious as tiotropium OD 18µg open label and salmeterol BID 50µg and is expected to show a greater improvement than formoterol 12µg BID on trough FEV1.

Clinical Implications: Indirect evidence supports indacaterol 75µg as an alternative to existing long-acting β2-agonists and anticholinergics.
Medication Usage for Patients with COPD Following Hospital Discharge Following an Exacerbation

Brian W. Carlin, MD, Kim Wiles, RRT, Dan Easley, BS, Nan Rees, RN

Background: Appropriate medication use is an important component in the management of a patient with COPD following a hospitalization for an exacerbation. Readmission rates are likely dependent upon the actual medications being used. Therapy with a long acting beta agonist/inhaled corticosteroid combination or a long acting muscarinic agent has been shown to reduce exacerbation rates in outpatients with COPD. Optimal therapy for patients hospitalized with an exacerbation remains to be defined.

Objective: To evaluate the medication usage in a group of patients with COPD who were readmitted to the hospital following discharge for treatment of an exacerbation.

Method: The Discharge, Assessment and Summary @ Home (D.A.S.H., Klingensmith HealthCare) program was implemented for patients who require supplemental oxygen use following hospital admission and has been previously described in detail. For those patients with COPD who were readmitted to the hospital within the first 30 days following discharge, analysis of the respiratory medications being used by the patient was done. Data was obtained directly from the patient by the respiratory therapist who was visiting the patient in the home on the day following hospital discharge. Medications were classified based upon the following: short acting bronchodilator via metered dose inhaler (MDI), long acting beta agonist (LABA), long acting muscarinic agent (LAMA), inhaled corticosteroid (ICS), oral corticosteroid (OCS), antibiotic (ATB), aerosol (beta agonist and/or muscarinic), or leukotriene modifier (LTM). Three hundred and one patients with COPD from 23 different hospitals were studied.

Results: 14 of the 301 (5%) patients were readmitted within the first 30 days following discharge. The following medications/combinations were being used.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Number Patients</th>
<th>MDI use</th>
<th>Aerosol Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABA/ICS/LAMA</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>LABA/ICS/LAMA/OCS</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>LABA/ICS</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>LAMA alone</td>
<td>2</td>
<td>1</td>
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</tr>
<tr>
<td>LABA alone</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MDI alone</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ICS alone</td>
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</tr>
<tr>
<td>None</td>
<td>2</td>
<td>0</td>
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</table>

4/14 (28%) were receiving an MDI or ICS only and two patients were on no therapy. Only 1/14 (7%) was receiving an oral corticosteroid and 0/14 (0%) were receiving an antibiotic. 8/14 (57%) patients were on a combination that included LAMA and/or LABA, and an ICS and/or OCS. 2/14 were on a LAMA only.

Conclusions: In this patient population who required rehospitalization within 30 days of hospital discharge, 28% of patients were receiving only MDI or ICS or no therapy. Only one patient was receiving an oral steroid and no patients were receiving an antibiotic. 71% were receiving therapy with medications that have been shown to reduce exacerbation rates in the outpatient population. Variable usage as well as adherence patterns in this patient population exist. More well defined guidelines
regarding such therapy at discharge and within the first 30 days post discharge should be developed and implementation encouraged.
Rehospitalization Rates for Patients with COPD Who Require Supplemental Oxygen Therapy Following a Hospitalization for an Exacerbation [Refusal of Patients to Continue Program]

Brian W. Carlin, MD, FCCP, Kim Wiles, RRT, Dan Easley

Background: The overall 30 day readmission rate for patients who have been hospitalized following an exacerbation of COPD twenty five percent in western Pennsylvania. Various types of healthcare reform initiatives have been implemented to attempt to reduce such readmission rates. Patients following hospital discharge are often subject to personal preferences regarding participating in such preventive readmission measures.

Objective: To compare the hospital readmission rates for patients with COPD who require supplemental oxygen therapy following an exacerbation who are entered into a home-care based, respiratory therapist centered transition of care program versus usual care.

Method: Patients with a COPD exacerbation who required supplemental oxygen therapy on hospital discharge were entered into a post hospitalization transition of care program (Discharge, Assessment and Summary @ Home (D.A.S.H., Klingensmith HealthCare, Ford City, PA)). The program consists of face to face visits by a respiratory therapist with the patient on days 2, 7, and 30 following hospital discharge. The visits are supplemented by 12 care coordinator phone interviews. Education, behavior modification, skills training, oxygen titration during performance of activities of daily living, clinical assessment, and adherence data collection are components of the program. The 30 readmission rates following discharge for all patients entered into the program over a nine month period (March 2010 through January 2011) were evaluated.

Results: 229 consecutive patients with COPD (mean age 72 ± 11 years) from 23 different hospitals were enrolled into the program. 40 (17%) patients refused additional followup after the first home visit. The 30 day readmission rate for those patients who chose to continue the program (189/229) was 3% while the 30 day readmission rate for those patients who refused to continue the program (40/229) was 13%.

Conclusions: The use of a respiratory therapist based patient centered management program resulted in a decrease in the 30 day readmission rates for those patients who elected to continue with the management program.
Patient Satisfaction Following a Transition of Care COPD Management Program in the Home

Wiles, Kim1, Easley, Dan†

Abstract Body: COPD patients are often discharged from the hospital with minimal information and very little follow up. The 30 day readmission rate in western Pennsylvania is 25%. With rehospitalization penalties imminent, it is important to implement programs targeting chronic disease management. The imperative with a transition program is that the patient and caregivers are given the knowledge to achieve an independent lifestyle.

Objective: To evaluate 30 day patient satisfaction following a respiratory therapist driven COPD management program.

Method: COPD patients requiring supplemental oxygen were admitted into a chronic disease management program, DASH (Discharge + Assessment & Summary @ Home). The program consisted of 3 home visits by a respiratory therapist within 30 days to educate, titrate oxygen during activities of daily, monitor oxygen compliance and adherence, etc. The patient established a motivational goal and a plan of care was developed around the achievement of that goal. The RT visits were supplemented with several phone calls by an in-house clinical care coordinator. A survey was completed by the patient after 30 days.

Results: 20/31 patients completed the 30 day DASH program and completed a 30 day satisfaction survey.
- 100% reported a better understanding of the disease
- 55% achieved their motivational goal that was established on the initial home visit
- Zero patients reported a hospital admission due to COPD
- 85% knew what to do in a “flare up”
- 2 patients called their physician regarding a “flare up”, but avoided a hospital admission
- 95% knew how and when to take their medications
- 80% understood how the various breathing techniques to help control shortness of breath
- 90% were able to complete home activities on their own at the end of the 30 day program
- 3 of the 20 patients were involved in a pulmonary rehab program

Conclusion: A respiratory therapist driven COPD transition of care program significantly increases patient confidence and perception of independence, while decreasing hospital 30 day readmissions.

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>YES</th>
<th>NO</th>
</tr>
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<tbody>
<tr>
<td>1. Do you have a better understanding of your disease and how to control it?</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>2. Have you been able to achieve your goal?</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>3. Have you been in the hospital the last 30 days for a respiratory related illness?</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>4. Do you know the symptoms of a “flare up” and what to do if it occurs?</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>5. Have you had to call your doctor for a “flare up”?</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>6. Do you know when and how to take your medications?</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>7. Do you understand how to do your breathing exercises to control your SOB?</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>8. Have you been able to do home activities on your own?</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>9. Are you involved in a pulmonary rehab program?</td>
<td>3</td>
<td>17</td>
</tr>
</tbody>
</table>
How to Start a Pulmonary-Cardiac Rehabilitation Program in Under 90 Days

Sherri Newman and Collaborating Staff at St. Mary’s Hospital

Great strides have been made in advancing the care of patients with COPD. Pulmonary Rehabilitation (PR) is an invaluable tool which has been proven to aid patients physical and social functioning along with enhancing quality of life. This has been demonstrated through both peer reviewed research and the success of PR programs throughout the country. The multi-disciplinary support and high-end technological needs required for a quality pulmonary rehabilitation program have made providing these services in rural communities extremely challenging. Program development requires space allocation, renovation, procuring equipment, establishing policy and procedure, partnering with other facilities for best practice, literature review, and support from national organizations and community entities. In this presentation, you will journey with St. Mary’s Hospital in its partnership with the Dorney Koppel Foundation to learn how one rural facility successfully developed a thriving pulmonary rehabilitation program in a small community in only 90 days.

Reference
Efficacy and Safety of Indacaterol 75 µg Once Daily In Patients With Moderate-to-severe COPD

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2Clinical Research Advantage, Henderson, NV, USA
3Novartis Horsham Research Centre, Horsham, West Sussex, UK
4Novartis Pharmaceuticals, East Hanover, NJ, USA

Introduction: Indacaterol is a novel, inhaled, once-daily (od) long-acting β2-agonist for the treatment of COPD.

Methods: Two identically designed, randomized, double-blind, placebo-controlled 12-week studies were conducted in patients with moderate-to-severe COPD and smoking history ≥10 pack-years. Patients received indacaterol 75 µg od or matching placebo. The primary endpoint was ‘trough’ FEV1 (mean of values at 23 h 10 min and 23 h 45 min post-dose) after 12 weeks. The key secondary endpoint was transition dyspnea index (TDI) total score after 12 weeks. Additional efficacy data (rescue albuterol use, health status [St George’s Respiratory Questionnaire, SGRQ]) and safety data were collected.

Results: Study 1 randomized 323 patients (85% completed); study 2 randomized 318 patients (91% completed). At baseline, mean age was 64 and 61 years with post-albuterol FEV1 54% and 55% predicted, FEV1/FVC 52% and 53%; 45% and 37% of patients were taking inhaled corticosteroids. Treatment with indacaterol increased trough FEV1 at Week 12 by a clinically relevant amount (≥120mL) (p<0.001 versus placebo), and demonstrated a fast onset of bronchodilator effect following the first dose (Table 1). Indacaterol-treated patients had reduced use of rescue albuterol and improved health status in both studies, and decreased dyspnea in Study 1 (Table 1). Patients treated with indacaterol were more likely to achieve a clinically relevant improvement in TDI total score (≥1 point) in Study 1 (Study 1: odds ratio 2.19, p=0.002; Study 2: odds ratio 1.58, p=0.065), The probability of a clinically relevant improvement (≥4 units) in SGRQ total score was greater with indacaterol than placebo in both studies (odds ratios 1.80 and 1.71, both p<0.05). Raw mean changes from baseline to Week 12 in SGRQ total score with indacaterol and placebo, respectively, were −6.0 and −2.2 (Study 1) and −5.0 and −1.4 (Study 2).

Table 1. Differences in efficacy variables between indacaterol (IND) and placebo (PBO)

<table>
<thead>
<tr>
<th></th>
<th>Difference, IND – PBO (Study 1, N=323)</th>
<th>Difference, IND – PBO (Study 2, N=318)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trough FEV1 at Week 12†</td>
<td>120 mL***</td>
<td>140 mL***</td>
</tr>
<tr>
<td>FEV1 at 5 min after 1st dose</td>
<td>90 mL***</td>
<td>100 mL***</td>
</tr>
<tr>
<td>TDI total score at Week 12†</td>
<td>1.23***</td>
<td>0.45</td>
</tr>
<tr>
<td>Change from baseline in mean daily number of puffs of rescue albuterol use over 12 weeks</td>
<td>−1.2 puffs/day***</td>
<td>−0.7 puffs/day**</td>
</tr>
<tr>
<td>Percent of days without rescue albuterol over 12 weeks</td>
<td>13.7 percentage units***</td>
<td>8.4 percentage units**</td>
</tr>
<tr>
<td>SGRQ total score at Week 12†</td>
<td>−3.8**</td>
<td>−3.6**</td>
</tr>
</tbody>
</table>

**p<0.01; ***p<0.001 vs placebo. †Missing values imputed by carrying forward last observation.
The safety profile of indacaterol was comparable with placebo (Table 2). Two patients died in Study 1, both in the placebo group.

Table 2: Safety results (% of patients)

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IND (N=163)</td>
<td>PBO (N=160)</td>
</tr>
<tr>
<td>Adverse events</td>
<td>49.1</td>
<td>46.3</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>2.5</td>
<td>5.6</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>IND (N=159)</td>
<td>PBO (N=159)</td>
</tr>
<tr>
<td>Adverse events</td>
<td>44.7</td>
<td>40.9</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Conclusions:** Indacaterol 75 µg od provided effective bronchodilation, reduced use of rescue medication and improved health status in both studies, reduced dyspnea in one study (with numerical improvements in the second) and demonstrated an acceptable
Efficacy of Roflumilast in Elderly Patients with Chronic Obstructive Pulmonary Disease

Nicola A. Hanania, Mark T. Dransfield, Udo-Michael Goehring, Hassan Lakks, Paul Rowe

1Baylor College of Medicine - Houston, TX, USA; 2University of Alabama Birmingham - Birmingham, AL, USA; 3Nycomed GmbH – Konstanz, Germany, 4Forest Research Institute

Aim: Research has shown age to be a risk factor for exacerbations in patients with chronic obstructive pulmonary disease (COPD). Thus, a COPD patient’s age may be an important consideration when deciding on a treatment strategy. The new, oral phosphodiesterase-4 inhibitor roflumilast has demonstrated efficacy in reducing exacerbations and improving lung function in COPD patients. The results of 2 pivotal studies of COPD patients treated with roflumilast (M2-124 and M2-125) were pooled to examine efficacy in patients within different age groups.

Methods: Data were pooled from two 52-week pivotal trials examining the effect of roflumilast (500μg QD) in patients with severe-to-very severe COPD. A prespecified analysis compared the effect of roflumilast with placebo among patients aged 40-65 or >65 years. Rates of moderate or severe exacerbations and changes from baseline in pre- and postbronchodilator FEV1 were examined.

Results: A total of 3091 patients were randomized to receive roflumilast (878 patients aged ≤65 years and 659 aged >65 years) and placebo, (883 patients aged ≤65 years and 671 aged >65 years). Baseline demographics were comparable between roflumilast and placebo-treated patients within the age stratifications, although there were slight increases in the percentages treated during the study with short-acting muscarinics, long-acting beta-2 agonists, or previously treated with inhaled corticosteroids in the older age groups. Roflumilast significantly reduced the rate of moderate or severe exacerbations compared with placebo in both the ≤65 (15.3%; P=0.0128) and >65 age groups (21.2%; P=0.0035). Treatment with roflumilast in both the ≤65 and >65 year age ranges resulted in similar and significant improvements in pre- and postbronchodilator FEV1 at all time points versus placebo (P<0.0001). Those treated with roflumilast from baseline to 52 weeks showed increases in prebronchodilator FEV1 of 50mL and 49mL over placebo (both P<0.0001) in patients ≤65 years and >65 years, respectively. For postbronchodilator FEV1, increases of 55mL and 57mL over placebo (≤65 and >65 years, respectively) were also observed following roflumilast treatment for 52 weeks (both P<0.0001). Adverse event (AE) rates in all AE categories were higher in patients >65 years versus patients ≤65 years, but differences between the roflumilast and placebo arms remained consistent for both age groups.

Conclusions: Treatment with roflumilast compared with placebo reduced the rate of exacerbations and improved lung function in both younger and older patients with severe-to-very severe COPD. These data suggest that roflumilast can be used effectively and safely in COPD patients regardless of age.
EFFORTS: COPD Advocacy From the Ground Up

Edna Fiore, Jean Rommes

EFFORTS (Emphysema Foundation For Our Right To Survive) was established in December, 1997 by Gary Bain, Mickey Wagner and Sharon Adkins. They were interested in beginning an on-line site dedicated to COPD advocacy and research, as well as support to individual members; something not available at that time through existing COPD on-line groups. Their first task was the development of a website (www.emphysema.net) which provides pertinent information on treatment, support, research projects and links to other sites on COPD. EFFORTS’ focus during the tobacco suits was to urge states to use the funds available toward disease education and awareness, diagnosis, research and treatment. In addition, they began a listserv (EFFORTS@EFFORTSLIST.ORG) which provided members with a place to ask questions, exchange information and experiences and deal with the feelings of isolation and depression that often accompany the disease.

Through the tireless efforts (pun intended) of our founders and early members, EFFORTS was instrumental in holding rallies in Washington, DC in 2000, 2001 and 2002 that brought COPD awareness to both legislative and public attention, and in working with other, similar, organizations to plan, organize and hold the first U.S. COPD Coalition National Conference in conjunction with the second World COPD Day in November of 2003. EFFORTS’ members monitor news outlets for information pertinent to persons with COPD, and work with other COPD advocacy organizations to generate support or opposition to legislation that will influence the quality of the daily lives of persons with COPD. EFFORTS supports issues and initiatives that will have a positive effect on people with COPD and other lung diseases and does not support any political position or party. EFFORTS, along with many other patient interest groups, attends the American Thoracic Society’s annual conferences and participates actively in the ATS and NIH Patient Interest Organization annual meetings. EFFORTS has developed relationships with the American Association of Respiratory Care and the American Association of Cardiovascular and Pulmonary Rehabilitation. These relationships are critical in helping both patients and professionals develop a collaborative care approach to managing and controlling this chronic disease.

EFFORTS members have been active in the development of state COPD Coalitions all over the country. Working with the COPD Foundation and other organizations, EFFORTS members have helped to develop COPD Coalitions in more than half the states. In addition, EFFORTS members in many states have been holding informal sessions where individuals with COPD can gather to socialize, share information and gain support.

EFFORTS members work hard during November, writing letters to the editor, requesting state proclamations for November as COPD Month and engaging in many different awareness campaigns in their local communities. They talk with their local leaders regarding initiatives for clean air in their communities. They speak to local groups about COPD, describing the illness and how it can be managed and controlled. They work with other local groups to encourage smoking cessation and help pass legislation regarding smoke free areas in their communities.

Background: COPD patients experience a gradual decline in their functional status which is associated with exertional dyspnea and physical deconditioning which results in fatigue. Due to this decline these patients are unable to perform their activities of daily living without discomfort. Two of the most common symptoms that a COPD patient experience is dyspnea and fatigue which decreases their
perceived quality of life. Pulmonary rehabilitation that includes upper extremity training is one of the few interventions that can lessen these incapacitating progressive symptoms. Research demonstrates that upper extremity training demonstrates a tendency to improve arm muscle endurance, which results in reduction of perceived dyspnea in patients with COPD. The purpose of this study is to examine the effects of upper extremity strengthening training on dyspnea and fatigue perceptions in the patient with moderate to very severe COPD.

Methods: A convenience sample of 10 to 20 outpatient pulmonary rehabilitation program patients with a diagnosis of moderate to severe COPD will be asked to participate in the study. Study criteria include an age range of 50 to 80 years, COPD as defined by American Thoracic Society spirometric criteria of FEV1/FVC <70% and moderate to very severe COPD based on BODE Index scores. The BODE Index score is calculated using body mass index, FEV1, dyspnea, and a six minute walking test and ranges between 0 to 10 with higher scores indicating higher disease severity. Upper extremity strengthening training exercise will be the pulmonary rehabilitation component of focus in the study and with examination of its effect on patients’ level of perceived dyspnea and fatigue. Participants will complete the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M), which provides opportunities to rate perceived dyspnea and fatigue with activity of daily living. Participants will complete the PFSDQ-M prior to beginning upper extremity strengthening training, then 1 month, and 3 months following the beginning of the training. In addition, repeat spirometry and calculation of the BODE Index score will occur along with the subsequent administration of the PFSDQ-M. Statistical analysis will include t-tests and ANOVA to compare the survey ratings, spirometry results, and BODE Index scores between the three time frames.

Results: Anticipated outcomes over time will be a reduction of perceived dyspnea and fatigue on activity of living items in the Pulmonary Functional Status and Dyspnea Questionnaire, possible improvement in FEV1/FVC, and reduction in disease severity as measured by the BODE index. Anticipated end of data collection is January 2012.
Reduction in the Risk of Initial and Subsequent Exacerbations Following Roflumilast Treatment: Pooled Results from Two Pivotal Trials

Fernando J. Martinez1, Klaus Rabe2, Udo-Michael Goehring3, Manja Brose3, Dirk Bredenbroeker3, Hassan Lakkis4, Paul Rowe4, Ulo Palm4

1. University of Michigan Medical Center, Ann Arbor, MI, United States; 2. Krankenhaus Grosshansdorf, Grosshansdorf, Germany; 3. Nycomed GmbH, Konstanz, Germany; 4. Forest Research Institute, Jersey City, NJ, United States.

Aim: Disease severity is associated with increased frequency of acute exacerbations of COPD (AECOPD). Some patients experience repeated AECOPD. These frequent AECOPD result in decreased quality of life, increased hospitalizations, and mortality. Therefore, preventing not only the first AECOPD event but also subsequent exacerbations is likely important. Roflumilast is approved to reduce the risk of AECOPD in COPD patients with severe spirometric disease, chronic bronchitis, and a history of AECOPD. This post hoc analysis examines the effect of roflumilast in delaying the time to first AECOPD and its effects on reducing the risk of subsequent AECOPD events (up to the 5th).

Methods: Roflumilast (500 μg QD) was examined in two 52-week pivotal trials (M2-124 and M2-125) in severe-to-very severe COPD patients with ≥1 moderate or severe AECOPD in the previous year. Data were pooled for the efficacy of roflumilast compared with placebo for median days to first moderate or severe AECOPD (Kaplan-Meier estimate), and hazard ratios (HR) for first, second, third, fourth, and fifth moderate or severe AECOPD (Cox proportional hazards model).

Results: A total of 3091 patients were treated with roflumilast (n=1537) or placebo (n=1554). As previously shown, the median time to first AECOPD was longer with roflumilast (303 days) than placebo (236 days). The results below enumerate the HR for time to AECOPD for roflumilast compared with placebo.

1st AECOPD HR=0.886 (95% CI 0.802-0.980; P=0.019)
2nd AECOPD HR=0.791 (95% CI 0.685-0.914; P=0.001)
3rd AECOPD HR=0.730 (95% CI 0.593-0.899; P=0.003)
4th AECOPD HR=0.596 (95% CI 0.437-0.814; P=0.001)
5th AECOPD HR=0.477 (95% CI 0.297-0.764; P=0.002)

Conclusions: Roflumilast significantly delayed time to the first AECOPD, while also decreasing the risk of up to a fifth AECOPD in severe-to-very severe COPD patients compared with placebo. These data suggest a decrease in exacerbation burden with roflumilast therapy.
Transition of Care Program and Rehospitalization Rates for Patients with COPD Who Require Home Oxygen Therapy Following an Exacerbation: An Update

Carlin, Brian W.¹; Wiles, Kim²; Easley, Dan²; Rees, Nan³

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Abstract body: Background: The overall 30 day readmission rate for patients with COPD following hospitalization for an exacerbation approaches 25% in the Western Pennsylvania area. Strategies need to be developed to effect a reduction in this readmission rate.

Objective: To evaluate the effects over the past year of a home care based, respiratory therapist centered transition of care program for patients who require home oxygen therapy following hospital discharge from an exacerbation.

Method: The Discharge, Assessment and Summary @ Home (D.A.S.H., Klingensmith HealthCare) program was implemented for patients who require supplemental oxygen use following hospital discharge. Data from the initial six months was reported previously. This data is a summary of the fourteen months of the program. The program consists of face-to-face visits by a respiratory therapist with the patient in the home environment on days 2, 7, and 30 following hospital discharge. Phone interviews by a care coordinator are then conducted in between these visits. Education, behavior modification, skills training, oxygen titration during performance of activities of daily living, clinical assessment, and adherence data collection are key components of the program. Four hundred thirty nine patients who were discharged from the hospital and required supplemental oxygen were enrolled into the program.

Results: The 439 patients enrolled were from 23 different hospitals in the Western Pennsylvania area from March 2010 through May 2011. The primary discharge diagnosis was: COPD in 301 (69%); CHF 57 (13%); hypoxemia 33 (8%); pneumonia 19 (4%); and other 29 (7%). The 30 day readmission rate for the entire group was 7%. The 30 day readmission rate for those with COPD due to a recurrent exacerbation was 3% (8/301), for those with CHF due to an exacerbation was 5% (3/57), and for those with non-COPD diagnoses for any reason was 7% (3/81). 6% (18/301) patients with COPD were readmitted within 30 days for a diagnosis other than an exacerbation.

Conclusions: Since the inception of the respiratory therapist based transition of care program, the 30 day rehospitalization rate remains below 7% for patients who were discharged from the hospital and required supplemental oxygen.
The Role of Imaging in Phenotyping Chronic Obstructive Pulmonary Disease Compared with Lung Function Testing

Brigitte Walter

Purpose: Increased resistance due to airway obstruction, and a loss of the elastic recoil pressure of the lung because of parenchymal destruction are the most important components for the airflow limitation observed in COPD. The progressive epithelial damage of the alveolar walls decreases diffusivity by chronic airway inflammation.

Methods: Computed tomography (CT) is a non-invasive procedure to assess the structure of lung parenchyma and airway wall due to COPD. The presence of emphysema is correlated with altered lung function resulting in increased resistance and decreased forced expiratory volume in one second (FEV1). CT scans were performed for 60 patients (GOLD II till IV) using a multidetector-row CT scanner with reconstruction of the row data sets. Pulmonary function test were applied within 10 days of obtaining CT scans measuring FEV1 in standard techniques.

Results: Structural alterations were analysed in relation to airway wall thickness, losses of alveolar configuration and rarefication of vessels. The results were correlated with the GOLD classification. The features of the different lung pathology in distribution and extent correspond to the functional disorder of reduced diffusion capacity whereby airflow limitation was more associated with changes of the small airways.

Conclusions: Pulmonary function tests are gold standard used in diagnosis and staging of COPD which clinical presentation varies widely even within the same disease stage. CT can be an additional tool to define the severity by assessing the structural changes initially and as follow up.
**Smart Nasal Cannula: Clinical Utility Study on LTOT Patients**

*Beth Ann Davic, RRT, Healthy Lungs Pennsylvania*

**Introduction:** Long term oxygen therapy (LTOT) is an accepted medical intervention for individuals suffering from chronic hypoxemic respiratory insufficiency. Efficacy of LTOT is dependent on the uninterrupted delivery of the prescribed liter flow rate. However, all oxygen delivery systems can experience an unexpected leak, or total cessation of flow caused by system malfunction. Failure to recognize and correct these problems in a timely manner could negatively impact dyspnea and cardiopulmonary function. To optimize LTOT and ensure safety, both the user and caregiver need to periodically monitor the oxygen liter flow rate setting on the delivery system and ensure it corresponds with the flow rate emitted to the patient. Ingen-Technologies, Inc has designed the Smart Nasal Cannula™, a disposable nasal cannula and seven-foot tubing incorporating an inline flow gauge. The spring-loaded gauge is gravity independent and is positioned proximal to the cannula to monitor gas delivery to the patient.

**Study Objective:** To assess the user’s perception of the utility of the Smart Nasal Cannula.

**Method:** Patients receiving LTOT were evaluated with the Smart Nasal Cannula for eight days and provided feedback on their experience. Participants were instructed to observe the flow gauge and compare the reading with the flow rate set on their oxygen delivery system. If a discrepancy was found, the participants were encouraged to perform troubleshooting maneuvers, looking for gas leaks, tubing disconnections and power supply issues. Ten patients were enrolled with a mean age of 77 (66 – 83), half male. All patients had a diagnosis of COPD and no participant or caregiver had significant eyesight impairment. Oxygen delivery devices varied between stationary and portable, continuous and pulse dose, and liquid and concentrator type systems. The prescribed liter flows ranged from 2-12 lpm (median 3 lpm).

**Results:** Participants rated excellent, the ease of the inline gauge, and good, the feeling of assurance that the inline gauge could readily determine the oxygen flow rate delivered. All participants would recommend the inline gauge to LTOT patients. The beneficial observations included: positive verification of corrective actions for troubleshooting gas leaks and minimal training required to use the device. Cautionary observations included: pulse dose systems autotriggered and reduced available oxygen use time, and the non-tapered cannula was uncomfortable.

**Conclusion:** Study participants unanimously agreed that the Smart Nasal Cannula provided a visual indicator that their prescribed liter flow rate was being effectively delivered. When a disruption in flow occurred, the problem was easily identified and the flow gauge verified the results of the troubleshooting maneuvers.

Supplying the Oxyview or Smart Nasal Cannula to all patients requiring LTOT may be financially prohibitive and therefore more research is required to evaluate the cost effectiveness of these devices for routine use. However, serious consideration of the Smart Nasal Cannula use is warranted for selected patients who have experienced repeated hypoxemic episodes because of gas leaks or interruption in operation of their oxygen delivery system.
Background of Illinois COPD Coalition and Midwest COPD Network convened by Respiratory Health Association

Eileen Lowery

Respiratory Health Association’s work with the Illinois COPD Coalition is serving as a road map for the COPD Regional Network Development Project in Illinois, Indiana, Michigan and Ohio, which will build upon existing relationships, initiate new regional relationships, develop a regional network and coordinate a series of formal COPD activities funded through a subcontract from National Heart, Lung and Blood Institute (NHLBI) and partnership in the Breathe Better Network as a Breathe Better Leadership Partner.

COPD is now the third leading cause of death in the United States, and it affects an estimated 24 million Americans. In Illinois, COPD was the fourth leading cause of death in 2008. An estimated 557,120 Illinoisans are diagnosed with either chronic bronchitis, emphysema, or a combination of both. In 2007, Respiratory Health Association of Metropolitan Chicago (RHAMC) convened the Illinois COPD Coalition to begin to address the public health burden of COPD within the state. The group of more than 100 stakeholders put forth the State Plan for Addressing COPD in Illinois and is implementing sustainable solutions to reduce the burden of COPD in Illinois. The most recent success is the inclusion of COPD on the 2010 Illinois Behavioral Risk Factor Surveillance System (BRFSS). We are able to share preliminary data.

In Indiana, Michigan and Ohio, COPD is the third leading cause of death. Moreover, Indiana and Ohio have COPD death rates reported to be in the highest quartile, according to the November 2008 Centers for Disease Control and Prevention’s Morbidity and Mortality Weekly Report. In 2007, The Indiana Mortality Report stated there were more than 3,200 COPD deaths. In 2008, the Ohio Department of Health reported more than 6,850 COPD deaths, and Michigan reported more than 5,150 COPD deaths. COPD prevalence data is not available for these states; however tobacco rates serve to help understand the likely COPD rates. For Indiana, Michigan and Ohio, the smoking rates are 26%, 20.5% and 20.1% respectively, with tobacco use directly affecting more than 4.5 million people over the age of 18. Even more people are expected to be at risk for COPD due to environmental tobacco exposure. The overarching goal of the COPD Regional Network Development Project in Illinois, Indiana, Michigan and Ohio is to develop the Midwest COPD Network (MCN). Core partners include the Illinois COPD Coalition; Walgreens Infusion and Respiratory Services; Medical Specialist Center of Indiana; University of Michigan, Department of Internal Medicine, Division of Pulmonary and Critical Care Medicine; Center for Lung Health, Henry Ford Hospital (Detroit); The Ohio State University Medical Center; Office of Healthy Ohio, Ohio Department of Health; and CBS Radio. This broad range of partners reflects the need and readiness to address COPD.

Despite local efforts to increase awareness of COPD as a public health burden, many gaps remain. The MCN project will allow RHAMC to convene regional partners to better address common challenges and advance health goals. Activities of the regional network will increase awareness of signs and symptoms of COPD, promote early detection by healthcare providers for individuals at risk, and promote proper COPD management among people who have been diagnosed with COPD.
Smooth Sailing for Respiratory Patients: Rehabilitation on the High Seas

Bruce Toben, RRT, Carol Ann Kuczma, CRT, Arnold Young, RRT

Introduction: COPD and other chronic lung diseases are associated with decreased exercise endurance that leads to difficulty in conducting routine daily living activities. This condition often restricts mobility outside of confined boundaries, which compounds the psychological stresses and depression associated with lung disease and dyspnea. Vacationing, especially with oxygen, may cause uncertainty and anxiety that inhibit traveling, fostering a sedentary lifestyle.

Smooth Sailing was designed to put into practice those techniques taught in a formal pulmonary rehabilitation program. It allows those with chronic lung disease a chance to experience a cruise vacation accompanied by a medical team supporting their physical, psychological and therapeutic needs. The primary objectives of the Smooth Sailing program are to teach and demonstrate that vacationing with oxygen is technically possible and emotionally rewarding.

Program Design: Healthy Lungs Pennsylvania, a non-profit healthcare organization, recruits participants into the Smooth Sailing program by advertising at pulmonary rehabilitation programs, COPD support groups and home care companies. Oxygen, including delivery systems, wheelchairs and related supplies are provided by equipment manufacturers, durable medical equipment companies, and donations from private benefactors. Prior to sailing, a form must be completed by the traveler’s physician that contains current and past medical histories, medications, and results of relevant diagnostic tests. Advance notification to the cruise line ensures approval of transporting bulk oxygen and cooperation of the ship’s personnel.

Results: The Smooth Sailing program has conducted 17 consecutive years of cruise vacations for more than 1,600 participants and their families from the northeast region of the United States, and visited 20 ports in the US, Canada and Caribbean islands. Travelers have included those diagnosed with COPD, bronchiectasis, idiopathic pulmonary fibrosis, pneumoconiosis, bronchiolitis obliterans, and alpha-1 antitrypsin deficiency. Approximately 70% of those traveling with chronic lung disease have required continuous supplemental oxygen. The all volunteer medical team consists of respiratory care practitioners, nurses and physicians, typically with a 9:1 ratio of cruiser to staff. The medical staff provides the assurance that trained professionals, skilled in the care of chronic pulmonary diseases are available to supervise daily activities. Educational sessions are conducted that include: panic control, self-monitoring of respiratory function, breathing exercises, inhaled medications, oxygen therapy equipment, and preparing for the cold, flu and pneumonia season. The importance of hand washing, fluid intake and exercise are continually reinforced. Participants are encouraged to attend on-board and onshore activities graded at low to moderate intensity levels. All activities are accompanied by staff, oxygen and assistance with ambulation as needed.

Conclusion: A Smooth Sailing vacation allows individuals with chronic lung disease a chance to experience the excitement of travel with the assistance of caring medical professionals. By affiliating with a recreational and educational support network, participants acquire the knowledge and confidence to travel and successfully manage their physical requirements. Smooth Sailing promotes dignity, independence and improving the quality of life.

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Breathe New Hampshire’s COPD Awareness Team: Breathe, Engage, Unite

Diane Smogor, Deborah Chabot, RN, BS, AE-C, Katherine Labrie

The COPD Awareness Team is a dynamic group of Breathe New Hampshire (Breathe NH) volunteers who work collectively to raise public awareness about COPD. Breathe NH, the state’s oldest voluntary health organization, convened this Team in January 2008 to identify steps that could be taken to bring more attention to COPD in the state. The strength of the Awareness Team comes from its diverse membership, which includes: COPD patients and family members/caregivers; healthcare providers; respiratory/home care businesses; and public health professionals. Each member of this Team has been touched by COPD in some way and brings with them determination and unique strengths and resources. The Team’s main goal is to elevate public awareness and understanding of COPD in NH. The Team is spearheading a variety of COPD outreach efforts in NH aimed at: increasing recognition of COPD risk factors and symptoms, encouraging those at risk to get a breathing test and talk with a health care provider, and engaging those affected by COPD in local education and outreach efforts. The involvement of COPD patients in the Team has been a critical factor in its success.

As a Breathe Better Network member and through a partnership with the National Heart, Lung and Blood Institute, the Awareness Team has brought more attention to COPD through the following core activities:

- Coordinating free COPD screenings across NH.
- Publishing a special section about COPD in NH’s statewide daily newspaper.
- Producing a COPD Issue Brief, a document outlining the first state-specific data about COPD.
- Convening stakeholders as an initial step in creating a statewide COPD action plan.
- Creating a video that highlights NH residents affected by COPD and provides hope and information to others.
- Conducting community presentations across the state.
- Coordinating Country Conquers COPD events in NH.
- Launching a new Lung Health Support Group in Manchester, the state’s largest city.

The COPD Awareness Team is leading the charge to reduce the public health burden of COPD in NH. Collectively, Team members have volunteered hundreds of hours to help raise the profile of COPD in NH. As a result of their collective efforts, the following indicators demonstrate that the Team is making progress in NH: more than 650 individuals at risk for COPD have received a free spirometry test and thousands of NH residents have received COPD information; requests for COPD resources and presentations have increased; businesses and organizations are recognizing the importance of integrating COPD messages into their materials and prevention programs; and increasing numbers of COPD patients are feeling empowered and getting involved in local outreach efforts.

Engaging COPD patients in outreach, education and advocacy activities not only empowers and benefits the individuals involved, but helps to reduce the stigma associated with COPD in the community. Volunteers, particularly those who are directly impacted by COPD, have proven to be powerful advocates and effective champions in turning grassroots collaboration into statewide success.
Reversibility of obstruction, significant bronchodilator responsiveness, and mortality in the Lung Health Study

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Rationale: Defining response to a bronchodilator remains problematic in clinical and epidemiologic studies. This study is a secondary analysis of the Lung Health Study data and sought to determine how the measures of reversibility of obstruction and significant bronchodilator responsiveness changed over time and how well these measures predicted outcomes.

Methods: We included data from the baseline, years 1-5 and year 11 follow-up, and 14.5 year mortality follow-up. Lung function was analyzed pre and post bronchodilator (200 ug isoproterenol). Significant bronchodilator responsiveness comprised a 12% increase in the FEV₁ relative to the baseline FEV₁, and reversibility of obstruction comprised a change. Survival models were adjusted for age, sex, body mass index, race, smoking status, arm of study, baseline FEV₁ (pre-bronchodilator), bronchodilator responsiveness, and the presence of reversibility.

Results: The Lung Health Study recruited 5,887 subjects, of whom 721 died by year 14.5 of follow-up. As the Table shows, lung function declined in this cohort over time, with an increasing trend for the proportion of subjects demonstrating more than 12% improvement in their FEV₁ and a decreasing trend in subjects demonstrating “reversibility” (changing from obstructed to unobstructed).

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Mean Prebronchodilator FEV₁ (Standard Deviation)</th>
<th>Mean % Predicted Prebronchodilator FEV₁ (Standard Deviation)</th>
<th>Percentage with Greater than 12% Increase in FEV₁</th>
<th>Percentage with “Reversibility”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>5,885</td>
<td>2.64 (0.60)</td>
<td>74.7 (8.9)</td>
<td>6.2</td>
<td>20.9</td>
</tr>
<tr>
<td>Year 1</td>
<td>5,322</td>
<td>2.60 (0.62)</td>
<td>74.1 (10.3)</td>
<td>10.7</td>
<td>16.0</td>
</tr>
<tr>
<td>Year 2</td>
<td>5,258</td>
<td>2.56 (0.63)</td>
<td>73.6 (10.8)</td>
<td>12.0</td>
<td>13.9</td>
</tr>
<tr>
<td>Year 3</td>
<td>5,144</td>
<td>2.51 (0.64)</td>
<td>72.7 (11.4)</td>
<td>12.4</td>
<td>12.2</td>
</tr>
<tr>
<td>Year 4</td>
<td>5,023</td>
<td>2.46 (0.65)</td>
<td>71.7 (11/8)</td>
<td>13.6</td>
<td>11.4</td>
</tr>
<tr>
<td>Year 5</td>
<td>5,337</td>
<td>2.39 (0.65)</td>
<td>70.2 (12.5)</td>
<td>13.9</td>
<td>10.0</td>
</tr>
<tr>
<td>Year 11</td>
<td>4,148</td>
<td>2.07 (0.68)</td>
<td>63.9 (15.4)</td>
<td>24.9</td>
<td>7.3</td>
</tr>
</tbody>
</table>

A higher prebronchodilator FEV₁ was a consistent predictor of less mortality (hazard ratio [HR] of 0.87, 95% confidence interval [CI] 0.79 – 0.95 at baseline, decreasing to HR 0.74 [95% CI 0.65, 0.83] by year 11). Neither the presence of a 12% or great increase in the FEV₁ nor the presence of “reversibility” predicted mortality (Figures).

Conclusions: In the Lung Health Study cohort, neither the presence of significant bronchodilator responsiveness nor the presence of reversibility were predictors of mortality at 14.5 years of follow-up. Funded by and unrestricted grant from AstraZeneca.
Chronic Respiratory Disease, Comorbid Cardiovascular Disease, and Mortality in a Representative U.S. Cohort

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Rationale: Cardiovascular disease (CVD) is a common comorbidity in patients with chronic respiratory disease. We sought to determine the relationship between chronic respiratory disease, CVD, and mortality in a nationally representative cohort of the US population.

Methods: We analyzed data from the baseline (1988-1994) and follow-up (through 2006) of the Third National Health and Nutrition Examination Survey (NHANES III), restricted to the subset of adults ≥40 years of age who had pulmonary function data, complete baseline data, and linked National Death Index all-cause mortality data. Subjects were classified in to one of four categories: obstructed (FEV₁/FVC < 70% and FEV₁ < 80% predicted), restricted (FEV₁/FVC ≥70% and FVC < 80% predicted), respiratory symptoms (but neither obstructed nor restricted), and normal (none of the above). CVD was defined as reported prior diagnosis or baseline examination evidence of myocardial infarction, stroke, or congestive heart failure; CVD risk factors were a history or evidence of hypertension or hyperlipidemia in the absence of overt CVD. Analyses included logistic regression and Cox proportional hazards models, controlling for age, sex race/ethnicity, body mass index, education level, smoking, and diabetes. Analyses were weighted to account for the complex sampling design and weighted percentages are presented.

Results: The analysis data set included 9,054 subjects, of whom 1,132 (12.0%) were obstructed, 1,319 (10.3%) were restricted, and 2,457 had respiratory symptoms only (27.6%). CVD was present at baseline in 1,284 subjects (10.4%) and CVD risk factors alone were present in 4,900 (53.3%). Followed for a maximum of 18 years, 3,571 (28.4%) subjects died. When compared to ‘normal’ subjects, those in the obstructed group were more likely to have prevalent CVD (odds ratio [OR] 2.05, 95% confidence interval [CI] 1.37, 3.05), but not CVD risk factors only (OR 1.06, 95% CI 0.85, 1.31). The adjusted hazard ratios evaluating the association between chronic lung disease and mortality risk, modified by comorbid CVD and CVD risk factors, are displayed in the figure.

Conclusions: In this large US population-based cohort, the presence of obstruction, restriction, or respiratory symptoms alone was associated with higher adjusted odds of prevalent cardiovascular disease. In the longitudinal analysis, the presence of an obstructed pattern at baseline increased the risk of mortality independent of overt CVD or CVD risk factors.

Funded by GlaxoSmithKline R&D.
The Bronchiectasis Research Registry

*The Bronchiectasis Research Consortium Investigators and the Collaborative Studies Coordinating Center at the University of North Carolina*

**Description:** The Bronchiectasis Research Registry is a consolidated database of non-cystic fibrosis (non-CF) bronchiectasis patients from multiple clinical institutions. The goal of the Bronchiectasis Research Registry is to support collaborative research and assist in the planning of multi-center clinical trials for the treatment of non-CF bronchiectasis. The registry is in its third year of follow-up.

**Methods:** The Registry, funded by the COPD foundation, recruits bronchiectasis patients from 13 clinics around the country, with plans to add one new US clinic and a new disease group, non-tuberculosis mycobacteria (NTM), in the coming months. In addition to baseline data collected as patients enter the Registry, longitudinal data are collected during annual patient contacts. The type of information collected includes basic demographic information, past medical history related to the disease, respiratory symptoms, concomitant medications and other therapies, a history of images, cultures, and procedures, and information about possible specimen and images stored in repositories. Follow-up data provide an update on patients’ vital status, respiratory symptoms, laboratory microbiology, therapies, and clinical procedures conducted since the last patient contact.

**Results:** Registry data collection began in September 2008. To date, 1,008 patients have been enrolled, with 759 patients having reached their first anniversary. Of these, 444 have been successfully contacted for their first follow-up interview, and 393 are now eligible for their second follow-up interview. Registry demographics are predominantly female (79%), white (91%), and non-Hispanic (91%), with an average age of 65 years. The average age of bronchiectasis diagnosis is 56 years. Sixty-one percent have never smoked, 37% are former smokers, and 1.5% are current smokers. Of 938 patients with baseline data on exacerbations, 60% had suffered pulmonary exacerbations and 22% had been hospitalized for pulmonary illness or exacerbations in the two years preceding baseline. Among the 357 patients with follow-up data on exacerbations, 45% experienced an exacerbation in the past year and 14% experienced a hospitalization.

**Conclusion:** The Bronchiectasis Research Registry will facilitate research into the study of the causes of this condition. Patterns of characteristics of patients suffering from the condition can be identified for exploratory or hypothesis generating research from the Registry database. The addition of follow-up data provides the opportunity to improve our understanding of this disease by examining changes over time. The Registry will also aid in the planning of therapeutic clinical trials through information about the numbers of patients available who satisfy certain inclusion/exclusion criteria as well as information on background rates of certain concomitant illnesses or use of medications, or other pertinent information.

*Funding for the Bronchiectasis Research Registry is provided by the COPD Foundation and the Richard H. Scarborough Research Fund for Bronchiectasis.*
Effect of Upper Extremity Exercise on Dyspnea and Fatigue in COPD Patients

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Background and Purpose: COPD patients experience a gradual decline in their functional status which is associated with exertional dyspnea and physical deconditioning which results in fatigue. Due to this decline these patients are unable to perform their activities of daily living without discomfort. Two of the most common symptoms that a COPD patient experience is dyspnea and fatigue which decreases their perceived quality of life. Pulmonary rehabilitation that includes upper extremity training is one of the few interventions that can lessen these incapacitating progressive symptoms. Research demonstrates that upper extremity training demonstrates a tendency to improve arm muscle endurance, which results in reduction of perceived dyspnea in patients with COPD. The purpose of this study is to examine the effects of upper extremity strengthening training on dyspnea and fatigue perceptions in the patient with moderate to very severe COPD.

Patients and Methods: A convenience sample of 10 to 20 outpatient pulmonary rehabilitation program patients with a diagnosis of moderate to severe COPD will be asked to participate in the study. Study criteria include an age range of 50 to 80 years, COPD as defined by American Thoracic Society spirometric criteria of FEV1/FVC <70% and moderate to very severe COPD based on BODE Index scores. The BODE Index score is calculated using body mass index, FEV1, dyspnea, and a six minute walking test and ranges between 0 to 10 with higher scores indicating higher disease severity. Upper extremity strengthening training exercise will be the pulmonary rehabilitation component of focus in the study and with examination of its effect on patients’ level of perceived dyspnea and fatigue. Participants will complete the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M), which provides opportunities to rate perceived dyspnea and fatigue with activity of daily living. Participants will complete the PFSDQ-M prior to beginning upper extremity strengthening training, then 1 month, and 3 months following the beginning of the training. In addition, repeat spirometry and calculation of the BODE Index score will occur along with the subsequent administration of the PFSDQ-M. Statistical analysis will include t-tests and ANOVA to compare the survey ratings, spirometry results, and BODE Index scores between the three time frames.

Results: Anticipated outcomes over time will be a reduction of perceived dyspnea and fatigue on activity of living items in the Pulmonary Functional Status and Dyspnea Questionnaire, possible improvement in FEV1/FVC, and reduction in disease severity as measured by the BODE index. Anticipated end of data collection is January 2012.
The Mid-Atlantic Regional COPD Center and the Corporate Education and Awareness Toolkit

The COPD Foundation in Collaboration with the Maryland COPD Coalition and Discern Consulting

**Background:** COPD is a common, but often unrecognized and under-diagnosed disease. COPD affects approximately 12 million individuals in the US. Prevalence and burden of COPD are projected to increase in the coming decades. Early diagnosis and appropriate management is increasingly essential to improving patient outcomes; however, it can be extremely expensive, both in terms of missed work and increased benefit payments. COPD patients have 2-3 times higher hospitalizations than persons without COPD and employers are in a unique position to minimize the burden of COPD through increased awareness and education efforts that lead to earlier detection and improved management. Direct relationship with employees, health plans and their oversight on health environment in the work place allows them to implement and promote programs to address the burden of COPD.

**Goal:** To conduct qualitative and quantitative research with employers to develop a COPD employer toolkit and increase employer engagement in COPD.

**Results:**
- Low knowledge levels: There was a general understanding that COPD is related to breathing, but little knowledge about particulars
- Top issues include depression, diabetes, heart disease, overweight/obesity, smoking cessation.
- Perceived reasons COPD is not among the top wellness issues include:
  - Lack of knowledge about costs of COPD to the employer.
  - Asthma misdiagnoses.
  - “People haven’t heard of/don’t talk about” COPD the way they do other diseases.
  - Other diseases produce competition for the relatively small amount of time, space, and outreach wellness programs have.
  - Lack of knowledge that COPD is not a disease that only “old people” live with.

**Methods:**
- 80% of employers responded they are somewhat knowledgeable about COPD as a chronic condition.
- 70% are not sure how many employees in the organization are at-risk for COPD or are currently diagnosed with COPD
- 70% of employers have not conducted claims analysis to evaluate the impact of COPD on the employee population
- Employers are likely to consider implementing patient education, smoking cessation, and health coaching program to reduce COPD prevalence and costs.
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