Volume 2 Number 6 December-January 2007/2008

# Respiratory Technique

Pneumonia HFCC BPRV Blood Gas Ventilation Homeopathy COPD Hypoxemia AARC Product Previews

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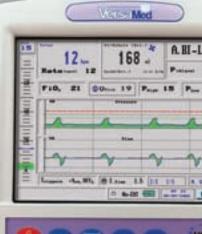


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# Editorial

# What We All Know

Healthcare coverage is a mess. It's inarguable. We can have all the debate we want, and it's still a mess. Just so you know where we stand, I'll let the following commentary stand for itself. It is excerpted from a recent article in The Guardian.

No care or concierge care: between two extremes is where America's healthcare system has unraveled. Tens of millions regularly put their health on hold because they cannot afford basic treatment, prescriptions, or even a visit to the doctor.

The disparities seem to have brought America to a tipping point. America spends more money on prevention and treatment of disease than ever before, yet it is falling behind on such basic indicators of health as infant mortality and life expectancy.

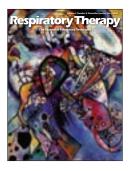
The US spends about 16% of its GDP on healthcare. At \$6,700 per capita, it's double what is spent in countries such as France. And yet that still leaves some 47 million Americans entirely without health coverage, and tens of millions of others underinsured and also fails to guarantee a better service to those Americans with access to healthcare. The US ranks last or near the bottom on quality, access, efficiency, equity and healthy lives. Since 2000, there has been a steady decline in the number of employers who offer health coverage. Others are scaling back on the range of coverage.

The average cost of insurance premiums rose 7.7% last year, far above the rate of inflation or rise in salaries. The rising costs have shifted the burden of cover on to the individual. By 2003, people were spending almost 20% of their income on insurance premiums and other healthcare costs. For those at the lower end of the income scale, healthcare is not affordable.

Healthcare experts say that there is sometimes no rational reason for the rising costs, and that there are huge disparities across the country. None of the current mainstream proposals would move America towards the national healthcare systems of Europe or Canada. That idea remains taboo.

Les Plesko, Editor

PS: Call for papers: Now is the time to submit papers for the 2008 issues of Respiratory Therapy and Sleep International. All submissions will be considered, including case studies and works in progress. Special themes for 2008 include ventilation and neonatal ventilation, ARDS, asthma, oximetry, surfactants, COPD, emergency planning, CPAP, apnea, spirometry, blood gas analysis, and more. Our process for publication is simple: just e-mail your manuscript to us in an unformatted, word-compatible file, and we will notify you of its status in about a week after receipt. Respiratory Therapy strives to provide an open forum for its readers. As such, all submissions from any segment of the respiratory care community will be considered. Please contact me if you have any questions.



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# News

December-January 2007/2008

# CORRECTION

In the article The Primary Ciliary Disorders on page 16 of the October issue, under "History," the last sentence should have read Interestingly, only 50% of persons with *sitis inversus* also have dysmotile cilia.

# **BREATH CONTROL**

The National Asthma Education and Prevention Program (NAEPP) issued the first comprehensive update in a decade of clinical guidelines for the diagnosis and management of asthma. The guidelines emphasize the importance of asthma control and introduce new approaches for monitoring asthma. Updated recommendations for managing asthma include an expanded section on childhood asthma with an additional age group, new

guidance on medications, new recommendations on patient education in settings beyond the physician's office and new advice for controlling environmental factors that can cause asthma symptoms. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma - Full Report, 2007 provides new guidance for selecting treatment based on a patient's individual needs and level of asthma control. Assessment and Monitoring: EPR-3 takes a new approach to assessing and monitoring asthma by using multiple measures of the patient's level of "current impairment" (frequency and intensity of symptoms, low lung function, and limitations of daily activities) and future risk (risk of exacerbations, progressive loss of lung function, or adverse side effects from medications). The guidelines stress that some patients can still be at high risk for frequent exacerbations even if they have few day-to-day effects of asthma. EPR-3 confirms the importance of teaching patients skills to self-monitor and manage asthma and to use a written asthma action plan, which should include instructions for daily treatment and ways to recognize and handle worsening asthma. New recommendations encourage expanding educational opportunities to reach patients in a variety of settings, such as pharmacies, schools, community centers, and patients' homes. EPR-3 describes new evidence for using multiple approaches to limit exposure to allergens and other substances that can worsen asthma; research shows that single steps are rarely sufficient. EPR-3 also expands the section on other common conditions that asthma patients can have and notes that treating chronic problems such as rhinitis and sinusitis, gastroesophageal reflux, overweight or obesity, obstructive sleep apnea, stress, and depression may help improve asthma control. EPR-3 continues the use of a stepwise

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AT AARC ORLANDO BOOTH 1813 approach to control asthma, in which medication doses or types are stepped up as needed and stepped down when possible. Treatment is adjusted based on the level of asthma control. The stepwise asthma management charts are revised and expanded to specify treatment for three age groups: 0-4 years, 5-11 years, and 12 years and older. The 5-11 age group was added (earlier guidelines combined this group with adults) as a result of new evidence on medications for this age group and emerging evidence that suggests that children may respond differently than adults to asthma medications. Recommendations on medications are updated to reflect the latest evidence on effectiveness and safety. EPR-3 reaffirms that patients with persistent asthma need both long-term control medications to control asthma and prevent exacerbations, as well as quick relief medications for symptoms as needed. EPR-3 also reaffirms that inhaled corticosteroids are the most effective long-term control medication across all age groups. EPR-3 includes new recommendations on treatment options such as leukotriene receptor antagonists and cromolyn for long term control; long acting beta agonists as adjunct therapy with inhaled corticosteroids; omalizumab for severe asthma; and albuterol, levalbuterol, and corticosteroids for acute exacerbations. EPR-3 also describes areas of current research to improve asthma management, such as new ways for monitoring asthma control (for example, tests using a patient's sputum and exhaled air), and tailoring treatment based on the particular characteristics of a patient's asthma and the patient's genetic makeup.

# **BLACK IN HOSPITAL WHITES**

Hospitalization or a visit to the emergency department is more

likely for black patients with asthma than for white patients, regardless of what the managed care settings are, according to an article published in Archives of Internal Medicine. Researchers at the University of California, San Diego reported that black patients who suffer from asthma have worse control of their symptoms and are more likely to be hospitalized than white patients. The reasons could be differences in access to good healthcare, lower socioeconomic status, behavioral, genetic, environmental, poor communication between patient and doctor, and racial bias among doctors. Prior studies had found that even when such variables as socioeconomic status were factored in the racial disparities in asthma outcomes persisted. Researchers looked at 678 patients from a large health plan who had been hospitalized for asthma during the period 2000-2004. Of the 678 patients, 154 were black and 524 were white. Despite there being no difference in asthma severity, physical health status or controller medication use, the black patients were much more likely than the white ones to have had outpatient visits because of their asthma during the follow-up: 35.7% of black patients and 21% of white patients visited the emergency department for asthma symptoms. Hospitalization rates post follow-up were 26.6% for blacks and 15.3% for whites. Even when socioeconomic status and differences in asthma therapy were taken into account, the figures persisted, say the authors.

# **GO SEE A DOCTOR**

Data from an international survey presented at the European Respiratory Society Congress in Stockholm, Sweden, have shown that the majority of patients with asthma are uncontrolled, despite frequent visits to their doctor. Results



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The website, like the journal, offers clinical studies, product reviews, news, facility reports, commentaries, and special sections about the current trends in respiratory care.

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from the National Health and Wellness Survey (NHWS) show that, although control has improved amongst adult asthma patients since the Asthma Insights and Realities in Europe (AIRE) study in 1999, overall 55% of treated asthma patients are still not well controlled. The NHWS was conducted in France, Germany, Italy, Spain and the UK between June and August 2006 and surveyed 2,337 patients with diagnosed asthma of which 1,862 were receiving treatment. Additional findings from the survey showed that patients with asthma who were not well controlled had a high symptom burden, including 70% having shortness of breath 3-6 times a week, 80% using rescue medication 2-3 times a week and 58% waking once a week due to asthma symptoms. In addition these patients use more healthcare resources and visit their doctors more frequently. The study also found that patients overestimate their own level of asthma control: 40% of not well-controlled asthma patients consider themselves to be completely or well controlled, despite their symptoms. The authors concluded that the simple question whether or not the patient's asthma is "OK" is not sufficient. Tools such as the Asthma Control Test have been highlighted in global guidelines as a validated measure for assessing clinical control of asthma.

### **SWOLLEN**

Eoxins may be another piece in the puzzle helping us to understand the mechanism for airway inflammation. Eicosanoids is the collective name for a large number of fatty acids, all having important functions in the body. The most wellknown are the prostaglandins, which for example regulate blood flow and parturition, but also cause fever and pain. The recently discovered eoxins are mainly produced by cells in the respiratory tissue, where they can cause inflammation and edema leading to airway obstructions. According to Professor Hans-Erik Claesson, Karolinska Institutet, who addressed the ERS congress, this discovery could lead to the development of medicines with a completely new mechanism of action. Another new group of eicosanoids is the lipoxins, which have antiinflammatory activity. Patients suffering from severe asthma may have reduced production of these substances. In the future, severe asthma could possibly be treated with new medicines based on lipoxins.

# **MERRY ER CHRISTMAS**

People with asthma or chronic obstructive pulmonary disease (COPD) are at increased risk of being hospitalized during the Christmas period, according to an international study. The main cause appears to be the family get-togethers, which facilitate the spread of respiratory viruses. Scientists with the Firestone Institute for Respiratory Health, McMaster University, Hamilton, Ontario, Canada, based their research on analysis of annual hospitalization patterns for asthma, COPD and respiratory infections in a range of countries. Their original study revealed that Christmas hospitalization risk rose by 16-62%. New Zealand was the only country to escape this trend, perhaps because Christmas comes in summer in New Zealand. The Christmas epidemics seem to occur independently of flu virus, RSV or parainfluenza virus and adenovirus isolation rates.

# THAT TIME OF LIFE

The way menopause-related hormonal changes affect the lungs has been little studied in the past. It appears that menopause brings a sharp increase in respiratory symptoms and a worsening of lung function. Francisco Gómez Real (Bergen,

Norway) and an international team undertook an original study on a group of 1,304 menopausal women. The volunteers, aged 45 to 55, were all drawn from the enormous cohort of the European Community Respiratory Health Survey (ECRHS). The women completed a detailed questionnaire with a focus on their respiratory health and menstrual cycle, and received an objective assessment of their lung function. This included spirometric testing for forced expiratory volume in one second (FEV1) and forced vital capacity (FVC). Blood tests were conducted to measure sex hormones (FSH, LH and oestradiol) and IgE. Compared to women with regular menstruation, those who had not had a period for six months or longer suffered a significant drop in lung function, with a reduction in FEV1 and FVC. The researchers also found an increase in respiratory symptoms, particularly of the allergic type. Asthma rates were almost doubled (a relative risk of 1.84). These phenomena were particularly marked in lean or thin women and overweight women. Normal weight, on the other hand, or a slightly round shape, did not seem to be associated with respiratory risks during menopause. The conclusions remained unchanged when the analysis was restricted to women who have never smoked. Researchers noted that estrogen may provide protection of the respiratory function.

# **BLOOD SUCKING WORMS!**

A copyrighted story in Medical News Today by Christian Nordqvist said that blood-sucking hookworms may be used to treat asthma and other allergies, as well as type 1 diabetes and MS. Researchers at the University of Nottingham noted that people with hookworms didn't suffer from allergies, and wondered if there was a reason related to the worms. According to researchers, hookworms slow down the work of the immune system, and it's people with very active immune systems who typically suffer from allergies. The worm lives in the small intestines of about 800 million people throughout the world. Infected people typically suffer from anemia, and the worms damage the gut through blood sucking.

# **GOLD STANDARD**

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) has released new standards for the diagnosis, management and prevention of COPD. The latest recommendations emphasize the importance of proper diagnosis, assessment of the disease's severity, and the need for a better understanding of co-morbidities to improve treatment of disease. The new standards reflect the evolution of current scientific and medical thought. The report includes new staging guidelines for determining the severity of COPD, management recommendations for exacerbations including the use of antibiotics, and recommendations for identifying and building the comprehensive healthcare teams that are necessary for the coordinated treatment of patients with COPD, who frequently present with co-morbidities. The GOLD report notes that despite the significant progress that has been made in the understanding and management of the disease, the behavioral and cultural factors that have pushed the disease into the topfive list of killer diseases worldwide remain largely unchanged. Cigarette smoking and secondhand smoke exposure are the most commonly encountered risk factors for COPD in the developed world. In developing countries, COPD arises primarily from long-term exposure to smoke from biomass fuel used for indoor cooking and heating. Women, who began smoking in higher numbers after World War II, and who bear the brunt of indoor exposures in developing countries, are now

more likely to die of the disease than men. Furthermore, because COPD generally develops over a period of decades, the current rise in cases is unlikely to abate soon. Children with allergic sensitizations in economically developed countries are much more likely to develop asthma than similarly sensitized children in poorer countries, according to a team of international researchers. The global research study is the first to link economic development to differences in rates of asthma symptoms and allergic sensitization, based on examination of a large, multi-center cross-sectional study of 8- to 12-year-old children. Children living in affluent countries with allergic sensitizations were 4 times as likely to have asthma than their non-sensitized counterparts; in non-affluent countries, children with allergic responses were only 2.2 times as likely to have asthma. The researchers speculated that a possible explanation could be that some factors that protect children with allergic sensitization from developing asthma are less present in affluent settings, or that acquired commensal bacteria (gut flora), which may also differ with GNI, play a role in development of tolerance and immune function. The findings were published in the second issue for September of the American Thoracic Society's American Journal of Respiratory and Critical Care Medicine.

# TAKE A WHIFF

The FDA proposed a change to its regulation on the use of CFCs in metered dose inhalers for epinephrine that would remove the "essential-use" designation that allows the use of CFCs in these medical devices. The agency has tentatively concluded that there are no substantial technical barriers to formulating epinephrine as a product that does not release CFCs. Under the proposed rule, epinephrine MDIs containing CFCs would be removed from the market by the end of 2010. A 60-day public comment period will commence following publication of the proposed rule in the Federal Register, and an open public meeting on the essential use of epinephrine will be held on a date to be announced later. The Clean Air Act permits CFCs to be used in medical products, if the use is determined to be essential by FDA. The use of CFCs has been generally banned in consumer aerosols, such as hairspray since 1978 because of adverse effects on stratospheric ozone levels. Epinephrine MDIs are the only devices currently marketed over the counter. Should this rule become final, epinephrine MDI users will have to obtain a prescription for alternative drug products if a non-CFC epinephrine inhaler still does not exist.

# **TRUCKS AND BUSES**

Researchers at Deakin University have found that diesel exhaust is far more damaging to our health than exhaust from biodiesel, the plant-based fuel. Researchers compared the effects of diesel exhaust and biodiesel exhaust on human airway cells. They found that diesel exhaust damaged and killed the cells, while biodiesel exhaust had little effect. They noted that fumes from burning fuels, including diesel, can cause heart disease, bronchitis and asthma. The researchers conducted their research on human airway cells grown in a culture. The cells were exposed to the particulate matter emitted in diesel and biodiesel exhaust fumes. It was found that particulate matter from diesel exhaust stimulated a "death pathway" response that the body uses to dispose of damaged cells. This response caused the airway cells to fuse together and die.

# GET OUT WHILE YOU CAN

Emergency department length of stay is a major risk factor for

pneumonia, according to an article by Jeff Borrink in Hamilton Medical's Newsletter. A recent article by Brendan Carr et al, published in the Journal of Trauma-Injury Infection & Critical Care, sought to study the association between prolonged Emergency Department (ED) length of stay (LOS) and rates of pneumonia. In the United States, ED overcrowding has become a major problem due to an increase in patient volume and a decrease in available hospitals/ED. Often, trauma patients are intubated by emergency responders prior to arriving to a healthcare setting or ED, further prolonging the time involved prior to being admitted to an ICU. The study by Carr et al was a 2-year retrospective case-control study of pneumonia risk among 509 blunt trauma patients presenting to an urban Level I trauma center who were emergently intubated either prehospital or in the ED. Thirty-three of the patients developed pneumonia and were compared to a group of matched controls with equivalent age, injury severity score, abbreviated injury score (AIS) chest, and AIS head who did not develop pneumonia. A comparison of ED LOS between the two groups was assessed using conditional logistic regression. The ED LOS for the 33 patients that developed pneumonia was significantly longer than the LOS for the control group (281.3 minutes vs 214.0 minutes, p < 0.05). Each additional hour spent in the ED increased the risk of developing pneumonia by approximately 20%. Carr et al concluded that in blunt trauma patients who are emergently intubated, increased ED LOS is an independent risk factor for pneumonia. Efforts should be made to minimize hospital crowding and ED LOS. And ventilator associated pneumonia interventions which have been successful in the ICU should be implemented early in the hospital course. Contact cdc.gov/mmwr/preview/mmwrhtml/rr5303al.htm. Reference: Carr, BG, Kaye AJ, Wiebe, DJ, Gracias, VH, Schwab, CW, Reilly PM. Emergency Department Length of Stay: a Major Risk Factor for Pneumonia in Intubated Blunt Trauma Patients. Journal of Trauma-Injury Infection & Critical Care. 63(1):9-12, July 2007.

# LOW TIDE

Hamilton Medical's newsletter reports on a recent review of mechanical ventilation in Acute Respiratory Distress Syndrome (ARDS), published by Dr. Timothy D. Girard and Gordon R. Bernard from the Division of Allergy, Pulmonary, and Critical Care Medicine at Vanderbilt University School of Medicine. Girard et al reviewed a large number of randomized controlled clinical trials that have evaluated the efficacy and safety of various methods of mechanical ventilation for the treatment of ARDS over the last three decades. These methods included high tidal volume ventilation, low tidal volume ventilation, permissive hypercapnia, high frequency oscillatory ventilation, high Positive End-Expiratory Pressure (PEEP), alveolar recruitment maneuvers, prone positioning during mechanical ventilation, inverse ratio ventilation (IRV), airway pressure release ventilation (APRV), partial liquid ventilation using perfluorocarbons, ventilation in a semirecumbent position, and liberation from mechanical ventilation. According to Girard, the only method of mechanical ventilation that has been shown in randomized controlled trials to improve survival in patients with ARDS is low tidal volume ventilation, and clinicians should utilize low tidal volumes as part of a ventilatory protocol that also limits plateau pressure. Specifically, they recommend that clinicians utilize the ventilatory protocol outlined by the ARDS Network investigators which includes the following: tidal volume size should be based on predicted body weight (calculated from sex and height), rather than actual body weight; tidal volumes should be systematically adjusted (from 4

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to 6 mL/kg of predicted body weight) to maintain a plateau pressure of 30 cmH20; the respiratory rate should be titrated as needed (from 6 to 35 breaths/min) to maintain a pH of 7.3 to 7.45; and an appropriate combination of fraction of inspired oxygen (FI02) and PEEP should be used to achieve adequate oxygenation (Pa02 of 55 to 80 mm Hg; or pulse oximetric saturation of 88 to 95%). Girard et al further conclude that other ventilation methods such as high PEEP, alveolar recruitment maneuvers, and prone positioning during mechanical ventilation, may be useful as rescue therapy in carefully defined situations, but their use is not widely recommended as these methods do not improve mortality in the broad population of ARDS patients. Finally, protocol-driven weaning that utilizes a daily spontaneous breathing trial and ventilation in the semirecumbent position, although not specific to ARDS, has proven benefits and should be used in the management of ARDS patients. For the full article see chestjournal.org/misc/ reprints.shtml. The above report is by Jeff Borrink, who adds this editorial note: ARDSnetwork has proven that reductions in Vt/ Plateau pressure are beneficial in ARDS. The role of PEEP and recruitment maneuvers is not resolved as there are several randomized controlled trials providing evidence of improved outcomes when incorporating PV curve based titration of PEEP and/or recruitment maneuvers. Factors such as type of ARDS (extra vs intrapulmonary ARDS), "persistence" of ARDS after study entry and severity of ARDS affect results of trials. Reference: Girard T, Bernard G. Mechanical Ventilation in ARDS; A State-of-the-Art Review. Chest 2007;131;921-929.

#### INHALE

New data presented at the European Respiratory Society (ERS) congress demonstrate the efficacy of budesonide/ formoterol maintenance and reliever therapy (Symbicort SMART) in reducing exacerbations and improving daily asthma control in patients with uncontrolled asthma. This further illustrates the additional benefits of this new asthma management approach (one inhaler for both maintenance and for relief) over traditional treatment regimens; salmeterol/ fluticasone and budesonide/formoterol plus separate reliever medication in achieving reductions in exacerbations. The data, from further analyses of the COMPASS study, showed that budesonide/formoterol used as both maintenance and reliever therapy is more effective in reducing exacerbations in patients with average or above average need for reliever medication than fixed doses of salmeterol/fluticasone or budesonide/formoterol plus separate reliever medication. A further post hoc analysis of this patient population from COMPASS demonstrated that in patients symptomatic on high doses of inhaled corticosteroids, budesonide/formoterol used as both maintenance and reliever therapy reduced the rate of exacerbations by 57% when compared to higher, fixed maintenance doses of salmeterol/ fluticasone (p 0.03) plus separate reliever medication, and 42 percent compared to higher fixed maintenance doses of budesonide/formoterol plus separate reliever medication. Data from the AHEAD study demonstrated that budesonide/ formoterol used as both maintenance and reliever therapy had a numerically lower risk of a first exacerbation (p=0.12) and was more effective in reducing the incidence of asthma exacerbations by 21% (p=0.039) compared to the highest approved dose of salmeterol/fluticasone plus separate reliever medication. In addition, the rate of hospitalizations/emergency room visits decreased by 31% (p=0.046) using budesonide/ formoterol maintenance and reliever therapy. Similar improvements in daily asthma control were seen between

groups, with lower use of inhaled corticosteroids (ICS) in the budesonide/formoterol maintenance and reliever therapy group. Data from a clinical safety data review, also presented at ERS, further add to the evidence supporting the use of formoterol as a long-acting beta-agonist (LABA) in asthma treatment. An analysis of the AHEAD study also showed that budesonide/ formoterol maintenance and reliever therapy provides a more cost-effective management approach to asthma treatment than high-dose salmeterol/fluticasone, lowering the direct healthcare costs by  $\in 2330$  per 100 patients. The product in the study above is made by AstraZeneca, which presented its research at the European Respiratory Society.

# **RAPID RESULTS**

Almirall's aclidinium bromide achieves a significant, rapid and long-acting bronchodilatory effect in patients with COPD according to results of a key phase IIa trial presented at the European Respiratory Society (ERS) Annual Congress in Stockholm. Preclinical and phase I data disclosed at ERS 2007 also support the selective airway activity and safety profile of this novel muscarinic receptor antagonist. In the phase IIa trial, single doses of inhaled aclidinium produced a significant bronchodilatory response in patients with COPD. Mean FEV1 and FVC values were significantly increased with aclidinium over a 24-hour time period, as compared to placebo. This bronchodilatory effect of aclidinium was both rapid and longacting. Onset of significant bronchodilation was observed as early as 15 minutes after aclidinium treatment and was sustained for at least 24 hours. Up to 32 hours worth of bronchodilation was achieved with certain doses of the drug. Aclidinium was well-tolerated during the phase IIa trial and no patients withdrew from the study because of adverse events. Phase I study findings also presented at ERS 2007 confirm the bronchodilatory efficacy of aclidinium seen in phase IIa. Results of pharmacology studies also presented at the congress show that aclidinium has strong selectivity and a long duration of action as its target M3 receptors in the airway, but is rapidly cleared from the plasma. When compared to other bronchodilatory agents in vitro, aclidinium demonstrated potent anticholinergic activity comparable to both tiotropium and ipratropium, but with a faster onset of action than tiotropium and a significantly longer duration of action versus ipratropium4, allowing for a 24 hour duration of action.

# SQUEAK!

Researchers from London's Imperial College have successfully implanted lung cells grown from embryonic stem cells into the lungs of mice. For their research, the Imperial College team decided to work with mouse ESCs that are capable of differentiating into any other type of cell. They had already succeeded in cultivating cells of this type in order for them to develop into specialized lung cells that expressed certain markers (epithelial, endothelial or adult stem cell markers). The researchers marked the stem cells using iron oxide nanoparticles containing a fluorescent green marker visible with the aid of a microscope. Then they injected them into the tail veins of two groups of mice. One group was made up of normal mice, while the other group had been treated with a toxin that damaged the pulmonary epithelium. Two days later, the mice had marked cells in their lungs, in the exact location where the researchers had expected to find them. In the main, the stem cells had colonized the areas of the pulmonary epithelium where gas exchange takes place. Better still, no fluorescent cells Continued on page 45...

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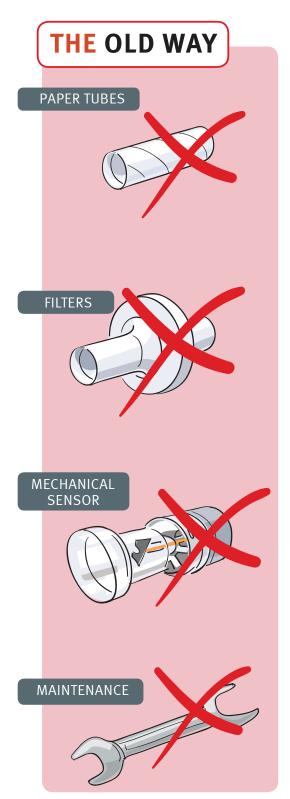


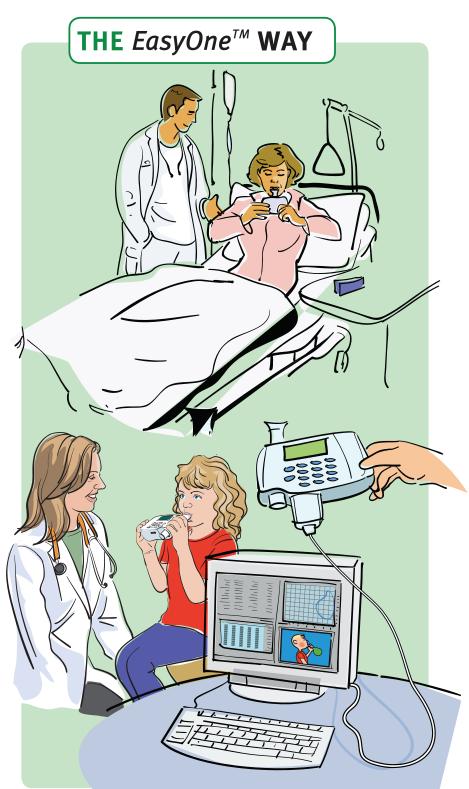


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# The Process and Results of Implementing the Ventilator Bundle to Reduce Ventilator-Associated Pneumonia Rates

Charles D. Burger, MD; Karen W. Hampton, RRT; Cynthia L. Sorensen, RN; Gavin D. Divertie, MD

#### Abstract

**Introduction:** Ventilator-associated pneumonia is a common cause of morbidity in the intensive care unit. Effective preventive strategies can reduce the burden of this nosocomial infection. The purpose of this study was to evaluate the strategy and impact of implementation of the ventilator bundle in our intensive care unit.

**Methods:** We designed a process for implementation of the ventilator bundle, a preventive strategy to reduce the rate of ventilator-associated pneumonia. A multidisciplinary team was created, and process changes were determined and implemented. The strategy was first implemented in the medical intensive care unit and then the surgical intensive care unit.

**Results:** The process was successfully implemented over several weeks. The ventilator bundle was used in all eligible patients. The rate of ventilator-associated pneumonia decreased in the medical intensive care unit from 8.5 to 0.4 per 1,000 ventilated days and in the surgical intensive care unit from 12.5 to 5 per 1,000 ventilated days.

**Conclusions:** Our process of implementation of the ventilator bundle was successful. The ventilator bundle is an effective preventive strategy to reduce the rate of ventilator-associated pneumonia.

#### Introduction

Ventilator-associated pneumonia (VAP) is a lower respiratory tract infection that develops more than 48 hours after intubation and is a serious consequence of mechanical ventilation. It occurs in approximately 20% of patients requiring ventilatory assistance and remains a leading cause of death among patients with hospital-acquired infections, causing an estimated 26,000 deaths annually in the United States.<sup>14</sup> Additional consequences of VAP include prolonged duration of mechanical ventilation, requiring longer intensive care unit (ICU) stays, and increased cost of care.<sup>34</sup> The majority of the published literature on VAP

Authors Burger and Hampton are from the Division of Pulmonary Medicine; Divertie and Sorensen are with the Department of Critical Care Medicine, Mayo Clinic, Jacksonville, FL, and RKR is with the Department of Medicine, Luther-Midelfort, Mayo Health System, Eau Claire, WI. ©2007 Mayo Foundation for Medical Education and Research. Editing, proofreading, and reference verification were provided by the Section of Scientific Publications, Mayo Clinic. focuses on the diagnosis and treatment of VAP,<sup>5,6</sup> although a few key publications discuss prevention.<sup>7,9</sup> Only one published study mentions the ventilator bundle, a new strategy developed and promoted by the Institute for Healthcare Improvement (IHI).<sup>9,10</sup> The ventilator bundle is 1 of the 6 primary interventions in the IHI 100,000 Lives Campaign to reduce hospital-based mortality.<sup>11</sup>

The ventilator bundle promotes the use of 4 evidence-based care elements for all patients requiring ventilatory assistance (unless patients have specific medical contraindications). Each of the primary components is individually supported by published literature.<sup>12-19</sup> Two recent publications suggest a relationship between implementation of the elements of the bundle and a marked reduction in VAP.<sup>11,20</sup>

None of the publications previously cited provide instruction or experience in the implementation of the ventilator bundle. The process by which we reviewed our current practice and then implemented the use of the ventilator bundle on all patients receiving ventilatory support is the focus of this manuscript. The subsequent reduction in ventilator-associated pneumonia is also described.

#### Methods

In the medical ICU (MICU) at St Luke's Hospital in Jacksonville, FL, we adopted the ventilator bundle as a quality improvement project to reduce the rate of VAP. St Luke's Hospital, a community hospital of more than 300 beds, is the sole admitting hospital for the Mayo Clinic practice in Jacksonville. The MICU has 15 beds and supports both the Mayo Clinic practice (80% of the census) and a community-based practice. The unit has 24hour intensivist coverage.

We reviewed the published literature on prevention of VAP.<sup>1,7,13,16,21,22</sup> The ventilator bundle seemed to offer a straightforward strategy that could be implemented in our ICU population. The components of the ventilator bundle are 1) elevating the head of the bed to a semirecumbent position; 2) interrupting sedation daily; 3) assessing for weaning daily; and 4) taking measures to prevent deep vein thrombosis (DVT) and peptic ulcer disease (PUD).

Respiratory therapy and nursing partnered with our quality officer to perform reviews on all ventilated patients in multiple 2-week blocks to establish our baseline compliance with the individual components of the bundle.

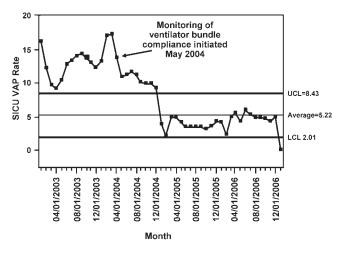


Fig. 1. Ventilator-associated pneumonia (VAP) rates in the medical intensive care unit (MICU) before and after implementation of the ventilator bundle. The rates are displayed on the vertical axis as the number of cases of pneumonia per 1,000 ventilator-days. The upper and lower limits were calculated using year-to-date data as of January 1, 2004. UCL, upper confidence limit.

To focus on a composite rate of compliance, we adopted an "all or none" approach.<sup>23</sup> That is, for each ventilated patient, all the elements of the bundle had to be in place and in use for full compliance (full credit). If one of the elements was not performed, then a score of zero was applied. No partial credits were awarded, although credit could be assigned if a component was not being performed and there was a legitimate and documented reason. For example, the head of the bed may not have been elevated in a hypotensive patient requiring ongoing resuscitative intervention. To calculate the compliance rate, the number of ventilated patients receiving all 4 components of the ventilator bundle was divided by the total number of ventilated patients. Data were collected daily by caregivers who were not team members (to avoid bias) and entered into a spreadsheet to calculate the compliance rate. The baseline compliance was reviewed by a multidisciplinary team of respiratory therapists, nurses, nutritionists, physicians, and case managers.

To facilitate improvement in the baseline, we adopted 2 innovative methodologies: rapid-cycle quality improvement<sup>24</sup> and small tests of change. Multiple ideas to improve our compliance resulted from team-based brainstorming sessions. We challenged each other as clinicians to adopt all reasonable ideas immediately as long as there was no risk of harm to the patient and then to test the impact on our compliance within 1 to 2 weeks (rapid cycle). The first example of a small test of change that was applied to a rapid-cycle improvement cycle was an idea to place signage in the room and on the ventilator that the head of the patient's bed was to be elevated at all times. Any of the staff (allied health staff or physicians) were free to raise the head of the bed if it was not in proper position. The expectation was that the head of the bed would always be elevated unless there was a physician order or an acute clinical change (such as hypotension) that dictated otherwise.

After initial success with improving the rate of semirecumbent positioning of all ventilated patients, our team was motivated to approach the entire bundle similarly. Implementation of the component elements was then incorporated into standardized ICU order sets as the default practice. The daily sedation interruption and weaning assessments were discussed on daily physician and twice-weekly multidisciplinary rounds.

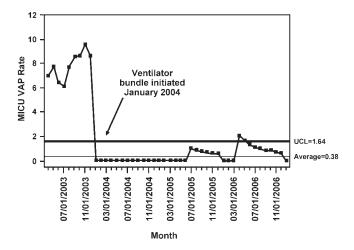


Fig. 2. Ventilator-associated pneumonia (VAP) rates in the surgical intensive care unit (SICU) before and after implementation of the ventilator bundle. The rates are displayed on the vertical axis as the number of cases of pneumonia per 1,000 ventilator-days. The upper and lower limits were calculated using year-to-date data as of May 1, 2004. LCL, lower confidence limit; UCL, upper confidence limit.

#### Results

Our initial compliance rate with the ventilator bundle was 13%, using the all or none scoring system. Of the recommended practices, only DVT and PUD prophylaxis was performed regularly and consistently in 92% to 100% of patients. The other 3 measures were performed much less often: semirecumbent positioning in 67%, sedation interruption in 45%, and daily weaning assessment in 38%. After applying the small test of change method, the compliance rate for elevating the head of the bed increased from 67% to 100% within 1 week. With the ventilator bundle established as our default practice, compliance increased to 100% after 8 weeks.

The initial impact on patient outcomes in the MICU have been published previously.<sup>20</sup> Before the intervention, the rate of VAP was generally at the 50th percentile of the National Nosocomial Infections Surveillance Data (http://www.cdc.gov/ncidod/dhqp/ pdf/nnis/2003NNISReport\_AJIC.PDF) for comparable facilities in both the MICU and SICU. After institution of the ventilator bundle protocol in the MICU in January 2004, no VAP occurred for 18 months (Fig 1). Overall, since adopting the ventilator bundle as standard practice, only 2 cases of VAP have occurred. One patient had been in the hospital more than 1 month and was immunocompromised after orthotopic liver transplant (July 2005). In the second patient, methicillin-resistant Staphylococcus aureus pneumonia developed (April 2006) after the patient was intubated and received ventilatory assistance for congestive heart failure. The bundle was implemented in the SICU in May 2004. The results are displayed in Figure 2. The absolute numbers of patients with VAP and the rates have shown a steady decline in both ICUs.

#### Discussion

There appears to be a direct relationship between implementation of the elements of the bundle and a marked reduction in VAP.<sup>20</sup> Our experience suggests that appropriate preventive strategies can be implemented with a high degree of compliance and positive impact on outcomes.<sup>11</sup> The published literature on the process of implementation most commonly focuses on educational programs.<sup>7,9</sup> The ventilator bundle offers a legitimate, alternative intervention. The challenge of preventive strategies is often in the details of implementation. Establishment of a multidisciplinary team provided the basis for our success with implementation of the ventilator bundle. Such teams have been previously recommended.<sup>9</sup> The team members were encouraged to participate at every level of identification of barriers to implementation and new ideas to be tested using the rapid-cycle quality improvement and the small test of change strategy described in the Methods.

Of importance in the bundle is the lack of specificity. The degree of elevation, how to interrupt sedation, how to assess for weaning, or which DVT or PUD prophylaxis to use is not mandated. The bundle allows individual ICUs to decide how to address each of these elements. Once the elements are clearly defined, then the ICU is held to these standards and outcomes are measured. Reliably applying these 4 elements may also allow the treatment team to observe other variables to improve overall quality of care and subsequently prevent VAP.

As hospitals apply new methods of improving quality and safety, the ventilator should be considered a legitimate option to achieve both. The description of the process by which we successfully implemented the ventilator bundle and reduced the rate of VAP may prove useful to those wishing to adopt the bundle in their practice.

#### Conclusion

The ventilator bundle is easy to understand although implementation may be challenging. The bundle promotes teamwork in ways we did not anticipate, and the results in our institution have been remarkable. The reduction in patient morbidity has become a considerable source of pride for allied health staff. We would advocate consideration of a trial of the ventilator bundle in all ICUs—the interventions are backed by science, present no additional risk to patients, and add negligible cost to patient care.

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# High-Frequency Chest Compression: A Practical Intervention for Secretion Retention in the ICU

Jane Braverman, PhD

In a sweeping Medicare policy change, Bush administration officials announced in August, 2007 that the program will no longer reimburse medical institutions for the extra costs of treating conditions identified as hospital-acquired illnesses or injuries... "that could reasonably have been prevented."1 Despite the government's approach to reduce excess expenditure by mandating improvements in care practices, healthcare professionals know that adverse outcomes persist even with the most rigorously applied preventative programs. Inevitably, complications occur as a natural consequence of treating seriously ill patients for prolonged periods of time. No professional healthcare team member knowingly neglects evidence-based care guidelines. Unfortunately, complex realities are not easily communicated to policy makers. No matter how unfairly some poor outcomes may be labeled as "preventable," budget-strapped hospitals now must even more aggressively identify cost-effective ways to prevent and/or manage complications associated with suboptimal recovery.

#### **Pulmonary Complications: An ICU Nemesis**

Pulmonary complications (PC) are an ever-present threat in acute care medicine. Mild problems may delay recovery. More severe PC may progress and worsen until they pose serious, even life-threatening challenges. Clinically important PC include atelectasis, interstitial and alveolar edema, pneumonia, hypoventilation, aspiration and respiratory failure.<sup>24</sup> In patients undergoing thoracic or upper abdominal surgery, PC are a major cause of postoperative mortality.17 Even after uncomplicated procedures, 30-60% of patients experience hypoxemia and some go on to develop respiratory failure.8 Depending upon severity, mortality following respiratory failure ranges from 10-60%.8 Moreover, the costs incurred for extended ICU stays are substantial. Additional expenditures for complication-related interventions including reintubation, mechanical ventilatory support, treatment of infections or nosocomial pneumonia account for a significant proportion of Medicare dollars.

Jane Braverman is Director: Clinical Programs, RespirTech. This article is provided by RespirTech.

Laboratory services and specialized nursing care further increase total costs.

#### The Economic Cost of PC: Current Estimates

Although PC are a significant source of ICU morbidity and mortality, until recently few studies have attempted to quantify their impact on health care resource utilization. The data are striking:

- Khan, et al [2006] assessed costs associated with clinically important PC with total hospital costs and length of stay (LOS) in patients undergoing noncardiac surgery.<sup>9</sup> After adjusting total hospital costs and LOS for preoperative and surgical characteristics, data showed:
  - » Of 7,457 eligible surgical patients, 6.9% (514/7,457) developed at least one clinically important PC
  - $\ast$  These complications increased hospital costs by 78% and LOS by 114%
  - » Postoperative pneumonia was the most common complication (3%) and was associated with a 55% increase in hospital costs and an 89% increase in LOS.

When mechanical ventilation is part of the clinical picture, costs skyrocket:

- Warren, et al [2003] found that patients with ventilatorassociated pneumonia had significantly longer ICU and hospital LOS, with higher crude hospital costs and mortality rates compared with uninfected patients.<sup>10</sup> After adjusting for underlying severity of illness, the attributable cost of ventilator-associated pneumonia (VAP) was approximately \$11,897. Data from 819 intensive care patients in a suburban medical center followed prospectively for the occurrence of VAP showed an overall incidence of 15.5% (127/819). Compared with uninfected ventilated patients, patients with VAP:
  - » Had higher Acute Physiology and Chronic Health Evaluation II scores on admission (p<.001);</p>
  - » Were more likely to require multiple intubations (p<.001), hemodialysis (p<.001), tracheostomy (p<.001), central</p>

venous catheters (p<.001), and corticosteroids (p<.001).

- » Were more likely to be bacteremic during their ICU stay (36 [28%] vs. 22 [3%]; p<.001).</p>
- » Had significantly higher unadjusted...
  - $\circ$  ICU LOS (26 vs. 4 days; p<.001)
  - $\circ$  Hospital LOS (38 vs. 13 days; p<.001)
  - Mortality rates (64 [50%] vs. 237 [34%]; p<.001)</li>
  - Hospital costs (\$70,568 vs. \$21,620, p<.001).
  - Estimated attributable cost of ventilator-associated pneumonia (\$11,897 – [range \$5,265 – \$26,214] p<.001].</li>
- Dasta, et al [2005] studied intensive care costs of 51,009 adult ICU patients treated in 2002 at 253 US hospitals and found...<sup>11</sup>
  - $\,$  » 36% received mechanical ventilation (MV) during their stay
  - $\times$  Mean MV duration: 5.6 days ±9.6.
  - » Mean intensive care unit cost and length of stay: \$31,574 ±\$42,570 and 14.4 days ±15.8 for patients requiring MV
  - »  $12,931 \pm 20,569$  dollars and  $8.5 \text{ days } \pm 10.5$  for those not requiring mechanical ventilation.
  - » Mean incremental cost of MV in intensive care unit patients was \$1,522 per day (p<.001).

### The Status Quo

Inadequate removal of tracheobronchial secretions is wellrecognized as a common and potentially lethal problem associated with major surgery, serious acute illness or significant trauma. Nevertheless, despite advances in both surgical technique and emergency/acute care medicine, the prevalence of serious PC remains stubbornly high. A rapidly aging population, together with increased access to advanced medical care among a growing population of medically complex, higher-risk individuals, accounts for a large part of this persistent problem. Other patients with few or no obvious risk factors are also affected. An abundance of recent medical literature reflects the magnitude of the problem. Editorial pieces and review articles examine current practices and seek to identify institutional or systemic weaknesses that may contribute to high PC rates.<sup>12-15</sup> Several studies identify patients with a predisposition to PC, stratify risk factors and suggest interventions to modify those risks.<sup>1,2,5-7,16</sup> Numerous protocols outline steps to help recognize and manage developing signs and symptoms of PC.<sup>17-20</sup> However, few papers address identification of risk for the single factor both necessary and sufficient for PC to occur: a breakdown of the mucociliary clearance system.

#### Secretion Retention: A Proximate Cause of Acute PC

Lung health is impossible to maintain without effective mucociliary clearance (MCC). MCC plays an essential role in the defense of the respiratory system by entrapping inhaled particles, including bacteria, in a layer of mucus and then moving it forward via coordinated structures and mechanisms aptly called the mucociliary escalator.<sup>21</sup> When sufficient mucus is accumulated in the central bronchus, it is easily cleared by coughing and/or swallowing. Normal MCC may be disrupted by one or more factors that arrest or delay mobilization of mucus from distal lung regions to central airways. These factors include 1) increased mucus production; 2) abnormal mucus rheology; 3) abnormal ciliary activity and; 4) loss of ciliated cells.<sup>21</sup> Most acutely ill patients present with some degree of one or more of these anomalies. Measurements of tracheal mucus veleocity (TMV) in acutely ill patients establish the presence of impaired MCC definitively.<sup>22-24</sup> Closer scrutiny of this fact provides new insight into the high susceptibility for PC among

ICU patients.<sup>25</sup> Impaired TMV appears to be the common denominator in development of secretion retention and pneumonia.

- MV patients are disproportionately at-risk for developing serious PC-especially nosocomial pneumonia. Konrad, et al [1994] measured tracheal mucus veleocity (TMV) with technetium 99-labeled albumin microspheres during the first three days of MV in 34 ICU surgical patients and found significantly reduced TMV and a correspondingly high incidence of PC:<sup>22</sup>
  - » Average TMV in healthy subjects is about 10 mm/min.<sup>21</sup>
  - » Median TMV in MV subject's right primary bronchus was 0.8 mm/min and 1.4 mm/min in the left
  - » No measurable particle movement occurred in 9/34 subjects
  - » 14/34 subjects experienced 19 PC (10x secretion retention; 9x pneumonia)
  - » One or more PC occurred in 8/9 patients with no measureable TMV
  - » Subjects with PCs had significantly lower TMV than those without [median with range] – left bronchus: 0 (0 to 6.5) mm/min vs 3.5 (0 to 10.5) mm/min 9 p<0.01); right bronchus: 0 (0 to 3.0) mm/min vs 4.7 (0.11.7) mm/min (p<0.01)</p>
- Patients with COPD are shown to be at significant risk for serious exacerbation of existing pulmonary problems during ICU admissions; Morgan, et al [2004]: <sup>23</sup>
  - » Scintographic measurements of TMV in 32 normal subjects [20 young (<50 years) and 12 older (>50)] and 34 subjects with COPD showed significantly decreased TMV in older individuals and markedly impaired TMV in COPD subjects.
  - » TMV (mean ±SD) in young normal subjects: 10.7±3.5mm/min<sup>-1</sup>
  - » MV in older normal subjects: 6.6 ±2.6mm/min<sup>-1</sup>
  - » TMV in COPD subjects: 2.1 ±2.7mm/min<sup>-1</sup>
- Nakagawa, et al [2005] reported that markedly impaired MCC occurred even in stable acutely ill patients without any form of airway manipulation (i.e. tracheostomy, intubation, MV or gastric or enteral tubes).<sup>24</sup> Contributing factors may be drug effects and type/length of anesthesia.
- Bonde, et al [2002] showed a strong correlation between impaired MCC (p<0.01) and the incidence of atelectasis, pneumonia and respiratory failure that occurred in 30% (108/361) consecutive thoracotomy patients. Seventeen patients died; nine deaths were caused by pneumonia attributed to secretion retention.<sup>25</sup>

# **Clinical Implications**

TMV is a reliable measure of ineffective MCC.<sup>23,26</sup> Decreased TMV is common and frequently predictable in a subset of acute care patients. Studies in various patient populations confirm that patients at high risk for decreased TMV are the same as those at high risk for PC.<sup>22-25</sup> Patient-related high risk factors include chronic lung or systemic disease, a significant smoking history, immunodeficiency, obesity and advanced age.<sup>3</sup> Procedure-related risk factors include type of surgery-especially upper abdominal and cardiothoracic-and kind and duration of anesthesia.<sup>3</sup> When TMV is significantly slowed, secretion retention inevitably follows. Stagnant secretions not only cause airway obstruction, atelectasis and suboptimal gas exchange; prolonged exposure to entrapped bacteria and viruses promotes development of pneumonia. ICU pneumonias are frequently antibiotic-resistant; respiratory failure, re-intubation, need for MV and, all too often, death may follow. The impact of preventable PC on patients, institutional resources and the healthcare dollar is unacceptable. Effective interventions are urgently needed.

#### Treatment

In theory, use of routine prophylactic and therapeutic airway clearance therapy (ACT) to prevent or relieve secretion retention is both intuitive and logical.<sup>17-19</sup> In practice, technique-related, patient-related, and institutional barriers limit both systematic implementation and fair assessment ACT outcomes.<sup>27-29</sup>

Most ICUs utilize a graduated array of ACT methods; few stand out as notably effective.<sup>30</sup> With the exception of a recently introduced therapy, high-frequency chest compression (HFCC), none of these modalities adequately address the primary cause of secretion retention: decreased TMV secondary to ineffective MCC. Each ACT technique used in the ICU has advantages and disadvantages. Post surgical patients and those with severe acute illness or injury may be weak, in pain and attached to sensitive or invasive equipment; many are disoriented or comatose. Such factors must be considered in choosing a therapy. ACTs used in the ICU:

- *Incentive spirometry*: Promotes lung expansion and cough; requires patient effort and cooperation
- *Nebulizers and brochodilators*: Humidify and loosen secretions and open airways; do not significantly mobilize tenacious secretions
- *Deep breathing and post-exhalation cough maneuvers*: Help expel secretions from primarily central airways; require effort and compliance
- *Nasal CPAP*: May improve functional residual capacity; does not affect refractory secretion stasis; suitable for severely ill patients and/or comatose patients
- *Minitracheostomy*: Permits secretion suctioning; invasive, labor-intensive, risk for infection
- *Rigid or flexible bronchoscopy*: invasive and expensive: works well to clear accumulated secretions; risk for infection; requires sedation and sometimes anesthesia
- *Chest physiotherapy (CPT)*: Works well to mobilize retained secretions; reduces atelectasis; improves peak expiratory flow rates; labor-intensive, technique-dependent and poorly tolerated by acutely ill patients. Moreover, it is difficult for RT departments to provide therapeutically effective doses of CPT. In a series of 361 lung surgery patients...196 required two CPT sessions per post-op day; 118 needed more than two but fewer than four; 35 needed more than four but fewer than six; 12 required more than six sessions/day.<sup>25</sup>

#### **High-Frequency Chest Compression Therapy**

High-frequency chest compression therapy (HFCC) is rapidly gaining acceptance as an ideal therapy for ICU patients. It is safe, easy to use, requires no active participation from the patient and only minimal staff effort. Equipment consists of 1) an inflatable jacket or wrap; 2) two interconnecting hoses and; 3) a pulsating therapy unit (PTU). The therapy works by administering rapid but gentle compressive forces via the inflatable jacket/wrap to the chest. These forces produce increased airflow and oscillatory effects within the airways, thus enhancing mucus mobilization and clearance. HFCC is the only secretion clearance modality shown to mimic all the mucokinetic and mucolytic effects of a normal MCC system: HFCC...

- $\,$  » Increases TMV up to 340x that of spontaneous breathing  $^{31,32}$
- » Reduces the viscoelastic and cohesive properties of mucus<sup>33</sup>
- $\,$  > Promotes mucus clearability by the air-liquid interactions associated with cephalad airflow bias  $^{34\cdot35}$
- » Mobilizes secretions from peripheral towards central airways for removal by cough, swallowing or suctioning.<sup>36</sup>

#### HFCC: Safety and Tolerance in the Acute Care Setting

Clinical studies and twenty years of experience have established HFCC as a safe and effective therapy for home use in diverse patient populations. A series of studies suggest that, with appropriate care, HFCC is safe and well-tolerated in the ICU as well.

- Allen, et al [2003] assessed HFCC safety and tolerance in 25 elective thoracic surgical patients receiving HFCC as soon as 24 hours after surgery. Pre and post HFCC treatment, hemodynamic and pulse oximetric values remained stable; 84% of patients tolerated and accepted the therapy; no major adverse events were observed.<sup>37</sup>
- Brierly et al [2003] observed HFCC safety and tolerance in 73 critical care/post-surgical patients treated with HFCC concurrently with therapies or equipment including 1) sternal incision/sternal wires (n=48); 2) chest tubes (n=24); 3) external pacer wires (n=30); 4) swan-ganz catheters (n=27); 5) penrose drains (n=23); 6) central venous pressure lines (n=21); 7) implanted cardiac pacemakers (n=11); 8); CPAP (n=5); 9) mechanical ventilation (n=1); 10) internal cardiac defibrillator (n=1).<sup>38</sup> In an evaluation of a total of 179 therapy days HFCC was well tolerated by 84% of users; 16% discontinued citing discomfort. No significant adverse events were reported.
- Ndukwu et al [1999] conducted a randomized, controlled study comparing chest physiotherapy (CPT) with high frequency chest compression (HFCC) in 54 long-term acute care patients who had been ventilator-dependent for a median of 84 days.<sup>39</sup> Subjects were randomized to receive either CPT or HFCC 4 x daily for 15 minutes for 40 days. After 21 days, the HFCC group...
  - » Produced larger volumes of sputum
  - » After 40 days, 38 % were weaned from ventilator dependence compared with 15% in the CPT group
  - » No adverse events occurred

#### Summary

Removal of static airway secretions is a critical component of pulmonary care in the ICU. HFCC is an established "standard of care" therapy used widely for out-patients with chronic lung disease. HFCC clears mucus from distal lung regions and significantly accelerates TMV. These effects minimize exposure of lung tissue and airways to bacteria and byproducts of inflammation. By controlling the proximate cause of secretionrelated PC, the prevalence of preventable PC may be reduced and patient outcomes improved. Substantial reductions in total inpatient costs may be inferred.

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# Biphasic Pressure Release Ventilation: Improving patient comfort when prolonged inspiratory times are clinically necessary

Cyndy Miller

#### Introduction

Pressure release ventilation is identified by a number of different names. Newport calls it Biphasic Pressure Release Ventilation (BPRV). Other manufacturers use terms like Biphasic Positive Airway Pressure (BIPAP), Bi-Vent, Bi-Level, Airway Pressure Release Ventilation (APRV) or Dual Positive Airway Pressure (DuoPAP).

This type of breath delivery is similar to traditional pressure controlled ventilation in that the ventilator manages circuit pressure at two different pressures, a lower pressure/PEEP setting and an upper pressure/Pressure Limit setting. The main difference is that when pressure release ventilation is enabled, the ventilator allows free inhalation and exhalation during the upper pressure phase of the breath cycle by partially opening and actively controlling the exhalation valve.

The goal of Biphasic Pressure Release Ventilation is to improve patient comfort, reduce the expiratory work of breathing, reduce the amount of sedation and/or paralysis needed<sup>1</sup> and possibly improve oxygenation<sup>2</sup> when using prolonged inspiratory times on patients who have an intact respiratory drive.

#### Background

Acutely ill patients may be ventilated with Pressure Control Ventilation and optimized PEEP levels<sup>3</sup> in order to improve gas exchange at the alveolar level while limiting overdistention and damage to the lungs (see Figure 1).

To further enhance gas exchange, the inspiratory time may be set longer than the patient's spontaneous or "neural" inspiratory time. If the patient is not assisting ventilation, this usually presents no conflict. If the patient is assisting, it might (see Figure 2).

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### Patient Interaction with Closed Systems Not Utilizing BPRV

When ventilating with a closed exhalation system, an actively breathing patient can inhale freely but cannot exhale freely until the ventilator switches to the exhalation phase of the breath cycle. If the inspiratory time is extended longer than the patient's neural inspiratory time and they try to exhale prematurely or cough, they will likely experience expiratory resistance and discomfort. They may also experience disruption of breath delivery if the breath cycles off early due to a high pressure alarm violation. Studies show that this has the potential for increasing oxygen consumption and inducing myocardial ischemia.<sup>2</sup> It may be necessary to dampen the patient's respiratory drive through increased sedation in order to prevent this problem from occurring (see Figure 3).

#### Patient Interaction with Open Systems Utilizing BPRV

Ventilators with BPRV have the ability to actively control the exhalation valve during the inspiratory phase of a pressurecontrolled breath. The valve pressure is managed at or close to the set pressure target. Flow is readily available for inhalation and when a patient exhales or coughs, the ventilator maintains the target pressure by releasing the excess pressure.

Since patients are more comfortable and breathing efforts do not disrupt breath delivery with this type of system, it may not be necessary to sedate patients to the point of eliminating respiratory drive when using extended inspiratory times (see Figure 4).

Studies show that BPRV-type ventilation (BIPAP) has similar hemodynamic effects as SIMV and/or Pressure Support Ventilation (PSV) in the awake patient.<sup>1</sup> Henzler et al have demonstrated that preserving spontaneous breathing with BPRV-type ventilation is effective at preserving oxygen delivery compared to conventional Pressure Control Ventilation in this application.<sup>2</sup> It is thought that this might be attributed to the unrestricted spontaneous breathing in all phases of the respiratory cycle, even when extended inspiratory times are in use. In addition, other studies have indicated that allowing

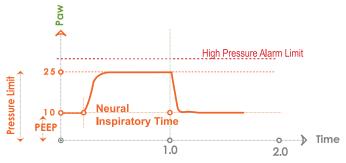


Figure 1: Pressure Control with PEEP. Inspiratory Time is set at approximately the same duration as typical neural inspiratory time.

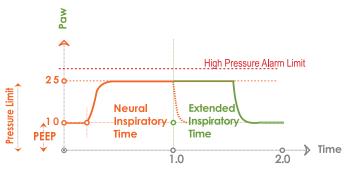


Figure 2: Inspiratory Time is extended longer than typical "neural" inspiratory time on a patient who is not assisting ventilation.

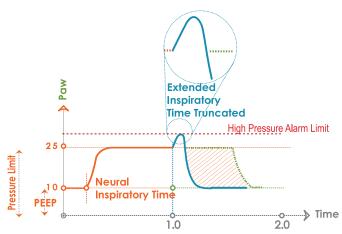


Figure 3: Extended inspiratory time on a patient with intact respiratory drive, early cycling off from overshoot of pressure during early exhalation.

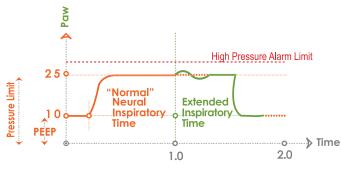


Figure 4: Extended inspiratory time on a patient with intact respiratory drive, Newport e360 Open Exhalation Valve ON (BPRV).

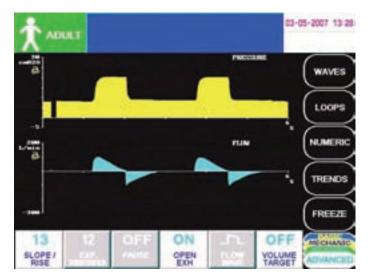


Figure 5: e360 Graphic User Interface screen,Advanced data set, shows Open Exh ON. BPRV is enabled for Pressure Control breaths.

respiratory efforts on any ventilated patient will preserve diaphragmatic force and prevent muscle atrophy.<sup>1</sup>

#### How Do You Access BPRV on the e360 Ventilator?

BPRV is enabled/disabled using the Open Exh (Open Exhalation Valve) button in the "Advanced" Data Set at the bottom of the Graphical User Interface screen (see Figure 5).

When this feature is turned ON, Pressure Controlled Ventilation becomes Biphasic Pressure Release Ventilation (BPRV) during both A/CMV and SIMV modes.

# How Does Biphasic Pressure Release Ventilation Work on the e360 Ventilator?

During BPRV, pressure controlled mandatory breaths may be patient or time triggered. During the inspiratory phase of the breath, the e360 raises airway pressure and exhalation valve pressure from the PEEP/CPAP setting to the Pressure Limit setting for the duration of the inspiratory time setting. A small amount of flow vents continuously from the floating exhalation valve. Gas flow and exhalation valve pressure are actively managed so patient breathing efforts are quickly accommodated. The pressure waveform will show a slight variability with active patient breathing during this phase of the breath. If the patient makes no effort, the graphic waveforms will look the same whether or not BPRV is in use.

Recent results of an independent performance comparison of ventilators with actively-controlled open exhalation valves showed that Newport's BPRV performed equal to or slightly better than three other major manufacturer's pressure release ventilation when comparing pressure overshoot during spontaneous exhalation and resistance to patient exhalation.<sup>4</sup>

#### How is the Newport e360 BPRV Unique?

- 1. The e360 allows the user to adjust Slope Rise. The Slope/Rise setting determines the rate of pressure rise at the beginning of each BPRV breath.
- 2. During the inspiratory phase of a BPRV-Pressure Controlled breath, circuit pressure rises from the PEEP level to the Pressure Limit level for the duration of the set Inspiratory Time.
- 3. Pressure is actively managed at the Pressure Limit setting

whether or not the patient makes breathing efforts. Additional efforts during the inspiratory phase are not supported above the pressure limit level with Pressure Support during this phase because the pressure limit should already be set to an optimal pressure and any additional pressure could result in barotrauma and overdistention of the lungs.

- 4. The Inspiratory Time setting determines when a BPRV-Pressure Control breath will cycle off. When the set inspiratory time elapses, pressure is time cycled from the upper pressure (Pressure Limit) setting to the lower pressure (PEEP/CPAP) setting. This begins the expiratory phase of the breath cycle.
- 5. BPRV-Pressure Controlled mandatory breaths are available in both the A/CMV and SIMV modes. In A/CMV, circuit pressure switches between the PEEP setting and the Pressure Limit setting in response to a patient effort or timing sequence determined by the e360's respiratory rate setting. The respiratory rate setting determines the minimum number of breaths. In SIMV, the respiratory rate determines the total number of times per minute that pressure will switch between the PEEP and Pressure Limit settings. They will be synchronized with patient efforts if available. Spontaneous breathing efforts in-between these breaths can be supported with Pressure Support. The Expiratory Threshold setting (rather than the inspiratory time setting) controls cycling off for Pressure Support breaths.

#### Summary

The e360 is a new generation, servo-controlled ventilator with sophisticated controls that allow you to make the patient more

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comfortable in all phases of ventilation. When using BPRV, the actively-controlled, open exhalation valve prevents patient discomfort by easing the resistance to the patient's exhalation during the inspiratory phase of a pressure controlled breath and minimizing pressure overshoot and the potential for early breath cycling off. This can lead to reduced WOB and potentially improve ventilation/perfusion ratio.<sup>1</sup> For some patients, unrestricted free breathing and improved comfort can also mean less sedation.

Unlike some other ventilators, the e360 does not add pressure support during the inspiratory phase of BPRV Pressure Control breaths, thus avoiding the increased potential for overdistention. In SIMV mode, Pressure Support may be used in between BPRV-Pressure Control breaths in order to facilitate weaning.

It is important to consider a ventilator with this feature. BPRV can simplify ventilator breath management for your patients.

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# Utilizing Recruitment Maneuvers in ARDS and ALI

Recruitment maneuvers certainly remain controversial, but are utilized by many clinicians and the management of acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). In order to be of any benefit, recruitment maneuvers must be applied appropriately only to select patients. A recruitment maneuver is a brief application of pressure high enough to open recruitable portions of the lung. For any recruitment maneuver to be successful, appropriate positive and expiratory pressure (PEEP) must be applied following the maneuver so that the recruitment may be maintained. An appropriately recruited lung reduces the potential opening and closing of unstable lung units during inspiration causing lung injury. Unrecruited lungs require higher peak pressures to ventilate and higher FiO<sub>2</sub> for oxygenation as well as decreased surfactant production and are more likely to induce inflammatory mediator response. PEEP can recruit, but higher pressures may be needed to open collapsed alveoli than typical PEEP ranges. A growing body of evidence suggests that PEEP sustains recruitment whereas higher pressures are needed to recruit the lung.

There are several different methods used to do a lung recruitment maneuver. One is the use of high levels of continuous positive airway pressure (CPAP) where 30-50 cmH<sub>2</sub>O of CPAP is applied for a 30-40 second period.<sup>4,6,10,11</sup> Another is to use pressure control ventilation with high PEEP. Other methods include using sigh breaths and raising PEEP over several breaths.<sup>8,9</sup> Lastly, the use of Hamilton PVTool II allows a pressure volume curve to be generated at the bedside to a specified peak alveolar pressure with a designated pause held at that pressure. One advantage to this method is that the clinician is able to actually see recruitment happening on the screen as the recruiting pressure is sustained as a novel pressure ramping technique allows the lung volume to increase during the recruitment maneuver. Also, with the PVTool II, the clinician can set an after recruitment PEEP level which allows recruitment to be sustained.

This article was provided by Hamilton Medical.

In patients with ARDS and ALI, there is a window of opportunity in which a recruitment maneuver is valuable. Ideally, it should be performed as early as possible. Grasso et al<sup>4</sup> showed that for ARDS patients, recruitment maneuvers if done on day 1 +/- 0.3, were able to successfully recruit the lungs versus trying to recruit patient's lungs on day 7 +/- 1. In addition, Gattinoni et al<sup>7</sup> was also able to show similar results with limited recruitment in patients who were already well established in the course of ARDS. Borges et. al. also found remarkable lung recruitment as they performed recruitment maneuvers early in the course of ARDS. From their studies, one can see that the benefit is realized only if the recruitment maneuver is done early in the course of ARDS or ALI. There is also evidence that extrapulmonary ARDS patients respond more favorably to recruitment maneuvers than those with an intrapulmonary source of ARDS.

In order for any recruitment maneuver to be successful, PEEP must be set appropriately to maintain that recruitment. One way to do that is to set PEEP higher than expected, and then do a decremental PEEP trial. The optimal PEEP would be identified as the PEEP associated with the best compliance and /or oxygenation during the trial. Once this PEEP is identified, a recruitment maneuver can once again be performed while setting the PEEP at 2 cm H<sub>2</sub>O above the PEEP identified in the decremental PEEP trial. Another way would be to identify the lower inflection point (LIP) on the pressure volume curve done with the PVTool II and add 2 cm H<sub>2</sub>O to that point for optimal PEEP. This could then be followed by performing a recruiting maneuver using PVTool II while setting the end PEEP to the above identified optimal PEEP level to begin ventilation once the recruitment maneuver is finished. Current studies are looking at setting the PEEP needed to sustain recruitment at the pressure equivalent to the point of maximum hysteresis between the inspiratory and expiratory limbs of the PV curve.

There are some contraindications to performing recruitment maneuvers. It should not be performed in patients with hemodynamic compromise, bullae or blebs identified on chest radiographs, or in patients with existing barotraumas. Extreme caution should be used in patients with increased intracranial pressures. Initially, recruitment maneuvers should be utilized by applying only a minimal peak alveolar pressure (approximately 40 cm H2O) and increased to a maximum of 50 cm H<sub>2</sub>O only if the patient does not respond to the lower pressures and is able to tolerate the sustained pressure.

Lung recruitment maneuvers are best utilized when they can be performed early and are used in conjunction with optimal PEEP so that the benefits are sustained. Without optimal PEEP to prevent derecruitment, the physiological benefits are only transient. More trials are needed to study the outcomes of using recruitment maneuvers in conjunction with optimal PEEP to prevent derecruitment after the maneuver.

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# Case Studies The Triage Tool

# Russell Chisholm

The author is a firefighter/paramedic with Miami Beach Fire Rescue, Miami Beach, FL. Miami Beach Fire Rescue serves a 7.1 square mile barrier island in Dade County, FL, which hosts over 7.5 million tourists annually. Beach populations usually run around 91,000, swelling to 200,000 on a normal weekend, and to 500,000 on holidays. The department has 200 firefighters divided into three shifts, with each shift running six ALS ambulances with three medics. The department responds to 20,000 calls per year, of which 85% are medical.

### The Call: Food Poisoning

On October 23, 2006 Rescue 1 "C" shift was dispatched to a suspected food poisoning call at a hotel on Ocean Drive. Upon arrival, we knocked on the door and had to wait several minutes before the guest, who could barely walk, was able to answer. He was very altered, complaining of nausea and a really bad headache. We found the patient's wife, who was on the commode, in the same state of mind as her husband. Both patients were severely incontinent and their skin was a blotchy red color.

Both patients'  $\text{SpO}_2$  levels were in the low 90's. Our crew had only been in the room for about five minutes before we started getting headaches. There was a distinct stale odor in the room so the windows were opened for some ventilation. Both patients were moved into the hallway, placed on high flow  $O_2$  and within 5-10 minutes started to feel better.

We called for the four gas meter and one of the two Masimo Rad-57s in field that night to be brought to the scene. (The other nine Rad-57s were going into service the next day.) The equipment arrived as the two rescue units were transporting the

# The Missed Diagnosis

# John Andrews, EMT-P

The author is Field Training Officer with Tuolumne County Ambulance, Sonora, CA. Tuolumne County Ambulance service's area includes a large portion of Yosemite National Park. The service covers over 2,000 square miles, with an annual call volume of more than 6,000 calls.

#### The Call: Dizziness

On November 11, 2006 at 2307 hours, Tuolumne Medic 41 and a California Department of Forestry engine were dispatched out to a 58 year-old female complaining of dizziness. Upon arrival, we found the patient sitting in a recliner in her mobile home, complaining of severe dizziness that had caused her to fall four days ago. The prior fall resulted in an ambulance transport and an emergency room visit with repair of soft-tissue injuries to her face. She returned home after the ER visit and continued to have problems with dizziness which remained undiagnosed.

The patient had a very extensive respiratory and cardiac history. She answered questions appropriately (GCS 15) and did not appear to be in severe distress. When the Masimo Rad-57 sensor was applied to obtain the  $\text{SpO}_2$  reading, the alarm began to sound due to a SpCO level of 13%. Given that the patient's  $\text{SpO}_2$  level was 83%, her fractional saturation was at best 70%, so it

patients to Mt Sinai Medical Center in Miami Beach. Upon arrival at the ER, we alerted the nursing supervisor to the suspected CO poisoning. She took the initiative to run ABGs.

We transported another patient to the same hospital 45 minutes later. The RN showed us the blood gas report on the two patients – the male was 38%, the female 37%. The hotel was immediately closed down and the guests evacuated. The Rad-57 was used to triage the 60 guests, who ranged from a low of 3% to a high of 21%. There were two families of four who were transported to the hospital, with the parents' CO levels in the low teens and the children anywhere from 6% to 10%. In total, 14 people were transported for CO poisoning. All patients taken to the hospital had blood gas CO levels almost identical to the Masimo Rad-57 readings.

The suspected cause of the incident was a hot water heater on the north side of the building whose venting stack ran under the crawl space and up the south side of the building. The facility was closed for three weeks while repairs were made.

Masimo Rad-57 proved invaluable to patients, rescue personnel and hospital. The City of Miami Beach is now actively trying to get an ordinance passed that would require CO detectors in all buildings and would be part of the annual fire inspection. This call could have had a disastrous outcome if everyone from the hospital staff to the rescue crews, engine and ladder crew, and the command staff didn't work together. The Masimo Rad-57 was immensely helpful with the triage of a large number of patients. If we only had the four gas meter to base treatment decisions off of, we could have tied up rescue units transporting patients who did not need transport or worse yet, left people on scene who really needed to go to the hospital.

was no surprise she was dizzy. The room was filled with cigarette smoke and after further questioning, we discovered that her husband had turned on their furnace for the first time that season about five days before.

The patient was removed from the house, placed on a non-rebreather oxygen mask at 15 liters and taken to the local hospital. She continued to improve throughout transport. Her  $O_2$  saturation came up to 96% and her SpCO fell from 13% to 7% over the 45 minute transport. Upon our arrival at the hospital, the patient had no complaint of dizziness and continued to improve during her emergency department stay. The hospital did not have a CO-Oximeter in the facility and relied on the Masimo Rad-57 readings to make their assessment and treatment decisions.

The Masimo Rad-57 helped us identify the CO poisoning that had most likely been missed four days prior by fire, EMS and ER crews. While a SpCO of 13% by itself is not terribly high, combined with her complex medical history the patient's condition became dangerous. The positive CO reading from the Masimo Rad-57 led to the woman's prompt diagnosis and treatment, prevented her condition from continuing or worsening, and kept her husband from becoming the next patient.

# Bridging the ICU and the MR Suite with Advanced Ventilator Support

#### Abstract

Often, critically ill patients on acute care ventilators require diagnostic radiology exams such as MR imaging. Yet, strong magnetic fields severely limit the types of medical devices that can be nearby the MR scanner. Transferring patients outside of the intensive care environment is commonly done to carry out these diagnostic tests. However, the transport of mechanically ventilated patients is not without inherent risks which require properly trained staff and state-of-the-art equipment.

The number of individuals eligible for Medicare benefits is expected to increase by 50% within the next 30 years. Since older beneficiaries currently account for more than half of all ICU days, this will increase the number of patients who may require mechanical ventilation and ultimately additional



diagnostic testing such as MRI procedures. This presents both clinical and business challenges to modern hospitals. This Report describes these challenges and presents potential solutions offered by newly available technologies.

With escalating demand for critical care, respiratory therapists will find it increasingly difficult to maintain quality mechanical ventilation and proper monitoring of acute care and anesthetized outpatients who require MRI exams, because the types of medical devices allowed in this environment have been severely limited due to the strong magnetic fields generated during imaging.

Previous transport ventilators, specifically designed for use in the MR examination room, have had significant limitations that may adversely impact patients. All medical disciplines can agree that disconnecting a patient from an ICU ventilator poses risks such as loss of lung recruitment, hemodynamic changes, and adverse effects on gas exchange.<sup>1</sup>

#### **Issues and Concerns**

It is useful to consider these problems from the perspective of these disciplines including: Radiology, Respiratory Care, Nursing, Bio-Medical Engineering, Administration, and Physicians.

**Director of Radiology:** Currently, mechanically ventilated patients require enormous resources for transporting to and from the MRI examination room and proper monitoring during the exam. This includes outpatients who may require anesthesia to complete the exam. These complex preparation and monitoring procedures reduce the revenues per hour that can be generated by the MRI department. Disruptions in this work flow may affect timing of services rendered to walk-in patients and reduce their level of customer satisfaction as well.

Speed of service and customer satisfaction drive the way the hospital is perceived in the healthcare market, and may affect its costs of public relations and marketing.

**MRI Technician:** MRI technology represents a huge advance in medical care, yet it is not available to every patient who is critically ill, because of safety concerns driven primarily by the high magnetic fields. Too often specialized equipment needed to



provide proper care for ICU patients cannot be used in the MR environment. The MRI technician, responsible for the safety of patients and caregivers, must enforce policies which may prevent patients from receiving the diagnostic scans they need. Playing the role of enforcer can add to the MRI technician's workload and overall job satisfaction.

**Director of Respiratory Therapy:** Transporting patients to effectively minimize complications requires a high level of sophistication. ICU patients require a multidisciplinary team to ensure patient safety. To meet these challenges, it is necessary to maintain the same level of ICU care throughout the transport and diagnostic imaging process.

Clinical objectives sought:

- Maintain continued use of sophisticated ICU ventilator.
- Minimal loss of lung recruitment.
- No need to transport and conduct MRI exam using different machine

The inability to meet these clinical objectives increases the complications and workload of the respiratory therapist, and can affect their job satisfaction.

**Physician:** Many physicians have struggled weighing the risks against benefits when critically ill patients are too unstable to

tolerate transport and lengthy diagnostic procedures are required. Thus, patients cannot be treated effectively. These complex patient situations will increase the number of ICU days and may increase morbidity rates. The number of complex situations can be expected to increase given current demographic trends. This increases the future operating costs that hospitals will be expected to absorb, unless alternatives can be found when dealing with these problems in a more costeffective manner.

**Director of Bio-Medical Engineering:** Too often, hospitals use many different types of equipment to perform the same function. This increases the need for maintenance, education, parts, and services. Yet, the complexity of interactions among equipment seems to drive special situations such as those found in the MRI where high-powered magnetic fields can impact normal equipment functions. Many hospitals have compromised and purchased redundant, less capable equipment because they had no other choice. This has increased operating costs because of the additional requirements for maintenance contracts, spare parts, as well as training for biomedical personnel.

**Nurse:** Being responsible for the direct care of the patient, the nurse must ensure that all clinical needs of the patient are met before, during, and after transport. This includes maintenance of vital signs, patient comfort, and avoiding complications associated with transport. Limitations associated with MRI equipment pose a challenge to overseeing the required care of the critically ill patient. These situations drive increased needs for nursing staff to ensure that patients receive the minimum acceptable level of care.

**Hospital Administrator:** Hospital administrators must reconcile conflicting objectives: maximizing quality of patient care versus escalating pressures to reduce costs. ICU care remains one of the most expensive services provided. Therefore, minimizing ICU days is critically important. Patients who cannot undergo diagnostic procedures (because of limitations imposed by the MRI) cannot receive definitive care, and thus may remain in the ICU longer. This increases operating costs and adds stress to caregivers, facilities and of course, the patient.

#### Current vent equipment performance in MRI suites

Typically, pneumatically powered ventilators lack some of the key features of ICU ventilators, including high flow and high airway pressure capabilities, advanced ventilation modes, and monitoring/alarm systems. Moreover, hospital personnel may not be familiar with their operation.

In addition, transport vents designed for MRI use are made of non-ferrous components that are not affected by, or can be easily shielded from, the effects of high magnetic fields. Some of these pieces of equipment lack important features such as:

- Auditory alarm systems. The lack of this feature requires caregivers to stand close by in order to monitor the patient's vent readings, thus increasing labor required for the procedure.
- Advanced modes of ventilation, such as non-invasive, BiVent, PRVC, and PCV. Patients needing these modes of therapy must be forced to do without them during the MRI procedure (if medically tolerated). This may increase patient risk and recovery time in the ICU.
- High ventilatory parameters, such as PEEP and inspiratory



flow rate are not available. Patients with high ventilatory needs may deteriorate and become unstable.  $^{\rm 2,3}$ 

The ideal solution to these problems is a critical care ventilator that can optimize ventilation during transport, through the MRI procedure, and beyond. Unfortunately, most ventilator technology utilizes components that can not be shielded against the effects of magnetic fields. Furthermore, each MRI suite produces a unique magnetic pattern based on scanner configuration within the suite. This makes solving the shielding problem more complicated. As a result, respiratory therapists have struggled for years with antiquated devices that were troublesome to operate. They could not offer the safe care that they would have preferred in an MRI environment.

#### **A Solution**

On March 1, 2007, MAQUET announced availability of the SERVO-i MR environment option—enabling critically ill patients, who require an MRI exam, to stay connected to the same state-of-the-art SERVO-I ventilator that serves them in the ICU.

The new SERVO-i MR environment option is capable of providing critically ill patients with advanced ventilatory care using the same machine wherever they are in the hospital—in the ICU, in the MR examination room, and during transport to and from the MR room.

The SERVO-i ventilator is intended for treatment and monitoring of all patients—neonatal, pediatric, and adults—who require mechanical ventilation. SERVO-i's MR environment option has been thoroughly tested with several MR scanners including 1.0, 1.5 and 3.0 Tesla MR units. The SERVO-i MR environment option has been classified as "MR conditional," meaning it is safe for operation in the MR examination room, provided that certain conditions are met. These conditions are described in depth in the SERVO-i MR Environment Declaration. One important condition is the need for the hospital to have internal procedures for MR environment according to the information in the MR environment declaration.

How do you determine your organization's need for the SERVO-i MR option? Every hospital has its unique needs and requirements. To gain additional assistance in assessing your needs, as well as more information on the SERVO-i MR Environment Option, visit mrivents.com or call (888) MAQUET3 (ext 2306).

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## Homeopathic and Conventional Treatment for Acute Respiratory and Ear Complaints: A Comparative Study on Outcome in the Primary Care Setting

Max Haidvogl, David S.Riley, Marianne Heger, Sara Brien, Miek Jong, Michael Fischer, George T. Lewith, Gerard Jansen, André E.Thurneysen

#### Abstract

**Background:** The aim of this study was to assess the effectiveness of homeopathy compared to conventional treatment in acute respiratory and ear complaints in a primary care setting.

**Methods:** The study was designed as an international, multicentre, comparative cohort study of non-randomised design. Patients, presenting themselves with at least one chief complaint: acute ( $\leq$  7 days) runny nose, sore throat, ear pain, sinus pain or cough, were recruited at 57 primary care practices in Austria (8), Germany (8), the Netherlands (7), Russia (6), Spain (6), Ukraine (4), United Kingdom (10) and the USA (8) and given either homeopathic or conventional treatment. Therapy outcome was measured by using the response rate, defined as the proportion of patients experiencing 'complete recovery' or 'major improvement' in each treatment group. The primary outcome criterion was the response rate after 14 days of therapy.

Max Haidvogl is with the Ludwig Boltzmann Institute for Homeopathy, Graz, Austria; Riley is with the University of New Mexico School of Medicine and Integrative Medicine Institute, Santa Fe, New Mexico; Marianne Heger, who passed away in 2005, was with HomInt, Karlsruhe, Germany; Sarah Brien and George Lewith are with the Complementary Medicine Research Unit; Primary Medical Care, University of Southhampton, Southhampton, UK; Miek Jong is with VSM Geneesmiddelen, Alkmaar, The Netherlands; Michael Fischer is with ClinResearch GmbH, Cologne, Germany; Gerard Jansen is from Tilburg, The Netherlands; Andre Thurneysen is with the Institute for Complementary Medicine (KIKOM), University of Bern, Bern, Switzerland. This study was carried out by the HomInt organisation, Karlsruhe, Germany. The IIPCOS-2 collaborators would like to thank Sytze de Roock for preparation of tables and figures, Rolf Hövelmann for data analysis, Wolfgang Mayer for monitoring the study and Rainer Lüdtke for his comments on the drafted manuscript. The authors are especially grateful to the physicians and all the patients for participating in the study. Reprinted from BioMed Central, BMC Complementary and Alternative Medicine, © 2007, BioMed Central. This is an open access article distributed under the terms of the Creative Commons Attribution License.

Results: Data of 1,577 patients were evaluated in the full analysis set of which 857 received homeopathic (H) and 720 conventional (C) treatment. The majority of patients in both groups reported their outcome after 14 days of treatment as complete recovery or major improvement (H: 86.9%; C: 86.0%; p = 0.0003 for non-inferiority testing). In the per-protocol set (H: 576 and C: 540 patients) similar results were obtained (H: 87.7%; C: 86.9%; p = 0.0019). Further subgroup analysis of the full analysis set showed no differences of response rates after 14 days in children (H: 88.5%; C: 84.5%) and adults (H: 85.6%; C: 86.6%). The unadjusted odds ratio (OR) of the primary outcome criterion was 1.40 (0.89-2.22) in children and 0.92 (0.63-1.34) in adults. Adjustments for demographic differences at baseline did not significantly alter the OR. The response rates after 7 and 28 days also showed no significant differences between both treatment groups. However, onset of improvement within the first 7 days after treatment was significantly faster upon homeopathic treatment both in children (p = 0.0488) and adults

Table 1 - Demographic data

Children	Homeopathy, n=407	Conventional n=252	<i>p</i> -value, if <0.05	
Male (%)	51.1	50.0		
Female (%)	48.9	50.0		
Age	$6.6 \pm 4.3$	7.4 ± 4.7	=0.0282*	
BMI	$16.6 \pm 3.0$	17.9 ± 3.7	=0.0001*	
Adults	Homeopathy n=445	Conventional n=462	<i>p</i> -value, if < 0.05	
Male (%)	24.0	32.3	=0.0064 <sup>b</sup>	
Female (%)	76.0	67.7	=0.0064*	
Age	37.1 ± 12.5	39.6 ± 13.9	=0.0124*	
ВМІ	$24.3\pm4.8$	$25.0\pm4.5$	=0.0031*	

Full-set analysis values are either expressed as % of total or as mean ± SD, <sup>a</sup>Wilcoxon rank-sum test, <sup>b</sup>Fisher's exact test.

Table 2 - Distribution and se	everity score of chief	complaints at Day 0
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Children	Homeopathy n=407		Cor		
Chief complaint	(%)	Severity score	(%)	Severity score	p-value <sup>*</sup> if <0.05
Runny nose	9.8	1.1 ± 0.5	15.5	$1.9 \pm 0.7$	=0.0001
Sore throat	24.6	$1.7 \pm 0.6$	23.0	$1.6 \pm 0.6$	
Ear pain	23.1	$1.4 \pm 0.6$	21.0	$1.0 \pm 0.5$	=0.0002
Sinus pain	2.0	$1.6 \pm 0.4$	3.6	$1.7 \pm 0.6$	
Cough	40.5	$0.9 \pm 0.5$	36.9	$1.1 \pm 0.6$	
Adults	Homeopathy n=445		Conventional n=462		
Chief complaint	%	Severity score	%	Severity score	p-valuc <sup>a</sup> if <0.05
Runny nose	15.1	$1.5 \pm 0.8$	14.7	$1.9 \pm 0.7$	=0.0005
Sore throat	43.4	$1.6 \pm 0.7$	32.3	$1.5\pm0.6$	
Ear pain	3.4	$1.0 \pm 0.3$	5.4	$1.3 \pm 0.5$	
Sinus pain	8.3	$1.5 \pm 0.6$	13.4	$1.5 \pm 0.6$	
Cough	29.9	$1.0 \pm 0.5$	34.2 1.3 ± 0.5		=0.0002

Full-set analysis values are either expressed as % of total or as mean  $\pm$  SD. <sup>a</sup>Wilcoxon rank-sum test, indicating the differences between severity scores (from 0 - not present to 4 - very severe) in the homeopathy and conventional group.

(p = 0.0001). Adverse drug reactions occurred more frequently in adults of the conventional group than in the homeopathic group (C: 7.6%; H: 3.1%, p = 0.0032), whereas in children the occurrence of adverse drug reactions was not significantly different (H: 2.0%; C: 2.4%, p = 0.7838).

**Conclusion:** In primary care, homeopathic treatment for acute respiratory and ear complaints was not inferior to conventional treatment.

Table 3 - The most frequently prescribed medications
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Children		Adults	
Homeopathic treatment n=407	%	Homeopathic treatment n=445	%
1. Belladonna	13.3	1. Hepar sulphuris	9.7
2. Pulsatilla	10.6	2. Belladonna	8.3
3. Hepar sulphuris	6.6	3. Bryonia alba	7.2
4. Mercurius solubilis	6.4	4. Lycopodium clavatum	7.2
5. Phosphorus	4.9	5. Kalium bichromieum	5.8
6. Bryonia alba	3.7	6. Mercurius solubilis	4.9
7. Calcarea carbonica	3.7	7. Allium cepa	4.5
8. Lycopodium clavatum	3.7	8. Phosphorus	3.4
9. Sulphur	3.7	9. Causticum	3.1
10. Phytolaeca decandra	3.4	10. Gelsemium sempervirens	2.7
Conventional treatment n=252	%	Conventional treatment n=462	%
1. Antibacterials	28.2	1. Antibacterials	39.4
2. Nasal preparations	22.6	2. Nasal preparations	15.2
3. Analgesics	12.7	3. Analgesics	9.5
4. Stomatological preparations	8.7	4. Cough/cold preparations	8.7
5. Anti-asthmatics	5.6	5. Stomatological preparations	5.2

#### Background

The evidence base for complementary and alternative medicine (CAM) in general is limited and there is certainly a need for more research in areas such as homeopathy.1 Objective data collection and evaluation is needed to assist physicians in patient care and advance the quality of medical practice.<sup>2</sup> Clinical trials, especially randomised controlled trials (RCTs), are generally accepted as producing the highest level of evidence for medical interventions. Driven by the discovery of new pharmaceutical substances, demands from regulatory authorities for clinical data and the need of physicians for evidence based treatment strategies, the methodology of RCTs became the subject of research itself. Within this context, the strengths and weaknesses of such trials have been debated.3 Placebocontrolled RCTs are indispensable for the development of pharmaceutical agents with unknown efficacy and safety profiles. Their limitations result from highly standardized study protocols and patient populations, which may create artificial situations that differ from daily practice. Moreover, even the fact that patients are enrolled into a placebo-controlled clinical trial will influence treatment outcome, sometimes leading to high placebo or low verum response rates.<sup>4</sup> Consequently, more practice-based studies have been developed such as pragmatic RCT's or non-randomised cohort studies. Especially noninterventional outcomes studies have only few inclusion and exclusion criteria. Therefore they may provide information about a broad and heterogenous patient population thus resulting in high external validity for daily medical practice. However, the fact that patients are not randomly assigned to treatments in such outcome studies may lead to baseline differences between groups and makes the interpretation of the results more susceptible to bias. This disadvantage may be overcome, at least in part, by the application of statistical methods to control for baseline differences between treatment groups.

Apart from the ongoing discussion about clinical evidence, complementary therapies are well integrated into primary care in most Western countries. Among these, homeopathy is the most frequently used form in various acute and chronic conditions.<sup>5-9</sup> The value of homeopathy in chronic conditions has been demonstrated in several studies. A comprehensive analysis of outcome and cost-effectiveness showed that chronically ill patients had a better overall outcome with homeopathic than with conventional care.<sup>10</sup> Another large-scale observational study showed a positive impact of homeopathy on the health status in a substantial proportion of patients suffering from a wide range of different chronic diseases.<sup>11</sup> To our knowledge, no large comparative cohort studies have been performed to investigate the outcome of homeopathic treatment for acute illnesses. Results of the first phase of this study, the International Integrative Primary Care Outcomes Study 1 (IIPCOS-1), suggest that homeopathic treatment is at least as effective as conventional treatment for acute complaints of the upper and lower respiratory tract.12 The aim of the present study, IIPCOS-2, was to evaluate on an international basis and in a large sample size if homeopathic treatment is non-inferior to conventional treatment in patients with acute respiratory and ear complaints.

#### Methods

**Study design:** IIPCOS-2 is an international, multi-center, comparative cohort study of non-randomised design, which was conducted between October 1998 and April 2000. Patients suffering from acute respiratory and ear complaints were

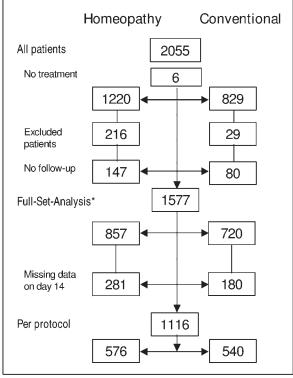


Figure 1

recruited by physicians in 57 primary care practices in Austria (8), Germany (8), the Netherlands (7), Russia (6), Spain (6), Ukraine (4), United Kingdom (10) and USA (8). The physicians belonged to 3 different groups: providing homeopathic treatment only (22), providing either homeopathic or conventional treatment (9), and providing conventional treatment only (12). The physicians, prescribing primarily homeopathic single remedies, had in addition to their conventional medical qualifications, graduated from a homeopathic training program and at least 5 years experience using homeopathy in their medical practice. The protocol was approved by the International Ethics Committee in Freiburg, Germany. The study was conducted in accordance with the declaration of Helsinki, Good Clinical Practice (GCP) guidelines and national legal requirements.

**Patients:** Patients older than one month, presenting themselves with at least one of five chief complaints (runny nose, sore throat, ear pain, sinus pain or cough), and onset of symptoms not more than 7 days before, were eligible to participate. Each chief complaint comprised of 5 to 9 individual symptoms, which were rated by the physicians with scores from 0 - not present to 4 - very severe. The mean score for each chief complaint was used to measure severity at baseline. Patients meeting the inclusion criteria, respectively in case of children their parents/legal guardians, were informed by the physician about the nature of the study. Prior to enrolment into the trial each patient/parent had to provide written informed consent to participate. Exclusion criteria were among others severe mental impairment, severe chronic diseases such as spinal cord injuries and alcohol or drug abuse. At centers providing both therapies (mixed centres) the treatment was chosen by the physicians and/or following the patients' preference.

**Study protocol:** During the initial patient contact the physician documented the onset of chief complaint, severity of symptoms,

clinical diagnosis, concomitant medical problems and medication and primary treatment prescribed. Patients completed a questionnaire asking for demographic and healthrelated information. Additionally some general questions addressed the patients' willingness to pay, patient confidence in health care provider and therapy, treatment preference, willingness to be randomized (at mixed centres only) etc. The patient follow-up was carried out by telephone 7, 14 and 28 days after the initial contact. Independent external study collaborators performed the calls. According to the study protocol they were blinded for the patient's treatment. The following parameters were documented: severity of complaintrelated symptoms, time until occurrence of first improvement, therapy outcome (assessed with complete recovery, major improvement, slight improvement, no change or deterioration), patient's satisfaction with the treatment (very satisfied, satisfied, neutral, dissatisfied or very dissatisfied) and general health condition. In case any adverse events had occurred, the physician was informed in order to collect more information and medically assess the case.

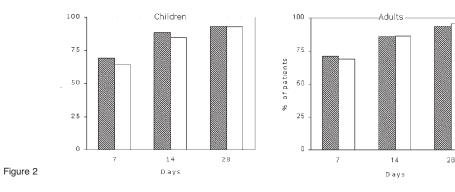
The response rates were defined as the proportion of patients assessing themselves as completely recovered or major improved after 7, 14 and 28 days of treatment. The main outcome criterion was the response rate after 14 days. Other outcome criteria were the response rates after 7 and 28 days, time to onset of first improvement (patients' assessments after how many days they had experienced a first improvement), patient satisfaction with treatment and health care provider and the occurrence of adverse events. Adverse events were coded by using the WHO-ART terminology.

A total of 72 selected homeopathic medications in potencies of 12C and higher (manufactured according to the German Homeopathic Pharmacopoeia), were given to the physicians as the basic set of study medication. Nevertheless, the physicians were free to prescribe any other remedy, any other potency or dosage form. Conventional treatment, registered in each participating country, was prescribed by the investigator and picked from a pharmacy.

Data collection and monitoring: Data were collected with a validated remote data entry system that was accessed via the Internet. The physicians entered their data online into electronic case report forms. The remote data entry system checked each entry for completeness and consistency. It recorded all data values with date and time of entry as well as all changes in the database in an audit trail. Access to the database was protected by password identification. Each user had a unique password that was provided in a sealed envelope. After entering was completed, data were transferred via Internet to the data collection centre at the former Institute for Numerical Statistics (IFNS, acquired by Omnicare Inc. in 1999) in Cologne, Germany. Monitoring was performed adherent to GCP-guidelines by an independent clinical monitor. Monitoring visits took place at least twice in order to inspect the course of the trial and to carry out source data verification. A data review tool enabled the monitor to identify missing data values, data values deviating from the normal range and among other things, data needing source verification.

**Statistical methods:** Data analysis was conducted by ClinResearch, Cologne, Germany, using the statistical software package SAS 9.1.3 under Windows XP Professional. The study

#### Homeopathy Conventional



was designed to confirm non-inferiority of the primary outcome criterion in the total patient population after homeopathic treatment in comparison to conventional treatment, using the one-sided equivalence test at the 2.5% significance level. The non-inferiority margin was defined by 5%-points. Subgroup analyses were performed on age groups (children: <18 years; adults:  $\geq 18$  years) with respect to demographic data, response rates, patient satisfaction and other outcome criteria using the Chi-square test, Fisher's exact test and Wilcoxon's rank sum test. The treatment groups were checked for baseline comparability and logistic regression analysis was performed to control for baseline differences. The primary and secondary outcome criteria were analysed on the full-set population, comprising all patients who received at least one dose of investigational medication and having at least one follow-up contact. Missing data in case of patient withdrawals from the trial were replaced by applying the last observation carried forward (LOCF) principle. A secondary analysis was performed on the per-protocol set population, comprising all patients with follow-up data on day 14.

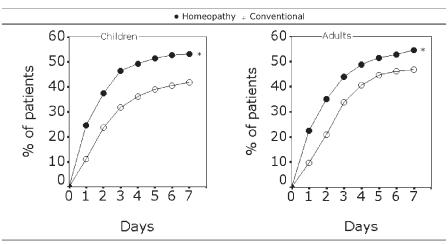
#### Results

**Patients:** A total of 2,055 patients suffering from at least one chief complaint (acute runny nose, sore throat, ear pain, sinus pain or cough) were enrolled in the study and given either homeopathic (H: n = 1,220) or conventional treatment (C: n = 829) (Figure 1). Six patients did not receive any treatment and were excluded from further analysis. All patients from the USA

and Spain (H: n = 216; C: n = 29) were excluded since telephone interviews were not performed according to the study protocol. For another 227 patients no follow-up data were available because either interviews could not be carried out or the patient withdrew from the study. Data of 1577 patients with at least one follow-up contact were evaluated (full-set analysis), 857 patients in the homeopathy group and 720 patients in the conventional treatment group. For 1116 patients (H: n = 576; C: n = 540) follow-up data on day 14 were documented, being the perprotocol set (Figure 1).

Upon enrolment in the study, patients, or the patients' legal guardians were asked for their treatment preference. In the homeopathy group, 81% of patients had a preference for homeopathy, 18% had no treatment preference. In the conventional group, 55% of the patients' preferred conventional treatment, 2% homeopathy and 43% had no treatment preference. Patients at mixed centres were additionally asked whether they would agree to be randomized if the choice of treatment was made randomly. With 68.1%, the majority of patients in the homeopathy group refused to be randomized, 30.6% had no problem with randomisation and in 1.3% no remark was given. In the conventional group willingness and unwillingness to be randomized were equally distributed (51.9% yes, 47.9% no, 0.1% no remark).

**Baseline characteristics:** Demographic data of children (< 18 years of age) and adults ( $\geq$ 18 years of age) are presented in



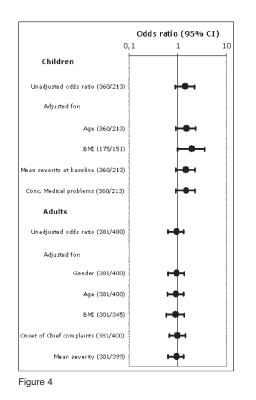


Table 1. The proportion of children under 18 years was 47% of patients receiving homeopathic compared to 35% receiving conventional treatment. Within this subpopulation the average age and Body Mass Index (BMI) differed significantly between both treatment groups. In adults, the distribution of males and females, average age and BMI differed significantly between the homeopathic and conventional group.

As shown in Table 2, cough was the most frequently reported chief complaint in children, followed by sore throat and ear pain. In adults sore throat was the most frequent, followed by cough and runny nose. The overall distribution of the five chief complaints in children was comparable in both treatment groups, but differed significantly in adults (p = 0.0026, Chi-square test). The mean severity score differed significantly at baseline for 2 out of 5 chief complaints, both in children and adults (Table 2).

With regard to the diagnosis of the chief complaints, in children otitis media was most frequently diagnosed (H: 18.9%; C: 13.5%) followed by bronchitis (H: 16.7%; C: 10.7%) and laryngitis (H: 12.3%; C: 12.7%). In adults, pharyngitis (H: 23.1%; C: 14.7%), bronchitis (H: 11.5%; C: 17.1%) and tonsillitis (H: 13.9%; C: 8.9%) were most frequently diagnosed. In adults, no significant differences were observed with respect to concomitant medical problems (H: 34.2%; C: 36.6%) or concomitant medication (H: 20.7%; C: 20.1%). In the homeopathic group 21.6% of the children had concomitant medical problems versus 13.5% in conventional group (p = 0.0098; Fisher's exact test). The proportion of children receiving concomitant medication was higher in the homeopathic group (9.1%) than in the conventional group (6.7%) as well but did not reach a statistical significant level (p = 0.3098; Fisher's exact test).

**Medication:** A total of 62 different homeopathic remedies were prescribed primarily on an individual basis. The top 10 (Table 3) of the most frequently prescribed homeopathic remedies

included typical acute remedies and accounted for about 60% of the prescriptions. In the conventional group 190 different medications were prescribed. Most of them were antibiotics followed by nasal preparations and analgesics (Table 3).

**Treatment outcome:** The primary outcome criterion, defined as the percentage of patients with complete recovery or major improvement after 14 days, was first calculated for the total patient population. The one-sided test of the full-set analysis showed non-inferiority of homeopathic in comparison with conventional treatment (H: 86.9%; C: 86.0%; p = 0.0003). These results were confirmed by the analysis on the per-protocol set (including all patients with data at day 14) since similar response rates were obtained in both treatment groups (H: 87.7%; C: 86.9%; p = 0.0019).

The response rates at various time points in children and adults are shown in Figure 2. The primary outcome criterion (response rate at day 14) in children was 88.5% after homeopathic and 84.5% after conventional treatment. In addition, response rates after 7 days (H: 68.8%; C: 64.3%) and 28 days (H: 93.1%; C: 92.5%) did not differ between both treatment groups either. In adults, the response rates after 7 days (H: 71.2%; C: 68.8%), 14 days (H: 85.6%; C: 86.6%, LOCF) and 28 days (H: 93.9%; C: 95.9%; LOCF) of treatment were not significantly different as well.

Since the majority of patients (> 84%) were fully recovered or major improved after 14 days of treatment, it was of relevance to look at outcome differences within the first 7 days. As shown in Figure 3, the percentage of children experiencing a first improvement at different time points within the first week of treatment was significantly higher in the homeopathy group compared to the conventional group (p = 0.0488). For adults, a similar significant difference in favour of homeopathy (p = 0.0001) was observed.

Additional analysis on the primary outcome criterion in order to correct for demographic differences at baseline was carried out (Figure 4). The unadjusted odds ratio (OR) of the primary outcome criterion was 1.40 (0.89–2.22) for children and 0.92 (0.63–1.34) for adults. In the subgroup of children, adjustments for age, mean severity and concomitant medical problems had little effect on the OR. The unadjusted OR for the Body-Mass-Index was 1.92 (1.03–3.60) and the only one showing a significant difference in favour of homeopathy. Adjustment for BMI differences between both treatment groups at baseline minimally reduced the OR to 1.89 (1.00–3.57). In adults, individual adjustments for all variables had little to no effect on the OR of the primary outcome criterion (Figure 4).

Another outcome measure was the occurrence of adverse drug reactions. The percentage of children experiencing a suspected adverse drug reaction was not significantly different in both groups (H: 2.0%; C: 2.4%, p = 0.7838, Fisher's exact test). In adults, the number of suspected adverse drug reactions was significantly higher after conventional than after homeopathic treatment (C: 7.6%; H: 3.1%; p = 0.0032, Fisher's exact test). Both in children and adults, the suspected adverse drug reactions occurred predominantly in the body as a whole (upon homeopathic treatment) or in the gastro-intestinal system (upon conventional treatment).

In addition, patients' satisfaction with treatment and healthcare provider was evaluated. Almost all patients in both treatment

groups were either satisfied or very satisfied with the treatment after 28 days (children: 95% H; 93% C, adults: 91% H; 95% C). A very high percentage of children (H: 98%; C: 95%) and adults (H: 97%; C: 97%) were either satisfied or very satisfied with the healthcare provider.

#### Discussion

The overall outcome of the first phase of the IIPCOS study<sup>12</sup> is confirmed in the present study on a larger group of patients and a greater number of medical practices, showing that homeopathic treatment is not inferior to conventional treatment for the treatment of acute respiratory and ear complaints. In IIPCOS-1 the response rate of homeopathically treated patients was with 82.6% significantly higher than in the conventional group. In IIPCOS-2 the response to homeopathic treatment was with 86.9% even higher, confirming the good effectiveness. However, no difference was observed between both treatment groups. This is due to a much higher response rate in the conventional group in IIPCOS-2 of 86.0% compared to 68% in IIPCOS-1. One difference between both studies is that in IIPCOS-2, only patients from Europe were analysed since those recruited at practices from the USA were excluded due to protocol deviations. In IIPCOS-1, the majority of patients included had their residence in the USA. However, despite these differences, the overall conclusion from both studies can be drawn that homeopathy is not inferior to conventional therapy. Due to the study design, the findings of IIPCOS-1 and IIPCOS-2 do not provide firm data on the comparative efficacy of homeopathic and conventional treatment in acute diseases but rather underline the potential value of homeopathy in every day clinical practice. Both studies reflect the situation in every day homeopathic practice in an international setting with average patients receiving the usual treatment of a homeopathic doctor. Furthermore, patients were recruited on the basis of chief complaints and related symptoms, rather than on the clinical diagnoses. This symptomatic approach coincides with the homeopathic nature of prescription by treating each patient individually, based on specific key symptoms and patient characteristics.

In IIPCOS-2, differences for various demographic parameters and symptom-related variables were found between both groups. Thereby the profile of typical patients seeking homeopathic therapy was confirmed,<sup>13,14</sup> ie, they were more likely to be women, younger of age, less likely to smoke and to have a lower BMI. The severity of symptoms at baseline was significantly different between treatment groups as well. However the differences were small and their clinical relevance is doubtful. Indeed regression analysis had little effect on the primary outcome criterion, showing that treatment effects were only minimally affected by selection bias. Based on the unadjusted and adjusted odds ratios of the primary outcome criterion it appears that homeopathic treatment, in comparison to conventional treatment, is more beneficial for children than adults. This observation is in accordance with previous studies in which the improvements after homeopathic treatment were greater in children than in adults.<sup>11,13</sup>

Another possible source of bias is that the outcome criteria were assessed by the patients themselves. Since it was not possible to blind patients for their treatment, potential reporting bias from patient's expectations may have influenced the outcome. On the other hand, the patients' reports were collected by independent external study collaborators in order to minimize the influence of the patient's relationship with their physician on the treatment outcome. Although blinding of the external study coordinators was foreseen in the protocol, it cannot be ruled out that they received information from the patient revealing the nature of their medication. Therefore, blinding may not have been guaranteed in each case. Furthermore, it should be noted that at mixed centres, the choice of treatment was made by the physicians and/or following the patients' preference. The treatment decision may have been influenced by the kind or severity of the symptoms or the motivation and expectations of the patient.

Since acute respiratory and ear complaints are self-limiting conditions, it can be argued that the chosen primary outcome criterion after 14 days of treatment is not sufficiently sensitive. Patients experiencing these acute complaints may have undergone spontaneous recovery within 1 to 2 weeks. However, this outcome parameter was taken to confirm and reproduce the results of IIPCOS-1 by using a similar study design. Therefore other outcomes criteria such as the response rate after 7 days of treatment have to be considered more carefully. Moreover, the findings that the percentage of patients experiencing a first improvement within the first week was higher at all time points in the homeopathy group than in the conventional group, are at least supportive of the 14 days finding that homeopathy is not inferior to conventional medicine.

Other observational studies on the comparability of homeopathic treatment and conventional treatment of upper respiratory tract infections (URTI) have shown positive outcomes for homeopathy.<sup>15,16</sup> Recently, the value of homeopathic treatment for the prevention of URTIs has been demonstrated in a controlled clinical trial.<sup>17</sup> The consistent findings in IIPCOS-1 and IIPCOS-2 further contribute to the evidence that homeopathic treatment plays a beneficial role in the primary care of patients. Furthermore, the good tolerability of homeopathic treatment of acute respiratory and ear complaints was confirmed by the low number of patients that experienced adverse drug reactions.

The major limitation of the present study is that patients were not assigned randomly to their treatment group. The majority of patients in the homeopathic group had a strong treatment preference and consequently, they were not willing to be randomized. A similar reluctance towards randomisation has also been reported elsewhere for patients seeking anthroposophic therapy.<sup>18</sup> These results reveal a substantial limitation to the suitability of performing large randomized controlled trials on the efficacy of homeopathy in such a primary care setting.

#### Conclusion

This comparative cohort study, involving more than 1,500 patients in primary care practices of at least 6 different European countries, demonstrates that homeopathic treatment for acute respiratory and ear complaints was not inferior to conventional treatment. Although no firm conclusions can be drawn about the efficacy of homeopathic treatment, these results certainly contribute to the growing evidence that homeopathy is a safe and beneficial treatment strategy for acute diseases in primary care settings.

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were found in any other organs. Researchers now need to determine the precise nature, functions and longevity of the grafted cells. It is also important to rule out any possible toxicity from this therapy, in particular the potential for accidental implantation of undifferentiated cells.

#### GET OUT OF THE POOL

Warnings about adverse effects of chlorinated swimming pools, particularly where they affect children's airways, are becoming increasingly prominent in the scientific literature. The harmful impact of air breathed in close to the chlorinated water could even be one cause of the upsurge in child asthma recorded in the industrialized countries. Children who use chlorinated openair swimming pools have an increased risk of developing asthma. This was illustrated by young competitive swimmers, as seen in a study presented at the ERS by researchers at the University of Genoa and Gaslini Hospital in Italy. The authors studied thirty adolescents, with an average age of 14, who had not previously been diagnosed with asthma. They measured their level of sensitization to typical airborne allergens and their degree of bronchial hyperreactivity; these two elements are generally considered predictors of asthma onset. The results demonstrated a risk to the young swimmers in regular training for competitions. The Italian team found that 73% of them were sensitized to airborne allergens, a level almost double that of the general population, and over half of them (17 subjects) suffered from bronchial hyperreactivity. Previously, the received wisdom was that harmful levels of airborne chlorine were only found in covered swimming pools. But researchers at the Catholic University of Louvain's Department of Toxicology, showed that this risk can also affect regular users of open-air pools. The Louvain team examined 847 adolescents, aged 15 years on average, enrolled at three Belgian secondary schools. The conclusions revealed that the use of open-air swimming pools correlates strongly with atopy levels as measured by serum IgE concentration and considerably increases the asthma risk. Adolescents who had spent a total of more than 500 hours in open-air swimming pools, had a risk of developing asthma three times higher than those who had never swum in a chlorinated pool.

## Palliative Care Provision for Patients With Chronic Obstructive Pulmonary Disease

Abebaw Mengistu Yohannes

#### Abstract

Chronic obstructive pulmonary disease (COPD) is a major cause of disability, morbidity and mortality in old age. Patients with advanced stage COPD are most likely to be admitted three to four times per year with acute exacerbations of COPD (AECOPD) which are costly to manage. The adverse events of AECOPD are associated with poor quality of life, severe physical disability, loneliness, and depression and anxiety symptoms. Currently there is a lack of palliative care provision for patients with advanced stage COPD compared with cancer patients despite having poor prognosis, intolerable dyspnea, lower levels of self efficacy, greater disability, poor quality of life and higher levels of anxiety and depression. These symptoms affect patients' quality of life and can be a source of concern for family and carers as most patients are likely to be housebound and may be in need of continuous support and care. Evidence of palliative care provision for cancer patients indicate that it improves quality of life and reduces health care costs. The reasons why COPD patients do not receive palliative care are complex. This partly may relate to prognostic accuracy of patients' survival which poses a challenge for healthcare professionals, including general practitioners for patients with advanced stage COPD, as they are less likely to engage in endof-life care planning in contrast with terminal disease like cancer. Furthermore there is a lack of resources which constraints for the wider availability of the palliative care programmes in the health care system. Potential barriers may include unwillingness of patients to discuss advance care planning and end-of-life care with their general practitioners, lack of time, increased workload, and fear of uncertainty of the information to provide about the prognosis of the disease and also lack of appropriate tools to guide general practitioners when to refer patients for palliative care. COPD is a chronic

The author is with the Department of Physiotherapy, Manchester Metropolitan University, Elizabeth Gaskell Campus, Manchester, UK. Reprinted from BioMed Central, Health and Quality of Life Outcomes, © 2007 Yohannes; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License. incurable disease; those in an advanced stage of the disease pursuing intensive medical treatment may also benefit from the simultaneous holistic care approach of palliative care services, medical services and social services to improve quality of end of life care.

#### Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality worldwide.<sup>1,2</sup> Studies in the US have reported death rate from COPD doubled in the past two decades while significant decline occurred in deaths rate from other chronic diseases, for example, chronic heart disease and stroke.<sup>3,4</sup> The trends of increasing annual death rate of COPD was also marked by the first time the number of women dying from COPD surpassed men<sup>5</sup> in contrast to demographic changes in the general population. In the same period healthcare utilization was exponentially growing because patients with severe COPD were hospitalized three to four times per year and utilization of intensive care units for patients admitted with acute exacerbations of COPD in developed countries.<sup>1,4-6</sup> In the US in 2005, the National Heart, Lung and Blood Institute reported that the annual direct medical costs for COPD were about \$21.8 billion and indirect costs (restricted days, lost workdays, and productivity) estimated at \$17 billion respectively.<sup>7</sup> Au and co-workers<sup>8</sup> examined retrospectively patients who died in the previous six-months with advanced stage COPD in comparison with lung cancer patients and their healthcare utilization. They found that patients with COPD had 'twice the odds of being admitted to an intensive care unit and received fewer opiates and benzodiazepine compared with patients with lung cancer'. The total direct medical costs were \$4,000 higher for COPD patients compared with lung cancer patients because of the intensive care unit utilization.8 A recent population survey that investigated the health status of COPD patients in five European countries and US have reported that a significant but minority of European Union patients reported that their 'health status was worse than death' because of significant impairment in physical daily activities, severe dyspnoea, fatigue, pain and psychological morbidity due to anxiety and depressive symptoms.9

Table 1: Potential barriers of discussing the prognosis end-stag	ge of COPD [22-24]
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Patients	General practitioners
<ol> <li>Unwillingness to discuss end of life care</li> <li>Lack of communication (not sure which doctor will be taking care of me)</li> <li>Ignoring not to discuss the issue</li> <li>Lack of knowledge what type of care available</li> <li>Loss of hope</li> </ol>	<ol> <li>Lack of confidence (ill-prepared to discuss the issue adequately)</li> <li>Lack of time in busy surgery (increasing workload)</li> <li>Uncertain about the information to provide about the prognosis in advance COPD</li> <li>Lack of patient education about the end stage of COPD</li> <li>Not in the priority list</li> <li>Lack of resources and facilities</li> </ol>

In patents with severe COPD (defined forced expiratory volume in one second,  $\text{FEV}_1 < 1$  litre), inpatient mortality of 7.4% and 90 day mortality of 15%<sup>10</sup> and one year mortality rate for elderly COPD patients range from 36%<sup>11</sup> to 59% reported in patients admitted to intensive care unit with acute exacerbations of COPD,<sup>12</sup> and compare unfavorably for cancer patients 'the 5year relative survival rate for persons diagnosed with cancer is 62.7%, with variation by cancer site and stage at diagnosis'.<sup>13</sup> This article examines why patients with severe advanced stage COPD do not receive appropriate palliative care simultaneously when receiving active treatment despite presenting with lowself-esteem, poor health status, low levels of physical activity, severe dyspnoea and fatigue compared with cancer patients. These symptoms are often associated with adverse events such as worsened functional impairment, frequent hospitalization, and premature death.

#### **Palliative care**

A typical palliative care team may comprise of a physician, mental health and palliative care nurses, auxiliary staff, a pharmacist, bereavement counselor, psychologist, chaplain, social worker and volunteers etc. However because of cost implication and different settings of the palliative care services, the team may comprise some or all members of the team. The purpose is to maximize care, relieve suffering and improve quality of life for the patient and provide support for the family and carers with a team approach. The level of care may vary depending on the availability of staff and the set up of the palliative care program, for example, inpatient or nursing home. In addition it may rely on the outcome of assessment of the palliative care team which may range from once daily or more to two or three times per week by the appropriate team members and with weekly review by the whole team.

Currently palliative care services are not widely available because of the high demand for care for patients with cancer and chronic progressive diseases which are costly to manage. However, a recent survey data in the US hospitals indicate an encouraging sign that the number of palliative care programs increased from 2000 [n = 632 (15%) of hospitals] to 2003 [n = 1027 (25%) of hospitals].<sup>14</sup>

Palliative care is not synonymous with terminal care and it should be apparent that palliative care approach focuses on symptom management, maintenance of a reasonable quality of life, good communication (patients, family members and physicians), increasing physical activities to maintain independence and practical support of emotional, spiritual and psychosocial support for patients and caregivers.<sup>15</sup> Currently, palliative care is mostly available for cancer patients who benefited from medical care to control physical symptoms of

pain, dyspnoea, and emotional and spiritual support, at the end of life care.<sup>15</sup> However, this kind of provision is not widely available for COPD patients. Gore and co-workers<sup>16</sup> investigated the morbidity of end stage COPD in comparison to patients with unresectable non-small lung cancer (NSCLC) [FEV<sub>1</sub> < 0.75 litres versus 1.47 litres]. The COPD patients were identified with poor quality of life, severe dyspnoea, and psychological burden of clinically relevant anxiety or depression (90% COPD versus 52% NSCLC). Despite having worse prognosis, the COPD patients received no palliative care compared with NSCLC patients. A recent systematic review<sup>17</sup> that investigated the prevalence of physical symptoms of five chronic progressive diseases (advanced cancer, AIDS, heart disease, renal disease, and COPD) identified common physical symptoms across the five conditions which were pain, breathlessness, and fatigue. In addition, a high prevalence of depression was reported in COPD patients. This indicates that palliative care is relevant for patients with all five chronic conditions. However the holistic aspects of care provision and management may require modification to satisfy individual patient's needs in order to improve quality of life and to support carers and families.

The impact of depression can be profound in influencing patient preferences of choice whether to receive a life sustaining treatment or not in patients with COPD.18 In an elegant qualitative study, Curtis and colleagues<sup>19</sup> examined the differences in end-of-life care provision from patient perspectives for patients with COPD, Cancer and AIDS. The three groups differed in socio-demographic characteristics, and COPD patients were older compared with the Cancer and AIDS patients. However they have reported similar concern of whether the family physicians are skilled enough in providing end of life care (emotional support, communication and accessibility and continuity of care). The COPD patients further reported the desire for education to know more about the disease process, treatment, and prognosis, what dying might be like and advance care planning which may be a territory for the palliative care team to address.

#### Why COPD patients do not receive palliative care

General practitioners and healthcare professionals are challenged by prognostic accuracy of patient survival in patients with severe end-stage of COPD, and they are less likely to engage in end-of-life care planning in contrast with terminal diseases like cancer. This poses a challenge about when to refer patients with advanced stage of COPD for palliative care even though their physical, emotional and psychosocial needs are as severe as or worse than patients with lung cancer.<sup>16,20</sup> Furthermore there is a lack of resources which constraints for the wider availability of the palliative care programs in the healthcare system.

#### Table 2: Indicators of physical symptoms with advanced end stage of COPD

Social isolation Depression Anxiety Poor quality of life Intolerable dyspnoea Frequent hospital admissions Housebound or chair bound Fatigue (excessive tiredness) Loss of hobbies Loss of weight Low self-esteem Long term oxygen therapy FEV<sub>1</sub> < 30%

FEV<sub>1</sub> = Percentage of forced expiratory volume in one second.

Currently there is no research data to persuade health care providers that palliative care provision for advanced stage COPD patients has beneficial effects in terms of reducing the healthcare utilization (for example, hospital readmission) or improving quality of life in this patient group. However, a recent study<sup>21</sup> that investigated in male patients the benefits of palliative care provision (predominantly cancer including cardiovascular, pulmonary and gastrointestinal etc) compared with the usual care (optimum medical treatment and hospital care provision). Patients that received palliative care were less likely to be admitted to intensive care unit during hospitalization, incur lower inpatient costs per day, and receive better medical care provision compared to the usual care patients. Hence palliative care may help in reducing healthcare costs and may avoid admission into the intensive care unit for patients with COPD.

Acute exacerbations are common in patients with severe COPD which require on average three-to-four times hospital readmission per year and patients are most likely to present with low self-esteem and suffer from a high level of depressive and anxiety symptoms. Our research group has reported recently that patients with severe acute exacerbation COPD identified at discharge with a co-morbid depression have increased likelyhood of (13% more) of dying in the following year compared with non-depressed patients.<sup>11</sup> This observation indicates the lack of holistic palliative care provision for psychological, social support (patient and carers) and spiritual care at the end stage of COPD.

Patients with severe COPD are most likely to be housebound, socially isolated, physically disabled, and lead poor quality of life. They can be a source of concern for family and carers, as some patients are chair-bound, and may be in need of continuous support and care including routine basic daily activities for example, bathing.

#### Benefits of palliative care for COPD patients

Palliative care for COPD patients will open an opportunity for better communication with patient, family, and physician in order to plan appropriate treatment strategies including advance care planning, and patient preferences with regard to choice of end of life withholding or withdrawing medical treatment and hospice care. For the details of topics and protocol guidelines to enhance patient-doctor-communication and treatment options see reviews.<sup>15,33</sup> The multidisciplinary nature of palliative care provision may encourage COPD patients to play an active role in self-management in order to optimize energy and function. In addition, the psychosocial support and the healthcare professionals' care and attention may promote confidence to over-come the disproportionate fear dyspnea on exertion brings may help to engage in routine daily activities.

It will also provide unmet needs of the patients psychological, spiritual, and psychosocial needs in the advance stage of the disease in order to improve patients' quality of life. In addition, the spouse and/or carers are more likely to suffer from anxiety and depressive symptoms providing continuous care during the advance stage of the disease and end of life care without having any periods of respite. Therefore, it will

open access to a specialist palliative care team including home nursing services and referral to hospice care.

#### What are the potential barriers?

Table 1 summarizes some of the potential barriers<sup>22-24</sup> from the patients and the general practitioners perspectives to provide satisfactory care for the patients at the end stage of the disease. It requires a multi-modal approach to tackle the barriers as follows.

The general practitioners may require further training on communication skills in how to break sensitive information such as the prognosis of the disease and advance care planning.<sup>24</sup> It is also possible that general practitioners may not have adequate time with increased workload to discuss such kind of issues at great-depth. Hence, referring those patients in advance stage of the disease to palliative care team is a worthy endeavor.

Education of the patients and carers about the disease, including the prognostic and advance care planning at the early stage of the disease should be part of the pulmonary rehabilitation program. This may increase patient's awareness and confidence to ask relevant questions at the end-stage of the disease and to have a meaningful conversation with their physicians in order to devise appropriate treatment strategies. In order to achieve these goals further training is required to specialize on palliative care for the pulmonary rehabilitation team and others (for example, advanced practice nurses) that may be involved in patient care to assist the general practitioners.

#### Assessment

Accurate assessment of the patients' psychological morbidity, physical disability and impaired quality of life, is the first step towards planning good end of life care. A recent study in our department identified physical disability, poor quality of life and depression as predictors of mortality following the events of acute exacerbations of COPD in a preceding year.<sup>11</sup> The Manchester Respiratory Activities of Daily Living (MRADL)<sup>25</sup> is a self-administered physical disability scale, and is specifically validated as a postal questionnaire for patients with COPD. The score ranges from 0 to 21, and a low score corresponds to severe physical disability in activities of daily living. It takes less than five minutes to complete. The MRADL<sup>11</sup> score < 10 showed predictive values for one year mortality (sensitivity 75% and specificity 63%), i.e. good at identifying mortality but less good

at predicting survival. The MRADL has a potential in identifying (selecting) severe COPD patients with physical disability that are most likely to benefit from palliative care provision while pursuing optimum medical treatment. The MRADL requires testing in future research. Others have suggested the BODE index (body mass index, airflow obstruction, dyspnoea and exercise capacity)<sup>26,27</sup> might be a useful tool as changes may relate to progression of disease and predicts mortality in this patient group.

## Treatment that may benefit COPD patients during palliative care provision

**Long acting bronchodilators:** It is important to be aware of the effects of drugs to keep the airways open for a long period time in order to reduce breathlessness and increase quality of sleep during the night for the patient suffering from severe dyspnea. Tiotropium (tiotropium bromide) is a safe long acting inhaled bronchodilator drug with a long duration of providing sustained bronchodilation throughout the day, and is relatively selective for muscarine  $M_1$  and  $M_3$  receptors, dissociating more quickly from  $M_2$  receptors.<sup>28,29</sup> A recent meta-analysis showed that Tiotropium reduced frequency of COPD exacerbations, relieved dyspnea, and improved quality of life in patients with COPD.<sup>30</sup> Once daily dosing is convenient for patients but close monitoring for adverse effects such as dry mouth and urinary tract infections are essential.

**Oxygen Therapy:** In the advanced stage of the disease, COPD patients often experience chronic hypoxia which may require oxygen therapy as it helps to relieve dyspnea and improve physical activities within a home environment. However, the long-term benefits of oxygen therapy for COPD patients remain inconclusive. A few studies have reported that patients with COPD on long-term oxygen therapy (LTOT) suffer from high level of anxiety and depressive symptoms, poor quality of life<sup>31</sup> and premature death compared to non-LTOT patients with COPD.<sup>11</sup>

**Opiates:** Morphine is commonly used for patients with intolerable dyspnoea in palliative medicine. It helps the patient to feel comfortable, reduce breathlessness and improves the quality of sleeping pattern. Dosing depends on the symptom burden and the patient history of exposure. A recent review<sup>32</sup> supports the use of opioids to treat dyspnoea (reducing the sensation of breathlessness) in patients with advanced progressive diseases, including COPD. However, close monitoring of the patient condition for side effects such as nausea, vomiting, dizziness and constipation is essential. Morison and Morison<sup>33</sup> advise when ever possible to use the lowest effective dose of opioid medication and titrate the bowel regimen accordingly.

**Benzodiazepines:** They can be considered in the treatment of severe dyspnoea and anxiety symptoms including panic attack which are common in patients with advance stage of COPD for example, regular low-dose longer-acting benzodiazepines such as diazepam 2–5 mg every 8 hours.<sup>34</sup>

**Psychosocial and spiritual needs:** COPD patients with severe dyspnea, tiredness and pain may compromise their physical, psychological, social, and spiritual aspects of their lives. Palliative care (a multidisciplinary care) holistic care approach addressing some of the issues may be a benefit for patients and families. However, to-date the benefits of spiritual care has not

been explored in patients with COPD. It was reported that spiritual and religious beliefs can play an important role at the end of life care, for example, a question "are you at peace?" offers a patient an opportunity to express his/her spiritual concerns and to have a dialogue with the doctor 'in treatment decisions for patients and families, particularly with regard to initiation of and continuation of life-prolonging therapies'.<sup>35</sup> In this regard chaplains and local church minister may play an active role to support the patient and family in spiritual care.

**Pulmonary rehabilitation:** There is strong evidence to suggest that a group based pulmonary rehabilitation program improves quality of life, exercise capacity, and increases confidence to pursue enjoyable hobbies for mild to moderate COPD patients. However, patients with the advanced stage COPD with physical and psychological symptoms (Table 2) especially those housebound may derive-benefits, if the exercise program is individually tailored, instructed and periodically supervised by the therapist as a part of home exercise program in that it may improve independence in physical activities and self-management. It is worth exploring whether the palliative care program has any additional benefits when simultaneously provided with pulmonary rehabilitation program.

Patients with severe dyspnea may benefit from relaxation therapy and breathing training (breathing control) exercises, appropriate positioning and advice on postural correction can also be useful in reducing sensation of breathlessness. Furthermore, providing a supportive listening environment, psychosocial counseling and reassuring patients and respite care for caregivers may also be beneficial. Devising coping strategies, adaptation of the home environment, energy conservation techniques to improve daily activities, for example, the inability to take a shower while standing upright can be overcome by placing a chair in the bath/shower-room are worthy of consideration. Malnutrition is common in advanced stage COPD. Factors that contribute to this are multifactorial and may include the increased work of breathing because of severity of lung impairment, decreased appetite and a lack of balanced diet. The dietitian may provide advice to the patient and carers about diet and supplementary diet intake. Patients with severe dyspnea while eating may benefit from dividing the daily intake into several small meals.

In summary, palliative care is not available for patients with advanced stage COPD despite their having a poor prognosis with lower levels of self-efficacy, greater disability, poor quality of life, and higher levels of anxiety and depression worse than subjects with terminal non-small cell lung cancer. COPD patients are twice as likely to be admitted to an intensive care unit compared with lung cancer patients. Indeed, COPD is a chronic incurable disease, especially those in advanced stage of the disease pursuing intensive medical treatment may benefit from the simultaneous provision of the holistic care approach of palliative care services, medical services and social services to improve quality of end-of-life care.

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## Which Clinical Signs and Symptoms Predict Hypoxemia in Acute Childhood Asthma?

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#### Abstract

**Objective:** To find the clinical signs that are the best predictors of hypoxemia ( $SpO_2 = 92\%$ ) in acute asthma in children.

**Methods:** Color of skin, dyspnea (by single breath counting), alertness, respiratory rate, presence of audible wheeze, wheezing on auscultation, accessory muscle use, nasal flaring, pulse rate, systolic and diastolic blood pressure, pulsus paradoxus and oxygen saturation at room air (by pulse oximetry) were recorded at the time of presentation and one hour after presentation after completion of 3 doses of nebulized salbutamol and budesonide.

**Results:** Hypoxemia (SpO<sub>2</sub>  $\leq$  92%) was seen in 45% of children at presentation and 14 (28.6%) after one hour. The clinical signs that correlated significantly with hypoxemia at both time points were dyspnea assessed by single breath count (OR 3.3, 95% CI 0.9–12.9), accessory muscle use score  $\geq$ 3 (OR 3.0, 95% CI 0.9–15.4) and pulsus paradoxus >10 (OR 3.0, 95% CI 0.7–13.6). In a multiple logistic regression model accessory muscle score  $\geq$ 3 and pulsus paradoxus >10 were identified as independent predictors of hypoxemia (sensitivity 64.3%, specificity 91%).

**Conclusion:** Physical assessment in a child with acute exacerbation of asthma should at least include accessory muscle use and pulsus paradoxus, since these predict hypoxemia the best.

Asthma is the most common chronic disease in children.<sup>1</sup> The management of acute exacerbation of asthma relies on careful

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ongoing clinical assessment, complemented by serial measurement of lung function.<sup>2</sup> The danger of inadequate assessment of acute asthma is that more effective therapy may be withheld in the acute stage, with possible increase in hospitalization and mortality rates. Since medical history taking and physical examination are only moderately effective in diagnosing and estimating severity of acute asthma, objective measures of lung function are necessary for the accurate assessment.3 Clinically the severity of an acute exacerbation of asthma is assessed by presence of tachypnea, tachycardia, a reduction of more than 40% in expected peak expiratory flow rate (PEFR), or an inspiratory fall of arterial blood pressure of >10 mmHg (pulsus paradoxus).<sup>4</sup> More recently the value of oxygen saturation by pulse oximetry  $(SpO_2)$  in the assessment of acute severe asthma has been a subject of study;<sup>5,6</sup> it is said to be a good predictor of prolonged bronchodilator therapy and hospitalization.<sup>7-9</sup> Since oxygen saturation (SpO<sub>2</sub>) and sometimes even PEFR measurement may not be available to physicians/health care providers in developing countries especially in the primary health care setting, they have to rely on clinical assessment based on simple physical signs at presentation. These physical signs include cough, the color of the skin (cyanosis), nasal flaring, degree of dyspnea, alertness level, fragmentation of speech, respiratory rate, accessory muscle use, amount of both audible and auscultational wheeze and heart rate. However, these signs have not been fully studied for their ability to predict hypoxemia and severity of the asthma attack. The objective of this study was to find which of the clinical signs mentioned above are the best predictors of hypoxemia (defined as SpO2 <92%) in an acute asthma attack.

#### **Materials and Methods**

**Population:** Children between 3 to 15 years of age, with acute moderate or severe exacerbation of bronchial asthma, presenting to the pediatric emergency service of a tertiary care teaching hospital in north India from April to June 2003 were included in the study. The study was approved by the Institute's Ethics Committee. Informed consent was obtained from the parents. All children were treated according to a standard protocol using salbutamol nebulization (0.15 mg/Kg/dose with a

TABLE 1. Categorization of Symptoms and Signs Studied in Children with Acute Attack of Bronchial Asthma

Symptom	Value		
	0	1	
Color of skin	Good	Pale or cyanotic	
Dyspnea	Absent	Moderate or severe	
Alertness	Normal	Obtunded or unconscious	
Pulse rate	≤ 30% increased above mean	> 30% increased above mean	
Systolic blood pressure	≤ 30% increased above mean	> 30% increased above mean	
Diastolic blood pressure	≤ 30% increased above mean	> 30% increased above mean	
Cough	Absent	Present	
Nasal flaring	Absent	Present	
Pulsus paradoxus	≤ 10 mmHg	> 10 mmHg	
Accessory muscle use	Score < 3	Score ≥ 3	
Auscultational wheeze	Score < 4	Score ≥ 4	
Hypoxemia	$SpO_2 > 92\%$	$SpO_2 \le 92\%$	

minimum of 2.5 mg) and budesonide (800  $\mu$ g) nebulization along with oxygen 5 L/min given through a simple facemask. This treatment was repeated every 20 minutes for 3 doses. In case of no or inadequate improvement nebulized ipratropium bromide (250  $\mu$ g every 20 min) and hydrocortisone (10 mg/kg, I.V.) were added. A detailed history including the complaints of the patients and medication use were recorded. The children were assessed at the time of presentation (0 hour) and at 1 hour after presentation (after 3 doses of nebulized salbutamol + budesonide).

**Measurements:** The color of the skin was assessed by observing the lips and tongue (pink, blue or pale). Dyspnea was assessed by the ability to count from one to ten slowly in one deep breath (maximum number count was recorded) and the ability to speak in full sentences. Alertness was noted as normal, when the child was able to answer questions and interact, and obtunded when it was difficult to get the child to answer or interact with the examiners. Respiratory rate was counted for one full minute, by looking at the child's abdomen and counting the numbers of each upward movement as one breath. Auscultational wheeze was assessed by stethoscope and for its presence during expiration and inspiration, and location. It was graded with help of an ordinal score.<sup>10</sup> Accessory muscle

use was noted by observation of supraclavicular, inter-costal and sub-costal retractions.<sup>11</sup> Each of these items were divided into absent, mild, moderate and marked.<sup>10</sup> Nasal flaring was noted as either absent or present assessed by observing movement of the nostrils for 30 sec. Pulse rate was counted by palpation and heart-rate per min by the pulse oximeter (Nonin® 8500). For blood pressure measurement and pulsus paradoxus mercury sphygnomano-meters with small cuffs (10 cm) were used for the younger children and normal cuffs (15 cm) for the older children. Pulsus paradoxus was defined as a decrease in blood pressure of more than 10 mmHg during inspiration. The SpO<sub>2</sub> was measured while the child was breathing room air, with a pulse oximeter (Nonin 8500) using a finger clip on the second finger of the right hand. All the observations about clinical signs were made and recorded by MSR and RPG who were blind to  $SpO_2$  measurement, which was measured by a research staff. In 73% of the cases there was no significant inter-observer difference in various clinical signs measured; in the remaining cases the measurement was repeated and the mean of the two values measured was recorded.

For analysis most symptoms were categorized into a dichotomus scale with values of 0 and 1 (Table 1). Auscultational wheeze was recorded objectively using a scoring

Variable	At admission (n-51)	After one hour (n-49)	Р	
Sex (Boys : Girls)	34:17		<u></u>	
Age, months	$90.5 \pm 38.8^{\circ}$			
Height (cm)	$124 \pm 18.7$			
Breath count	$7.0 \pm 3.7$			
Respiratory Rate, breaths/min	$40 \pm 11$	$34.1 \pm 8.5$	.0001	
Pulse Rate, pulse/min	$129 \pm 23$	$135 \pm 20$	0.01	
Systolic BP, mm Hg	$112 \pm 9.6$	$111 \pm 8.8$	.98	
Diastolic BP, Hg	$71.5 \pm 7.8$	$72 \pm 8.0$	.68	
Oxygen saturation (SPO <sub>2</sub> ), %	92.6 ± 3.5	$93.8 \pm 3.6$	.006	
Number of children with:				
- Dyspnea	30	19	.045	
- Cyanosis	14	7.	11	
- Accessory muscle use score ≥3	15	13	.75	
- Nasal flaring	10	7	.48	
- Pulsus Paradoxus	14	12	.73	
- Auscultable wheeze score $\geq 4$	25	13	.02	
- Audible wheeze	7	1	.03	
- Oxygen saturation $\leq 92\%$	23 (45.1%)	14 (28.6%)	0.08	
- Oxygen saturation $\leq 90\%$	14 (27.5%)	11 (22.4%)	0.56	

"Mean ± SD

Clinical sign	Patients v	with			Pati	ents with		
-	SpO₂≤92% (n-23)	$\frac{\text{SpO}_2 \ge 93\%}{(n-28)}$	Odds Ratio	P value	SpO₂ ≥ 92% (n-14)	• SpO₂ ≥ 93% (n-35)	Odds Ratio	P value
Age, months	86.8 ± 34.35	93.5 ± 42.6	-	0.54	92.0 ± 41.6	91.5 ± 38.7		0.97
Respiratory rate/min	$42 \pm 10$	39 ± 13		0.44	$37 \pm 10$	32 ± 7	-	0.072
Single breath count <sup>®</sup>	$5.5 \pm 3.0$	$8.8 \pm 3.7$	-	0.027	$6.4 \pm 3.6$	9.5 ± 2.9	-	0.031
Pulse Rate/min	131 ± 18	$127 \pm 26$	-	0.47	145 ± 12	$131 \pm 20$	-	0.014
Systolic blood pressure- mmHg	$111 \pm 10$	112 ± 9	-	0.77		- 0.77		
Diastolic blood pressure mmHg	71 ± 7	72 ± 9	-	0.94	71 ± 8	$72 \pm 8$	-	0.69
Accessory muscle use Score	$3.4 \pm 2.6$	$2.1 \pm 1.7$	-	0.044	$3.1 \pm 2.6$	$1.2 \pm 1.2$	- ,	0.008
Auscultational wheezing score	$4.8 \pm 2.1$	$4.1 \pm 2.0$	-	0.20	$4.4 \pm 1.8$	$2.7 \pm 2.1$	-	0.015
Oxygen saturation, %	89 ± 2.2	$95 \pm 1.8$	-	0.0001	$89.1 \pm 1.7$	95.6 ± 2.1	-	0.0001
Number of patients with								
Male sex	17	17	1.83 (0.5-7.25)	0.32	11	22	2.17 (0.43-12.0)	0.29
Cynosis	8	6	1.96 (0.5-8.1)	0.29	4	3	4.3 (0.64-30.2)	0.74
Dyspnea	17	13 3	3.27 (0.86-12.9)	0.049	8	11	2.91 (0.69-12.7)	0.098
Tachypnea <sup>b</sup>	23	24	undefined	0.06	14	32	undefined	0.26
Auscultatory								
Wheeze score $\geq 4$	15	10	3.38 (0.9-12.8)	0.038	6	7	3.00 (0.65-14.3)	0.10
Accessory Muscle use Score ≥ 3	10		3.5 (0.85-15.4)	0.048	8	5	8.0 (1.6- 43.5)	0.002
Nasal Flaring	6	3	2.9 (0.5-17.6)	0.16	4	3	4.2 (0.64-30.2)	0.073
Fast Pulse	6 12		0.95 (0.27-3.3)	0.18	12		4.2 (0.64-30.2) 5.05 (0.85-38.4)	0.073
			0.95 (0.27-3.3)	0.92	12		undefined	0.04
Syst B.P. High Pulsus Paradoxus	1	2 5	· · · · ·		-	1 3		0.52
	9		3.0 (0.7-13.6)	0.09	9	-	19.2 (3.1-139.8)	
Audible wheeze	5	2	3.6 (0.6-30.7)	0.13	1	0	undefined	0.11

<sup>a</sup>n-12 and 13 respectively at presentation and 19 and 7 respectively at one hour

<sup>b</sup>Tachypnoea – using age specific cut offs: > 40 breaths/ min for children 1-5 years, > 30 breaths/min beyond 5 years of age

system in which children could score between 0-8 points.<sup>10</sup> Wheeze during expiration was categorized as 0 for no wheeze, 1 for end expiratory wheeze, 2 for wheeze during half of the expiration, 3 for wheeze during three-fourth of the expiration and 4 for wheeze during the entire expiration. Likewise, wheezing during inspiration was categorized into 3 categories '0' for no wheeze during inspiration, 1 for wheeze in a part of inspiration and 2 for wheeze during the entire inspiration. Finally, the location of the wheezing sound in the lung was categorized in '0' for no wheeze, 1 for wheeze in 1 or 2 segments of the lung and 2 for wheeze audible in 3 or 4 segments of the lung. By adding up the individual scores of each item, a total wheeze score was acquired. For accessory muscle a child could score 0-9 points.<sup>10</sup> Supra-clavicular, intercostals and sub-costal retractions were categorized into, 0 for none, 1 for mild, 2 for moderate and 3 for marked retractions. By adding up the individual scores of supra-clavicular, intercostals and sub-costal retractions, a total accessory muscle use score was acquired.

Analysis: All the gathered data were analyzed at two time points: at presentation and after one hour. Hypoxemia was defined as a SpO<sub>2</sub> ≤92%. Descriptive statistics (mean ±SD) and percentage was used for presentation of data; t-test was used for 'between the groups' comparison of continuous variables and x<sup>2</sup> test for discreet variables. The associations between various clinical signs and hypoxemia was evaluated by calculating odds ratios (OR) and 95 percent confidence intervals (95% CI). For this purpose tachypnoea was defined as a respiratory rate >40/min in children 1 year to 5 years, and >30/ min in older children. Ordinal scores on auscultational wheezing and accessory muscle use were changed to discrete variable using a cut off, which reflected mild and severe grade of the sign. Cut off score for wheezing was <4 and ≥4, and for accessory muscle use was <3 and ≥3. The variables that were significant on univariate analysis were entered in a multiple logistic regression analysis to identify independent predictors of hypoxemia. All analysis were done using SPSS version 11 and Epi–info 2000.

#### Results

A total of 51 consecutive patients (34 boys and 17 girls) were assessed at two time points, at admission and after completion of three dosage of salbutamol and budesonide nebulization. The patients were between 29 and 186 months old. (median 82 months and mean  $\pm$ SD 90.5  $\pm$ 38.8 months). The clinical profile of patients at presentation and after one hour is given in table 2.

Hypoxemia was seen in 23 (45%) patients at admission and 14 (28.6%) patients after 3 dosage of nebulization. Single breath count, accessory muscle use, dyspnoea, auscultatory wheezing score  $\geq$ 4 and pulsus pradoxus were the clinical signs that showed significant association with hypoxemia at presentation and after one hour (Table 3). All the above variables except single breath counting were entered in a logistic regression analysis (backward stepwise) for both the time points using hypoxemia as dependent variable. At both the time points accessory muscle use (score  $\geq$ 3) and pulsus paradoxus were identified as the two independent predictors of hypoxemia (Table 4). None of the models were highly predictive of hypoxemia (Table 4). Alertness, respiratory rate, auscultational wheezing, cough, pulse, systolic and diastolic blood pressure, and audible wheezing, did not correlate with hypoxemia.

#### Discussion

Our study shows that at presentation and after initial bronchodilator therapy pulsus paradoxus and accessory muscle use were significantly related to the hypoxemia. Other clinical signs, namely single breath count, auscultatory wheeze score  $\geq 4$ 

## TABLE 4. Predictors of Hypoxemia in a Multiple Regression Model Derived from Data at Admission and After one Hour

		β	Odds ratio, 95% C.I.	P value
A.	At presentation Pulses Paradoxus	-1.22	0.29, 0.8 - 1.1	0.08
	Accessory muscle use Constant	- 1.39 .34	0.25, 0.7 – 0.96	0.044
B.	After one hour Pulses Paradoxus Accessory muscle use Constant	- 3.1 - 2.3 .054	0.04, 0.01 – 0.30 0.1, 0.02 – 0.64	0.001 0.015

The model at presentation predicted 66% of normoxemic and 72.7% of hypoxemic patients and after one hour 91% of normoxemic and 64.3% hypoxemic patients correctly.

and fast pulse rate also did reach significance individually but on multiple logistic regression these factors did not stand out as independent predictors of hypoxemia in this population. Single breath count (a reflection of dyspnea) may have reached significance in a larger population sample but it was available in only 50% of the study populations; at younger ages it was not possible to assess this sign properly. Our finding is important since both signs are easy to measure in primary care and may be used as clinical guideposts in the initial assessment of acute childhood asthma. Although both variables have been mentioned in literature as markers of severity of acute asthma, this is the first time that an evidence base is provided in comparison with other clinical variables for evaluation of hypoxemia in acute asthma.

Previous studies on the predictive value of pulsus paradoxus in asthma showed contradictory results.<sup>12-15</sup> In our study pulsus paradoxus showed a highly significant association with oxygen saturation both at presentation and after 1 hour. It may be considered as a very valuable clinical sign, both in assessing the severity of an asthma attack and predicting hypoxemia.

Impaired alertness and audible wheeze were not common and did not correlate with oxygen saturation at any time. With the exception of one case, none of the patients showed impaired alertness, even when they were hypoxemic. Therefore, alertness and audible wheeze cannot be considered as useful signs in assessing the severity of acute asthma in children. In the way that we categorized the continuous values of respiratory rate, pulse, systolic and diastolic blood pressure and auscultational wheeze none of these symptoms showed any significant correlations with oxygen saturation.

There are some shortcomings in our study. First, we expected to include more patients in our study. Patients came in at a rate of 2-4 per day in April and the inflow decreased to 0-1 per day in June. Nevertheless we believe that the number of patients studied, was sufficient for measuring the association and coming to conclusions. Another possible consequence of the seasonal manner of patient inflow is that there might be a different etiology of asthma in these patients. However, this is considered less relevant to our study, since we were studying the predictability of oxygen saturation by the clinical symptoms in children with asthma, irrespective of the etiology. Our study was conducted in a hospital, which serves both as a referral centre as well as a first contact health care facility. This might result in some selection bias: patients with more severe attacks might have been referred to us. However, since the aim of our study was to assess the symptoms in an acute attack, we did not consider this as a serious limitation to our conclusion and outcome.

We conclude that in assessing an asthma exacerbation, a full clinical assessment of the patient including oximetry is warranted. However, in the absence of a pulse oximeter or peak flow, pulsus paradoxus and accessory muscle use (score  $\geq$ 3) seem to deserve priority in assessing presence of hypoxemia. We recommend further studies to assess our results in a rural, primary care setting, using a larger sample.

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## **PRODUCTS/PEOPLE**

#### NEW VP

MAQUET has announced the appointment of Steven Greenfield as Vice President of Critical Care Sales. Greenfield will be responsible for managing the critical care division's U.S. organization of sales representatives. He began his career as a Registered Respiratory Therapist and worked his way up to department director. He brings over 20 years experience in sales and management in which he has distinguished himself in many leadership roles at world-class companies such as Baxter, Stryker and most recently Johnson & Johnson. Contact maquet.com/us.

#### VENDOR OF THE YEAR

MAQUET, a leading developer, manufacturer and distributor of innovative medical devices, was named Vendor of the Year by the New Jersey Society for Respiratory Care (NJSRC) in Atlantic City. This will be the second Vendor of the Year award received by MAQUET. To be recognized as Vendor of the Year, a company must actively support the respiratory care field in New Jersey by providing services, equipment or supplies to respiratory care practitioners, have a reputation for quality, integrity and fairness, offer state-of-the-art products, and demonstrate commitment to respiratory care education. MAQUET was one of three companies nominated by respiratory care directors and homecare providers. It was a letter from a local hospital that captured the attention of the NJSRC board of directors. The letter described the efforts of sales representative Frank Gervasi, and the local clinical applications team, who went above and beyond expectations and were instrumental in guiding the respiratory care department through significant changes. With its SERVO product range, MAQUET Critical Care is the global market leader in ventilation. Contact maquet.com/us.

#### **CHANGING POSITIONS**

Mochida Pharmaceutical Co., Ltd., and Siemens K.K. Japan have agreed to change the ownership interest both companies hold in their joint venture Mochida Siemens Medical Systems Co, Ltd. Mochida Pharmaceutical transferred 16 percent of its outstanding shares to Siemens KK, making Siemens KK a 51% equity stakeholder. The share transfer means that Mochida Siemens Medical Systems Co, Ltd will become a fully consolidated subsidiary of Siemens and an equity-consolidated affiliate of Mochida Pharmaceutical Co, Ltd. Employing more than 41,000 people worldwide and operating in over 130 countries, Siemens Medical Solutions reported sales of euro 8.23 billion, orders of euro 9.33 billion and group profit of euro 1.06 billion for fiscal 2006.Contact siemens.com/medical.

#### RELOCATED

Compumedics Neuroscan announced that it has completed the relocation of its USA Headquarters into Charlotte, NC. This move lands Compumedics in a large metropolitan area with access to a major international airport hub and allows it to draw upon a large, highly skilled, technical workforce. The company reported, these changes will provide easier access to our customers and to a workforce allowing us to continue to attract the very best talent available to support our customers. In addition our new building features a state-of-the-art training facility to host our future SCAN, ProFusion and DWL training courses. The toll-free contact lines will remain the same,

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though direct lines have changed. The new business address is: Compumedics USA, Compumedics Neuroscan and Compumedics DWL, 6605 West WT Harris Blvd, Suite F, Charlotte, NC 28269, general toll-free number: (877) 717-3975, Customer Technical Support: (877) 294-1346, phone: (704) 749-3200, fax: (704) 749-3299.

#### HAPPY BIRTHDAY

Draeger Medical, Inc celebrated 100 years of ventilation technology in October. In 1907, the company delivered the Pulmotor, the first-ever mobile short-term respirator. As part of its ongoing celebration of these milestones, Draeger Medical showcased an original Pulmotor alongside of its latest respiratory care devices at the annual ASA Annual Meeting in San Francisco and at the AARC. Due to its use in the harsh environments of underground mines and in high altitudes, the reputation of the Pulmotor quickly grew. The first users of the ventilation products were soon dubbed "Draegermen," and ever since, the term has been synonymous with mine rescue teams worldwide. The use of Draeger breathing apparatus quickly spread to other emergency services fields and 1913, the New York and Pittsburgh city fire departments began equipping their firefighters with the respirators. Today, both cities are still using Draeger self-contained breathing apparatus (SCBA). Draeger has continued to build upon its impressive heritage of breathing innovation. For example, the new SmartCare/PS option for the EvitaXL ventilator is an automated knowledge-based ventilation system developed to improve the efficiency and effectiveness of the weaning process. One of the company's most recent innovations was the introduction of the Oxylog 3000 emergency transport ventilator. In the US, Draeger Medical, Inc also recently released the Carina Home home care ventilator. This system offers clinical-standard ventilation control for patients in the comfort of their own homes. With products such as these, the company is laying the foundation for another 100 years of life-saving success. For a look at Draeger Breathing Milestones, visit draeger.com, and read "The History of Draeger" brochure.

#### TO THE BEAT

For more than two decades the Bunnell Life Pulse High Frequency Ventilator has proven to be an effective therapy for early intervention and treatment of pulmonary interstitial emphysema and for rescue of patients failing on conventional or high frequency ventilators. The "WhisperJet," a new inspiratory valve, reduces noise output by 75%. The development of the LifePort ET tube adapter, in 1996, eliminated the need to reintubate with a special ET tube, making implementation of the Life Pulse faster and easier than ever. For a free trial call (800) 800-4358 or visit us online at bunl.com.

#### **NEW TECH**

Hi-Tech Medical introduces these new products: Type 444 Plus Hose, a tube technology breakthrough, this product can be completely stretched or crushed and will return to its original dimensions and shape immediately. Smooth interior for excellent flow characteristics. Type 444 Plus is an excellent choice for home or institutional medical equipment applications. The tubing is available with plain ends or injection molded cuffs. The Type 480 Hydro Hose is Hi-Tech Medical's first Medical hose that has the ability to absorb moisture from the interior of the hose and transfer it in a directional manner to the exterior atmosphere. This product is a great solution to ending "rainout" in CPAP and other respiratory equipment applications. The Type 1250 Hose Life is a new CPAP system accessory that allows for suspension of the CPAP system hose over the bed. This system is uniquely light in weight, durable in construction, super compact for travel, and easy to set up. The Type 1260 Hose Wrap is a new style of hose cover that assists in controlling vapor condensation in CPAP and other respiratory circuits while providing a super soft tubing surface. The ease of inserting and withdrawing the hose from the wrap is due to the unique end finish and fabric design. These Hi-Tech products are engineered to allow for use by those who are physically challenged. Contact hitechmedical.net.

#### **FREE-BREATHING**

Newport Medical Instruments, Inc's newest generation of ventilator, the Newport e360, has added a new Biphasic breath type in its latest software version. The Newport e360's compact size, comprehensive features, safety management and low cost of ownership make it ideal for today's hospital and sub-acute facilities. The e360's Biphasic Pressure Release Ventilation (BPRV) allows free inhalation and exhalation during a pressurecontrolled breath by means of a partially open, actively controlled exhalation valve. The goal of BPRV is to improve patient comfort, reduce the expiratory work of breathing (WOB) and possibly improve oxygenation when the patient has an intact respiratory drive. BPRV can make pressure controlled ventilation with extended inspiratory times more comfortable for the actively breathing patient and therefore may reduce the amount of sedation and/or paralysis needed. On the e360, there are no new modes, hidden menus or controls to figure out to use BPRV. The open exhalation valve feature simply works as an adjunct to pressure control and can be enabled via the Graphic User Interface. The Newport e360's compact size, comprehensive features, safety management and low cost of ownership make it ideal for today's hospital and sub-acute facilities. Contact ventilators.com.

#### **READY FOR ANYTHING**

Newport Medical Instruments, Inc announced that they have signed an agreement with The Virginia Hospital and Healthcare Association, the group that manages the State of Virginia's Emergency Preparedness program, to provide HT50 ventilators for deployment to six regions throughout the state. In California, the San Bernardino County Department of Health, Office of Preparedness and Response just took delivery of over a quarter million dollars worth of HT50 ventilators as part of their ongoing disaster preparedness plan. Additional HT50 sales to regions in Texas, Oregon and Pennsylvania demonstrate that the rugged, simple to use HT50 is ideal for State EP programs. It has a long lasting internal battery and complete ventilation capability for pediatric to adult patients, for invasive or noninvasive applications. Contact ventilators.com.

#### SO SWEET

Radiometer has announced the availability of glucose on its ABL80 FLEX, delivering superior accuracy, stability and interference-free glucose performance in a portable STAT analyzer. The analyzer's glucose sensor demonstrates a wide measuring range (0-75 mmol/L) and exceptional linearity. Extremely stable, the sensor cassettes require no special handling and can be stored at room temperature. Consistent with Radiometer's standards for interference-free performance, the ABL80 FLEX glucose sensor demonstrates non-interference (< 0.1 mmol/L) from common therapeutic substances. Contact radiometeramerica.com.

#### LOOKING INSIDE

Siemens Medical Solutions and Xintek Inc announce that they have signed an agreement to establish a joint venture company in Research Triangle Park, NC. The mission of the new company, named XinRay Systems, is to develop a new multipixel X-ray source technology for a broad range of diagnostic imaging applications. Siemens and Xintek have developed a nanotechnology-based field emission X-ray source technology that fundamentally changes how X-ray radiation is generated and utilized. This technology is expected to enable new diagnostic imaging systems with enhanced performance and new capabilities. The joint venture company combines the activities Siemens and Xintek have been undertaking jointly over the last two years under one roof in North Carolina and is staffed by a strong technical team transferred from Xintek and Siemens facilities in Germany and China. Contact siemens.com/medical and/or xintek.com.

#### HOLDING FAST

Hollister Incorporated is proud to introduce the Anchor Fast Oral Endotracheal Tube Fastener. Its enhanced design minimizes pressure on the upper lip and surrounding tissue and promotes easy, secure movement of the shuttle along the track. The Anchor Fast Endotracheal Tube Fastener is indicated for use in securing medically applied oral endotracheal tubes ranging in size from 5 to 10mm in diameter. Please refer to the complete Instructions for Use for directions on how to properly use this product. To place an order or for more product information, please call Hollister Incorporated toll-free at (800) 323-4060.

#### TRY THIS AT HOME

Respironics, Inc offers its Respironics' BiPAP AVAPS noninvasive home ventilator. The new device features AVAPS (Average Volume Assured Pressure Support) technology, an algorithm that provides an average target tidal volume by automatically adapting pressure support to meet the patient's needs. With the BiPAP AVAPS home ventilator, clinicians no longer have to choose between pressure or volume ventilation because the device has the comfort of pressure ventilation and the consistent clinical efficacy of delivering a target tidal volume, all in one compact and lightweight machine. Utilizing Digital Auto-Trak Sensitivity, AVAPS estimates the patient's target tidal volume with each breath and compares it to the desired target tidal volume. If the patient is not achieving the target tidal volume, AVAPS recognizes it and gradually changes the inspiratory pressure so that the patient can breathe more comfortably and achieve synchrony. Because the pressure increase is smooth, patient comfort and safety are never compromised. Weighing only 4.2 pounds, the BiPAP AVAPS noninvasive home ventilator is simple to operate, offering a straightforward user interface and an integrated heated humidifier that allows for easier set-up and management. It also comes with built-in alarms and Respironics Encore SmartCard technology. Contact respironics.com.

#### ACQUIRED

The rights to Verus Pharmaceuticals' pediatric asthma development programs that utilize PARI's eFlow electronic nebulizer for aerosol delivery were acquired by AstraZeneca. Following Gilead Sciences' acquisition of Corus Pharma in August 2006, this is the second major pharmaceutical acquisition where a licensed eFlow is featured prominently in the development pipeline. Included in the AstraZeneca acquisition are the North American rights to a Captisol enabled budesonide solution (controller medication), a proprietary short-acting beta-agonist solution (rescue medication), a customized version of eFlow (novel aerosol delivery device) for use with both products, and other intellectual property and related assets from Verus. In August 2006, Gilead Sciences acquired Corus Pharma for \$365 million. In December 2006, Gilead Sciences released positive preliminary results of their Phase III trial on AIR-CF2, a potential treatment for cystic fibrosis patients that have pulmonary Pseudomonas aeruginosa. These positive preliminary results were the first Phase III clinical trial results highlighting the optimization of drug to device and device to drug with PARI's eFlow, an advanced electronic nebulizer. The eFlow uses a vibrating, perforated membrane that enables extremely efficient aerosolization of liquid medications. Compared to other nebulizer systems, eFlow can produce aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible amount of time. PARI Pharma develops aerosol delivery devices and inhaled therapies and specializes in treatments for pulmonary and nasal administration optimized to advanced delivery platforms. Contact paripharma.com.

#### POCKETFUL

Siemens Medical Solutions launched the world's smallest and first pocket ultrasound system. The ACUSON P10(TM) hand held diagnostic ultrasound system is a little larger than a common PDA, weighs only 1.6 pounds, and fits easily into a lab coat pocket. It is intended for complementary initial diagnostic care and triage, particularly in cardiology, emergency care and obstetrics. The ACUSON P10 system can be used by physicians and medical personnel in a number of environments including intensive care units, ambulances and medevac helicopters. It can also be used to detect conditions that may be clinically significant, but have previously required expansive or invasive diagnostic testing in asymptomatic patients. The pocket ultrasound device has FDA 510(k) clearance. Contact pocketultrasound.com.

#### **IN YOUR LAP**

Cardinal Health, a global provider of products and services that improve the safety and productivity of health care, introduced its Lap Top Ventilator 1150 (LTV) at the Medtrade Conference and Exposition in Orlando. Representing a significant step in bringing advanced patient care to the home, the LTV 1150 enables caregivers to support patients' challenging ongoing ventilation needs outside a clinical setting. The LTV 1150 reliably provides clinically sophisticated ventilation with alarms that are easy to understand for family members who provide ongoing care. It features active controls and alarm settings that are illuminated for easy identification. Patients receiving ventilatory support on the LTV 1200 in the hospital easily transition to the LTV 1150, since the systems share a common interface and settings. A consistent and intuitive interface simplifies training, saves time and reduces the potential for errors. The system features internal Positive End Expiratory Pressure (PEEP) and Spontaneous Breathing Trial (SBT) while maintaining the light weight and small dimensions of the LTV series. This newest ventilator for the home environment also offers a quick and easy setup. Presets allow the clinician to select the patient type, and the LTV 1150 automatically configures nominal ventilation settings for infant, pediatric or adult patients. At 14.5 lbs (6.5 kg), the LTV Series ventilators are a fraction of the size of comparably equipped ventilators, offering home care customers greater mobility. The hallmark LTV Series ventilators are a result of the company's dedication to offering products that provide better patient care and economic value for the healthcare provider. Contact cardinalhealth.com.

#### HIGH PERFORMANCE

Visit AARC booth #537 to see ventilation at its finest! \$2 billion strong, eVent Medical provides high performance, patented Swiss-designed Inspiration ventilators. Reliable and accurate, our ventilators are backed by a standard 5-year warranty (US) and 3-year warranty (outside US). Our NEW Inspiration Infant ventilator delivers precision to a new level... and! let us show you how to view your patients via Intra/Internet using our patented MiniWeb. Contact event-medical.com.

#### PLETH-PLUS

Masimo, the inventor of Pulse CO-Oximetry and Read-Through Motion and Low Perfusion pulse oximetry, reported that a new independent and objective clinical study presented at the 2007 American Society of Anesthesiologists (ASA) Meeting in San Francisco demonstrated the ability of Pleth Variability Index (PVI) to accurately and noninvasively detect changes in ventricular preload. The newest addition to the Masimo Rainbow SET technology platform, PVI is a continuous and noninvasive quantified measurement of changes in the perfusion index, capturing volume changes that may compromise cardiac function and affect systemic circulation. The study entitled "New Algorithm for Automatic Estimation of the Respiratory Variations in the Pulse Oximeter Waveform," indicated that while respiratory variations in the pulse oximeter plethysmography waveform amplitude are sensitive to changes in preload and can predict fluid responsiveness in mechanically ventilated patients, they previously were not easily measured noninvasively from a bedside monitor. However, a new algorithm, PVI, available in the Masimo Rainbow SET technology platform may provide a new method for noninvasively predicting fluid responsiveness.

The study tested the ability of PVI to detect changes in ventricular preload in 20 vascular surgery patients under mechanical ventilation. The researchers stated that the study is the first to demonstrate the ability of PVI, an index automatically derived from the pulse oximeter waveform analysis, to detect changes in ventricular preload. This new index has potential clinical applications for noninvasive hypovolemia detection and fluid responsiveness monitoring. The company also announced it will launch Masimo Patient SafetyNet, a new remote monitoring and clinician notification system, and showcase its upgradeable Masimo Rainbow SET technology platform. Contact masimo.com.

# EXECUTIVE PREVIEWS Pari Respiratory Equipment

Information provided by Norm Tiffin, VP, Marketing

#### What new products do you plan to exhibit?

Pari is excited to present to respiratory therapists a novel technology for humidification of high flow gas therapy, The Pari Hydrate G. The Hydrate is based on technology licensed from Vapore, Inc (vapore.com) which is unique in the medical market. Using a capillary force vaporizer which creates phase transition from water to vapor, the Hydrate can heat and humidify up to 40 L/min of dry gas by uniquely allowing the clinician to set the heat and humidification independently so the RT can provide each patient with customized care according to their needs. The unit is so small that it is placed immediately proximal to the short nasal cannula. There are no heated wires circuits, water traps, large multi-lumen tubes, temperature probes, etc. required. And the only part of the Hydrate humidification system that is in contact with water is completely disposable eliminating infection or contamination issues. Controlled through smart software, the Hydrate can adapt to room temperatures, indicate low/no flow situations and even identify when the water reservoir is running low. The clinician is provided with information not previously possible with other humidification devices including the actual volume of water being vaporized that is added to the gas. Smart humidification that is customizable, small, powerful and efficient. The Hydrate is the future of humidification.

## What new or ongoing educational materials will be available at the convention?

We will be providing demonstrations at our booth at the AARC (#102) and visitors will be able to take home a CD showing how the device works at the bedside. We will also have copies of posters presented at the AARC and other conferences.

#### Why should our readers stop by your booth?

If respiratory clinicians want to see tomorrow's humidification technology today then they will want to stop in to see the Hydrate at booth #102. Although we are introducing the Hydrate G for high flow gas therapy we will also feature the mechanical ventilator model, the Hydrate V. Using the same technology but adapted for ventilator circuits, this remarkable tool will finally enable RTs to fully control and monitor humidification like they never have been able to before.

## nSpire Health, Inc

Information was provided by Krystanne Borgen, Manager, Marketing Communications.

#### What new products do you plan to exhibit?

We will be exhibiting new PFT technology to see smaller changes in lung function sooner.

**iFlow** is an advanced technology that ensures flow & volume measuring accuracy and reproducibility at more than three times the industry standard.

## What new or ongoing educational materials will be available at the convention?

We will be demonstrating our new web browser format training for lung function testing applications.

#### What in-booth promotions will you be offering?

Our marketing department is continually providing promotions to the respiratory care market administered through our field sales team.

#### Why should our readers stop by your booth?

To see new technology that changes how PFT labs test their patients. To see new advances in personal lung health monitoring and disease management.

## **Alliance Tech Medical**

Information was provided by John Snobarger of Alliance Tech Medical.

#### What new products do you plan to exhibit?

Alliance Tech Medical will be promoting the New **Funhaler** Chamber for Children, **All Flow Spirometer** and the **Levelhaler** chamber for adults.

#### Speakers and products:

Asthma educators, product specials.

#### Why should our readers stop by your booth?

Customers should visit Alliance Tech Medical due to the new products we are promoting, as well as our new contract awards. Professionals who work in government facilities that utilize, GSA, DAPA and FSS should visit to see our product line, along with Alliance Tech having Novation contracts for multiple products. The AARC is an excellent way for the respiratory market to see our full product line and new products.

## **Respironics**

Information provided by Sandra Binder, MarCom Department.

What new products or services do you plan to exhibit? Respironics will be exhibiting many new products that will be of interest to respiratory and sleep clinicians, including: the **BiPAP® AVAPS** noninvasive ventilator for the home, Speaking Mode Option for the **Esprit** critical care ventilator, **MicroElite** compressor nebulizer system, **Flex Family** of pressure relief technologies, **BiPAP autoSV** system, **System One** Standard sleep therapy system, **EncoreAnywhere** patient management system, **SnoreSilencer** Pro mandibular advancement device and **RUSleeping** RTS apneic event screener.

## What new or ongoing educational materials will be available at the convention?

Respironics will host a series of 20-minute educational presentations in its booth (#725) that will cover topics on sleep and respiratory therapy and technology.

## What speakers will your company be working with or featuring?

Various speakers will be presenting our in-booth educational sessions.

#### What in-booth promotions will you offer?

Demonstrations of our advanced breathing technology will be available at the designated System One Breathing Station in the booth.

#### Why should our readers stop by your booth?

Attendees will have an opportunity to see and experience some of the latest and most advanced therapies and technologies being presented by a global leader in the sleep and respiratory markets.

## **Roche Diagnostics**

Information provided by Larry Healy, Marketing Manager, Blood Gas Products.

#### What new products do you plan to exhibit?

Cobas b 221: The newly introduced v6.0 software for the **cobas** b 221 blood gas system offers several features designed to help technicians and lab managers improve operational efficiency. The most significant is a continuous self-monitoring feature that tracks the status of electrodes, sensors and consumables, provides real-time onboard maintenance logs, lists all scheduled maintenance activities to be performed, and even gives the operator advance notice of needed maintenance via the user screen. The notification feature allows operators to schedule and control maintenance activities in advance, helping them prevent extended system downtime, streamline workflow and improve productivity. The new software also provides enhanced diagnostic information to help improve patient care through an exclusive new tool known as acid-base map trending. The graphic program presents a clear picture of a critically ill patient's acid-base map data over time, offering contextual information that can help the healthcare provider evaluate the patient's response to treatment and make a more informed therapy decision.

OmniLink: **OMNILink** v3.5 software is a network-level program that allows centralized control over multiple cobas b 221 systems. It offers users the capability for remote diagnostics (through Axeda protected remote access) and virtual 24/7 onsite technical support from Roche Diagnostics. The remote diagnostics and support can greatly simplify network troubleshooting, virtually eliminating the need to schedule onsite diagnostic calls and helping to enhance both lab and operator productivity. The OMNILink upgrade also provides a new screen sharing capability that enables real-time data sharing between as many as 1,000 users. The feature gives pointof-care coordinators, RT supervisors and lab managers the ability for remote command and control – to help simplify a variety of logistical and management functions, from instrument setup to file transfers and in-house troubleshooting.

Connectivity for cobas b 221: A new connectivity capability for the cobas b 221 blood gas system enables point-of-care (POC) coordinators, respiratory therapists and other hospital clinicians to manage POC testing data for Roche blood gas and blood glucose testing devices through a single data management program. The joint connectivity is provided by RALS-Plus, a multi-vendor POC information management program from Medical Automation Systems (MAS) that is currently being used for POC testing data management in more than 1,200 hospitals across the US (go to rals.com). The program is designed to help clinicians with a variety of POC testing program needs, including operator management and certification, results management and evaluation, quality control management and program reporting.

## What new or ongoing educational materials will be available at the convention?

Roche will be highlighting our ongoing blood gas teleconference series and continuing education program through the MyLabOnline web site.

## What speakers will your company be working with or featuring?

Les Foss, RRT, Director of Respiratory Services at Mission St. Joseph's in Ashville, NC, will be available in the booth to discuss the critical role IT solutions play in delivering patient results to healthcare providers in decentralized areas.

#### What in booth promotion will you be offering?

On the first day of the conference, there will be registration for the annual Roche 5K Fun Run race and walk, which will take place Sunday, December 2, 2007, at 7 am. All registered participants will receive a Fun Run T-shirt the morning of the race. The race is open to all conference attendees. Raffles will be held on Sunday for a Littmann stethoscope and on Monday for a 5th edition of Clinical Application of Blood Gases by Shapiro et al. All AARC members are eligible for both raffles.

#### Why should our readers stop by your booth?

This is a great opportunity for the readers to experience firsthand how Roche IT solutions, coupled with the cobas b 221 blood gas system, can quickly provide healthcare providers with actionable information to better manage patient health outcomes in decentralized locations.

## **Thayer Medical Corporation**

Information was provided by Karen Kiburz at Thayer Medical Corporation.

#### What new products do you plan to exhibit?

Thayer Medical Corporation will be exhibiting their line of handheld products, including: the **LiteAire**, **PrimeAire** and **Quake**. Also on display will be their in-line components for delivery of aerosolized and meter dose inhaler medications.

## What new or ongoing educational materials will be available at the convention?

Thayer Medical Corporation will have respiratory therapists on site to demonstrate and instruct on the use of their devices and for discussion of their use within a variety of facilities.

## What speakers will your company be working with or featuring?

Thayer Medical Corporation will be presenting an abstract related to their airway clearance device, the Quake.

#### What in booth promotion will you be offering?

Thayer Medical Corporation will be providing samples of its collapsible, disposable, dual-valved holding chamber, the LiteAire.

#### Why should our readers stop by your booth?

Thayer Medical Corporation would like to invite conference participants to stop by its booth to see its innovative line of handheld devices and in-line components.

## **Kimberly Clark**

Information provided by Kimberly Clark

#### What new products do you plan to exhibit?

Kimberly Clark is proud to introduce an oral care kit designed by nurses, for nurses. The new Kimberly-Clark KimVent 24-Hour Oral Care Kit is a comprehensive, flexible, easy-to-use system that contains everything needed to clean, debride, suction and moisturize. The easy access carton with individual packs allows caregivers to choose the right tool at the right time based on patient need and hospital protocol. The Kimberly-Clark MICROCUFF endotracheal tube is an airway management device designed to reduce the possibility of micro-aspiration of potentially infectious secretions into the lungs, a leading cause of ventilator-associated pneumonia. Kimberly-Clark is proud to introduce a cuffed endotracheal tube designed for pediatric patients. MICROCUFF Pediatric Endotracheal Tube virtually eliminates the hassle of airway leaks or replacing oversized uncuffed tubes. You can now confidently seal the airway using a micro-thin cuff which compensates for various airway shapes and sizes. Minimal tube replacement, improved efficacy of ventilation and monitoring, and reduced aspiration are only some of the advantages of sealing the airway with a cuff.

## What new or ongoing educational materials will be available at the convention?

Educational CEU programs and literature will be available at the booth.

#### What in-booth promotions will you be offering?

We will be drawing for 3 free registrations for the 2008 AARC meeting.

#### Why should our readers stop by your booth?

Kimberly Clark is committed to providing a range of innovative, effective clinical solutions to help clinicians address the risk factors for VAP including: Kimberly-Clark KimVent 24-Hour Oral Care Kit; MICROCUFF Pediatric Endotracheal Tube; and MICROCUFF Adult Endotracheal Tube.

## MAQUET

Information provided by Bridget Tomlinson of Maquet, Inc.

What new products do you plan to exhibit? The SERVO-i MR Environment Option: MAQUET recently released an upgrade of the SERVO-i ventilator system for conditional use in the magnetic resonance (MR) environment. The new SERVO-i MR environment option is capable of providing critically ill patients with advanced ventilatory care using the same machine wherever they are in the hospital- in the ICU, in the MR examination room and during transport to and from the MR room. NAVA (Neurally Adjusted Ventilatory Assist) Technology: NAVA technology is for optional use with the SERVO-i ventilator and is intended for treatment and monitoring of all patient types. NAVA technology detects respiratory signals sent from the brain to the diaphragm and transmits those signals to the SERVO-i ventilator. By enabling the respiratory signals from the patient's brain to control ventilator function, NAVA technology results in unprecedented coordination between diaphragmatic activation and ventilatory support throughout the breathing cycle.

## What new or ongoing educational materials will be available at the convention?

MAQUET will provide educational DVD's such as the SERVO-i Open Lung Tool which discusses restoring healthy alveolar dynamics by the ventilator strategy and the U.S. symposium DVD, Paradigm Shifts in Mechanical Ventilation, which presents cutting-edge knowledge on mechanisms and therapy opportunities related to ventilator-induced lung injury.

## What speakers will your company be working with or featuring?

MAQUET will be hosting a Science and Practical Implementation of NAVA breakfast seminar featuring Christer Sinderby, PhD and Jennifer Beck, PhD on December 3, 2007 from 6 to 8 am at the Marriott World Center (room to be announced). This program has been approved for 2.0 contact hours of Continuing Respiratory Care Education Units (CRCEU) by the American Association for Respiratory Care. Clinical presentations will take place every hour throughout the three day conference in the MAQUET booth featuring Al Fantasia, RRT from Rhode Island Hospital, Scott Small, RRT from AnMed Health System and Kim Watkins, RRT from Swedish Medical Center.

#### What in-booth promotions will you be offering?

Dana Oakes, author of Critical Care Pocket Guides will be present at the MAQUET booth to autograph his latest set of respiratory books. Educational DVD's will also be available, as well as a variety giveaway items.

#### Why should our readers stop by your booth?

Stop by the MAQUET booth to learn more about the latest advances in medical technology such as NAVA and MR environment option. Conference attendee's can hear presentations on real life stories from SERVO users on auto-mode ventilation in the neonatal intensive care unit, lung recruitment using the SERVO-i Open Lung Tool, transitioning a ventilator fleet to SERVO-i's and utilizing the MR environment option.

## IngMar Medical, Ltd.

Information provided by Stefan Frembgen, President of IngMar Medical.

#### What new products do you plan to exhibit?

We are very excited about the new software version 3.0 for our ASL 5000 Breathing Simulator. The ASL 5000 is our high fidelity simulator for neonatal through adult patients. It is used in R&D and in simulation training - as a stand alone respiratory task trainer or interfaced with a manikin or intubation trainer. The new Interactive Control Panel allows you to select preconfigured disease states such as COPD and asthma, or craft real life respiratory scenarios such as weaning a difficult patient from a ventilator. These can then be run with the instructor in the "driver's seat", paced to the learners' progress. With our live, online support system our technical assistance experts can remotely operate your ASL 5000 to quickly help you with most issues. Another exciting new product is the QuickTrigger (QT), which transforms IngMar's QuickLung into a spontaneously breathing test lung. QuickTrigger's ingeniously simple design makes it an easy to use and cost-effective tool for ventilator training and testing. Our new Parabolic Resistor Ring is yet another example of ingeniously simple design. The Resistor Ring provides seven switch-selectable parabolic resistance orifices for ventilator testing (with an available

calibration certificate). Because the resistors are embedded into the Ring, switching between settings is very easy and does not require disconnecting tubing. Seven resistors (Rp 5-500) always remain at your fingertips and won't be easily misplaced.

## What new or ongoing educational materials will be available at the convention?

Our products are educational tools in themselves. We look forward to the opportunity to discuss our customers' particular simulation challenges in person at the show. We will also be offering a free whitepaper on "Risks in Manual Ventilation."

#### What in-booth promotions will you be offering?

Our new Respiratory Resistor Ring for an introductory price of \$299.00 with calibration certificate (a \$100 value).

#### Why should our readers stop by your booth?

Simulation is rapidly becoming a standard methodology in healthcare training, much as it did in aviation training already some time ago. Our article "A Lung by any Other Name" tells more about how we approach the universe of respiratory training through simulation. IngMar Medical is the global expert in respiratory simulation. We have a comprehensive product line, a great team of clinical and technical experts, as well as an exceptional customer orientation. Because of these factors, we can provide solutions for a wide range of respiratory simulation challenges in R&D, ventilator testing, and respiratory simulation training.

## Newport Medical Instruments

Information provided by Janus Baker, Marketing Communications Manager.

#### Products

Newport Medical will be exhibiting in booth # 937 at the 2007 International Respiratory AARC Congress in Orlando, FL. We will feature our newest ventilator, the Newport e360. The e360 gives you all the critical care features you demand in a compact size that might surprise you. We call it Sophisticated Technology Made Simple. Simple to use, in less than 10 minutes you can learn to navigate the controls and graphics screens with ease. Sophisticated modalities include Automatic Leak Compensation, adjustable Slope/Rise and Expiratory threshold, Dual Adaptive Control and a Biphasic Pressure Release Ventilation breath style. In addition we will have the popular HT50 Ventilator. The HT50 has become a leader in the portable ventilator market. Reliable, durable and clinically effective for pediatric to adult patients, the HT50 is also meeting the needs for many emergency preparedness programs around the country and around the world. Stop by for the latest news on the exciting new technology we will be introducing.

#### Education

Do your patients "Sip and Puff?" This is an exciting new technique that allows you to provide noninvasive ventilation without the limitations of a face mask. Newport has put together some training materials on this technique; stop by the booth if you'd like a copy. We also have new white papers (as seen published in this magazine), a quick in-service DVD and other training material for the Newport e360 Ventilator that will be available at the show.

#### Speakers

This year Newport Medical has the honor of hosting a special presentation by the world-renowned clinical researcher and physician, Marcelo Amato, MD, of the University of Sao Paulo, Brazil. Dr Amato is famous for his research into lung protective ventilation strategies for ARDS patients. He is also known for his work in resolving dys-synchrony issues for spontaneously breathing patients during pressure support ventilation. Dr Amato's presentation will focus on the interactivity of the slope rise and expiratory threshold settings and how these ventilation settings impact synchrony during pressure support ventilation. Afterwards, guests will have the opportunity to ask individual questions of Dr Amato. Guests at Newport Medical's special presentation will earn Continuing Respiratory Care Education credit while being treated to lunch. The AARC provides a full day schedule of classes but you need to eat so stop by the booth for an invitation to join us for this special "Lunch and Learn" event. Seating is limited so stop by on the first day of the exhibits to ensure that you can attend.

#### Promotions

We will unveil our new branding campaign at the AARC meeting. After months of research and careful review we found that it was time to freshen our corporate look. It's an exciting new millennium for Newport Medical and we are kicking it off at this meeting. We'll have special promotional items and booth activities to celebrate our new look so please do come by booth # 937. If ventilators are a part of your job then you need to put Newport Medical on your list of 'must see' exhibits at the 2007 AARC Congress. See you in Orlando!

### Compumedics

Information was provided by Compumedics.

What new products do you plan to exhibit?

Computedics will be featuring two of our new products, the SomtéPSG and our ProFusion Sleep software with AASM scoring compliance feature. The SomtéPSG is a 17 channel patient wearable PSG recorder that is suitable for either attended or unattended sleep studies. With Bluetooth wireless connectivity the SomtéPSG size, performance and flexibility is unmatched by anything else out there. Our latest version of ProFusion Sleep software is more than just an upgrade, it is a whole now interface. Most notably, the new software is fully compliant with the new AASM scoring recommendations. Loyal Computedics customers can choose to continue to work in the R and K mode, or easily upgrade to AASM mode with a quick pull-down menu change. With our new fully compliant mode there are no work-around steps necessary as with some other devices. You can even bring older Compumedics patient files into compliance if you choose. Nothing could be more flexible or simple as ProFusion PSG 3.

## What new or ongoing educational materials will be available at the convention?

Compumedics will have details available about all of our online training opportunities. We provide several methods to learn about your equipment and sleep medicine while being eligible to receive CEC credits without ever even having to leave your lab. Convenience is enhanced with flexible scheduling and a variety of topics available from basic to advanced, based on your needs.

#### What in-booth promotions will you be offering?

Purchase a SomtéPSG as a result of visiting our booth and you will receive a credit for \$250 in consumable items from our NeuroMedical supplies catalog. Simply register with our staff and pick up our new catalog so that you can start shopping.

#### Why should our readers stop by your booth?

With several exciting new products including SomtéPSG and our AASM compliant software and two ways to save money while increasing productivity you can't afford not to stop by and see what great new innovations that Compumedics has to offer. (Plus, we're really nice people!)

## **Hamilton Medical**

Information provided by Annette Dusek, National Account Executive, Marketing Support.

#### What new products do you plan to exhibit?

Hamilton Medical plans to showcase the most dramatic improvement in mechanical ventilation in the last 25 years. The new **Hamilton Ventilators** will forever change what the market considers the "standard of care." Every other ventilator is now obsolete.

## What new or ongoing educational materials will be available at the convention?

Hamilton Medical will be offering free registration for our bimonthly Intelligent Ventilation Newsletter, which keeps the healthcare community abreast of issues and events that affect the field of Respiratory Care. Hamilton will also be providing CD copies of presentations from our September 2007 Clinical Expert's Workshop, presented in conjunction with the Rochester Academy of Medicine and the University of Rochester. This CD contains presentations by top clinicians, including Peter Papadakos, MD, University of Rochester Medical Center; James E. Szalados, MD, Park Ridge Hospital; Yuh-Chin Huang, MD, Duke University Medical Center; David Wheeler, RRT-NPS, Cleveland Clinic; Robert Chatburn, RRT-NPS, Cleveland Clinic; David Grooms, RRT, Sentara Health System; Gary Nieman, BS, SUNY Upstate Medical Center; Dwayne Westenskow, PhD, University of Utah and Carlos Lopez, MD, SUNY Upstate Medical Center. Hamilton Medical will also be offering free tuition at our 2008 educational events for anyone who registers at our booth. Hamilton educational events are quickly becoming "must attend" events for anyone with an interest in patient safety and lung protective ventilation.

#### What in-booth promotions will you be offering?

Hamilton Medical will be featuring drawings for attendance at a 2008 Clinical Expert's Workshop and daily drawings for respiratory care textbooks from Robert Chaturn and Peter Papadakos. Selected attendees will also have the opportunity to participate in a preview "workshop" that demonstrates Intelligent Ventilation's unique benefits.

#### Why should our readers stop by your booth?

Intelligent Ventilation makes virtually every other mechanical ventilator obsolete. Hamilton Medical has set a totally new standard in patient safety, error reduction, and risk reduction while improving healthcare quality. This solution is hassle-free for the physician and other healthcare professionals. This solution assists your clinical team in the compliance with known quality indicators. There is simply nothing that equals what Hamilton Medical is offering. We ask that you consider this completely new technology. Any other ventilator without the protections of Intelligent Ventilation is simply obsolete. We urge attendees to confront this rather bold statement. Your attendees and Hamilton Medical are all in this for the patient first. We are confident that with the patient as the focus, there simply is no argument to our bold statements. Hamilton will be in Booth 621.

### Aerogen

Information was provided by John Power, MD and CEO.

#### What new products do you plan to exhibit?

We are very excited to be exhibiting our new single patient use disposable nebulizer, the **Aeroneb Solo**. The Aeroneb Solo is a disposable version of the established Aeroneb Pro nebulizer favoured by leading ventilator manufactures and RT's as their high performance nebulizer of choice. The Aeroneb Solo provides effective dose delivery of physician-prescribed inhalation solutions for infants through adults requiring mechanical ventilation. It produces a fine particle, low velocity aerosol optimized for deep lung deposition with the increased flexibility of intermittent and continuous use. The Aeroneb Solo has been FDA 510 (k) approved since last June.

## What new or ongoing educational materials will be available at the convention?

As a leader in the field of aerosol science we promote continued education and research in the field and will continue our policy of supporting relevant Researcher and RT programs and studies which further knowledge of ventilator nebulization. We will be demonstrating our innovative technology and our exciting Aeroneb Micropump Nebulizer product line for pulmonary drug delivery. All our staff are on hand to answer any questions people may have regarding nebulization of the mechanically ventilated patient. Attendees can take away product information leaflets.

## What speakers will your company be working with or featuring?

We are very pleased to have Jim Fink, Fellow Scientist, Respiratory Therapy with us at our booth.

#### What in booth promotions will you be offering?

Following its huge success last year in Las Vegas we will again be inviting our customers and distributors to join us at our "Irish Party Night" in Orlando. We will also have a competition to win a beautiful piece of hand crafted Irish Crystal.

#### Why should our readers stop by your booth?

Readers should stop by our booth if they want to learn more about how to improve the quality of ventilated patients' lives through the use of our highly efficient nebulizers. We will demonstrate how our nebulizer range saves RTs valuable time as our products operate without changing patient ventilator parameters therefore not setting off ventilator alarms and can be refilled without interrupting ventilation. It may change the way you nebulize forever.

## VIASYS

Information provided by Daniel Van Hise, Vice President of Marketing, Critical Care; Steve Birch, Director of Marketing, Sleep Diagnostics and Therapy and Todd Austin, Sr Director of Marketing and Sales Operations, Diagnostics.

#### What new products do you plan to exhibit?

At the AARC, VIASYS Healthcare will be featuring the new Enve and LTV1150 ventilator systems. Introducing the newest ventilators from VIASYS Healthcare, the ENVE ventilator is a comprehensive, full feature Intensive Care Ventilator with unique ActivCore Technology in an extremely compact package. Featuring an integrated full color LCD display, 4 hour hotswappable internal battery the ventilator is fully wall independent. The comprehensive selection of modes, including non invasive, integrated spontaneous breathing trial and active exhalation valve represent a major paradigm shift in critical care ventilation. A second model based on the breakthrough technology of the ENVE ventilator will bring ICU performance to the sub-acute and home care environment. The easy to use LED display provides exceptional viewing in a variety of environmental conditions, including full sun light. A complete selection of modes, 4 hour, hour hot-swappable internal battery and unique axial compressor technology provide you the clinical performance you need and unprecedented freedom for your patient. Whether in the hospital or in the post acute care facility, the LTV 1150 enables patients to experience the freedom to go home. Patients receiving ventilation support on the LTV 1200 can go home on the LTV 1150 using the same settings! The LTV 1150 extended feature set, including internal PEEP and SBT, is derived from the legendary LTV 1200 and provides a warmer new look that maintains the light weight and small dimensions of the LTV series in a modern, people friendly package.

Additionally, we will be showing several new products in the sleep product family including the new **SomnoStar Orbit**, the BreatheX Journey CPAP system and several updates to our patient interfaces. The SomnoStar Orbit is a compact nine channel portable sleep monitoring which records respiratory movement, nasal air flow, pressure, oximetry and pulse rate, limb movement and body position and is easily downloaded for scoring. The monitor uses zRIP technology for accurate respiratory motion analysis. The BreatheX Journey is the first fully portable CPAP and provides patients with a new way of integrating CPAP into their lifestyle. We will also be introducing new patient interfaces used for CPAP therapy as part of our ongoing program to provide new, innovative and effective technologies to enhance acceptance treatment. Finally, we will be showcasing many new additions and enhancements to our Pulmonary Diagnostic Family including the newly released MicroLoop Office Spirometer which meets all 2005 ATS/ERS Standards, the new MasterScreen PFT Pro with fast-gas DLCO and our VLink Connectivity Solution providing interconnectivity between our diagnostic solutions and commercial EMR platforms.

## What speakers will your company be working with or featuring?

Dr Samuel L. Krachman the Medical Director of the Sleep Disorders Center at Temple University Hospital will speak about COPD and Sleep. The company will also be featuring John H. Arnold, MD, Associate Professor of Anesthesia (Pediatrics), Harvard Medical School, Senior Associate, Anesthesia and Critical Care, Medical Director, Respiratory Care/ECMO/Biomedical Engineering, Children's Hospital and Mark Rogers, BS, RCP, RRT the Clinical Applications Manager of Advanced Product Development at VIASYS Healthcare, Respiratory Care Group will speak on Closed-loop FiO2 control. Other speakers are: Dr Arvind Bhome, International AARC Fellow, Professor of Respiratory Medicine at Bharati Vidyapith Medical College at Pune, India and Programme Director, Intensive Care at Seth Ramas Shah Memorial Hospital and consultant and head of the Department in Pulmonary Medicine, Aditya Birla Memorial Hospital and Research Center. Also speaking will be Gus Ghion, President of Cooperfit, Cooperative of Physiotherapists, Sao Paulo, Brazil, supervisor of home mechanical ventilation at Home Doctor International; Yuki Nakayama, RN, Phd, a nurse from Japan, and respiratory therapist Angela King.

#### Why should our readers stop by your booth?

The new Enve ventilators are a must see. The new ventilator system is the most compact, full-featured ICU ventilator on the market today. In fact, you can actually hold these critical care ventilators in the palm of your hand! The ENVE ventilator is a comprehensive, full feature Intensive Care Ventilator with unique ActivCore Technology in an extremely compact package. A second model based on the breakthrough technology of the ENVE ventilator will bring ICU performance to the sub-acute and home care environment. Our sleep offering is constantly evolving with the introduction of innovative products for polysomnography in the sleep center, for portable sleep monitoring and sleep therapy including devices and patient interfaces. In sleep there is always something new. As the market leader in Pulmonary Diagnostics, our PFT, Exercise and Spirometry line continue to deliver solutions to meet the complete spectrum of our customer's diagnostic needs.

VIASYS Healthcare is now part of Cardinal Health. The global provider of products and services that improve the safety and productivity of health care, acquired VIASYS Healthcare in the 3rd quarter of 2007. The acquisition of VIASYS expands Cardinal Health's clinical and medical product offerings for global, acutecare customers and, will establish the company as a leader in the more than \$4 billion respiratory care market. The business will be integrated into Cardinal Health's Medical Products Manufacturing segment.

## MediServe

**Breathe Easy:** MediServe Knows Respiratory. For over 25 years, MediServe has been in the Best Practice business. In a field where Investment Strategy and IT have merged, survival requires more revenue, less risk, and better medical outcomes. By combining financial intelligence with clinical expertise, we help Respiratory Care facilities improve their bottom line. MediServe clients are partners for life. We provide ongoing engagement and solutions assessment to ensure continued client success. The results speak for themselves:

- Sutter Health Sacramento Sierra Region experienced a \$10M improvement in total net revenue.;
- Santa Clara Valley Medical Center (San Jose, CA) experienced a 20% increase in charge capture within six months;
- SUNY Upstate University (Syracuse, NY) saved \$500,000 in traveling therapist costs within eight months;

• Methodist Hospital (Henderson, KY) experienced a total net revenue improvement of \$162,000 within one year.

## How did our respiratory clients achieve these outstanding returns?

MediServe helps clients to implement a top-down vision for how IT can support operations as a whole. Best practices we recommend include the formulation of an IT steering committee, led by the CFO and including appropriate clinical decision makers. This committee, with whom MediServe continues to consult, evaluates the most suitable technology while instituting effective process changes throughout the entire organization. Regarding suitable technology, our leading application, MediLinks for Acute Respiratory Care, has achieved the following:

- 25% Revenue Increase in First Year
- Lower costs
- Decreased length of stay
- Decreased mean hours of ventilation
- 15% increase in charge capture
- 15% increase in the rapist productivity - 90 minutes saved per FTE per day; - Improved morale

Improved Clinical Care

- Worklist Generator Assigns tasks at the therapist level
- Inappropriate the rapies reduced by 50% or more
- Superior outcomes and data capture
- Easy access to patient history and results

#### Reduced Risk

- Minimizes potential liability via thorough, timely, accurate documentation
- Enhanced compliance: Facilitates conversion to Electronic Medical Record (EMR) format; - Meets respiratory clinical data requirements; - Meets patient care and HIPAA/CMS regulatory standards

MediServe applications are easy to use so that clients experience smooth system migration and realize prolonged, comprehensive efficiencies. When clients operate in an environment that does not yet support optimal performance, we are prepared to make recommendations that touch on everything from HR, to patient scheduling and outcomes, to revenue management. A service-orientation is critical on the part of those that design systems for respiratory information management. MediServe is there at the forefront. For more information, call MediServe at (480) 831-7800.

## Radiometer

#### What new products do you plan to exhibit?

Radiometer will be exhibiting its **ABL800 FLEX STAT** analyzer with creatinine (new parameter) and its **ABL80 FLEX POC** analyzer with glucose (new parameter).

#### What in-booth promotions will you be offering?

We will be conducting a video game racing contest in our booth ("Satisfy your need for speed"). Player with the best time wins. The winner gets a \$500 Best Buy gift card.

## **Masimo Corporation**

Information provided by Dana Banks, Manager, Public Relations

#### What products do you plan to exhibit?

Masimo will be showcasing its innovative, upgradeable technology platform-the Masimo Rainbow Platform, and introducing a new remote monitoring and clinician notification system, Masimo Patient SafetyNet, at this year's 53rd International Respiratory Congress in Orlando. The Masimo Rainbow Platform is a multi-functional technology platform with maximum clinical flexibility, allowing respiratory care professionals to choose the features and parameters needed to meet their specific clinical requirements. Masimo Rainbow devices come standard with "gold standard" Masimo SET pulse oximetry, providing accurate and reliable SpO2, pulse rate and perfusion index measurements, even in the most difficult clinical conditions. In addition, clinicians can choose to upgrade to additional measurements including continuous noninvasive carbon monoxide (SpCO) and methemoglobin (SpMet) monitoring and Pleth Variability Index (PVI) simply by purchasing field-installed software upgrades whenever they need them. As Masimo scientists continue to develop additional clinically relevant measurements, these new features can be added through simple software upgrades as they become available. Masimo Patient SafetyNet combines the "gold standard" of Masimo SET pulse oximetry with wireless clinician notification via pager to provide a new level of safety to patients on general care floors, where nurse-to-patient ratios preclude the level of direct surveillance required and recommended to preempt sentinel events. Masimo Patient SafetyNet offers a comprehensive solution to patient safety issues, with the availability of continuous monitoring of oxygenation and trustworthy alarms sent directly to qualified clinicians today, and the ability to upgrade the system to add other features, measurements and parameters such as ETCO2 and respiration rate as they become available in the future.

## What new or ongoing educational materials will be available at the convention?

General Floor Monitoring Biblio – A literature summary of relevant articles that demonstrate the prevalence and pervasive need to monitor patients on the general floor, with emphasis on patient safety, monitoring patients under opioid pain management strategies (especially those with concommitant sleep apnea), improved healthcare delivery efficiency and enhanced patient throughput. General Floor Monitoring Whitepaper – A needs assessment and solution definition for monitoring patients on the general floor, with focus on postsurgical patients, patients with OSA, patient-controlled analgesia, alarms annunciation and alarm escalation.

## What speakers will your company be working with or featuring?

RESPIRATORY CARE OPEN FORUM #2, Monitoring. VAP. Sleep, 12:30-2 (Saturday Dec 1): Mark Macknet, MD, Loma Linda CA – Continuous Non-Invasive Measurement of Hemoglobin Via Pulse CO-Oximetry During Major Surgery. Frank Marx MEd, Wesel, Germany – Detection of CO-Poisoning Through Pulse-CO-Oximetric Measurement. Jason Elliot PA, Turlock CA – RAD 5 and MRL SpO2 Comparison Trial: A Prospective Analysis of Pulse Oximetry During Air Transport.

RESPIRATORY CARE OPEN FORUM #17, Devices/Techniques/

Results—Part 3, 1-2:55 (Tuesday Dec 4): Mitchell Goldstein, MD, Loma Linda CA – The Use of Pleth Variability Index (PVI) to Detect Changes in Intrathoracic Pressure; Mark Macknet MD, Loma Linda CA – Accuracy of a Novel Bioacoustic Sensor in Postoperative Patients; Benzocaine Induced Methemoglobinemia After TEE.

#### Why should readers stop by your booth?

Only Masimo combines an upgradeable platform for growth with an unbeatable record of innovation. Stop by booth #1121 to see a live demo of the Masimo Rainbow Platform, Masimo SET and the new Masimo Patient SafetyNet in action.

## VORTRAN Medical Technology, Inc.

Information provided by Jody McCarthy, Director of Sales and Marketing.

#### What new products do you plan to exhibit?

We plan to exhibit and show our new products and services expanding our product offering and customer service. We are excited about our future new products and services expanding our product line and customer service offering.

## What new or ongoing educational materials will be available at the convention?

Demonstration of our products and services adds to the element of interactivity that connects the prospect to our future. Ongoing educational materials available for the convention is our interactive CDROM containing a multi-medias presentation for PC platform, which includes three instructional videos, brochures and user guides in pdf for all VORTRAN products. Our CDROM will help answer questions on the operations and applications of our products and provide for future training needs. In addition to our CDROM, we'll have Educational Module Sponsorship program flyers for free "CEU" that provides online continuing education, 1 contract hour (CEU) at no charge to medical professionals at accessce.com. Course title "Gas Powered Automatic Resuscitator for Short Term, Emergency Ventilator." New Educational Modules are being developed for a workshop and information packet providing subject matter pertinent to mechanical ventilation in Disaster and Mass Casualty Incident (MCI) scenarios. The program will assist clinicians and serve as a re-certification tool with emphasis on the use of pneumatic ventilatory assist devices and provide general ventilatory augmentation in high-impact Disaster and MCI medical operations.

## What speakers will your company be working with or featuring?

Our company sponsorship and speaker opportunities will take place in the 2008 Congress. We are working with a pre-eminent expert in developing presentation programs and a workshop that supports clinician skill and commitment to respiratory care as well as foster guidance for the medical community charged with preparing for Mass Casualty and Mechanical ventilation.

#### What in-booth promotions will you be offering?

We will be offering in-booth promotional office accessory giveaway items. Colorful, translucent orange and bright yellow imprinted with company logo and contact information. Daily use items not only drive traffic to our booth they create and keep our message awareness of our products in the public eye.

## Why should Respiratory Therapy readers stop by your booth?

We recommend Respiratory Therapy readers to stop by our booth (1029-1031) for the opportunity of obtaining flyers for FREE online "CEU", product setup instruction and demonstration, information for upcoming workshop "Mechanical Ventilation in Disaster/Mass Casualty Incident" scenarios and giveaway items.

## VersaMed Medical Inc.

Information provided by Wayne Wrolstad, Director of Marketing.

## What new products will you be showing at the AARC this year?

Our current **iVent201 Ventilator** has been significantly enhanced and will showcase upgrades such as an integral, programmable Nebulizer, extended life 4-hour battery and optional, integral pulse oximetry. Our new **Disaster Preparedness iVent** has undergone significant modifications to accommodate those special needs and will be on display. Finally, our enhanced leak compensation software will be demonstrated in our non-invasive mode – Adaptive Bi-level.

## What new or ongoing educational materials will be available at the convention?

A complete and comprehensive new educational CD, providing clinical and product specific training, will be available at no charge to existing and new customers during the AARC meeting. In addition, our new **Total e-Support Solutions** (TeSS) will be featured, demonstrating our dedication to top notch customer service and the ability now for our customers to conduct on line product and clinical training, from basic 'buttonology' to advanced waveforms and graphical analysis at any time.

## What speakers will your company be working with or featuring?

VersaMed has numerous and on-going working relationships with leading researchers in mechanical ventilation whose expertise is presented in the products VersaMed is featuring at AARC.

#### What in-booth promotions will you be offering?

VersaMed will offer a contest challenging participants to walk through a simple Adaptive Bi-level set up with out iVent201 Ventilator. Each participant will be entered into a follow-up drawing. Several winners will be announced and prizes distributed on Monday, December 3rd. Special pricing for an allinclusive 3-Year Warranty will be announced and offered for the month of December and the first quarter of 2008.

#### Why should our readers stop by your booth?

Over the past few years, VersaMed has emerged as the leader in cost effective versatility and NIV in the mechanical ventilation marketplace. Our high performance yet rugged ventilators are used non-invasively in the ICU setting to treat hypercapneic and/or hypoxemic respiratory failure and insufficiency as well as invasive application, the MRI suite, air transport, in-house transport, subacute setting, LTAC, disaster preparedness national stockpile, as well as militaries in the US, Canada and Israel. The combination of features, performance, price, clinical support and technical support brings forth a value proposition the AARC attendees cannot afford to miss.

## **Optimedical**

Information provided by Chris Southerland, VP of Sales and Marketing.

#### What new products do you plan to exhibit?

OPTI Medical plans to exhibit the **OPTI R blood gas analyzer.** 

#### What in-booth promotions will you be offering?

OPTI Medical will offer ComfortSampler arterial blood gas collection device trial kits at no charge.

#### Why should readers stop by your booth?

Please stop by our booth to learn why the OPTI point of care critical care analyzers, which use state of the art optical fluorescence technology, are beneficial for your hospital testing needs. Stop by our booth to register to win a new iPod nano by filling out a brief market survey.

### **Hollister Incorporated**

Information provide by Connie Wilson at Hollister.

What new products do you plan to exhibit? Anchor Fast Oral Endotracheal Tube Fastener.

What new or ongoing educational materials will be available at the convention? Updated product literature.

#### What speakers will your company be working with or featuring?

Please join Hollister Incorporated for State of the Science: Securement of Oral Endotracheal Tubes, Sunday, December 2nd from 6:30 am to 8:15 am. This educational breakfast symposium will highlight the science of endotracheal tube attachment and will be presented by Michael J Hewitt, RRT-NPS, RCP, FAARC, Director of Respiratory Care and Pulmonary Diagnostic Services at Memorial Hermann Texas Medical Center, Houston, TX and Shirley, Ambutas, RN, CCRN, Critical Care Nurse Specialist, Provena Saint Joseph Medical Center, Joliet, IL.

What in-booth promotions will you be offering?

Opportunity to touch and feel the new Anchor Fast Oral Endotracheal Tube Fastener.

#### Why should our readers stop by your booth?

See the latest technology for securing oral endotracheal tubes without tape.

### Vapotherm, Inc.

Information provided by Kevin Thibodeau, Vice President – Sales & Marketing.

#### What new products do you plan to exhibit?

We will be exhibiting Vapotherm's new **Precision Flow.** This is a brand new product that is pending FDA clearance and which incorporates a unique array of functionalities, creating a new state of the art in the expanding category of High Flow Oxygen Therapy via nasal cannula.

#### What functionality has been added?

Precision Flow integrates flow controllers, air oxygen blender and oxygen sensor along with humidification technology in one device. As a result, we now have a single device that not only uses a nasal cannula to deliver flows from 0.5 L/min to 40 L/min at body temperature and humidifies up to 100% relative humidity, but which also controls and measures oxygen for synchronized  $FiO_2$  management. This greatly simplifies usage for the clinician. One device perfectly orchestrates the optimal conditioning of high flows of oxygen at the right heat, at the right level of humidity and at the right percentage of oxygen. It's easy for the clinician to use, and it's great for keeping patients in need of respiratory assistance from regressing to more invasive modalities of therapy.

## What new or ongoing educational materials will be available?

Vapotherm continues to build its online **Vapotherm Education Center**, delivering continuing education offerings for respiratory therapists and other health care professionals. We also have included an online knowledgebase customer support program and service. This enables a quick search of a wide variety of materials associated with high flow oxygen therapy for clinicians and patients alike. We also will be distributing a helpful Inservice Video DVD that introduces new users to the Precision Flow.

#### What clinical support does Vapotherm offer?

Vapotherm has been a research leader with more than 80 clinical studies spread among adult, pediatric and neonatal patient populations. Since we consider this to be our backbone, we always have multiple studies in the pipeline. In addition, we have a team of Clinical Product Specialists in the field, and each one of them is a Respiratory Therapist. We believe education is the key to our success, so we consider thorough inservicing by qualified individuals to be an essential part of our service.

#### What in-booth promotions will you be offering?

We will have several in-booth promotions as well as press events to announce the launch of Precision Flow .

#### Why should our readers stop by your booth?

Put simply, to see the new state of the art in High Flow Oxygen Therapy. We have witnessed a dramatic level of interest in High Flow among the respiratory care community and this launch is a major event. We are unveiling a revolutionary device that adds significantly to the medical equipment arsenal of the healthcare professional. Precision Flow presents the discerning clinician with the opportunity to decrease the incidence, risk and cost of more invasive respiratory therapy.

## Dräger

Information provided by Robyn Whalen, RN, BSN, MBA, Director, Marketing Critical Care (Care Area Director, Dräger).

#### What new products do you plan to exhibit?

Dräger will demonstrate how we are revolutionizing the acute point of care with comprehensive **CareArea Solutions** for Critical Care. We will showcase our full line of ventilation products that support all patient categories – neonatal, pediatric and adult – in typical and advanced hospital settings. In addition to products for hospital use, Dräger offers homecare ventilation solutions and a full line of emergency and transport ventilators for helicopter and ambulance use. The focus will be on access to information, workflow, and enhanced patient care through Dräger's innovative advanced technologies such as **SmartCare**, our open airway breathing system, and our NIV (Non-Invasive Ventilation) capabilities.

## What new or ongoing educational materials will be available at the convention?

Dräger will present AARC attendees with an **Evita Trainer** upon completion of an introduction to the SmartCare option for the EvitaXL ventilator. This real-time simulation tool was created to educate respiratory therapists on the use and handling of the **EvitaXL**, **Evita 4**, and **Evita 2 dura**. The trainer is currently being used in hundreds of hospitals around the world to teach new practices in ventilation therapy to other healthcare professionals. The simulation mode reproduces curves and measured values similar to real patient settings.

#### What in-booth promotions will you be offering?

Dräger will promote the SmartCare option for the EvitaXL ventilator. Introduced in late 2005, SmartCare is a knowledgebased ventilation system developed to improve the efficiency and effectiveness of the weaning protocols. Ventilation weaning protocols have been shown to reduce length of stay [E.Wesley Ely, New England Journal of Medicine (1996), Vol. 335:1864-9]. SmartCare automates the weaning process, based on the user's input, and uses continuously measured parameters and patient respiratory profiles. As the level of ventilator support is adjusted automatically, the patient's response and ability to adapt to each change in support is evaluated.

#### Why should our readers stop by your booth?

In 1907, Dräger introduced the Pulmotor, which was the beginning of a new era in life-support patient ventilation. Over the past 100 years, Dräger has developed into a world-leading solution provider for ventilation therapy through a series of innovations focused on ventilation performance for improved patient outcomes. We offer products, services and integrated CareArea Solutions throughout the patient care process - all designed to help you improve the quality of care and increase your productivity. We invite you to stop by our booth to discover how all our innovative Critical Care solutions can impact your care process. Dräger offers ventilation products that support all patient categories-neonatal, pediatric and adult-in typical and advanced hospital settings. In addition to products for hospital use, Dräger offers homecare ventilation solutions and a full line of emergency and transport ventilators for ambulance use.

## **B&B Medical Technologies**

Information provided by Beth Keifer, Vice President, Sales and Marketing.

#### What new products do you plan to exhibit?

B&B Medical Technologies' legacy of developing and delivering useful and needed specialty airway management solutions for use in adult, pediatric and infant patients continues to expand A World of Products for Better Breathing with our introduction of several new and improved products. **Baby E.T. Tape** has been improved to better accommodate sensitive skin conditions. Made of a latex-free hydrocolloid material, Baby E.T. Tape safely provides a hypo-allergenic solution to secure the endotracheal tube, the NG tube, OG tube and nasal CPAP prongs. It provides durable support to the tube and is very soft to the tender skin. Baby E.T. Tape is used in busy NICUs, labor and delivery and transport conditions where babies are frequently repositioned. Likewise, for pediatric patients, B&B Medical Technologies has introduced the new Pediatric E.T. Tape, which provides the same hypo-allergenic solution for care using latex-free, hydrocolloid materials as found in our Baby E.T. Tape. The Pediatric E.T. Tape can be trimmed to fit the small infant to pediatric patient. Also new in the B&B product line is the addition of hydrocolloid features to B&B's Stabilitube, our premier long-term endotracheal tube stabilizing system that secures the endotracheal tube in less than 10 seconds. Always latex-free, the addition of hydrocolloids now makes Stabilitube even more effective for use with patients where secretions or wound exudate must be considered.

B&B Medical Technologies' **Test Lung** for use with Adult and Pediatric patients will provide the respiratory and pulmonary care community an integral tool for demonstration and testing of mechanical ventilators. The Test Lung imitates the respiratory system of both an adult and pediatric patient, and provides nominal levels of resistance and compliance as well as a variable leak function to simulate a patient circuit leak. The high-quality, durable, yet economical Test Lung features a silicon bag that allows for easy cleaning and sterilization. For securing and controlling cables, cords and hoses, B&B Medical Technologies' **Wrap-Safe** is the answer. The Wrap-Safe is designed to permanently stay on the cord, cable or high pressure hose. The cord, cable or hose can be wrapped to assure a securely fastened, tangle-free cable, cord or hose ready for transport or storage.

## What new or ongoing educational materials will be available at the convention?

B&B Medical Technologies recently has redesigned and updated our website to make it more effective and easy for practitioners to access information about B&B's World of Products for Better Breathing. At BandB-medical.com, site visitors can see our complete line of specialty airway management products, download training modules, product specific Policies and Procedures and pathways to contact us.

#### What in-booth promotions will you be offering?

B&B Medical Technologies will provide the updated B&B Educational CD at the ARRC. Educators and Managers will find the CD particularly useful in providing inservice education and training to the Respiratory Care Practitioners.

#### Why should our readers stop by your booth?

B&B Medical Technologies' legacy is providing cost-effective specialty airway management solutions for adult, pediatric and infant patients. Our products are: • Safe for all Patient Populations • Easy to Use • Convenient in all Emergent Conditions • Compliant with 2005 AHA Guidelines for securing Endotracheal tubes • Improved with Hydrocolloid materials for tender skin conditions • Latex-free • Cost-effective • Versatile – Products designed for all critical care environments.

## Medical Graphics Corporation

#### What new products do you plan to exhibit?

CCM Express - Indirect calorimeter used to optimize nutritional support, monitor patients with metabolic disorders and reduce the number of ventilator days in ICU. The system's Direct Connect preVent Pneumotach allows measurement at the endotracheal tube eliminating the need to correct for bias flow & pressure support. The system can easily be used with a wide variety of ventilators found in the ICU/CCU. Spontaneous breathing patients can be assessed using mouthpiece, mask or face tent. The small, compact design, gasless calibration and onboard computer with intuitive software make the Express a cost effective and simple to use system. Also exhibited will be Medical Graphics' BreezeSuite 6.3 Software – New BreezeSuite software is compatible with Microsoft Vista. Offering customized displays and Microsoft SQL Database, BreezeSuite is easy to learn with real time on-screen instructions to take you through the entire testing process. Point and click navigation allows you to focus on the patient not the system.

## What new or ongoing educational materials will be available at the convention?

Monograph - "Nutritional Assessment via Indirect Calorimetry."

#### What in-booth promotions will you be offering?

Prize Drawing:

- 1st Prize Airfare, hotel, and tuition for the annual Medical Graphics Cardio-Pulmonary Seminar in Las Vegas, Nevada;
- 2nd Prize Hotel and Tuition for the Medical Graphics Cardio-Pulmonary Seminar
- 3rd Prize Tuition for the Medical Graphics Cardio-Pulmonary Seminar. (Registration for drawing to take place at the Medical Graphics booth). Also offered will be introductory pricing on the CCM Express.

#### Why should our readers stop by your booth?

- Participate in the prize drawings (worth up to \$3,000)
- Learn about the latest products from Medical Graphics, including the CCM Express
- Visit our booth to help us celebrate our 30th anniversary of providing clinical solutions for cardio-pulmonary diagnostics.

## **Fisher & Paykel Healthcare**

Information provided by Rob Cornell, MS, RRT, Clinical Products Manager.

Fisher & Paykel Healthcare has a long history of developing innovative products for respiratory care, and we are pleased to be featuring several of these new products at the AARC 53<sup>rd</sup> International Respiratory Congress in Orlando, FL. Some of the items featured include the **Evaqua** breathing circuit technology, **Optiflow High Flow Humidity Therapy**, the **Neopuff Infant T-Piece Resuscitator**, **ThermoSmart** humidified CPAP for OSA and the **Opus** <sup>360</sup> **Nasal Pillows Mask** for OSA.

As part of the MR850 Humidification System and the strategy of One System All Patients, we are featuring the Evaqua breathing circuit technology and the Optiflow High Flow Humidity Therapy. The Evaqua breathing circuit technology is an important and unique technology exclusive to Fisher & Paykel Healthcare High Performance Breathing Circuits, which helps to further improve circuit condensate control performance.

Evaqua breathing circuits have a heated expiratory limb made from a unique material that allows water vapor to exit the circuit rather than collecting as condensate inside the circuit. Optiflow High Flow Humidity Therapy provides a large bore nasal interface capable of handling gas flows to 50 LPM for adults with low system back pressure and superior condensate control performance. Optiflow was originally developed 5 years ago for xerostomia and mucusitis applications, but recently this device has also been used successfully in many more common clinical scenarios from acute respiratory failure and trauma to long term support for chronic COPD, cystic fibrosis and asthma. Optiflow also has applications with neonatal patients with a slightly different setup configuration. The key to success with Optiflow<sup>TM</sup> is applying it with body temperature and saturated gases with the MR850 humidifier. Attendees at the AARC will be able to experience Optiflow High Flow Humidity Therapy at the Fisher & Paykel Healthcare Booth 1329, as well as enter a daily drawing for an Apple iPod and other prizes.

The Neopuff Infant T-Piece Resuscitator mentioned in the new Neonatal Resuscitation Program Guidelines will also be on display, and attendees at the AARC can try their resuscitation skills against the resuscitation simulator. Also on display are a unique line of neonatal resuscitation masks with the first ever 35 mm mask for extremely low birth weight patients.

ThermoStart humidified CPAP and Opus <sup>360</sup> Nasal Pillows Mask are Fisher & Paykel Healthcare's latest offering for the treatment of Obstructive Sleep Apnea. ThermoSmart is a CPAP with an integrated humidifier and a heated circuit that provides the benefits of humidification for OSA patients and the simplest and easiest to maintain delivery system with superior condensate control.

The Opus <sup>360</sup> Nasal Pillows Mask is small, quiet and superbly comfortable, offering unprecedented freedom. The slim-line design allows for almost any sleeping position without mask displacement.

Fisher & Paykel Healthcare invites you to visit us at the AARC, Booth 1329 for a closer look at these new exciting products. Contact Rob Cornell, MS, RRT, Clinical Products Manager, (800) 792-3912 x 1301, rob.cornell@fphcare.com.

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