

Volume 6 Number 4 August-September 2011

# Respiratory Therapy™

The Journal of Pulmonary Technique



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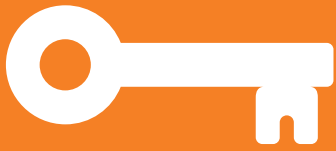
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## Respiratory Therapy™

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Vol. 6 No. 4  
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## Editorial

### HUMAN SUBJECTS

Here's an interesting take on research that appeared recently on BioMed Central, by Mark Rice, with the Department of Anesthesiology at the University of Florida College of Medicine, who makes a compelling argument for using humans, not animals.\*

Rice says: "Biomedical research today can be generally classified as human-based or nonhuman animal-based, each with separate and distinct review boards that must approve research protocols. Researchers wishing to work with humans or human tissues have become frustrated by the required burdensome approval panel, the Institutional Review Board [IRB]. However, scientists have found it is much easier to work with the animal-based research review board, the Institutional Animal Care and Use Committee. Consequently, animals are used for investigations even when scientists believe these studies should be performed with humans or human tissue. This situation deserves attention from society and more specifically the animal protection and patient advocate communities, as neither patients nor animals are well served by the present situation...

"Numerous groups have endorsed the reduction or elimination of nonhuman animals (hereafter referred to as animals) from research, but judging by the best estimates, this has not happened. Indeed, the number of animals used in research is skyrocketing. Although the exact number of animals used per year in the USA have never been available, estimates now [are] approximately a half-billion, with genetically-modified animals counting for the majority. Clearly, efforts to reduce the total number of animals used in research have failed. It is statistically more likely to get animal-based research funded by the National Institutes of Health and other funding agencies than human-based research. Moreover, the amount of basic research being translated into human treatments appears to be at an all time low. An editorial in Nature lamented the fact that every week the scientific community hears of animals being cured of some disease, but these advances are not translating to humans... I am not an animal protectionist, welfarist, or rightist. I am a physician-scientist who prefers to do human clinical research. I have migrated to this position, in part, because I now question if animal-based research per se is predictive for the human being modeled... As my career progressed, I became more interested in doing human clinical research. One reason was my disillusionment with using animals to model human conditions. Sometimes, animal models worked very well but many times they did not—the problem was that prospectively we didn't know into which category the laboratory work would fall. It seemed my time, effort, and valuable resources could be better spent working directly with humans.

"Our group has recently been successful in several research areas including our recent debunking of a myth regarding the anatomical nomenclature of the airway. This study was done in humans because we were interested in the anatomy of ... humans. In addition, the airways of the animals most commonly used in laboratories are not the same as the human airway and we believed animal imaging would have been of no assistance in proving our hypothesis.

"I have no ethical inhibition about using animals to find cures for human disease. The current law allows using animals in research and regulates the process. But using them as predictive models or what has been called causal analogical models, in applied research, such as drug and disease research specifically, has not been a useful exercise.

"One reason for the high cost of medications today is the fact that drugs fail late in development. Only about 11% of all drugs entering Phase I human clinical trials make it to the market (the failure rate for cancer drugs is around 95%). [A researcher stated,] "The higher failure rates in [some] areas are in part due to the relatively unprecedented nature of the drug targets being pursued and to the lack of animal models with a  
*Continued on page 58...*



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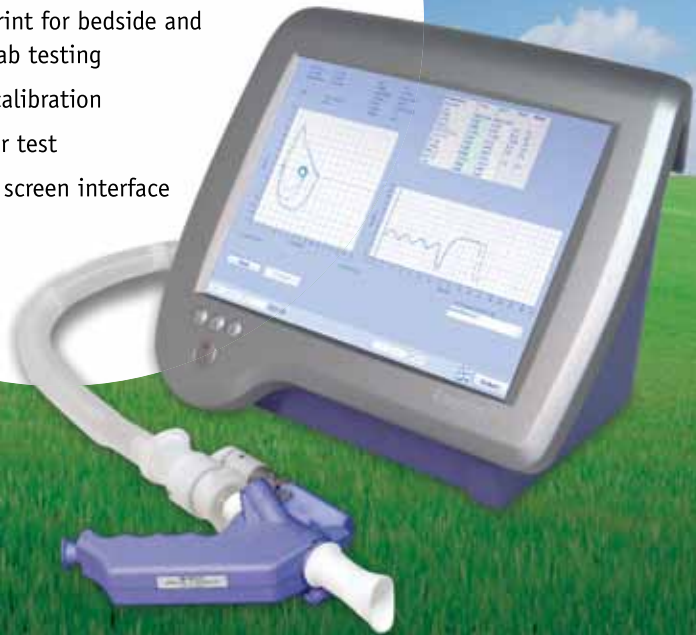
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## AARC CAPNOGRAPHY GUIDELINES

AARC Clinical Practice Guideline: Capnography During Mechanical Ventilation. [Reported by Jeff Borriak, BS, RRT, Clinical Support Specialist, Hamilton Medical, Inc. This item appeared in Hamilton's Newsletter.] Capnography is the continuous analysis and recording of the carbon dioxide (CO<sub>2</sub>) concentration in expired gas from the lungs. Capnography provides a CO<sub>2</sub> waveform. It is generally used for verification of artificial airway placement, assessment of pulmonary circulation and optimization of mechanical ventilation. Capnograph devices generally utilize either mainstream sampling technology, which incorporates a sampling window into the ventilator circuit for continuous measurement of CO<sub>2</sub>, or sidestream sampling technology which samples gas from the ventilator circuit and then analyzes it in another location. Capnograph monitoring capability utilizing either sampling technique can now be incorporated into the monitoring package of some mechanical ventilators. In the April 2011 issue of *Respiratory Care*, the American Association for Respiratory Care published its Clinical Practice Guideline for capnography during mechanical ventilation for 2011. The updated clinical practice guideline is based on a systematic review of 234 clinical studies and 19 review articles of capnography during mechanical ventilation published between 1990-2010, and the 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. The guidelines are graded by the available evidence. Confirmation of ERR placement with capnography received the highest grading recommendation, followed by use of a CO<sub>2</sub> detector without waveforms, for buiding ventilator management, during transport, to detect expiratory obstruction, to assess deadspace and CO<sub>2</sub> elimination (volumetric CO<sub>2</sub>) and to assess adequacy of chest compressions and circulation during CPR. [Reference: Walsh BK, Crotwell DN, Restrepo RD. AARC Clinical Practice Guideline. Capnography/ Capnometry During Mechanical Ventilation: 2011. *Respir Care*. 2011 Apr; 56(4): 503-9.]

## BIOMED CENTRAL

BMC International Health and Human Rights, Diabetology and Metabolic Syndrome, Italian Journal of Pediatrics, Journal of Ethnobiology and Ethnomedicine and Journal of Ovarian Research have been accepted for Impact Factor tracking and will receive their first 2011 Impact Factors in 2012... Systematic Reviews: Increasing transparency and innovation, is a new journal encompassing all aspects of the design, conduct and reporting of systematic reviews in healthcare. Systematic Reviews is now accepting submissions. To mark Stem Cell

Research & Therapy's first anniversary, the journal has published an editorial from the Editors-in-Chief selecting some highlights from its first year. Journal of Medical Case Reports launches its first thematic series on the importance of case reporting across all fields of medicine. The aim of the series is to highlight the useful aspects of case reports and encourage doctors everywhere to continue the practice... Tobacco Induced Diseases has published a collection of reviews on mentholated cigarettes and public health... BMC Medicine is seeking submissions of original research offering novel translational and clinical insights into stem cell therapies, to be presented as part of an ongoing stem cell series. Raymond Hutubessy and colleagues from the World Health Organization (WHO) have published a series of three articles for BMC Medicine that aim to make decision makers more aware of the intricacies of different types of cost effectiveness models for vaccination programs, and to encourage modelers to share their expertise. In other BioMed news, BioMed Central will hold the second Open Access Africa conference at the Muhimbili University of Health and Allied Sciences (MUHAS), Tanzania, in partnership with Computer Aid International. It'll take place October 25-26. Complementing the conference, BioMed Central has launched a free Foundation Membership and an Open Access Package for university libraries in low-income countries. Contact [biomedcentral.com](http://biomedcentral.com).

## INCOMPARABLE

Placebo Journal reports: "The Centers for Medicare & Medicaid Services has launched a website called Physician Compare. It shows a doctor's name, practice location, phone number, Medicare participation status, gender, any foreign languages spoken, the doctor's education and if he or she successfully participated in Medicare's Physician Quality Reporting System in 2009. Unfortunately, it is filled with misspellings, locality mistakes and other errors. It is all explained in the AMA's American Medical News. One clinic spokesman said, 'The lack of effective and timely assistance we have received in response to our questions, as well as the lack of coordination among the entities supposedly involved in the Physician Compare website, is maddening.' What? A government run program with these kind of problems? Yup. Actually, that quote basically will sum up all health care in the future." Placebo Journal quoted the AMA's website, [amednews.com](http://amednews.com), as follows: "Doctors and other health professionals have been disheartened with what they've found out about themselves on Medicare's Physician Compare website. Name misspellings, locality mistakes and other errors have physicians questioning the integrity and accuracy of the information on the site and wondering if it can become a legitimate comparison tool for health care consumers... A patient can view the doctor's education and see if he or she successfully participated in Medicare's Physician Quality Reporting System in 2009. But physicians, other health professionals and office staff checking their own information on the site found numerous errors shortly after the launch date. Only four of the 14 physicians at Midlands Orthopaedics, PA, in Columbia, SC can be found on the website as being a part of the practice, said Midlands CEO AnnMargaret McCraw. In addition, two physicians no longer with the practice, one who left in 2004 and the other who left in 2007, still appear to be a part of the group to anyone searching for them online. McCraw and the group's human resources specialist, Kimberly Chapman, have attempted to correct the online directory without success. 'I have no objection to the concept of the Physician Compare website as a resource for patients if we could rely on the information presented there to be accurate,' McCraw said. "The lack of

effective and timely assistance we have received in response to our questions, as well as the lack of coordination among the entities supposedly involved in the Physician Compare website, is maddening.' The American Medical Association recently solicited feedback from physicians about the site, and numerous practices from all over the US reported that information was incorrect or missing. Typical errors were name misspellings, the inclusion of physicians who either had retired or died, and incorrect Medicare participation status... Physicians [are] concerned that if CMS can't get relatively simple biographical information right, expanding the site by 2013 to include performance scores or other quality data might not result in a trustworthy resource for patients." Visit placebojournal.com for more relevant news and humor.

### TB TRIALS

Results from one of the largest US government clinical trials on tuberculosis preventive therapy to date suggest that treatment for latent tuberculosis infection – normally a difficult and lengthy regimen – may soon be easier than ever before in countries with low-to-medium incidence of TB. The trial results showed that a supervised once-weekly regimen of rifampine and isoniazid taken for three months was just as effective as the standard self-administered nine-month daily regimen of isoniazid, and was completed by more participants. The multi-country, CDC-sponsored trial tested the effectiveness of this new preventive TB treatment regimen (using currently available anti-TB drugs) among persons with latent TB infection who are at high risk for progression to TB disease. The results were presented at the American Thoracic Society International Conference in Denver by principal investigator Timothy Sterling, MD, of Vanderbilt

University. The new regimen to treat latent TB reduces the doses required for treatment from 270 daily doses to 12 once-weekly doses, making it much easier for patients. The study lasted approximately 10 years and included 8,053 participants over the age of 2 who lived in countries with low or medium TB incidence, with the majority from the United States or Canada. Participants were randomized to receive one of two preventive treatment options – a regimen consisting of three months of once-weekly rifampine 900 milligrams and isoniazid 900 milligrams given with supervision (that is, directly observed therapy), or the current standard regimen used to treat latent TB infection, consisting of nine months of daily isoniazid 300 milligrams, which was not supervised. Each participant was evaluated for treatment-related adverse events, adherence to treatment, survival, and development of TB disease for a total of 33 months after the date of their enrollment. The new regimen was found to be safe and as effective as the standard regimen in preventing new cases of TB disease, with very few cases of TB disease developing in either study arm. Seven cases occurred among those receiving the new treatment regimen compared to 15 among those receiving the standard treatment. Additionally, the percentage of participants completing the new, shorter regimen was substantially higher (82%) than the percentage completing the standard regimen (69%). Given the promise of these results, CDC has held an expert consultation to review the data and begin working on new guidelines for its use in the United States. Researchers caution that these results are only directly applicable to countries with low-to-medium incidence of TB. Additional studies will likely be needed before this new regimen can be recommended in countries with a high incidence of TB, especially those with high HIV prevalence and where the

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risk of TB re-infection is greater. The research was conducted through the TB Trials Consortium (TBTC), a CDC-funded partnership of domestic and international clinical investigators who conduct research on the prevention and treatment of TB.

## **WAR IS HELL**

The Wall Street Journal reported that veterans who served in Iraq and Afghanistan have a higher rate of debilitating respiratory illness than those deployed elsewhere. Soldiers who served in Iraq or Afghanistan complain of lingering coughs, shortness of breath, dizziness and other symptoms. Now, scientists say troops who served in the Middle East have higher rates of respiratory problems compared to those who served elsewhere. In many cases, the soldiers can no longer pass a required physical to continue with active duty. Data collected from more than 7,000 veterans who served between 2004 and 2010, thought to be the largest study of its kind to date, show that some 14.5% of the 1,816 of the veterans in the study who had served in Iraq or Afghanistan had respiratory illnesses, including bronchitis and asthma. That compares with 1.8% of the 5,335 veterans deployed anywhere else, according to researchers in New York state who conducted the study. "We're confident we are detecting airway obstruction," said Anthony Szema, a professor of medicine and surgery at the State University of New York at Stony Brook School of Medicine, who presented the findings. Congress and the military have launched investigations into the issue, including a Senate hearing focused on one possible cause: toxins released from facilities known as burn pits, open-air fires used to dispose of trash at military bases in Iraq and Afghanistan. In the past, the pits have burned everything from plastic water bottles and computers to medical waste. Other possible culprits, according to researchers, include Mideast dust storms where tiny, porous particles carry metals, fungi or bacteria from other sources, and blast pressure from explosive devices. The military said in a recent report that particles released from the burn pits didn't exceed levels sanctioned by the EPA. Determining whether the symptoms are due to exposure while on duty has been difficult, because most soldiers never had a lung function test prior to deployment for comparison, although they would have had to pass certain physical tests. In addition, some veterans have post-traumatic stress disorder, which can impair breathing. Reported by Shirley Wang in the Wall Street Journal.

## **ZZZZ**

While CPAP remains the gold standard treatment for snoring and sleep apnea, mandibular advancement splints or surgery are also viable treatment options, according to researchers in Australia, who noted that at least 30% of patients can't or won't use CPAP for the long term. Mandibular advancement splints are intraoral appliances designed to improve or cure snoring by increasing the retrolingual airway and, due to the tongue's attachment to the soft palate via palatoglossus and overlying mucosa, may even improve the retropalatal airway at the same time. Such surgical treatment options are multiple and often staged, despite patient perceptions that a single procedure will be curative. In patients with large tonsils and favorable tongue size, modified uvulopalatopharyngoplasty with bilateral tonsillectomy should be considered.

## **ON STEROIDS**

Adding corticosteroids to antibiotics might reduce the severity of community acquired pneumonia, according to researchers at St Antonius Hospital in The Netherlands. Researchers enrolled 304 patients admitted to hospital with CAP and randomly

assigned them to usual antibiotic treatment plus either low-dose dexamethasone (5 mg once a day; 151 patients) or placebo (153 patients) for 4 days. Patients given dexamethasone recovered faster and had a more rapid decline in their blood c-reactive protein and interleukin-6 levels, indicating less inflammation in their lungs. Dexamethasone reduced the length of hospital stay by one day (6.5 days vs 7.5 days) and significantly improved social functioning by day 30, without an increase in severe adverse side effects or hospital mortality. The researchers did note that hyperglycemia was noted more often in the dexamethasone group.

## **GASPING**

Researchers at Children's Hospital Boston have found a previously unknown biological pathway explaining why influenza induces asthma attacks. Apparently, influenza activates a newly recognized group of immune cells called natural helper cells, presenting a completely new set of drug targets. If activation of these cells, or their asthma-inducing secretions, could be blocked, asthmatic children could be more effectively protected when they get the flu and possibly other viral infections, according to the researchers. Natural helper cells were first discovered in the intestines and are recognized to play a role in fighting parasitic worm infections. Experiments showed that the cells were present in the lung in a mouse model of influenza-induced asthma, but not in allergic asthma. The model showed that influenza A infection stimulates production of the compound IL-33, which activates natural helper cells, which then secrete asthma-inducing compounds. Without the helper cells being activated, infection did not cause airway hyperreactivity.

## **HOW TO SCORE**

A new scoring system has been developed to report treatment benefit, ie, utility, from a questionnaire administered to patients with COPD. Researchers at the London School of Hygiene and Medicine have come up with "The EXACT-U," Exacerbation of COPD Tool, a daily diary used in clinical trials to measure the frequency, severity, and duration of COPD exacerbations. It is a condition-specific questionnaire for economic evaluations, said to be better because current methods may overlook change or exacerbation severity differences for patients.

## **VENUS = MARS**

A study involving 14 million blood tests, reported by Quest Diagnostics, contradicts previous studies which claim that women are more likely to have an allergy than men. The company's ImmunoCAP specific IgE (Immunoglobulin E) blood tests detect 11 common allergens people might be susceptible to, including ragweed, mold, dust mites, dog dander, cat epithelia, and five different foods (egg white, milk, peanut, soybean, and wheat). Researchers reported that the IgE allergen sensitization rate for the 11 allergens evaluated in the blood tests was about 10% higher for adult males than adult females overall (all age groups). The results in this study challenge previous ones, including a meta-analysis of 591 studies which showed that approximately 65% of adults with allergies were women. Information for the above is from Medical News Today, written by Christian Nordqvist, copyright Medical News Today.

## **LONG TERM = LONG CARE**

Children reliant on long-term mechanical ventilation often require costly hospital stays and emergency visits, said researchers at the University Michigan. They found that kids with complex chronic conditions who require long-term mechanical

ventilation have significantly higher mortality, longer length of hospitalizations, higher mean charges, and more emergency department admissions. The length of initial hospitalizations for children requiring long term mechanical ventilation remained the same between 2000 and 2006, but total admissions (for these children) were up 55%. Until now, researchers were unclear as to how often this technology was used and how often children requiring long-term mechanical ventilation were admitted for additional care. The study analyzed all hospitalizations for children 0-20 years of age requiring long term mechanical ventilation, and also found that infants and young children consumed the highest proportion of health care resources for this particular demographic. Infants less than one year old made up 25% of the population, but used about 50% of the healthcare resources for all the children requiring long-term medical ventilation. The study also found that infants have the longest length of hospitalization and the highest in-hospital mortality rates, noting a 55% growth in additional hospitalizations for children needing long-term mechanical ventilation support and a 70% increase in subsequent health care cost.

#### HOLD IT IN

Men with COPD who take inhaled anticholinergic drugs have a higher chance of suffering from urinary retention, according to researchers at St Michael's Hospital in Toronto. IACs make the smooth muscles in the airway relax by blocking stimulation from the cholinergic nerves and reduce obstructions in airflow. Researchers gathered information on patients aged at least 66 years with COPD and sought out data on IAC therapy and the development of acute urinary retention over a six-year period. Out of 565,073 individuals with COPD, 1,806 females and 9,432

males developed acute urinary retention. Males taking IACs for up to one month had a 40% higher chance of developing AUR, while those with an enlarged prostate on IACs had an 80% higher risk. Male patients who were taking both short and long acting IACs at the same time had a considerably higher risk of developing AUR. AUR risk was lower if patients take the lowest dose possible and avoid combinations that may increase risk. Information is from Medical News Today, written by Christian Nordqvist, copyright Medical News Today.

#### SO RELAX

People who have trouble breathing while exercising may have exercise-induced bronchoconstriction (EIB), commonly referred to as exercise-induced asthma, and now they can check to see if this is so. The American College of Allergy, Asthma and Immunology (ACAAI) has developed a free online tool to track symptoms, at myEIBJournal.org. Users can keep a daily log of exercise, symptoms and medication and create personalized, detailed reports and statistics. The tool is also accessible through mobile devices. EIB is said to affect 10% of people in the US, and about 85% of asthmatics have it, though they may be unaware of this.

#### ANTIBODIES

People with severe asthma are more likely to have antibodies against Chlamydia pneumoniae than the general population and in some cases antibiotic treatment can greatly improve symptoms according to researchers at the University of Massachusetts. Having previously demonstrated an increased prevalence of C. pneumoniae in the lungs of children and adults with asthma, the researchers conducted a study designed to

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determine if the presence of Chlamydia-specific antibodies could predict asthma severity and if these antibody-positive patients would benefit from treatment with antibiotics. The data revealed a statistically significant link between Chlamydia-specific IgE antibody production and the severity of asthma. Of the asthma patients analyzed, 55% had Chlamydia-specific IgE antibodies in their lungs compared to 12% of blood donor controls. Moreover, patients who were treated on the basis of asthma severity with antibiotics had significant improvements in asthma symptoms and some even experienced a complete abolition of these symptoms.

### **BREATHING CRAP**

Researchers from the University of Iowa have found that inhaled carbon black nanoparticles creates a double source of inflammation in the lungs. The researchers expected to find one level of inflammation when cells were exposed to carbon black nanoparticles but were surprised to find that nanoparticles activated a special inflammatory process and killed cells in a way that further increased inflammation. The intake of carbon black nanoparticles from sources such as diesel fuel or printer ink caused an initial inflammatory response in lung cells. But these nanoparticles killed macrophages in a way that also increased inflammation. The researchers noted that the doses of nanoparticles in the study were more concentrated than what one would regularly be exposed to, and that walking through a cloud of diesel exhaust didn't necessarily hurt the lungs. But of course, it wouldn't help them, either.

### **STRESSED OUT**

An impaired ability to handle oxidative stress that arises from exposure to secondhand smoke and other environmental triggers may contribute to the development of asthma, according to researchers at Vanderbilt University, who found that the host antioxidant defense system is compromised among those destined to develop asthma, and therefore these individuals may be less able to handle the environmental exposures that may cause it. Oxidative stress involves a battle between charged oxygen species that produce damage and our body's ability to fight them off. Researchers looked at the enzymatic and non-enzymatic ways that the body manages oxidative stress in the development of adult-onset asthma, focusing on the enzymatic defense system that precedes the onset of asthma symptoms and diagnosis. The researchers collected data from 65,732 women with no history of asthma who completed standardized questionnaires about asthma diagnoses and symptoms. From this group, the researchers selected 150 women with confirmed new development of asthma and 294 healthy controls. Levels of antioxidants and other enzymes associated with oxidative stress were measured from blood and urine samples prior to asthma development. Questionnaire data indicated 96% of the women were never-smokers and 44% were exposed to secondhand smoke through husbands or workplace exposure. The researchers found that increased host antioxidant defense enzyme activity measured prior to disease onset was associated with a reduction in risk of asthma. Specifically, high levels of an enzyme that prevents the formation of platelet-aggregating factor (PAF), which is linked with asthma, were associated with a decreased risk of asthma. The results of the study may point to nutrients or classes of drugs that could be studied to prevent asthma in those who are high-risk.

### **ROACH-DUST**

Researchers at Columbia University's Mailman School of Public

Health compared the household presence of cockroach, mouse, cat, dust mite and other allergens in neighborhoods with a high prevalence of asthma to that in low-prevalence neighborhoods, and found that cockroach, mouse and cat allergens were significantly higher in homes located in neighborhoods where asthma is more common, and that children in these higher-exposure homes were more likely to be sensitized to cockroach antigens. The researchers studied 239 children 7 to 8 years old who were recruited through the middle-income HIP Health Plan of New York, as part of the ongoing New York City Neighborhood Asthma and Allergy Study. A total of 120 children lived in high asthma prevalence neighborhoods and 119 were from low-prevalence areas. Based on a parent reported survey of symptoms, 128 were classified as having asthma and 111 were assigned to a control group. Allergen exposure was measured by collecting and analyzing bed dust samples from the upper half of the children's beds. Sensitization was measured by screening blood samples for antibodies to various household allergens. Earlier studies of inner-city children have found that exposure and sensitization to cockroach and mouse allergens is associated with having asthma. Cockroach, mouse and cat allergens were more prevalent in the bed dust taken from homes in high asthma neighborhoods than low asthma neighborhoods, and sensitivity to cockroach allergen was twice as common: 23.7% versus 10.8%. However, there was no significant difference by neighborhood in sensitization to mouse and cat antigens. In other words, poor neighborhoods have roaches, and breathing their dust causes more asthma.

### **WORRYWARTS?**

Concern over vaccine safety is one of the main reasons parents don't have their asthmatic children vaccinated for flu, according to researchers at C.S. Mott Children's Hospital in Ann Arbor, MI. Parents who do not vaccinate their children are also less likely to view flu as a "trigger" for their child's asthma. To determine parental attitudes toward the flu vaccine, and learn the reasons why some parents do not have their asthmatic children vaccinated, the researchers conducted a national survey of 1,621 parents; 237 parents indicated at least one child had asthma and were included in the final compilation of data. Of those surveyed, 70% reported that they vaccinated their child against seasonal or H1N1 influenza during the prior winter season and 65% said they planned to have their child vaccinated against influenza in the upcoming season. Parents who didn't vaccinate their asthmatic children against influenza were less likely than those that did to say that getting a viral infection was a "very important" trigger of their child's asthma (53% vs 72%), and were more likely to be concerned about vaccine side effects (60% vs 26%). Forty-one percent of non-vaccinating parents were worried about their kids getting sick from the vaccine itself, vs 13% of vaccinators. The study also reported other parental attitudes: 73% said asthma attacks were triggered by exposure to smokers, 81% said pollen and weeds, 77% said pollution, 71% said roaches and dust mites, 48% said exposure to furry or hairy animals, and 30% said food.

### **NO KIDDING**

Waiting to seek emergency care for asthma can result in worse outcomes, according to researchers at Cornell Medical College in New York. Researchers enrolled 296 patients in two New York City emergency departments and asked them about their duration of symptoms and self-management attempts before they came to the emergency department. Two out of three patients reported waiting 5 days or less before seeking treatment. One in three waited longer than five days. Patients who reported waiting



longer were as likely to have insurance as those who sought treatment earlier, and 80% of each group reported having a physician for asthma. Patients who postponed treatment were not more likely to consult physicians before coming to the emergency department compared to those who sought early treatment (23% vs 18%). They were not more likely to have used beta agonists, but were more likely to be sicker on arrival to the emergency room, and more likely to be admitted to the hospital than patients who sought earlier care. Patients who waited longer also were as likely to come to the emergency room by ambulance as those who came to the emergency room sooner. In other words, patients who waited to go to the ER didn't do anything more to try to help their asthma than those who sought quicker treatment. Nor did these patients make plans on how to get to the hospital, but waited 'till the last minute.

## PRODUCTS & PEOPLE

### BREATHING AWARD

Covidien announced that the abstract presentation, "The Impact of Obesity and Sleep Disordered Breathing on Postoperative Pulmonary Complications," received a 2011 Annual Scientific Award from the Society of Critical Care Medicine (SCCM). The study was one of the first to examine the relative significance of obesity and sleep-disordered breathing (SDB) on the development of postoperative pulmonary complications (PPCs). The study showed that these two common, frequently comorbid conditions are independently associated with increased rates of PPCs in adult surgical patients receiving parenteral opioids. In addition, the study revealed that PPCs result in significantly increased mortality and more than double a patient's length of stay and total costs. Investigators retrospectively reviewed postsurgical outcomes of more than 760,000 discharged adults (ages 18-64) who had received parenteral opioid therapy during their hospital stay. PPCs included pneumonia, respiratory failure, atelectasis and other conditions, such as tracheobronchitis, pleural effusion, pneumothorax, and ventilator-associated pneumonia. The results showed that obesity and SDB were significant independent risk factors for PPC. When both conditions were present, the risk was increased nearly twofold. Among discharged patients who met the study's inclusion criteria, seven percent experienced at least one PPC. Compared

to controls, PPC cases were associated with significantly increased mortality (6.5% vs 0.6%), length of stay (14.4 days vs 5.4 days) and total cost (\$44,223 vs \$16,930).

### NOT THAT WE'RE COMPLAINING!

Researchers who are submitting poorly written papers to medical journals (not to us, of course!) can now make use of a professional proofreading service to ensure that academic and professional work is written in good English. The company says it will check the grammar and style of your work and return it to you to meet your requirements. The company notes: "If your research has too many English spelling and grammar errors, or if the publisher's style guide has not been followed, your research may be rejected without due regard to its content. We strongly suggest sending the document to us for editing and proofreading before submission, particularly if English is not your first language. We can provide you with a professional proofreading service at a very reasonable rate. All our proofreaders are highly qualified native English speakers. Many work as leading academics in their fields and all have extensive experience of proofreading to the highest standards. We are one of the largest proofreading and editing services worldwide for research documents covering all academic areas. If you are interested in our service, please take a look at our website. All you have to do is send us your document as a Word/LaTeX attachment with the deadline and we will guarantee delivery of a perfectly written document to give you complete confidence when you submit your work. The fee is worked out on a flat rate (£7.49 per thousand words or 0.749 pence per word), so you know exactly how much the proofreading will cost in advance." Contact proof-reading-services.org.

### REINTUBATION & SURFACTANT

Discovery Laboratories, Inc announced that the Journal of Neonatal-Perinatal Medicine recently published a manuscript reviewing an important data analysis from the Surfaxin (lucinactant) Phase 3 clinical trial program. The manuscript is entitled "Reintubation and risk of morbidity and mortality in preterm infants after surfactant replacement therapy" (Guardia et al, Volume 4, Number 2, 2011). This is the first peer-reviewed manuscript describing neonatal patient compromise following reintubation. The analysis demonstrates that, for preterm infants at risk for respiratory distress syndrome

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(RDS) who received prophylactic surfactant therapy and were extubated, subsequent reintubation is a highly predictive risk factor for mortality and major complications of prematurity. The analysis also indicates that infants treated with Surfaxin had a significantly lower incidence of subsequent reintubation and improved survival without reintubation, compared with infants who received animal-derived surfactants Survanta (beractant) and Curosurf (poractant alfa), the current standard of care. Infants who are extubated following surfactant therapy often relapse and require reintubation. Although increased mortality and morbidity in adults requiring reintubation is well described in medical literature, the consequences of reintubation in preterm infants have not been previously reported. Data from Discovery Labs' Phase 3 RDS clinical trials were assessed in a post-hoc analysis to evaluate the consequences of reintubation as well as the potential effect of surfactant choice on reintubation rates and subsequent clinical outcomes in preterm infants. The recently published manuscript highlights the following observations: Infants who were successfully extubated and did not require reintubation experienced low mortality rates across all treatment groups, while infants who were subsequently reintubated had a statistically significant higher mortality rate, 0.5% vs 18%, respectively ( $p < 0.05$ ). Infants who required reintubation had significantly higher rates of six major complications of prematurity, including BPD, necrotizing enterocolitis, sepsis, and intraventricular hemorrhage. Infants treated with Surfaxin demonstrated a significantly lower reintubation rate compared with those infants treated with animal-derived surfactants, Curosurf (33% vs 47% respectively;  $p < 0.05$ ) and Survanta (35% vs 43% respectively;  $p < 0.05$ ). Infants treated with Surfaxin demonstrated a significantly higher combined outcome of survival without reintubation compared with those infants treated with animal-derived surfactants, Curosurf (67% vs 53% respectively;  $p < 0.05$ ) and Survanta (65% vs 57% respectively;  $p < 0.05$ ). Surfaxin is an investigational drug product that has not been approved by the FDA or any other world health regulatory authority. Top-line data of this post-hoc analysis was previously presented at the 2008 AARC International Respiratory Congress. Contact [www.discoverylabs.com](http://www.discoverylabs.com).



#### **FURTHER**

The Kimberly-Clark Education bus was created to help promote education and awareness of healthcare-associated infections. The bus now includes new environments, including learning and demo areas, a one-of-a-kind mobile classroom that offers accredited CE and CME education on HAIs to clinicians on-site, and a three year commitment to be on the road. The bus provides cutting-edge healthcare worker education around HAI

prevention. Last year, the bus visited 79 locations in the US and Canada, including stops at tradeshow and conferences. The stops occurred in 60 cities in 25 states and one Canadian province. In addition, an average of 29 CE credits were awarded per bus visit. The highest-attended stop was at the VA Hospital in Houston, with over 200 visitors (average of 54/day).

#### **WATCHDOG**

Kimberly-Clark Health Care announced the recipients of the HAI WATCHDOG Awards program, created to recognize the efforts of dedicated healthcare professionals working together to prevent healthcare-associated infections (HAIs). The awards program, an initiative of the HAI WATCHDOG Community, facilitates the sharing of best practices among clinicians, and will recognize four participating facilities with educational grants. The 2011 HAI WATCHDOG Awards began accepting submissions in the summer of 2011. The 2010 programs with measureable results were judged by a panel of infection prevention healthcare professionals. Education and awareness programs with non-measurable results were judged by online public voting of fellow healthcare professionals. The entries awarded an educational grant address issues including ventilator-associated pneumonia (VAP), surgical site infection (SSI), central line-associated bloodstream infections (CLABSI) and hand hygiene compliance. The names of the facilities who won are available through Kimberly-Clark Health Care. The HAI WATCHDOG Community is an online forum for sharing infection prevention best practices. Healthcare professionals can join the HAI WATCHDOG Community to share experiences or participate in existing discussions and gather effective strategies to replicate in their organizations. In addition, clinicians have access to tools and resources, such as customizable posters to educate and reinforce the importance of HAI prevention with staff. Contact [kchealthcare.com](http://kchealthcare.com).

#### **TEAMWORK**

Hamilton Medical is pleased to announce the expansion of its top-rated Clinical Applications Team. The clinical applications team is available 24/7 to all Hamilton customers, via a toll free hot line: (800) 426-6331. John Newton, RRT-NPS, brings over thirty years of experience as a Registered Respiratory Therapist to the team. John has been both a staff therapist and technical director in multiple institutions. Prior to joining Hamilton Medical, he worked with Hamilton Medical ventilators and developed policy that designated Adaptive Support Ventilation (ASV) as the default strategy within his former hospital system. Carl Sprow, RRT, has spent over nine years working in trauma, neonatal, cardiac and emergency departments. Working with a leading trauma center, Carl was the Lead Therapist in charge for both day and night shifts. He also worked with trauma to develop a ventilator weaning protocol using ASV and successfully implemented ACLS, BLS, NRP and specialized training to stabilize the neonatal patient for transport. Alton (Ray) Braxton, RRT, served six years serving in the Marine Corps and brings to Hamilton Medical thirty five years experience in the field of respiratory care both as a supervisor and clinical specialist. Ray has also spent many years serving on the North Carolina Society for Respiratory Care as a board member and an officer. Ray also brings experience with Hamilton Medical ventilators after retiring from a major medical referral center in eastern North Carolina.

#### **NEW APP**

ResMed has released the ResMed Sleep Assessment app, a novel

new app for iPhone that lets users record themselves during sleep. The app also includes a clinically validated questionnaire that assesses their risk and other helpful features to empower users to discuss their sleep health with their physician. ResMed's Sleep Assessment app combines a clinically validated questionnaire that quantifies a person's risk of sleep apnea based on known characteristics with an overnight snore recorder that lets them compare their snoring to the snoring of an actual sleep apnea patient. With the snore recorder feature, the user simply starts the app and sets their device by their bedside before sleep. The device records them throughout the night. Users can play back their recording and compare it to sample recordings from actual sleep apnea patients. They may also refer to their recording and questionnaire results when speaking with a physician about their sleep concerns. In addition to the snore recorder and questionnaire, ResMed's Sleep app also includes a Sleep Lab Locator, which helps users find a sleep center in their area. Additionally, the app includes a "Sounds to Sleep By" feature with recordings of soothing sounds to play while drifting off to sleep. Visit [resmedsleepassess.com](http://resmedsleepassess.com).

### ADVANTAGES

The new ABL80 OSM standalone CO-oximeter offers advantages for the cath lab. The ABL80 FLEX CO-OX (OSM version) is Radiometer's newest standalone CO-oximeter, replacing the company's OSM3. Its superior test accuracy, combined with the analyzer's test readiness, fast turnaround and intuitive operation, make it a great fit for use in the cardiac cath lab. Radiometer's safePICO ABG syringe with onboard mixing device is designed to reduce preanalytical errors caused by poorly mixed blood samples. You can attend Radiometer's preanalytics webinar to learn more about preventing preanalytical errors related to sample mixing. You may also see the safePICO mixing device in action by contacting Radiometer for a link. The company also has a downloadable e-book on preanalytical error prevention. This 20-page booklet offers you quick and straightforward information on the most common errors in the preanalytical phase and, most importantly, how you can prevent them. Contact [radiometeramerica.com](http://radiometeramerica.com).

### CEO NAMED

Siemens Healthcare has appointed Gregory Sorensen, MD, as chief executive officer of Siemens Healthcare in the US. Sorensen was Professor of Radiology and Health Sciences & Technology at Harvard Medical School, faculty member of the Harvard-MIT Division of Health Sciences and Technology, and Co-Director of the A.A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital. He is a practicing neuroradiologist and active researcher with significant experience in clinical care, clinical trials, and translational research. At Siemens, Sorensen is responsible for leading the marketing, sales, service, and support functions for Siemens Healthcare in the US, including medical imaging, therapy, healthcare information technology, and laboratory diagnostics. He will be based in Malvern, PA. Contact [siemens.com/healthcare](http://siemens.com/healthcare).

### ETHNIC STUDY

AstraZeneca announced results from a long-term study comparing SYMBICORT (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol 160/4.5 mcg with budesonide pressurized metered-dose inhaler (pMDI) 160 mcg in self-reported African American patients with moderate to severe persistent asthma. The data demonstrated that SYMBICORT

treatment resulted in significant improvement in lung function compared to treatment with budesonide alone, and safety results indicated that patients in the SYMBICORT group had fewer exacerbations over the randomized study period compared to patients treated with budesonide.<sup>1,2</sup> The incidence of adverse events (AEs) was similar between the two groups.<sup>2</sup> The results were presented in a poster at the 2011 American Thoracic Society (ATS) International Conference in Denver. SYMBICORT is a combination asthma medication that contains both an inhaled corticosteroid (ICS) (budesonide) and a long-acting beta-agonist (LABA) (formoterol). It is indicated for the treatment of asthma in patients 12 years of age and older not adequately controlled on a long-term asthma control medication, such as an ICS, or whose disease severity clearly warrants initiation of treatment with both an ICS and LABA.<sup>3</sup> There have been few prior studies evaluating combination asthma treatment in specific ethnic populations at higher risk for asthma prevalence. Results from this 52-week study are consistent with safety and efficacy data from the TITAN study, a 12-week study of SYMBICORT in African American patients, and with previous SYMBICORT studies conducted among predominantly Caucasian patients.<sup>4,6</sup> The 52-week, randomized, double-blind Phase III study included 742 self-reported African American patients 12 years of age and older with moderate to severe persistent asthma. After two weeks of receiving two inhalations, twice daily of budesonide 160 mcg, patients were randomized to receive two inhalations, twice daily of SYMBICORT 160/4.5 mcg or two inhalations, twice daily of budesonide 160 mcg.<sup>2</sup> Fewer patients receiving SYMBICORT (7.7%) compared to budesonide (14.0%) had  $\geq 1$  asthma exacerbation (oral/systemic corticosteroid use, an asthma-related hospitalization, or emergency room/urgent care visit) ( $P=.006$ ).<sup>2</sup> The time to first asthma exacerbation was longer in patients treated with SYMBICORT compared to budesonide ( $P=.018$ ).<sup>2</sup> Similar percentages of patients had  $\geq 1$  AE; the most common AEs were headache, nasopharyngitis, sinusitis and viral upper respiratory tract infection.<sup>2</sup> Treatment with SYMBICORT resulted in significantly greater improvements in predose forced expiratory volume in one second (FEV<sub>1</sub>), predose forced vital capacity (FVC), and morning peak expiratory flow (AM PEF) compared to budesonide.<sup>1</sup> Improvements in predose FEV<sub>1</sub> were observed after two weeks of randomized treatment with SYMBICORT, without diminution of effect relative to budesonide during the treatment period.<sup>1</sup> No new safety concerns were identified with SYMBICORT during the course of the study. The most common adverse events for patients receiving SYMBICORT or budesonide were headache, nasopharyngitis, sinusitis and viral upper respiratory tract infection.<sup>2</sup> [References: 1. Brown, R.W. Differential Long-term Pulmonary Function Outcomes of Budesonide/Formoterol Pressurized Metered-Dose Inhaler pMDI and Budesonide pMDI in African-American Patients with Asthma. [poster]. American Thoracic Society, May 13-18, 2011, Denver, CO. Abstract #17354. 2. Brown, R.W. Long-term Safety of Budesonide/Formoterol Pressurized Metered-Dose Inhaler Budesonide pMDI in African-American Patients with Asthma: Asthma Exacerbation Adverse Events. American Thoracic Society, May 13-18, 2011, Denver, CO. Abstract #17354. 3. Symbicort Prescribing Information. AstraZeneca. 4. Spector, S., Martin, U., Uryniak, T., O'Brien, C. Effect of Budesonide/Formoterol Pressurized Metered-Dose Inhaler Versus Budesonide Dry Powder Inhaler on Pulmonary Function in Black Adolescents and Adults with Moderate to Severe Persistent Asthma [oral presentation]. American College of Chest Physicians Annual Meeting, October 30-November 4, 2010. Vancouver, BC, Canada. 5. Spector, S., Martin, U.,

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## TRAINING

IngMar Medical, Ltd has recently released a new product, RespiSim-PVI, designed to create a new paradigm in ventilator management training. Coupled with the ASL 5000 Breathing Simulator, RespiSim-PVI provides a fully immersive training experience with immediate feedback for students. The ASL 5000 Breathing Simulator takes place of the patient by allowing instructors to create respiratory patient scenarios. RespiSim-PVI is the software interface that displays this "patient" information along with data from the ventilator for interactive training with powerful debriefing. RespiSim-PVI comes pre-loaded with curriculum modules for ventilator management training. These modules can be used with little preparation, giving the instructor more time to focus on students and directly observe their choice of ventilator settings and changes in "patient" condition. The training modules cover topics such as waveform interpretation, patient ventilator asynchrony, volume and pressure control ventilation, and weaning trials. When running a module in the classroom, the effects of adjusting ventilator settings and subsequent changes in patient condition become visible with an immediacy not previously possible. RespiSim-PVI, along with the ASL 5000 Breathing Simulator, provides respiratory care students hands-on experience with the full spectrum of patient conditions including rare but critical scenarios. This exposure can take weeks or months in the ICU to observe. Now, students can be put to the test with realistic clinical situations with no risk to a patient. The software includes a playback mode for instructors to review waveforms and ventilator data for powerful debriefing. In this way, instructors and students can review particular events during the session that the instructor would like to emphasize. These recordings can be replayed to highlight concepts that were demonstrated. This system was developed to enhance and accelerate student learning while reducing instructor workload. The RespiSim-PVI in combination with the ASL 5000 is the cornerstone of the FiRST (Fully Interactive Respiratory Simulation Technology) System. This fully interactive training method leverages shorter feedback loops and hands-on experience to train clinicians for the highest level of patient care. IngMar Medical believes that placing students in a fully interactive simulated environment that can accurately represent a real clinical setting is the future of respiratory care education. Contact [ingmarmed.com](http://ingmarmed.com).

## NEW SOFTWARE

IngMar Medical has introduced new software for the QuickLung Breather designed for training in analysis of pulmonary mechanics graphics. The Breather Option transforms the QuickLung precision test lung, a single bellow passive test lung, into one with spontaneous breathing capabilities. The QuickLung

Breather combination allows you to simulate patients in a variety of modes and patterns opening up opportunities to demonstrate and test ventilator triggering and important modes of ventilation such as SIMV, Pressure Support and PAV. The PMG (Pulmonary Mechanics Graphics) software is a new option for the QuickLung Breather. It displays loops, waveforms, and a host of other data on your personal computer for a complete picture of the interaction between the ventilator and the lung model provided by the QuickLung Breather. Instructors can display waveforms and twenty data parameters in a classroom setting while giving students an interactive experience with patient ventilator interaction. It is also perfect for anyone using a ventilator that does not display waveforms. The PMG software was designed to give students a deeper understanding of concepts with the opportunity for students to gain realistic experience adjusting ventilator settings in response to a range of patient conditions. Contact [ingmarmed.com](http://ingmarmed.com).

## FIBROSIS FIX

Stromedix is a clinical-stage biotechnology company developing novel drugs to treat fibrosis and fibrotic organ failure. Its lead program, STX-100, has recently completed a Phase 1 clinical trial. Stromedix is led by a team of seasoned biotechnology industry veterans with deep experience in drug development. The company has also created a strong network of medical and scientific advisers. The company is focused initially on chronic organ failure but plans to leverage its expertise and expand its therapeutic pipeline into related settings such as acute organ failure and cancer. STX-100 is a humanized monoclonal antibody targeting integrin  $\alpha\beta6$ . STX-100 exhibits significant anti-fibrotic activity in preclinical models of lung, kidney and liver disease and cancer. Stromedix is currently developing STX-100 for the treatment of interstitial fibrosis and tubular atrophy in kidney transplant recipients and for idiopathic pulmonary fibrosis (IPF). Stromedix believes that STX-100 may have therapeutic utility in a broad array of chronic organ failure settings, acute organ failure and cancer. The company has completed a Phase 1 study for STX-100. Contact [stromedix.com](http://stromedix.com).

## DIAGNOSIS

Philips has introduced its Sleepware G3 sleep diagnostic software. Philips Respironics Sleepware G3 diagnostic software is used in the sleep lab to record and view patient data acquired during a sleep study. The software is compatible with the Philips Respironics Alice in-lab diagnostic systems and Alice PDx portable diagnostic system. Sleepware G3 represents a new platform offering for what was formerly Sleepware software. The platform offers many benefits for sleep lab owners and technicians, including enhanced functionality, workflow, and performance efficiencies suited to the needs of a sleep lab. "The design of Sleepware G3 facilitates the unique workflow of each sleep center," said Tim Murphy, Senior Director and General Manager, Diagnostic and Clinical Software Applications, Philips Home Healthcare Solutions. "Managers can assign and monitor technologist and physician progress from initial patient referral to interpretation of the sleep study. Also, the User Login management feature allows laboratory managers more control over access to the program and patient data. Due to the multiple enhancements that have been incorporated into Sleepware G3, users should have a more productive and enriching experience when interacting with the software functionality." Sleepware G3 has enhanced functionality when compared to the original Sleepware software including: workflow and customization preferences, data acquisition, review, and data scoring

functionality; reporting capability; and the methods used for safeguarding data management files. Contact [healthcare.philips.com](mailto:healthcare.philips.com).

## STIMULATING

ImThera Medical, Inc reported results from its European study of the aura6000 neurostimulation device for the treatment of Obstructive Sleep Apnea (OSA) at the American Thoracic Society (ATS) 2011 Conference. Safety and efficacy outcomes of the Phase I (three-month data) protocol are positive. The study was completed at Université Catholique de Louvain, St Luc Hospital and was comprised of moderate to severe non-compliant CPAP patients. Ten patients have completed Phase I, with all patients demonstrating compliance to ImThera's Targeted Hypoglossal Neurostimulation (THN Sleep Therapy). Enrolled patients had a baseline diagnostic Apnea Hypopnea Index (AHI) ranging from 26.4 to 80 and a baseline diagnostic Oxygen Desaturation Index (ODI) ranging from 11.7 to 75.9. After three months of nightly use of THN therapy, subjects showed marked improvement: Mean AHI Reduction from Screening to Week 12 of  $24.7 \pm 13.2$  (50.2% Improvement); Mean ODI Reduction from Screening to Week 12 of  $19.3 \pm 15.8$  (54.3% Improvement); Mean HI Reduction from Screening to Week 12 of  $15.2 \pm 13.2$  (46.1% improvement); Mean ESS Reduction from Screening to Week 12 of  $5 \pm 7.3$  (50.5% Improvement). In a pre-defined subgroup, 7 of 10 patients showed a mean AHI reduction of 68.0%, ODI reduction of 68.1%, and HI reduction of 64.1%. Additionally, quality of sleep as measured by arousal events across study visits showed a mean decrease from Screening to Week 12 of  $94.6 \pm 102.4$  (64.9% improvement). The aura6000 system takes, on average, ninety minutes to implant surgically. It offers one of the world's smallest implantable and rechargeable stimulators and does not require additional sensors to function. Based on its recent analysis of the neurostimulation for sleep apnea market, Frost & Sullivan recognized ImThera Medical, Inc with the 2011 North American Frost & Sullivan Award for Technology Innovation for this pioneering sleep apnea device. ImThera's aura6000 electrically stimulates the hypoglossal nerve (HGN), a motor nerve that controls six muscle groups of the human tongue. Since the muscles lose tone during sleep, stimulation of the HGN can activate the relevant tongue muscles, which can tone them and prevent or reduce OSA episodes. This requires the implantation of a small device through a minimally invasive procedure, performed by an ENT surgeon. The aura6000 is an open loop system with a constant current implantable pulse generator (IPG), which causes a continuous current to be applied to parts of the HGN in a patient customized fashion. The device consists of two implantable components, a rechargeable pulse generator placed under the skin in the upper chest region, and a multi-contact electrode placed in the upper neck. The electrode encircles the HGN and delivers electric pulses to the nerve in up to six different spots through its multi-contact design, stimulating multiple muscles in the tongue and targeting specific regions. The system does not require complex triggers or pressure sensors as required in a closed loop system. The constant current IPG has potential advantages over the normally used voltage controlled devices for targeted stimulation. An external remote like device helps to recharge the battery and program the settings accordingly. (The aura6000 is not for sale in the US). Contact [imtheramedical.com](http://imtheramedical.com).

## GOOD SLEEP

National Sleep Therapy, a provider of equipment and services to patients with sleep apnea that uses a "closed-loop" model of

follow up care with patients throughout the duration of sleep therapy, has announced the release of new data that indicate that 88.5% of the patients they serve meet the Medicare standard for continued use of the Continuous Positive Airway Pressure (CPAP) device compared to a national rate of approximately 50%. National Sleep Therapy has achieved a higher adherence rate through its "touchpoints" model where patients have many different points of contact with their doctor and with the company as they become familiar with the CPAP device. Of utmost clinical importance is the very first touchpoint with the patient: the CPAP set-up. Using multimedia and new technologies like the iPad, patients are given a thorough education and set of expectations that promotes compliance. The company has developed proprietary software systems that track patients each night and alert clinicians to call patients proactively. In addition, these touchpoints include: online portals where patients can monitor their own CPAP usage; text messages to alert patients when compliance is low; links to support videos that illustrate how patients' bodies function with and without CPAP use; and an extensive network of sleep experts to call upon. National Sleep Therapy will walk members of the medical and insurer communities through their findings and answer questions about their research during four upcoming webinars. More information can be found at [nsttherapy.com](http://nsttherapy.com).

## ADVANCED SUPPORT

With the release of the American Heart Association's recent guidelines for CPR, hospitals are turning to the Oridion Microcap portable capnograph as a solution to meet AHA's call for capnography during Advanced Cardiovascular Life Support (ACLS) and Pediatric Advanced Life Support (PALS). The "2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" specifies the use of waveform capnography (etCO<sub>2</sub> monitoring) during CPR to confirm and monitor endotracheal tube placement, assess the quality of CPR, and detect return of spontaneous circulation (ROSC). With the release of the AHA guidelines, capnography has now become the standard of care for use by "Code Teams," whose crash carts must be equipped with capnography monitors to comply with AHA standards. The Oridion Microcap portable monitor employs Microstream capnography technology to provide accurate, continuous monitoring on intubated and non-intubated patients from neonate to adult in hospital and pre-hospital environments, including emergency transport. The Microcap Plus has Microstream capnography and Nellcor pulse oximetry in one convenient portable device. Contact [oridion.com](http://oridion.com).

## TRAVEL-FRIENDLY

Healthcare providers in the US whose patients require a reliable supply of oxygen while traveling by air, train or automobile now have access to a 24-hour oxygen travel service while traveling anywhere in the world. Using the travel-friendly and clinically sound oxygen supply system from Chart SeQual Technologies Inc, the Linde Eclipse portable oxygen concentrator is now available in the US from LifeGas, the medical gases business of Linde North America. LifeGas provides a full line of medical and quality critical gases and equipment to over 1,000 hospitals, clinics, nursing facilities, emergency management services and home healthcare providers. The Linde Eclipse portable oxygen concentrator is an advanced travel oxygen delivery system developed by Chart SeQual Technologies Inc, a San Diego-based medical device manufacturer. The Linde Eclipse portable oxygen concentrator comes with a sleek carbon graphite look and feel,

and is custom packaged for Linde in a plastic corrugated case intended for repeat courier shipments. The Linde unit is equipped with standard Eclipse accessories, including the universal cart that allows battery access while attached to the Linde Eclipse portable oxygen concentrator, AC and DC power supplies, a power cartridge, and an accessory bag. With continuous flow settings up to three liters per minute and pulse dosing up to 192 milliliters per bolus, the Linde Eclipse portable oxygen concentrator also utilizes Chart SeQual Technologies' well-known autoSAT technology. The Linde Eclipse portable oxygen concentrator is a 24/7 device meeting stationary, ambulatory and travel needs. Visit [sequal.com](http://sequal.com) or [us.lindegas.com](http://us.lindegas.com) or [lifegas.com](http://lifegas.com).

## SAFE AND CONTINUOUS

Aerogen of Galway, Ireland, has launched a new syringe and tube-set that enables medical personnel to safely continuously nebulize a patient by completely eliminating the danger of tubing misconnections. Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringes, have been at the heart of many catheter/tubing misconnections. The ease of connection between these luer lock connectors have led to misconnections that have inadvertently linked unrelated systems, and at times, have resulted in serious adverse events. Until now, this risk was inherent in continuous nebulization set-ups. Aerogen's new continuous nebulization tube set incorporates non-standard connectors that cannot be misconnected onto any other device being used with the patient. The new tube set is compliant with the European Harmonised Standard EN 13455-1 and with the FDA guidelines on prevention of tubing misconnections. Contact [www.aerogen.com](http://www.aerogen.com), or Tri-anim, Aerogen's US distributor.

## INHALE

United Therapeutics Corporation announced findings from a retrospective analysis of the pivotal Tyvaso (treprostinil) Inhalation Solution study at the 2011 American Thoracic Society International Conference. The data evaluated N-terminal brain natriuretic peptide (NBNP) levels as a marker for disease severity in patients with pulmonary arterial hypertension (PAH). Tyvaso is an inhaled therapy that is FDA approved for the treatment of PAH (WHO Group 1) to improve exercise ability in adults. Researchers hypothesized that patients with greater elevations in NBNP levels participating in the pivotal, randomized study of Tyvaso would have a greater response in six-minute walk distance (6MWD) with active therapy, and be more likely to deteriorate with placebo, than patients with lower baseline levels of NBNP. During the study, researchers analyzed the baseline NBNP levels (median 618 pg/ml, IQR 184, 1510), as well as baseline and 12-week 6MWD in 178 patients from the Phase III study. Patients were divided into four groups based upon their NBNP levels. Patients (n = 20) on active therapy with the highest baseline NBNP had a mean improvement in 6MWD of 50 (+/-38) meters vs 33 (+/-46) meters for the lower three groups. Meanwhile, patients on placebo with the highest baseline NBNP had a mean change in walk of -15.7 (+/- 56) meters vs a change of +16.2 (+/-52) meters for placebo patients in the lower three groups. Researchers noted that the combination of greater improvement in walk distance in actively treated patients with high NBNP and minimal placebo effect in the high NBNP patients enhances understanding of the clinical response in PAH patients with more advanced disease. The study results further support the use of NBNP as a marker of disease severity in clinical trials. Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO

Group 1) to improve exercise ability. Tyvaso is a registered trademark of United Therapeutics Corporation. Contact [unither.com](mailto:unither.com).

## SLEEP SHOWCASE

Royal Philips Electronics demonstrated the latest advances in sleep with the premiere of "Pathway to Compliance," at the recent SLEEP conference. The interactive showcase featured the latest breakthroughs for diagnosing, treating and managing the entire spectrum of sleep-disordered breathing. Philips Respironics also introduced the Alice 6 sleep diagnostic system, with a choice of three head boxes ranging from the Alice LDE for routine sleep studies to the full-featured LDx base station with either the LDxS or LDxN head box. The companion to the Alice 6 technology, the Sleepware G3 software, helps lab managers better meet workflow needs and offers staff members a richer, more productive experience. Sleepware G3 features an exclusive composite channel type useful when titrating complex sleep apnea patients with the BiPAP autoSV Advanced. The Sleepware G3 and the Somnoalyzer 24X7 provide a validated, computer-assisted service solution. Philips Respironics also featured its GoLife for Men, the company's first nasal pillows masks designed to fit the larger contours of the male facial structure. The newly released GoLife for Women features a smaller frame and headgear to more closely fit female facial dimensions. The company also premiered its TrueBlue gel nasal mask with Auto Seal technology. Thinner and lighter than previous masks, the premium blue gel, together with the thin, form-fitting outer silicone membrane, creates a self-adjusting seal. In sleep therapy, Philips Respironics' BiPAP autoSV Advanced System One simplifies treating complex sleep-disordered breathing patients. The newest entry in the System One sleep therapy platform – REMstar Pro with AutoIQ – is a CPAP system smart enough to track and deliver breath-by-breath therapy for up to 30 days while it learns the patient treatment needs. Based on what it learns, it sets a fixed pressure. AutoIQ checks back every 30 hours to see if the therapy pressure it established is on track. If not, REMstar Pro with AutoIQ automatically adjusts to obtain an ideal pressure. All without the need to send someone from the care team to patients' homes. With the release of EncoreAnywhere version 2.0, clinicians can easily customize the web-based patient compliance management system to better match their unique business and clinical workflow needs. Launching soon, Philips Respironics "Partners in Compliance Management Program" will offer essential tools via a comprehensive website to help support a customer's business goals and help their patients achieve compliance. The free website will house a resource center, best practices and protocols, clinical education and training materials, and reimbursement information. Contact [healthcare.philips.com](http://healthcare.philips.com).

## OSA TRIAL

Ventus Medical, Inc reported positive results from a 19 center clinical trial using its FDA-cleared Provent Sleep Apnea Therapy device to treat obstructive sleep apnea. Provent Therapy uses the patient's own breathing to create expiratory positive airway pressure (EPAP) to keep the airway open during sleep. The full results of this three month study were published in the April 2011 issue of the peer-reviewed medical journal SLEEP, an official publication of the American Academy of Sleep Medicine. The prospective, double-blind, sham-controlled clinical study enrolled 250 patients diagnosed with obstructive sleep apnea at 19 academic and private sleep centers in the US. The primary endpoint of the study was the reduction in AHI. In-laboratory

polysomnography was performed at the start of the study and after three months of treatment. Results at the start of the study showed that AHI was reduced by 52.7% in the Provent Therapy group compared to a 7.3% reduction in the sham group, representing a highly significant treatment effect ( $p < 0.0001$ ). A highly significant improvement in AHI was also demonstrated at the conclusion of the study. Using the Epworth Sleepiness Scale to evaluate daytime sleepiness, patients using Provent Therapy showed improved alertness, reducing sleepiness from  $9.9 \pm 4.7$  to  $7.2 \pm 4.2$  compared to the sham group of  $9.6 \pm 8.3$  to  $8.3 \pm 5.1$ , a statistically significant improvement compared to the sham group ( $p = 0.04$ ). Importantly, self-reported patient adherence was excellent, with the Provent Therapy device worn all night for 88.2% of nights in the study. Provent Therapy is a prescription device indicated for the treatment of obstructive sleep apnea. It is an easy-to-use, disposable treatment that works across mild, moderate and severe OSA. Provent Therapy is cleared by the FDA, and numerous peer-reviewed published studies have demonstrated that Provent Therapy improves sleep apnea and oxygenation. The device works through Ventus Medical's proprietary MicroValve technology that uses the patient's own breathing to create expiratory positive airway pressure (EPAP) to keep the airway open during sleep. For more information, visit [proventtherapy.com](http://proventtherapy.com).

## SPOTLIGHT ON VENTILATORS

### THREE NEW PLATFORMS

Earlier this year, the Respiratory and Monitoring Solutions business of Covidien announced three new platforms for its Puritan Bennett 840 ventilator. The Puritan Bennett 840 Neonatal ventilator, the Puritan Bennett 840 Universal ventilator and the Puritan Bennett 840 Pediatric-Adult ventilator are now available in the United States. The Puritan Bennett 840 Neonatal ventilator helps clinicians safely deliver, manage and monitor a ventilation regimen tailored for even the smallest and most critically ill neonatal patients. It offers the ability to set a tidal volume as small as 2 mL for neonates weighing as little as 300 grams without having to change to another ventilator. The Puritan Bennett 840 Universal ventilator for every patient type, from neonatal to adult, includes a neonatal CPAP mode that enables clinicians to flexibly deploy noninvasive ventilation in neonates. It supports patient-ventilator synchrony, which has been shown to facilitate spontaneous breathing. The ventilator includes features that effectively match the patient's respiratory demand and adapt to changes in patient condition. The Puritan Bennett 840 Pediatric-Adult ventilator for pediatric to adult patients helps clinicians provide improved levels of ventilatory support by offering multiple therapies of ventilation, including invasive and noninvasive methods, as well as more advanced modes of ventilation. The three new Puritan Bennett 840 Ventilator platforms, for neonates, pediatric-adult and the universal technology, provide clinicians with more flexible ventilation options than ever before. Contact [covidien.com](http://covidien.com).

### HEY BABY

Dräger offers its Babylog VN500: After over two decades of experiences and working with clinicians using the Babylog 8000 plus, Dräger continues its commitment to respiratory care with the newest technology for infant ventilation – the Babylog VN500. Designed to meet the specific needs of the patient and the neonatal care team, the VN500 offers a comprehensive and dedicated mechanical ventilation platform for the special care nursery as well as the pediatric intensive care areas. There is no

substitute for expertise that comes from years of dedication—experience the benefits of the Babylog VN500 for you and your tiniest patients. Contact (800) 437-2437, [draeger.com](http://draeger.com).

### INSPIRATIONAL

eVent Medical's Inspiration neonatal to adult ventilators are versatile, high performance ventilators designed with the clinician in mind. The patented Swiss pneumatic design allows high performance PSOL valves to provide outstanding breath delivery. Users find exceptional value in the straightforward interface, ease of transport, comprehensive monitoring and simple preventive maintenance. Practical advantages include standard battery, emergency backup compressor, integral nebulizer, Heliox and extreme ease of use. A unique capability within the Inspiration line is the ability to use eVent's CliniNet and CliniNet Virtual Report viewing system to bring centralized, real-time data and patient management to the entire care team. Contact [event-medical.com](http://event-medical.com), (888) 454-VENT.

### PORTABLE LIFE SUPPORT

Philips Respironics Trilogy200 is a portable life-support ventilator designed for use in the home and alternative care sites. It provides noninvasive and invasive ventilator support with added sensitivity for a wide range of adult and pediatric patients ( $\geq 5$  kg). Using a new single-limb circuit and proximal flow sensor, Trilogy200 offers improved triggering and leak compensation that allows for more sensitive delivery of therapy. This added sensitivity decreases work of breathing, resulting in greater therapy comfort, better ventilation, improved patient/ventilator synchrony and delivers effective and comfortable ventilator support to help clinicians transition patients from the hospital to home easier. Contact [healthcare.philips.com](http://healthcare.philips.com).

### NONINVASIVE

Philips Respironics BiPAP AVAPS is a noninvasive homecare ventilator developed to provide better, more efficient care for patients, including children as young as seven years old and who weigh over 40 pounds. An exclusive AVAPS (Average Volume Assured Pressure Support) technology automatically adjusts pressure support to meet changing patient needs while maintaining a target tidal volume. Neuromuscular, COPD, and obesity hypoventilation patients are strong candidates for this technology. AVAPS automatically adapts to disease progression, maintains optimal patient comfort without compromising care and efficacy, improves ventilation efficacy, and simplifies the titration process. Contact [healthcare.philips.com](http://healthcare.philips.com).

### PERFORMANCE

MAQUET SERVO ventilators are known worldwide for performance, reliability, and adaptability. Neonatal to adult, the SERVO-i can be used for transport, Heliox treatments, and conditionally in the MR environment. The platform offers all conventional modes of ventilation, capnography, and the revolutionary NAVA technology (Neurally Adjusted Ventilatory Assist). NAVA allows the patient and ventilator to work in synchronous harmony. NAVA provides monitoring of diaphragmatic activity during all modes of ventilation allowing the clinician to evaluate dyssynchrony and interpret effects of treatment. NAVA can also be used in non-invasive ventilation (NIV NAVA), which provides assist levels capable of matching the patient's neural demands regardless of leakage or user interface. For more information visit [maquetusa.com](http://maquetusa.com), [criticalcarenews.com](http://criticalcarenews.com), or call (888) 627-8383.

## CONFIDENCE

The Respiroics V60 ventilator takes NIV further by giving you the confidence to treat a wide range of patients. The V60 uses Auto-Trak auto-adaptive technology to help ensure patient synchrony and therapy acceptance. The six-hour internal battery supports emergency back-up and intra-hospital transport for continuity of care. The V60 is cleared for invasive and noninvasive treatment of pediatric and adult patients. Hospital ventilatory care is further supported with exclusive modes and comfort features. The Respiroics V60 fulfills the Philips commitment to simplify advanced healthcare. Contact [respiroics.com](http://respiroics.com).

## GO ANYWHERE

When transporting a critically ill patient you need a ventilator that can go anywhere in any situation. Smiths Medical PneuPac ventilators are lightweight, portable and durable gas powered alternatives to large or complex ventilators. PneuPac ventilators are MRI conditional, with an alarm option specifically designed for patient transports and noisy environments. These ventilators take the guess work out of providing respiratory support, and provide you with the feedback you need to make life-saving decisions. To learn more about the PneuPac line of ventilators: VR1, paraPAC, ventiPAC, and babyPac, visit the Smiths Medical website at [smiths-medical.com](http://smiths-medical.com).

## THE NEW GENERATION

The HAMILTON-C2 adds ventilation applications for neonates, nasal non-invasive ventilation, nCPAP-PS, via nasal prongs or masks. In addition, state of the art volumetric capnography with quantitative CO<sub>2</sub> measurement allows assessment of metabolism and sidestream capnography provides CO<sub>2</sub> measurement with minimal sample flow and minimal added deadspace. Equipped with the Ventilation Cockpit, you can view conventional waveforms, the ASV graphic, the Dynamic Lung, the Vent Status panel or a volumetric capnogram to assess the efficiency of the ventilation therapy. Each Intelligent Panel graphic visualizes the patient's status and ventilator dependency in an easy-to-understand display. Contact (800) 426-6331; [hamiltonmedical.com](http://hamiltonmedical.com).

## SPOTLIGHT ON PULMONARY FUNCTION TESTING

### STREAMLINED WORKFLOW

nSpire Health's introduces nSight streamlined PFT testing software with nSight Central configurable launch pad. Combined with HDpft's iFlow accuracy enhancement technology, nSight software's intuitive design mimics practice workflow, while its simple and flexible navigation mirrors a physician's thinking process. HDnet customized interfacing solution for EMR/HIS networking & connectivity seamlessly retrieves ADT and Order HL7 messages into the nSight SQL database, while HDweb provides anytime/anywhere remote rapid access to PFT related information on your iPad, Android tablet, or any Internet browser. nSpire Health puts you back in control of your day, interpreting patient tests in under a minute. Contact [nspirehealth.com/hdpft](http://nspirehealth.com/hdpft), (800) 574-7374.

## PRODUCT CASE STUDY

InterMune, Inc announced the publication of results from two Phase 3 trials demonstrating that treatment with pirfenidone, a

novel antifibrotic and anti-inflammatory drug, was associated with favorable effects on lung function, 6-minute walk test distance and progression-free survival (PFS) in patients with mild to moderate idiopathic pulmonary fibrosis (IPF). IPF is a rare and fatal lung disease affecting more than 200,000 patients in the EU and United States combined, with a survival rate of only 20% after five years. The results were published in *The Lancet*. The CAPACITY Program comprises two multinational, double-blind, placebo-controlled Phase 3 studies that were conducted simultaneously with 779 IPF patients (aged 40-80 years) across 110 centers in Australia, Europe and North America. Patients were randomly assigned to receive oral pirfenidone (2403 mg/day) or placebo for a minimum of 72 weeks to evaluate the impact of pirfenidone in reducing lung function deterioration in IPF patients. In Study 004 pirfenidone reduced the decline in FVC, an important measure of lung function, in IPF patients ( $p=0.001$ ). The mean FVC change at week 72 was -8.0% in the pirfenidone group compared to -12.4% in the placebo group – a significant difference of 4.4%. In addition, treatment with pirfenidone reduced the proportion of patients with FVC decline of 10% or more compared to placebo (35 of 174 patients vs 60 of 174 patients). Importantly, an FVC decline of 10% or more has been reported in multiple studies to be associated with an increased risk of mortality in patients with IPF. In Study 006, the difference between groups in FVC change at week 72 was not significant (-9.0% in the pirfenidone group compared with -9.6% in the placebo group); however, a consistent and statistically significant pirfenidone treatment was evident through one year of treatment. The repeated-measures analysis of % predicted FVC change over all study timepoints showed a favorable pirfenidone treatment effect in both studies. The primary endpoint analysis of the pooled population also showed a pirfenidone treatment effect on % predicted FVC at week 72 ( $p=0.005$ ). The mean change was -8.5% in the patients in the pirfenidone 2403 mg/day group and -11.0% in those in the placebo group, and a smaller proportion of patients had a decline in FVC of 10% or more in the pooled pirfenidone group. Pirfenidone 2403 mg/day significantly reduced decline in 6MWT distance at week 72 in study 006 but not in study 004. In the pooled population, a 31% relative difference was noted between treatment groups at week 72. The minimum clinically important difference in 6MWT distance in patients with idiopathic pulmonary fibrosis has been reported to be 24–45m. In a posthoc analysis, 62 (36%) of 170 patients in the pirfenidone group and 80 (47%) of 170 in the placebo group had a 50m or more decrement in 6MWT distance in study 004 ( $p=0.049$ ), and 56 (33%) of 169 and 79 (47%) of 168 patients, respectively in study 006 ( $p=0.010$ ). The Mantel-Haenszel relative risk was 0.74 (95% CI 0.62–0.89) for overall relative risk in the post-hoc analysis in the pooled population. Pooled data from the 2 clinical studies showed that numerically fewer overall deaths (6% vs 8%) and statistically fewer IPF-related deaths (3% vs 7%) occurred in the pirfenidone groups compared to placebo groups on-treatment ( $p<0.03$ ). In the pooled analysis, pirfenidone prolonged progression-free survival by 26% compared with placebo. Study results confirmed pirfenidone as a generally well tolerated, oral treatment with a favorable side effect profile; adverse reactions were generally mild or moderate. The most commonly reported (incidence  $\geq 10\%$ ) adverse reactions to pirfenidone compared to placebo were: nausea (32.8% vs 13.3%), rash (28.7% vs 8.6%), fatigue (22.3% vs 13.3%), diarrhea (21.7% vs 13.5%), dyspepsia (16.8% vs 5.5%) and photosensitivity reaction (12.2% vs 1.7%). Study treatment was discontinued because of adverse events in 51 (15%) of 345 patients in the pooled pirfenidone group and 30 (9%) of 347 patients in the pooled



placebo group. Treatment-emergent serious adverse events occurred in 113 (33%) of 345 patients in the pooled pirfenidone group and 109 (31%) of 347 patients in the pooled placebo group. Pirfenidone is an orally active, small molecule drug that inhibits the synthesis of TGF-beta, a chemical mediator that controls many cell functions including proliferation and differentiation, and plays a key role in fibrosis. It also inhibits the synthesis of TNF-alpha, a cytokine that is known to have an active role in inflammation. Recently, the European Commission (EC) granted marketing authorization for Esbriet (pirfenidone) for the treatment of adults with mild to moderate IPF. The approval authorizes marketing of Esbriet in all 27 EU member states. Esbriet has since been approved for marketing in Norway and Iceland. Pirfenidone is still under investigation for the treatment of IPF in the United States and has not been approved by the FDA for this use. InterMune currently plans to conduct ASCEND, a new Phase 3 study, toward the goal of bringing pirfenidone to IPF patients in the United States.

## COMPANY PROFILE

### Restech

Restech is a leader in engineering world class medical technologies that provide comfortable, reliable solutions to assist physicians in the diagnosis of reflux related health problems—such as chronic cough, asthma, and sleep-disordered breathing—quickly and reliably. The Dx-pH Measurement System is a revolutionary system that comfortably measures aerosolized pH and may be administered by a therapist or other mid-level provider (under physician supervision depending on state or scope of practice). Until now it has been difficult to detect reflux above the esophagus because available pH sensors were developed to measure liquid reflux in the esophagus. Supraesophageal reflux commonly takes a gaseous form that cannot easily be measured using conventional technology. The miniature pH sensor at the tip of the Dx-pH Probe is the only sensor able to measure aerosolized reflux. Restech conducts on-site in-service sessions for each of our customers in their clinic or hospital suite, and provides live technical support 24/7. The innovative engineering team at Restech is led by professionals with over two decades experience each in medical device development. Together, the Restech staff holds over thirty patents in the areas of sensor technology, data recording and monitoring systems, and other medical devices. The mission of Restech is to engineer novel, effective, world-class medical technologies that translate ideas into reality, visions into products, and needs into solutions.

## EMERGENCY ROUNDTABLE

### Hamilton Medical

**Please describe your products. Do they have a dual role or multiple applications?**

The turbine driven HAMILTON-T1 ventilator is a full ICU ventilator in a transport ventilators clothing. The HAMILTON-T1's compact and powerful design provides all major modes of ventilation, including ASV, for all patients. Whether they are in an intensive care ward, the recovery room, or in need of emergency medical or primary care, during transport within and outside the hospital or during transfer by rescue vehicles, jets or helicopters,

the HAMILTON T-1 can handle it all. Small enough to fit into almost any mobile ICU environment, the HAMILTON-T1 covers the full range of clinical requirements: invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and Non-Invasive Ventilation (NIV). The HAMILTON-T1 includes one backup and one hot-swappable battery with total of over 6 hours of battery life. The HAMILTON-T1 delivers a cost-effective ICU ventilation solution that's appropriate for all patients – from pediatric to adult. In mobile ICU ambulances, helicopters, and long-distance ambulance jets, the HAMILTON-T1's fast setup and easy management ensure the most appropriate treatment for every patient.

**What clinical or educational support do you provide, and how can it be accessed? (Also, do you offer any guide to policies and procedures for use with your product?)**

Hamilton Medical offers full support, be it directly to end users or to hospital technicians. The service procedure includes direct access to our distributors and Hamilton Medical authorized service personnel. Every complaint will immediately be answered and solved as quickly as possible. In case of any serious hardware problems, the affected device or component will be exchanged through our service providers and our worldwide network of distributors and technical staff. Our application specialists support every customer not only for product introduction, but post sale education as well. Hamilton Medical is known for its best in class customer support and on-site education for all users.

**Describe how your product has been used in actual emergencies or other relevant applications.**

The HAMILTON-T1 has already been used in several emergency departments for usability tests in Germany and Switzerland. Many opinion leaders of different institutions and hospitals evaluated the HAMILTON-T1 for air and ground transport. The feedback has been promising and unanimously positive. The HAMILTON-T1 technology is based on the HAMILTON-C1 platform, which is used in ICU environments. This device has been available worldwide except in the US (Pending FDA 501(k) clearance) since May 2011. The HAMILTON-C1 can also be used for intra-hospital transport..

**Is your product covered by a medical certification process (FDA, CSA, UL, etc)?**

The T1 FDA 510(k) is pending. CE and CB certification were expected as this article went to press.

**What is the life-span of your product, and what are its "in field" service requirements? Who can perform service on your product?**

The preventive maintenance program of Hamilton Medical requires a general service every 5000 hours or yearly, whichever comes first. A service-related preventive maintenance has to be performed every 5 years or after 30,000 hours. The detailed preventive maintenance procedures are explained in the HAMILTON-T1 user manual. Servicing "outer" parts like filters or cleaning issues has to be provided by the end-user, all other tasks have to be exclusively performed by authorized service personnel (distributors with its application and service people).

*Continued on page 29...*

# Ear and Fingertip Oxygen Saturation Measurements of Healthcare Workers Wearing Protective Masks

Raymond J. Roberge, MD, MPH; Aitor Coca, PhD; W. Jon Williams, PhD; Jeffrey B. Powell, MS; Andrew J. Palmiero, BS

## Abstract

Minor, but statistically significant, differences in oxygen saturation measured by pulse oximetry were noted between N95 filtering facepiece respirators with and without an exhalation valve and one model of an elastomeric air-purifying respirator worn by healthcare workers over one hour at two low work rates. Pulse oximetry determinations at the earlobe were significantly greater than concurrently-obtained fingertip oximetry values, but the absolute differences were small and would presumably not be of practical significance. The use of respiratory protective equipment by healthy healthcare workers over a one hour period is not likely to result in any clinically significant oxygen desaturations.

## Introduction

The relative insensitivity of visual recognition of hypoxia above arterial oxygen saturation ( $\text{SaO}_2$ ) of 80% by trained personnel (Jubran, 1999) led to the development of pulse oximetry in the 1980s (Tierney et al, 1997).  $\text{SaO}_2$ , the percentage of oxygen ( $\text{O}_2$ ) carried by arterial hemoglobin, has been routinely monitored in medicine and research since then and when measured by pulse oximetry ( $\text{SpO}_2$ ) is considered, by many, as the “fifth vital sign” (Tierney et al, 1997). Recent outbreaks of viral respiratory pathogens (eg, Severe Acute Respiratory Syndrome [SARS], avian influenza, pandemic influenza) have placed an emphasis on healthcare workers’ (HCWs) need for optimum respiratory protection. Filtering facepiece respirators (FFRs) are widely used by workers, and the N95 class of FFR (N95 FFR) is that which is most commonly used in the healthcare setting (Martyny et al, 2002). Elastomeric air-purifying respirators (EAPRs), though generally used by comparatively few HCWs (eg, pathologists, bronchoscopists, etc), are gaining some popularity by virtue of their reusability and potentially better fitting characteristics (Roberge (a) et al, 2010). The use of respiratory protective equipment (RPE) is recognized to be associated with negative physiological effects on the wearer

and some research has raised concerns that  $\text{O}_2$  parameters of HCWs and patients might be negatively impacted by the use of protective facemasks (Beder et al, 2008; Kao et al, 2004; Kao et al, 2010). The current study compares concurrent earlobe pulse oximetry ( $\text{SpO}_2$ ear) and fingertip pulse oximetry ( $\text{SpO}_2$ fingertip) in HCWs wearing N95 FFR and EAPR over the course of one hour of continuous use. This study was part of a National Institute for Occupational Safety and Health (NIOSH) investigation studying the physiological impact of RPE use by HCWs (NIOSH, 2009). Some of the results of the study have previously been published (Roberge et al, 2010a,b,c).

## Materials and Methods

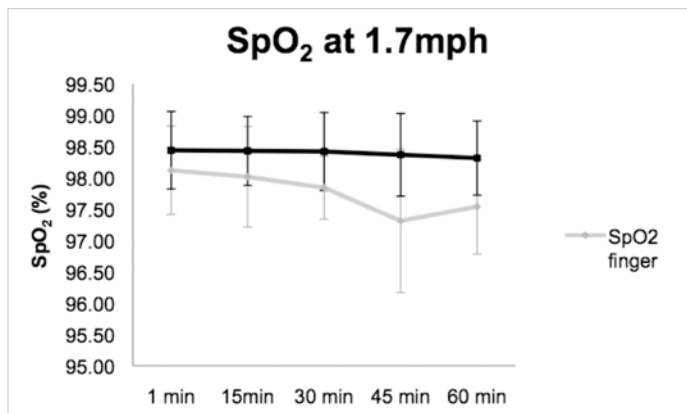
Ten HCWs (seven women, three men) with experience in the use of N95 FFRs, but not with EAPRs, were recruited for the study. Mean values (standard deviations) for subject demographic variables include: age 25.1 yrs ( $\pm 7.1$ ), weight 75.5 kg ( $\pm 24.3$ ), height 169.1 cm ( $\pm 11.4$ ), and body mass index (BMI) 26.4 ( $\pm 8.7$ ). Nine subjects had never smoked and one subject had not smoked in >one year (20 pack year smoking history). All subjects were Caucasian, had no history or hemoglobinopathies and did not wear fingernail polish. The study was approved by the NIOSH Human Subject Review Board, and all subjects provided oral and written informed consent.

Subjects were first quantitatively fit-tested for the respirator models used in the study and, based upon the fit test results, were assigned to wear one of two manufacturers’ cup-shaped N95 FFR models (3M 8000 or Moldex 2200), a corresponding cup-shaped N95 FFR having an exhalation valve (N95 FFR-EV) (3M 8511 or Moldex 2300), and one model of an EAPR with dual P-100 filters (North 5500). All subjects were able to be quantitatively fit tested for at least one model of N95 FFR and one model of N95 FFR-EV, and all subjects passed quantitative fit testing on the EAPR. The N95 FFR models were selected because they account for a large portion of US FFR sales and are in the Strategic National Stockpile, a repository of medical equipment likely to be first distributed to HCWs during emergencies (CDC, 2010). The N95 FFR-EV models were selected because they are counterpart models to the N95 FFR models (save for the presence of the exhalation valve) and the EAPR was selected because it had previously been utilized in a HCW study (Radonovich et al, 2009).

Subjects were tested in tee-shirts, shorts, and athletic footwear. A heated (42°C) combination transcutaneous carbon dioxide sensor/pulse oximeter (Tosca 500 Monitor, Radiometer,

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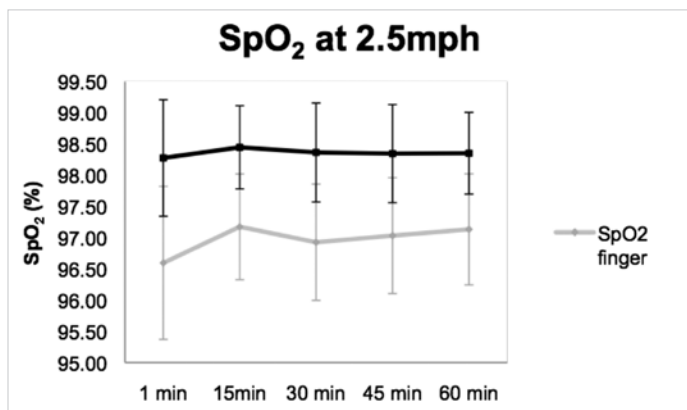
The authors are from the National Personal Protective Technology Laboratory/National Institute for Occupational Safety and Health/Centers for Disease Control and Prevention, Pittsburgh, PA. Acknowledgements: The authors gratefully acknowledge Nick Kyriazi, Drs Ronald Shaffer and Dr Jung-Hyun Kim of the National Personal Protective Technology Laboratory/NIOSH, and Dr Sean Gallagher of the Pittsburgh Research Laboratory/NIOSH for their manuscript reviews and helpful suggestions. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.



**Figure 1.** SpO<sub>2</sub> mean  $\pm$ SD at two measurement sites (finger and ear) for three respirators worn by 10 subjects at a low workload.

Copenhagen, DK) with adhesive backing was placed on the left ear lobe and linked to a viewing monitor with continuous readouts of SpO<sub>2</sub> ear. A pulse oximeter sensor with adhesive backing (Nonin Model 7000 A, Nonin Medical, Inc, Plymouth, MN) was attached to the left index finger and was connected to a standard pulse oximeter (Nonin XPod Pulse Oximeter) for continuous SpO<sub>2</sub> finger readouts. Both oximeters record and download data at  $\sim$ 3 second intervals continuously and both have a rated accuracy of  $\pm$ 2%. New oximeter sensors for the ear and finger were used for each one hour test session. Subjects were tested at treadmill speeds of 1.7 mph and 2.5 mph with zero degrees of inclination. These work rates were utilized because the 1.7 mph rate reflects desk-type HCW duties (eg, using a computer, answering a phone, etc) and the 2.5 mph rate is indicative of bedside nursing duties (eg, bathing a patient, administering medications, etc.) (Ainsworth et al, 2000). During respirator testing, the subjects were randomly assigned to the respirator type (eg, N95 FFR, N95 FFR-EV, EAPR) and the aforementioned work rates, and exercised continuously for one hour. A total of 60 hours of SpO<sub>2</sub> data while wearing a respirator was obtained (10 subjects x 3 respirators x 2 work rates x 1 hour = 60 hours). The study laboratory temperature was maintained at 22°C and the relative humidity averaged 54% (range 39% - 70%). For subjects completing more than one test per day, a minimum respite of 30 minutes was afforded between sessions. All control sessions (no respirator) were carried out within 3 weeks of study phases.

Statistical Analysis – SPSS version 18.0 (SPSS, Inc., Chicago, IL) was used for statistical analysis. SpO<sub>2</sub> ear and SpO<sub>2</sub> finger



**Figure 2.** SpO<sub>2</sub> mean  $\pm$ SD at two measurement sites (finger and ear) for three respirators worn by 10 subjects at a low-moderate workload.

data are reported as means (standard deviation). To assess differences between the RPE (N95 FFR, N95 FFR-EV, and EAPR), at the two different body sites (ear vs finger) with two intensity levels, at five staggered time intervals (1, 15, 30, 45, 60 min) during one hour of exercise, a 3 x 2 x 2 x 5 (respirator type x measurement site x work rate x time increment) repeated-measures analysis of variance (ANOVA) was performed. Significant interactions were further analyzed utilizing one-way ANOVA and paired t tests with Bonferroni corrections with the  $\alpha$ -level set at  $p < 0.05$ . SpO<sub>2</sub> ear and SpO<sub>2</sub> finger values for the 10 subjects were averaged over one hour and their relationship was analyzed by Pearson's correlation coefficient.

## Results

There was a significant difference in SpO<sub>2</sub> when comparing the use of N95 FFR-EV (98.14%), N95 FFR (97.59%) and EAPR (97.93%) over one hour at both work rates ( $p=0.02$ ). Subgroup comparison of FFRs indicated that use of N95 FFR-EV was associated with significantly higher SpO<sub>2</sub> than N95 FFR ( $p=0.002$ ). SpO<sub>2</sub> at the 1.7 mph work rate (98.14%) was significantly greater than at the 2.5 mph work rate (97.64%) ( $p=0.001$ ). SpO<sub>2</sub> ear readings (98.38%) were significantly higher than SpO<sub>2</sub> finger (97.40%) ( $p=0.000$ ) over one hour (Figures 1, 2). Correlation coefficients for SpO<sub>2</sub> ear and SpO<sub>2</sub> finger values for the various respirators over one hour were: N95 FFR @ 1.7 mph ( $r=0.14$  [ $p=0.000$ ]), N95 FFR@ 2.5 mph ( $r=0.34$  [ $p=0.000$ ]), N95 FFR-EV @ 1.7 mph ( $r=0.04$  [ $p=0.000$ ]), N95 FFR-EV @ 2.5 mph ( $r=0.03$  [ $p=0.002$ ]), EAPR @ 1.7 mph ( $r=0.07$  [ $p=0.000$ ]), EAPR @ 2.5 mph ( $r=0.09$  [ $p=0.000$ ]).

## Discussion

Pulse oximetry relies on the presence of an arterial pulsatile signal and differences in spectrophotometric measurements of changes in the optical absorption of hemoglobin species that is related to the presence of O<sub>2</sub> (ie, oxyhemoglobin absorbs less light in the red spectra [660 nm wavelength] and more light in the infrared spectra [940 nm wavelength] than reduced hemoglobin, and vice versa) (Jubran, 1999; Mendelson et al, 2006). The pulsating arterial vascular bed, by expanding and relaxing, creates a change in the light path length that modifies the amount of light detected (Yelderman and New Jr, 1983). The pulse oximeter positions an arterial pulse between a light source that transmits light through the blood at the aforementioned two wavelengths and a light detector that measures subsequent light absorption and computes the difference in absorption at the two wavelengths to arrive at the proportion of hemoglobin that is oxygenated (ie, SaO<sub>2</sub>) (Tierney et al, 1997; Jubran, 1999). SaO<sub>2</sub> can thus be defined as the ratio of oxyhemoglobin to the sum of oxyhemoglobin and reduced hemoglobin (Yelderman and New Jr, 1983). Transcutaneous sensors, utilizing Severinghaus-type electrodes, have been developed for the non-invasive monitoring of transcutaneous carbon dioxide (tcPCO<sub>2</sub>) levels. These sensors rely upon vasodilation of local veins and capillaries through the use of topical vasodilators or locally-applied heat to "arterialize" venous blood. The model used in the current study, the TOSCA 500 Monitoring System (Linde Medical Sensors, Basel, Switzerland), incorporates both a heated (42°C) tcPCO<sub>2</sub> sensor and a pulse oximeter for simultaneous readings of O<sub>2</sub> saturation and tcPCO<sub>2</sub> from the earlobe.

This study demonstrates that there was a statistically significant difference in SpO<sub>2</sub> of HCWs wearing N95 FFRs, N95 FFRs-EV, or an EAPR at low and low-moderate work rates over the course of one hour of continuous use, but that the impact on SpO<sub>2</sub> absolute

values is negligible and would have limited practical significance. As shown in earlier published data from this study (Roberge et al, 2010a,b), these SpO<sub>2</sub> values were attained despite the fact that the mean, mixed inhalation/exhalation O<sub>2</sub> concentrations in the breathing zone of the RPE (ie, RPE dead space) at the 1.7 mph and 2.5 mph work rates, respectively, were 16.6%/16.6% for N95 FFRs, 16.5%/17.2% for N95 FFR-EVs, and 17.85%/17.81% for EAPRs. Although technically these O<sub>2</sub> and CO<sub>2</sub> levels do not meet the Occupational Safety and Health Administration (OSHA) ambient workplace air standards of <0.5% CO<sub>2</sub> and ≥ 19.5% O<sub>2</sub> levels, these values do not apply to respirator dead space. These findings are encouraging for users of the types of RPE evaluated in the current study and may be especially important for user subgroups with special considerations (eg, those with airways diseases, pregnant users). The small absolute differences in SpO<sub>2</sub> values among the respirator types over one hour are not surprising given that N95 FFR and N95 FFR-EV, because of the enhancement of filter function through the use of electrostatic charging, are thinner and therefore offer less breathing resistance and better gas exchange (Richardson et al, 2006), and EAPR benefit from the presence of an exhalation valve and the greater filter surface area of EAPR (Lafferty and McKay, 2006). Although higher SpO<sub>2</sub> was noted for N95 FFRs-EV compared with N95 FFRs, the absolute difference was only 0.37% which, although statistically significant (p=0.002), would be of little practical significance (Stege et al, 2009; Martin et al, 1992). Similarly, although SpO<sub>2</sub> ear values were greater than SpO<sub>2</sub> finger (p=0.000) at the two workloads over staggered time intervals (Figures 1,2), the absolute differences are within the 1% - 2% accuracy limits of the sensors, a finding similar to that previously reported (Huese et al, 200; Stege et al, 2009; Jubran, 1999) and would likely not be of practical significance.

The weak correlations noted between SpO<sub>2</sub> ear and SpO<sub>2</sub> finger measurements, a finding reported previously (Stege et al, 2009), were nonetheless statistically significant chiefly because of the large number of data points (~1200 hr) included for each of the parameters. This discrepancy is partially due to the fact that response times for ear sensors are faster than for fingertip sensors because the lung-ear circulation time is less than that of the lung-finger circulation time (Young et al, 1992; Lindholm et al, 2007). Using earlobe and fingertip pulse oximetry, Senn et al (2005) and Lindholm et al (2007) found response times of five seconds for SpO<sub>2</sub> ear readings and 18-20 seconds for SpO<sub>2</sub> finger readings. Thus, SpO<sub>2</sub> readings in adults at the (unheated or non-vasodilated) earlobe are normally higher than that of the fingertip, but generally vary by <1% if blood flow is normal (Stege et al, 2009). It is also possible that the higher SpO<sub>2</sub> ear readings in this study were due to the tcPCO<sub>2</sub> sensor's heating of the earlobe (42°C) that increased local perfusion and, therefore, well-defined pulsatile signals (Heuss et al, 2004), although one previous study demonstrated no differences in SpO<sub>2</sub> ear values obtained by an unheated versus a heated ear sensor (Senn et al, 2005). Lastly, during exercise testing, ear sensors may display more accurate readings because of less motion artifact (and subsequently less signal interference) than occurs at finger sensors (Yamaya et al, 2002), if the earlobe size is sufficient to appropriately secure the sensor (Martin et al, 1992).

Limitations of the current study include the small number of subjects; nonetheless, each subject participated in multiple trials so that, in the aggregate, a sizeable number of trials (60) were accomplished. The data obtained at the low and low-moderate work rates used in the study might not be applicable

to high intensity work rates when arterial desaturation is most likely to occur (Martin et al, 1992), but most workers currently are employed in occupations with low-to-moderate work rates (Meyer et al, 1997; Harber et al, 2009) so that our data is apt to apply to a greater number of RPE users. The SpO<sub>2</sub> ear and SpO<sub>2</sub> finger values obtained in the study were not compared to concomitantly-obtained arterial blood gas values. However, SpO<sub>2</sub> has been investigated extensively and shown to be a valid and accurate predictor of SaO<sub>2</sub> (Lindholm et al, 2007), precludes the need for invasive and painful arterial puncture or cannulation, and offers continuous monitoring, whereas arterial blood gases offer the momentary data reflective only of the point in time of collection. Although prior studies have highlighted the possibility of a negative impact of RPE on O<sub>2</sub> parameters (Beder et al, 2008; Kao et al, 2004; Kao et al, 2010), the present study's findings cannot be directly compared because of the use of different RPE by Beder et al (2008) (surgical mask), significant subject differences in the Kao et al (2004) study (renal failure patients undergoing dialysis while wearing FFR), and the use of intermittent, rather than continuous, SpO<sub>2</sub> recordings by Kao et al (2010). We analyzed differences in SpO<sub>2</sub> ear and SpO<sub>2</sub> finger only at five staggered time intervals and could have missed some significant differences; however, because no subjects were hypoxic during the study, the practical significance of any possible differences would probably be minimal.

## Conclusions

Significant differences were noted in SpO<sub>2</sub> values of HCWs wearing N95 FFR, N95 FFR-EV and an EAPR continuously for one hour at low work rates, but the absolute differences were minor and no episodes of hypoxia were noted. SpO<sub>2</sub> ear recordings were statistically higher than SpO<sub>2</sub> finger readings, but the differences would not be of practical significance. Over the course of one hour, at the low and low-moderate work rates evaluated in this study, healthy HCWs should not experience any meaningful decrements in SpO<sub>2</sub> while wearing N95 FFR, N95 FFR-EV, and EAPR.

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*Roundtable...continued from page 25*

**Is your product single use or re-usable? Also, discuss upgrades to your products, and/or options for resupply of consumable parts.**

The HAMILTON-T1 is a reusable device with a wide range of single use and reusable accessories and consumables. All components can be exchanged. Therefore, we have a special exchange service procedure whereby outsourced service teams are in charge of local service tasks. The HAMILTON-T1 does not require any proprietary tubing, and the flow sensor comes in both single use and re-usable versions. A single use expiratory valve will be available soon and we will be able to offer either a single use or reusable set of tubing, flow sensor and expiratory valve.

**What lessons have you learned from the recent H1N1 experience?**

Hamilton Medical has realized that H1N1 has presented a new challenge in the ability to ventilate the severe cases of ARDS known to be caused by this new flu strain. H1N1 patients may also have to be transported to other locations within the hospital or even transported to other facilities hours away. In many cases, the patients have to be placed on a transport ventilator that is simply a beefed up emergency ventilator. It was this challenge, along with many others, that helped inspire us to build an ICU capable ventilator in a compact and rugged housing allowing for true secondary transport capability without compromising the patient's condition. The guidelines for chemical disinfection and sterilization procedures have also been analyzed and proven. During development of the HAMILTON-T1 any kind of critical aspect regarding contamination has been considered and implemented to help prevent cross contamination. For additional information, visit [hamilton-medical.com](http://hamilton-medical.com).

# Partnership for Patients: Next Step - Preventing Tracheostomy Associated Infections (TAI) And Complications

Joann Miller

On April 12, 2011 Department of HHS Secretary Kathleen Sebelius and CMS Administrator Donald Berwick launched the Partnership for Patients, a “new public-private partnership that brings together leaders of major hospitals, employers, health plans, physicians, nurses, and patient advocates along with State and Federal governments in a shared effort to make hospital care safer, more reliable, and less costly.”

Among the goals of the Partnership for Patients is the goal to decrease by the end of 2013 instances of (PPCs) Potentially Preventable Conditions while in hospital and Potentially Preventable Complications during transition from one health care setting to another and, more specifically, to decrease the amount of 2010 instances by 40% of hospital patients acquiring preventable conditions as well as decreasing by 20% of 2010 re-admission numbers of patients who experience preventable complications.

Achieving these goals holds potential to save both lives and money. The combined efforts of this partnership could save 60,000 American lives and reduce millions of preventable injuries and complications in patient care over the next three years. It also could save as much as \$35 billion to the health care system, including up to \$10 billion in Medicare savings.<sup>1</sup>

The Partnership for Patients has identified nine areas of focus. The Partnership will not limit its work to these nine areas, and will pursue the reduction of all-cause harm. But the following areas of focus are obvious and important places to begin.<sup>2</sup>

- Adverse Drug Events (ADE)
- Catheter-Associated Urinary Tract Infections (CAUTI)
- Central Line Associated Blood Stream Infections (CLABSI)
- Injuries from Falls and Immobility
- Obstetrical Adverse Events
- Pressure Ulcers
- Surgical Site Infections
- Venous Thromboembolism (VTE)
- Ventilator-Associated Pneumonia (VAP)
- Other Hospital-Acquired Conditions

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Joann Miller is a communications consultant for Wright Solutions LLC. This article, featuring Wright Solutions' products, was provided by the company.

## Tracheostomy Associated Mucus Plugs — A Preventable Complication

For tracheostomy patients mucus plugs can be deadly. “...A small mucous plug or bleeding can easily cause fatal obstruction. Airway obstruction may produce unyielding pneumonia. Prompt treatment is necessary.”<sup>3</sup> Transitioning from intensive care to acute care or acute care to home, Long Term Care (LTC), rehabilitation or nursing home, a lack of medical management results in avoidable tracheostomy complications such as mucus plugs. Mucus plugs are generally not a result of an underlying disease but result due to a lack of moisturization of the upper airway which not only thins secretions but also moisturizes bronchial tissues. Mucus plugging occurs through a build up of bronchial secretions which accumulate significantly enough to obstruct airflow. “Tracheostomy tubes increase the likelihood of mucus plug formation,” says John Bach, a physical medicine and rehabilitation specialist at University Hospital in Newark, NJ, and co-director of the MDA clinic there. “Mucus plugs affect anyone with very weak throat muscles,” he says, “but tracheostomy tubes cause mucus plugs even when throat muscles are not weak.” This is because the tracheostomy tube often stimulates increased secretion production. A trach also bypasses the natural defense systems that filter and humidify the upper airway. In addition, lack of airflow over the larynx can lead to reduced sensation in that area and decreased reflexes to cough or clear the throat.<sup>4</sup>

A 2007 study carried out at Robert Wood Johnson Medical School-Camden, Camden, NJ showed 28% of tracheostomy patients discharged from hospital were re-admitted which is higher than non-tracheostomized patients who had a 20% re-admission rate.<sup>5</sup> “The introduction of regular ENT-led multidisciplinary input for patients with a tracheostomy significantly improved compliance with nursing care standards.”<sup>6</sup> “Mucus plugs are the most common cause of respiratory distress for children with tracheostomies,” according to Joanne Wright, RN, MSN, CNS, Children’s Hospital/UHHSC.<sup>7</sup>

For trached patients who do not require O<sub>2</sub>, using The Wright Face & Tracheostomy Nebulizing Mask is preferred as it does not occlude the airway as HMEs may do in patients with copious secretions. The Wright Mask simultaneously humidifies the nose, mouth, sinuses and trachea thinning secretions complimenting follow-up activities such as suctioning.

**Preventing Tracheostomy Associated Infections (TAI)**  
Tracheostomy Associated Pneumonia and infections can be

equally as threatening to trached patients as mucus plugs are. Keeping trach tubes, trach masks and humidifiers, clean and germ free is imperative in the battle against infectious germs, mold, Nosocomial infections and community acquired pneumonia. "Patients with tracheostomy alone had half the pneumonia rate compared to invasive, ventilator-dependent patients. Tracheostomy has its own risk of associated pneumonia. The mechanical ventilator is an added risk."<sup>8</sup> "Approximately 40,000 cases of VAP occur each year, and these cases are associated with about 6,000 deaths. Patients in hospitals can also develop pneumonia for reasons unrelated to ventilators, and pneumonia is sometimes difficult to diagnose. It is therefore important to properly assess inpatient pneumonia cases to accurately identify cases that are associated with ventilators."<sup>9</sup>

Based on Partnership for Patients' estimates, 50% of VAP cases are preventable, Partnership for Patients has set a goal for hospitals to reduce preventable cases of VAP by 50% over the next few years.

TAI cases and Tracheostomy Associated Mucus Plug cases are also preventable. In a 17 year study that reviewed the charts of 72 children who had tracheostomy between Jan 1990 and Jan 2007, "Tracheostomy infection occurred in 90% of the patients and tracheal granulation in 56%."<sup>10</sup> 15% deaths occurred with 10% of those deaths due to a mucus plug.

It is estimated that 20,000 cases of Tracheostomy Associated Pneumonia (TAP) occur each year in the US resulting in about 3,000 deaths. As with cases associated with ventilators, it is imperative for health care professionals to assess inpatient pneumonia cases in order to correctly identify cases that are associated with trachs, in order to reduce TAP occurrences.

### **Opportunity for Improvement**

Tracheostomy Associated Mucus Plugs can be prevented by implementing specific preventive practices for trached patients that includes daily use of The Wright Face and Tracheostomy Nebulizing Mask. Simultaneous humidification of the nose, mouth, sinuses and trachea with the Wright Face & Tracheostomy Nebulizing Mask thins secretions while replacing moisture to the upper airway, reducing mucus plugs and re-hospitalizations. Implementing daily use of The Wright Face & Tracheostomy Nebulizing Mask in medical management of trached patients along with other recommended practices can successfully reduce preventable conditions and complications.

During a recent speech given by HHS Secretary Sebelius to the Atlanta Press Club, the Secretary addressed the need to choose a path in which to lower Medicare costs. In part she said, "We're now working to establish a very novel principle in our health care system, which is that we should reward the care that's most effective. To do that, CMS is helping groups of hospitals and doctors form 'accountable care organizations.' By keeping their patients healthy and not readmitted, these 'accountable care organizations' will share the savings. CMS is tying Medicare payments for hospitals to the quality of the care they provide." Referring to some of these changes, one Georgia hospital CEO said: "It isn't just good to do quality. It is going to be necessary to do quality." "We hope that attitude keeps spreading," Sebelius said.

Secretary Sebelius believes the best way to put Medicare's finances on a more stable path is by making Medicare a full

partner of the doctors and nurses who are working to improve care across the country.<sup>11</sup>

HHS and CMS have also created a new Innovation Center in Medicare and Medicaid that will develop and test new models for improving care. It's all part of an effort to improve the nation's health care system that includes a new national focus on prevention.

The Wright Face & Tracheostomy Nebulizing Mask will significantly reduce re-hospitalization costs while simultaneously delivering quality of care to patients. Accountable care organizations must improve readmission prevalence among this vulnerable population. To do so, ensuring trach patients receive clear instructions prior to being discharged on their medications and other follow-up activities will reduce the likelihood they will suffer a preventable complication requiring them to be readmitted to the hospital.

Changes in Medicare payment made in 2010 are leading to an influx of patients with tracheostomy and those who are ventilator dependent into sub-acute skilled nursing facilities. Health care reform will further influence this trend and reimbursement will depend on quality care and positive outcomes. Tracheostomy and ventilators can make even the most seasoned healthcare practitioners uneasy. For many RNs, LPN/LVNs, and CNAs working in skilled nursing facilities, these patients will provide a new challenge and demand that they develop new skills.<sup>12</sup>

Too often, nursing students, medical students and residents who dare to ask questions are told: "this is the way we do it." Such a dogmatic response suggests that medical knowledge is carved in stone, ie, "we have discovered the ultimate treatment."

Dr Jack Wennberg, the father of what is now known as "the Dartmouth Research" refers to such certainty as the "Doctrine of Manifest Efficacy": "this is what we do therefore, it must be right." (Wennberg notes that when his children were growing up, a similar argument was made to justify subjecting millions of children to unnecessary tonsillectomies. Some of those children died.)

How do we help students understand the ambiguities and uncertainties of medicine? One nurse at the symposium made an excellent suggestion: When showing a student a procedure, we might say, "This is the way we used to do it—but we realized that led to too many errors. So now, we do it this way." And a thoughtful mentor might add: "at some point in the future, we'll probably find an even better way."<sup>13</sup>

It is now time to think out of the box in order to reduce re-hospitalizations while lowering health care costs. Emphasis must be on getting all those who care for the patient on the same page, thinking and executing the same things. It is time to provide tracheostomy patients with The Wright Face & Tracheostomy Nebulizing Mask, giving them the ability to manage their homecare, ultimately keeping them from being re-admitted due to mucus plugs, dry sinuses, tracheostomy associated sleep apnea as well as sinus headaches—all of which are preventable complications.

The Department of Health and Human Services (HHS) launched a new initiative which will reward hospitals for the

quality of care they provide to people with Medicare and help reduce health care costs. Authorized by the Affordable Care Act, the Hospital Value-Based Purchasing program marks the beginning of an historic change in how Medicare pays health care providers and facilities—for the first time, 3,500 hospitals across the country will be paid for inpatient acute care services based on care quality, not just the quantity of the services they provide. “Changing the way we pay hospitals will improve the quality of care for seniors and save money for all of us,” said Sebelius. “Under this initiative, Medicare will reward hospitals that provide high-quality care and keep their patients healthy. It’s an important part of our work to improve the health of our nation and drive down costs. As hospitals work to improve their performance on these measures, all patients—not just Medicare patients—will benefit.” For example, ensuring heart failure patients receive clear instructions when they are discharged on their medications and other follow-up activities reduces the likelihood that they will suffer a preventable complication that would require them to be readmitted to the hospital.<sup>14</sup>

Beginning in 2013, hospitals will receive a payment reduction if they have excess 30-day readmissions for patients with heart attacks, heart failure, and pneumonia. By 2015, most hospitals will face reductions in their Medicare payments if they do not meaningfully use information technology to deliver better, safer, more coordinated care. In addition, beginning in 2015, hospitals with high rates of certain hospital acquired conditions will receive further payment reductions from Medicare.<sup>15</sup>

On May 2, 2011, HHS recognized the following 13 hospitals and health care facilities for their efforts to prevent – and eventually eliminate – healthcare associated infections (HAIs), specifically Ventilator-Associated Pneumonia, one of the Health care Associated Infections which is a leading cause of death in the United States. These hospitals received the Achievements in Eliminating VAP, Outstanding Leadership Award, for sustained success in reaching their target for 25 months or more: Seton Medical Center, Daly City, CA; University Hospital, Augusta, GA; St Catherine of Siena Medical Center, New York; Johnson City Medical Center, Johnson City, TN; Baylor University Medical Center Truett ICU, Dallas, TX; and St Luke’s Episcopal Hospital, Houston, TX. The Sustained Improvement Award, for consistent and sustained progress over an 18 to 24 month period went to: St Joseph Hospital Orange, Orange, CA; Huntington Memorial Hospital, Pasadena, CA; Palmdale Regional Medical Center, Palmdale, CA; Saint Anne’s Hospital, Fall River, MA; Carolinas Medical Center NeuroSurgical ICU, Charlotte, NC; Highland Hospital ICU, Rochester, NY; and Providence St Mary Medical Center, Walla Walla, WA.

HAIs are infections that are acquired while patients are receiving medical treatment for other conditions. At any given time, about 1 in every 20 patients has an infection related to their hospital care. These infections cost the US health care system billions of dollars each year and lead to the loss of tens of thousands of lives. In addition, HAIs can have devastating emotional, financial and medical consequences.<sup>16</sup> By FY 2015 up to 4.5% of hospitals’ CMS payments will be at risk due to HAI performance.<sup>17</sup>

Clearly hospitals have a challenge in the months and years ahead, however, more needs to be done to prevent—and eventually eliminate—infections acquired after patients leave the hospital setting. By providing patients with the tools to avoid future infections health care facilities will reduce re-

hospitalizations, lower health care costs and ultimately save lives. Reduction by 50% of preventable inpatient TAP & VAP cases, could save 4,500 lives, reduce 30,000 re-hospitalizations while saving the health care system billions of dollars per year.

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# Enabling Speech for Ventilator Dependent Trach Patients

Mellissa Turner, BA, RRT

For many long term and full time ventilator dependent patients, difficulty in communication can present a real life problem. These patients use a tracheostomy tube which bypasses the vocal cords but allows life saving ventilation to be supported via a mechanical ventilator. Since the vocal cords are bypassed, the patients are unable to speak and thus vocally communicate.

The lack of being able to communicate causes many negative feelings and emotions not limited to anxiety, insecurity, frustration and fear. Not being able to actively participate in conversations or communicate feelings to family and friends or even clinicians can be very hard to deal with, as one could imagine.

There have been methods developed to help patients in these scenarios to be able to talk. Some patients, but not all, can tolerate deflation of the tracheostomy tube cuff, which allows exhaled air to come up around the tube and through the patient's vocal cords, allowing them to speak. Another method, which also involves deflating the cuff, is to use a one-way valve which closes to the ventilator after inspiration and allows the exhaled air to pass through the vocal cords as in the previous example. There are downfalls to both of these techniques, which include aspiration of secretions, the patient not tolerating cuff deflation, and lastly, nuisance ventilator alarms. The ventilator alarms experienced are false low volume or disconnect alarms because the exhaled air is not returned through the ventilator to be measured but is instead exhaled through the mouth of the patient. Since in most cases these alarms can not be turned off or disabled, it becomes a nuisance to both patient and staff to have the continuous sounding of the low volume alarms. Some recommend use of non-invasive modes which disable some of these alarms, but this is contrary to the FDA "intended use" of these modalities.

As mentioned previously, some patients can not tolerate a cuff leak and therefore have no speech communication choice. There could be several reasons for the inability to tolerate a cuff leak. One is that they have a high risk of aspiration. Another is that they may not receive as much support from the ventilator as long as volume is being leaked out from around their cuff.

For the patients that are unable to tolerate cuff leaks and an

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answer to the low volume ventilator alarms, a new tracheostomy tube has been developed called the Blom Tracheostomy Tube and Speech Cannula.<sup>1</sup> The tracheostomy tube has a thin polyvinyl chloride cuff and fenestration. There are two types of cannulas that come with this tracheostomy tube. One is the Blom Standard Cannula and the other the Blom Speech Cannula. The standard cannula resembles any other standard inner cannula for a tracheostomy tube. The genius comes in where the speech cannula is concerned. The design of the speech cannula is such that there are two valves within the cannula. A flap-valve will open with inspiratory pressure as gas flows to the patient while occluding the bubble valve which covers the fenestration at the same time. Upon exhalation, the flap-valve closes and the bubble valve opens, which opens the passage through the fenestration, therefore forcing the air past the patient's vocal cords allowing them to speak. With the use of the speech cannula, this becomes the only available product that is able to redirect air in its entirety into the upper airway while still maintaining an inflated tracheostomy tube cuff. One could certainly see how this could be an advantage for many patients previously unable to communicate.

The next point of contention is how to deal with false low volume alarms. There is a separate component that was also developed to be used with the Blom Tracheostomy Tube. It provides the answer to preventing the false low volume/disconnect alarms. This device is a silicon bellows which is easily compatible with most ventilators. During the inspiratory phase, it expands to trap air and then returns gas to the ventilator upon exhalation so that an exhaled volume can be measured by the ventilator and not set off the low volume alarm.

The exhaled volume reservoir (ERV) has a couple of different placement options depending on the ventilator. If the ventilator measures exhaled volume at the ventilator itself, the reservoir should be placed at the end of the expiratory circuit. If the volume is measured by a proximal flow sensor, the reservoir should be placed between the flow sensor and patient. The ERV is used only when the speech cannula is in place.

A study was performed by Kunduk et al to study the safety, efficacy, patient tolerance and satisfaction of the Blom Tracheostomy Tube. It was found that the Blom Tracheostomy Tube appears "safe and effective in facilitating phonation"<sup>1</sup> in trached patients who are ventilator dependent. It was also found that suctioning the patients through the speech cannula did not  
*Continued on page 54...*

# Ambulatory Oxygen Therapy and Compliance: How Less Is Often More

## Introduction

Oxygen therapy is a well-established treatment for those afflicted with chronic obstructive pulmonary disease (COPD). Clinical studies reveal increased survival rates among long-term oxygen therapy (LTOT) patients directly related to the number of hours each day that oxygen is used.<sup>1,2</sup> In addition to reduced mortality and morbidity, oxygen therapy mitigates symptoms, improves exercise tolerance, enhances cognitive function and improves health-related quality of life (HRQL).<sup>3-8</sup>

Throughout the world, the stationary oxygen concentrator has become the most popular and cost-effective modality for providing oxygen therapy in the home; however, this device does not address portable oxygen needs outside of the home. One of the most difficult and expensive aspects of providing oxygen therapy is the portable component, which allows patients to resume activities outside the home and improve their quality of life. Portable oxygen is an essential component of therapy for ambulatory, supplemental oxygen patients.

This paper will discuss the types of portable oxygen systems, with an emphasis on portable oxygen concentrators (POCs), the incorporation of oxygen conserving devices into these systems, and the challenges encountered by patients and home medical equipment (HME) providers. Lastly, it will discuss the need to balance efficacy with compliance goals.

## Need for Portable Oxygen

Increased activity levels during ambulation increase the physiological demand for oxygen. Oxygen alleviates hypoxemia and the accompanying symptoms, mainly dyspnea, or shortness of breath. Portable oxygen is an essential component of pulmonary rehabilitation and exercise programs aimed at building muscle tone, flexibility, and endurance.<sup>9</sup>

LTOT patients experience psychosocial difficulties due to living in a restricted world. Limitations are both physiological and equipment driven. Without the availability of portable oxygen, daily use of oxygen is significantly less, leading to reduced life expectancy.<sup>10</sup> Patients remain homebound, reporting a decrease in daily activity and quality of life. LTOT patients who ambulate without oxygen become symptomatic and are forced to reduce their activity level and duration.

Portable oxygen allows patients to leave their homes, restore social activities, regain their independence through self-management, and improves HRQL by reducing symptoms of hypoxemia.<sup>11</sup>

## Types of Portable Oxygen Systems

Portable oxygen is supplied in three forms: compressed gas, liquid, or a portable oxygen concentrator (POC). Gas and liquid oxygen systems contain either the gaseous or liquid form of oxygen in a high-pressure cylinder or insulated container. These contents-based systems hold a specific amount of oxygen and need to be refilled when empty by the HME provider or the patient.

Typically, HME providers deliver oxygen cylinders and liquid oxygen, but there has been a trend toward equipment that eliminates frequent oxygen deliveries. Oxygen generating portable equipment (OGPE) includes POCs and cylinder refilling systems that utilize compressors to refill high-pressure gas cylinders from stationary concentrators.

A cylinder refilling system has 3 main components: an oxygen concentrator, a cylinder compressor, and specially adapted high-pressure cylinders. These systems require patients and caregivers to refill cylinders in the home instead of relying on deliveries by HME providers. As with other contents-based systems, these systems do not address travel needs or extended ambulatory times.

The POC is an electro-mechanical device that uses a molecular sieve material to separate oxygen from nitrogen in room air. POCs utilize the same process as stationary oxygen concentrators, however, on a smaller scale using less power. They operate on AC or DC power sources or a rechargeable battery. These devices make their own oxygen when in use and operate reliably for years.

POCs do not store oxygen like compressed gas or liquid systems, so they are able to obtain Federal Aviation Administration (FAA) clearance for use onboard commercial aircraft after meeting certain technical and safety standards.<sup>12</sup> Unlike contents-based systems, POCs allow extended ambulatory times and travel options, including overnight visits.

The size and weight of a portable oxygen system varies greatly, from less than 5 pounds to up to 20 pounds. Units weighing less than 5 pounds are considered “wearable,” since they are

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lightweight enough to be carried or worn by the patient. Units up to 10 pounds fall into the traditional portable classification and are carried by the patient or pulled on a cart. The heaviest of these systems, transportable POCs, may weigh up to 20 pounds, and provide a continuous flow option. Continuous flow capability substantially increases the system's size and weight, requiring the use of a cart. The weight of such systems significantly affects compliance, especially when a POC needs to be lifted up steps, into automobiles, or over such obstacles as sidewalk curbs.

### **Inefficient Continuous Flow Oxygen Delivery Yields to Oxygen Conserving Technology**

Portable systems incorporate oxygen conserving technology, which prevents oxygen from flowing wastefully during the exhalation phase of the breathing cycle. This extends the duration of oxygen contents, making smaller and lighter weight canisters and machines possible. Inhalation represents only 1/3 of the breathing cycle; as a result, 2/3 of the oxygen is saved by preventing oxygen flow during exhalation. Enhanced oxygen conservation technology, incorporated into many portable oxygen systems, allows the flow of oxygen as a pulse during only the beginning of inspiration, thus eliminating oxygen flow into anatomic dead space.<sup>9</sup>

Some conserving devices are extremely efficient, with almost 100% of the oxygen delivered into the vital functional capacity of the lung.<sup>13</sup>

In Fishman's *Pulmonary Diseases and Disorders* (1991), as cited by Drs Carter, Williams and Tjep,<sup>14</sup> the physiology of the breathing cycle is described as it relates to oxygen supplied with a standard flow nasal cannula. Essentially, this means that up to 5/6 of the oxygen administered from a continuous flow source goes unused by the patient and is wasted. Improvements in oxygen efficiency and the elimination of oxygen waste of continuous flow yields oxygen savings of up to 6:1.

Due to differences in delivery methodology, pulse size, triggering sensitivity, and pulse delivery time, SpO<sub>2</sub> blood saturations may differ when comparing pulsed devices to each other as well as to continuous devices.

### **Titration**

There is a growing concern regarding the need to measure and titrate each patient at rest, during sleep, and during exercise to specific oxygen equipment, whether the delivery method is via pulse- or continuous-flow. Current guidelines recommend selecting a setting and flow rate to maintain oxygen saturation levels of at least 90% for all levels of activity.<sup>9,15</sup>

If titration is performed, it usually involves an informal, non-standardized walk test to determine oxygen needs during ambulation. Perhaps a more accurate design to ensure saturation may involve titrating a patient throughout their normal daily activities. This would consider patient specific conditions such as stairs, work, or participation in strenuous activities or hobbies.

Unfortunately, healthcare systems do not adequately reimburse HME providers or physicians to titrate patients to these levels, and it would be unrealistic to expect this level of clinical assessment without proper reimbursement.

### **Portable Oxygen Costs**

Portable systems that are refilled or exchanged include gas cylinders or liquid oxygen systems. Routine home deliveries of oxygen are very expensive due to infrastructure and a sizeable investment needed by HME providers. Some of the many costs that need to be recouped are: outfitted delivery vehicles, bulk oxygen storage tanks, technicians, and staff for 24/7 service and support.

Although initially expensive, POCs and other oxygen generating portable equipment become very cost-effective over time, particularly when patients are able to rent equipment on a monthly basis.

### **HME Perspective**

Portable oxygen is much more expensive to supply than stationary oxygen. In countries with government or insurance reimbursement, the reimbursement for portable oxygen usually does not completely cover an equipment provider's costs.

Decreasing reimbursements, combined with escalating delivery costs, are making it increasingly more difficult for the HME providers to distribute cylinders and liquid oxygen to patients in a cost-effective manner. Subsequently, HME providers are shifting to POCs and cylinder refilling systems to eliminate recurring oxygen deliveries. Although these systems have a higher acquisition cost than traditional oxygen systems, prices have decreased substantially since their introduction. This creates a cost-effective model, even with reduced rates of reimbursement.

Where reimbursement or insurance does not cover equipment costs, HME providers offer a selection of oxygen models at different price points for rental or purchase.

### **Patient Perspective**

COPD patients have compromised respiratory systems with reduced lung capacity; so understandably, the most important consideration affecting compliance is the overall size and weight of a portable oxygen system.<sup>16,17</sup> Patients seek out the smallest and lightest portable that meets the requirements for alleviation of symptoms, and determine if it is light enough to be carried or transported during activities of daily living. This may include stair climbing, extended walks, working, social functions, outdoor activities, and hobbies. Oxygen patients become discouraged by systems that are "too heavy" and may impede or prevent an activity, causing a dependence on others.

The second consideration to patients, after weight, is the duration of the oxygen supply, ensuring that the system meets their personal requirements. There is a balance to be addressed in the current technologies, as increasing duration time adds size and weight to portable systems. This creates a dilemma for the patient, since one must weigh the added physical burden against the benefit of added duration time.

Embarrassment or self-consciousness also factors into patient compliance. Patients may not want to use portable oxygen in public due to the stigma of oxygen cylinders.<sup>17</sup> Future studies may demonstrate that compliance improves with lighter weight ambulatory systems that do not resemble cylinders.

Other factors and considerations that favor portable systems include cost, insurance coverage, appearance, features, sound

level, reliability, service, and support.

Patients who use gas and liquid portable systems become accustomed to the amount of time their oxygen systems last, and adjust their ambulation to match this time. When concerned about running low or out of contents, patients may turn their equipment down to a lower setting or even off to preserve or extend contents. Many fear running out of oxygen and becoming symptomatic. For trips or other periods of extended use, a patient may request from the HME provider additional cylinders or a larger, heavier portable that holds more contents to ensure longer duration.

Patients on POCs quickly adapt to managing power rather than contents by locating and plugging into AC or DC power sources. The rechargeable battery provides the time needed to bridge between power outlets when mobile in automobiles, homes, restaurants or businesses. Although oxygen patients may be concerned about running out of battery power, it is easier to find an alternate power source than an alternate oxygen source.

### **Manufacturer Perspective**

Manufacturers continuously strive to reduce the size and weight of ambulatory oxygen systems, due to the critical importance of system weight for the oxygen patient. In an effort to move the industry in this direction, a number of organizations have defined ambulatory oxygen as weighing less than 10 lbs while providing oxygen at 2 LPM (or equivalent) for at least 4 hours as an acceptable system for patients to carry.<sup>9,18</sup>

With the advent of conservation technology, gas and liquid portable systems are smaller and lighter, shifting the industry from cartable systems to those that can be carried. Previously used larger cylinders on carts are now considered inadequate for ambulation due to their size, and were rendered virtually obsolete by lightweight pulsing systems when oxygen conservation became widely accepted.

The introduction of the POC launched a new concept for portable systems by creating on-demand, oxygen-making capability. While contents-based systems provide fixed amounts of time, POCs provide unlimited intervals of time when connected to power. Thus, one-hour battery duration does not represent the time of use, but rather the maximum time between plugging into power sources for unlimited-use ambulatory oxygen.

The POC market is divided into 2 classes of devices: the lighter, portable, pulse-only devices, and the heavier, transportable models that provide a continuous flow option.

Pulse-only POCs for ambulation are commonly marketed as a package with a stationary oxygen concentrator for home use, priced comparably to the transportable POCs alone. This allows the majority (65 to 90%) of the hours to be utilized on a relatively inexpensive stationary concentrator, while the lightweight POC fulfills the portability and travel needs. This combination provides an additional oxygen concentrator back-up in the event of a product malfunction.

Transportable POCs are marketed as a single solution to be utilized both for portability as well as continuous flow oxygen for home use. During ambulation, these devices are typically used in the pulse mode to extend battery duration, and then

switched to continuous flow, particularly for nighttime use. The continuous flow capability significantly increases the size and weight of the POC to account for added oxygen production with up to 5/6 waste.

Transportable POCs, capable of providing up to 3 liters per minute of continuous flow oxygen, are promoted to increase patient saturation levels as well as the ability to meet the future oxygen requirements of the patient. Some manufacturers are promoting an increased target level of  $\geq 90\%$  oxygen saturation, although there is no research to support improved outcomes. Many patients find these systems too heavy, preferring lighter and smaller systems that they are able to carry.

### **Discussion**

HME companies are shifting from delivering oxygen to providing oxygen generating equipment, namely POCs and cylinder refilling systems. POCs have inherent advantages over contents-based portable systems (cylinders, liquid portables and cylinder refilling systems) by greatly increasing ambulatory times and by facilitating overnight and vacation travel.

When compared to patients using contents-based systems, patients using POCs ambulate for longer time periods; it is unclear if this is due to highly ambulatory patients being better candidates for POC use, the POCs' oxygen-making capabilities, or both.

The activity level of a patient and the time spent ambulating is inversely correlated with the severity of the disease state. In the early stages of COPD, patients are commonly prescribed oxygen at 2 liters per minute, and tend to be the most active during this time. There is a principle that they should be provided the lightest portable system that meets their current oxygen requirements. Providing a high-capacity, heavier POC may reduce outcomes and certainly, quality of life, by unduly forcing patients to deal with equipment that is too heavy for them and impedes their activities.

This situation is analogous to an obstructive sleep apnea (OSA) patient and the therapeutic continuous positive airway pressure (CPAP) device. When titrating an OSA patient, the pressure that eliminates 100% of the apneas may be so uncomfortable that the therapy is not tolerated. A lower, more comfortable pressure is selected that eliminates most, but not all, of the apneas so that the therapy will be utilized.

How patients feel physically and mentally, their perception of the therapy, and their compliance are fundamental to successful outcomes. In the case of CPAP, it is a difficult therapy, and only patients who experience a reduction in symptoms continue with the therapy. Patients may periodically skip the therapy to see if symptoms return. Compliance is greater if the therapy is perceived to be beneficial. It is challenging for medical providers to persuade patients who are complying with, and benefiting from, a particular therapy to use a device at a pressure or weight that they cannot tolerate in the belief that it will somehow benefit them.

With the proliferation of and increased marketing to patients of pulse oximeters,<sup>19</sup> individuals today are actively monitoring their saturation levels. This is a positive shift, since reductions in reimbursement have caused most HME companies to provide less clinical support and services. This trend provides evidence

that many LTOT patients are actively involved with and attuned to their therapy.

The pursuit of true ambulation for an oxygen patient involves properly matching the system to the patient to encourage the greatest compliance. For most patients, this means the lightest system that current technology has developed.

## Summary

For patients requiring oxygen therapy, the adage, some oxygen is better than none, and more oxygen is better than some, holds true and is well-supported clinically, as it related to duration (or hours) of use. Portable oxygen systems are an essential component to achieve full-time oxygen use for ambulatory patients. Compliance varies for a myriad of reasons, with system weight being the number one factor. With an increasing number of portable oxygen systems available in the market that incorporate oxygen conserving technology with different delivery methodologies, there has been an emphasis placed on titration, with a goal of at least 90% oxygen saturation. Knowing that most patients are symptomatic and that portable oxygen is intended to reduce the symptoms of breathlessness, perhaps the shift should be to balance the titration goal with patient compliance and system weight. While heavy, transportable POCs may improve saturations, if these systems are too heavy, then an additional physiological burden is placed on patients, limiting their activity and reducing their independence at best, and possibly leading to non-use altogether. Lighter weight POCs may improve compliance, independence and overall quality of life while reducing breathlessness, even at lower than ideal saturations. There remains a struggle to balance the functional limitations of a portable oxygen system because of its size and weight with the benefits derived by the oxygen patient. As patient involvement and awareness increases, it is apparent that patient compliance and preference will become significant factors in the shaping of the ambulatory oxygen market.

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# Home Mechanical Ventilation and Specialized Health Care in the Community: between a rock and a hard place

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## Abstract

**Background:** Home mechanical ventilation probably represents the most advanced and complicated type of medical treatment provisioned outside a hospital setting. The aim of this study was both to explore the challenges experienced by health care professionals in community health care services when caring for patients dependent on home mechanical ventilation, continual care and highly advanced technology, and their proposed solutions to these challenges.

**Methods:** Using qualitative research methods, a grounded theory influenced approach was used to explore the respondents' experiences and proposed solutions. A total of 34 multidisciplinary respondents from five different communities in Norway were recruited for five focus groups.

**Results:** The core category in our findings was what health care professionals in community health care services experience as "between a rock and a hard place," when working with hospitals, family members, and patients. We further identified four sub-categories, "to be a guest in the patient's home," "to be accepted or not," "who decides," and "how much can we take." The main background for these challenges seems to stem from patients living and receiving care in their private homes, which often leads to conflicts with family members. These challenges can have a negative effect on both the community health caregivers' work environment and the community health service's provision of professional care.

**Conclusions:** This study has identified that care of individuals with complex needs and dependent on home mechanical ventilation presents a wide range of immense challenges for community health care services. The results of this study point towards a need to define the roles of family caregivers and health care professionals and also to find solutions to improve their collaboration. The need to improve the work environment for caregivers directly involved in home-care also exists. The study also shows

the need for more dialogue concerning eligibility requirements, rights, and limitations of patients in the provision and use of ventilatory support in private homes.

## Background

Home mechanical ventilation (HMV) probably represents the most advanced and complicated type of medical treatment provisioned outside a hospital setting.<sup>1,2</sup> This is especially apparent in the group of patients, consisting of both children and adults, who have tracheostomies and depend on specialised and costly care, monitoring, and ventilation support around the clock or for the majority of the day. In Norway, this group accounts for 7.8% of the total HMV patient population.<sup>3</sup> The remaining patients use non-invasive ventilation. The majority of HMV patients are given ventilation support in their homes but some live in public health care institutions or nursing homes. Family members are often involved in daily care and perform technical procedures.<sup>4</sup> These families are assisted by community health care services, especially when the patient is completely dependent on mechanical ventilation support or lives in a health care facility. A number of studies have investigated the strain put on family caregivers for this patient group, especially the pediatric patient population, but few studies have focused on identifying the challenges of caring for at-home HMV patients using the perspective of community health care services.

Generally, care for someone in his or her own home takes place in a different context from caring for him or her in a hospital, and requires a different approach.<sup>5</sup> Home care nurses use the terms "guest" or "professional" to characterise their relationships with patients and it seems impossible to be both at the same time.<sup>6</sup> Guests do not typically make demands<sup>7</sup> and the nurse must be aware of the patients' right to influence their own care, especially in their own home. Previous research shows that nurses believe their position of power and authority may be threatened or challenged when family members participate in specialized nursing care for family members dependent on highly advanced technology.<sup>8</sup> Health care professionals (HCP's) not recognizing the parents of HMV technology-dependent children as experts may lead to conflicts.<sup>4</sup> Similar to family members, HCP's also experience fatigue, depression, and burnout, and very few professionals choose to work with this patient group.<sup>9</sup> High turnover rates among HCP's often lead to a dysfunctional relationship between family and health care providers,<sup>10</sup> and in contrast to this, continuity in care is described as a success factor for a good and active life for the patient.<sup>11</sup> Community nurses can be dissatisfied with the hospitals' discharge planning because the nurses

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are given little opportunity for involvement and too little time for practical preparations.<sup>12,13</sup> Determining whether the discharging hospital or the receiving community has medical responsibility for at-home HMV patients may cause confusion.<sup>12</sup> In the UK, it has been speculated that community health care development has not kept up with the medical and technical advancements that make it possible to discharge children with complex needs from hospital.<sup>12</sup>

The aim of this study was both to explore the challenges experienced by HCP's in community health care services when caring for HMV patients dependent on continual care and highly advanced technology, and their proposed solutions to these challenges. Several factors influenced our decision to conduct this study: • Norway being no exception, little research has been conducted in this specific area. • Specialized hospitals must recognize and be aware of these challenges to ensure a safe and successful transition from hospital to community care. • Communities providing care for this patient group for the first time could benefit from learning about these challenges. • This knowledge will be an important point of reference when health care authorities develop clinical guidelines for HMV, which is currently underway in Norway.

## Methods

**Study design:** Qualitative research methods using a grounded theory influenced approach and focus groups were selected to explore the experience of the community health care services.

**Study setting:** Organizing and financing care of HMV patients varies between countries and health care systems. We studied the Norwegian public financial health system in which specialized hospitals establish ventilation support and follow-up even after hospital discharge. Community health care services, in cooperation with family caregivers, have responsibility for the daily care provided in the patient's home. In Norway, family members can be paid employees as part of the health care team caring for the HMV-dependent family member.

**Table 1.** Characteristics of respondents, and the patients the communities cared for.

Focus gr/ community	Profession	Total patients *	Total years of experience with HMV	Patient's residence
1	RN/nurse manager, RN/previous nurse manager, RN, PA and 2 CNAs	1	9	1 Assisted- living facility
2	RN/nurse manager, RN/nurse manager, LVN, 2 CNA's and 4 RN's	3	39	2 Assisted- living facilities 1 Private residence
3	RN/Communal director, social educator/unit manager, critical care RN and 2 RN's	3	33	2 Assisted- living facilities 1 Private residence
4	RN/previous leader, social educator/unit manager, environmental therapist, child pedagogue, 2 PA's and 2 CNA's	5	48	5 Private residences
5	Child welfare social worker/unit manager, RN/case manager, RN/consultant, social educator and 2 RN's	2	20	2 Private residences

**Abbreviation:** RN: registered nurse, PA: personal assistant, CNA: certified Nursing Assistant, LVN: licenced vocational nurse

\*all patients had tracheostomies and were ventilator dependent for either the entire or majority of the day

**Sampling:** In classic grounded theory, the ongoing analysis steers the sampling and the data collection (theoretical sampling), but this can prove difficult to implement in practice. Strauss and Corbin state that, "as with all research, there is the ideal way of conducting a study and the practical way (or that for which one has to settle)."<sup>14</sup> At first, we established contact with five communities from different regions in Norway that currently provide highly advanced care to HMV-dependent patients. We were ready to recruit more if necessary, but data collection ceased after 5 focus group sessions, when we determined that new information did not add new knowledge or insight (theoretical saturation).

**Recruitment:** First, the home care administrators in each community were contacted via telephone to discuss their willingness to participate and an information letter was later sent. To extract a broad description of experience, home care administrators were asked to recruit all relevant HCP's involved in one way or another in care of tracheostomized and HMV-dependent patients; this being limited, however, to a maximum of 10 respondents in each group. Participation criteria included respondents with administrative or coordination responsibilities, and other personnel directly involved in practical care in the patient's residence. Unlicensed caregivers were also included. These caregivers had no formal health diploma, but instead received training and guidance from registered nurses, patients, and family members to perform HMV-related nursing tasks. Family members were not recruited as respondents. The characteristics of all 34 respondents are summarized in table 1. All of the five participating communities had extensive experience with this type of care. During the data collection period, a total of 14 HMV-dependent patients were cared for in the five communities. Two of the communities cared for a total of three HMV-dependent children, with the remaining 11 patients being adults (Table 1). All of the ventilator-dependent individuals had chronic neuromuscular disease (NMD), like, amyotrophic lateral sclerosis, Duchenne muscular dystrophy, infantile myofibromatose, limb-girdle muscular dystrophy, nemaline myopathy, spinal muscular atrophy type 1 and syringomyelia. Ages varied from eight to 78 and although the degree of disability varied, all were capable of being mobilized in a wheelchair during the day.

**Data collection:** Focus groups have proven to be particularly useful for gaining thorough descriptions of knowledge, experience, priorities, and attitudes.<sup>15</sup> The spontaneity of group-based conversations may provide insight into topics that could be difficult to gain using other methods.<sup>16</sup> In this study, the number of respondents in each of the five focus groups varied between five and nine. The focus group sessions lasted between 70 to 90 minutes and were conducted from June to December of 2009. To prevent issues of power differences in each group, the moderator encouraged equal participation in the group and guided the discussion so that every respondents was able to express his or her opinion. A moderator led the focus groups and used a discussion guide with a few open-ended questions (appendix). To gain a deeper understanding of the experience that were most important, relevant, and problematic for the respondents, and according to the principles of the Grounded methodology, we edited the discussion guide based on a continual analysis and comparison of collected data before moving on to the next focus group. Data collection and analysis occurred simultaneously.

**Data analysis:** The focus group discussions were recorded and transcribed verbatim. Memos were also noted during the

research process or immediately after data collection. In accordance with grounded theory, transcripts and memos were analyzed several times and line-by-line (open coding) to find the words or phrases used by the respondents to describe their challenges and how they are trying to solve it. In the final stage of data analysis, we manually sorted the codes into larger categories and sub-categories (selective coding). All codes were compared. This is what is called the “constant comparative method.”<sup>17,18</sup> A core category and four sub-categories of what was most important for the respondents were found. Quotes correlating to each of the categories are collected in separate tables and cross-referenced to focus group numbers and the respondents’ professions.

**Ethical considerations:** To save time, we asked the administrators of the community health services in question to recruit all relevant HCPs for the focus groups. Use of this procedure obviously leads to concern regarding the issue of coercing respondents to participate. However, a letter was given to all respondents informing them that participation was on a voluntary basis and that they could withdraw from the study at any time without any further obligation. All respondents gave written consent that they would participate. All gathered material has been treated anonymously. More detailed characteristics of the patients and the communities in Table 1 are omitted to ensure the anonymity of the patients, respondents, and the communities. The study was approved by the Norwegian Social Science Data Services (20781) and Regional Committee for Medical Research Ethics (REKNORD 5/2009).

## Results

The core category in our findings describes how the community health care services, at both administrative level and in practical care, experience the challenge of “being between a rock and a hard place.” Furthermore, we found four sub-categories describing the community health care services’ challenges related to the core category. When applicable, the respondents gave proposed solutions to solve problems. We found no variation in the experience of HCPs caring for HMV-dependent children compared with those caring for HMV-dependent adults. Discussions in the focus groups uncovered very detailed, gripping, and emotional stories of the daily struggles to help these patients and their family members to live a good, meaningful, and valuable life: “You get extreme respect for them. You don’t want to go and complain about small things when you see what they have to struggle with. You want to fight together with them. You want to be there until the bitter end” (4/Personal Assistant).

Many of the respondents expressed that, despite all the challenges they had been subjected to, they had gained unique, exciting, and learning rich experience that they did not regret obtaining. Many felt strong understanding of what a huge challenge it is to care for HMV patients in their own homes. Much was at stake and the smallest mistake could lead to serious and even life-threatening consequences.

Some of the respondents mentioned that they could understand the family members’ reactions and behavior and how they would have reacted the same way if put in the same situation.

“Between a rock and a hard place” (core category): To be “between a rock and a hard place” describes the dilemma of being in a position in which one must choose between two unpleasant alternatives, without the opportunity to satisfy all the impli-

cated parties’ needs. In this study, respondents described this dilemma in different ways because of the different roles experienced caring for HMV patients. Home care administrators were mostly concerned with describing the discrepancies between the hospital’s, the patients’, and the families’ expectations for the community to have adequate personnel competence, the necessary resources in place, and the daily struggle to keep it all at a professional level. Because of the high turnover rate of HCPs, the administrators constantly focused on staff recruitment, but most applicants were in fact unlicensed caregivers. The collaboration with the specialized hospitals was described as good, but the community workers did, however, complain about not being sufficiently involved in planning and decision-making. Another dilemma arising was the responsibility the communities had for many other patients in the community, while having to prioritize HMV patients because of life-support treatment. Despite this prioritizing, the communities claimed that it did not affect the lives and health of the other patients, but instead the workload became heavier for the HCP’s. The HCP’s providing the practical and everyday care in the patient’s home described the dilemma of having to answer to several counterparts simultaneously: the hospital responsible for the technical dimension of the treatment, the community as their employer, the families, often deeply involved in the care, and their own opinions about what was best for the patient. The following sub-categories describe these dilemmas in more detail, and in addition, the respondents proposed solutions to some of them.

Quotation examples “Between a rock and a hard place” (core category): • “What can the community contribute then? And what should the community get involved in? We are standing here between a rock and a hard place. We receive directives from the hospital: ‘Please take this patient.’ And the parents are completely stressed out and on the tips of their toes. And it’s an incredible difficult start to a collaborative relationship” (4/RN/previous leader). • “The patient and the family did not accept all of the guidelines we had there. We were not allowed to do what we were directed to do. I felt we were very much in between a rock and a hard place” (2/Certified Nursing Assistant). • “The technical issues, that you’re not involved in the testing, the medical issues, what happens in the hospital. We’re told to try this out for a period. This can be anything from antibiotics to new pressures and changes to the ventilator. And to initiate a single nursing procedure, you have to discuss with the parents and they try to challenge you. In a way, you’re never able autonomously to make decisions. You hear the same from others all the time. This is why we feel we are stuck between a rock and a hard place” (5/RN).

### To be a guest in the patient’s home

All of the respondents were most interested in describing the challenges associated with working in the HMV patient’s private home. Working inside a private residence was described as the biggest challenge and was the main trigger for the other challenges they described. The HCPs experienced that they were merely guests in the patients’ homes, and this was something they had to be constantly aware of while at work. They held a low profile in order not to disturb peace in the home and thereby to avoid conflicts. The staff consciously kept a neutral demeanor, did not stand out, stayed quiet, closed their ears, and held their tongues. They were, after all, in the patient’s home and had to behave in keeping. The relationship with the patient’s family was always the most difficult; less so was the patient himself/herself or the technical aspects of the care. Working alone with an HMV patient



in a private home was described by the HCP's as both socially and professionally lonely. In many instances, the patient's level of communication was limited, contributing to the HCP's loneliness. Loneliness also refers to how the HCP's were only able to discuss clinical questions with other colleagues during shift changes. Boredom could be explained by the mundane everyday tasks, or because some patients were unwilling to participate in outdoor activities. To solve the issues relating to the patient living in his or her own home, respondents from each community recommended that the patients be placed in assisted-living facilities to improve HCP's work environment.

Quotation examples "to be a guest in the patient's home": • "The biggest challenge for us is to be in a private home. This has to do with meeting the family in their residence and complying with them. This is the biggest challenge of this job" (5/Social Educator). • "I steadily learned that I was crossing a threshold into another home. I think this is important to think about. This is where they actually live. I am, in a way, a guest here. And I knew my role as a guest. Being humble with regard to what their wishes were, as best I could" (3/Critical Care RN). • "You're unable to get people to work with this. No one wants to work there. The patient on a ventilator is very demanding in how he wants the assistance. And the spouse. The demands are too big and too negative, so no one wants to work there" (3/RN). • "We thought they could live collectively so they could share personnel and a similar environment. Where they are able to combine their private lives in their personal living space, that is their own private arena, but where the personnel has a working environment with other patients and other personnel, so that they can be taken care of. I don't think we will be able to manage more HMV patients living completely isolated in the house they lived in when they were well" (3/RN/Communal Director).

### To be accepted or not?

In addition to attending formal courses, in collaboration with the community health services and the specialized hospitals, some of the HCP's had to undergo a sort of informal approval from expert family members, which many deemed problematic. The respondents sensed that the intention of this informal approval was a way for the family members to find out if the HCP's had the necessary skills, and further if they were suitable for the job. The HCP's believed they were put through a test, despite the community health service's leadership acknowledging they were qualified to fulfill the job. Others described that they were well accepted and regarded as an extension of the family, thereby putting the HCP's in between two roles: professional and friend. This was a difficult position to be in.

Quotation examples "to be accepted or not": • "It makes things worse when we don't have enough people who can visit him and be accepted there. You're first accepted when you've received training. There is always an incredibly high threshold to come in and receive training. It is always a struggle. And we can't continue like this, having too little people when the need for people is so huge" (1/RN). • "I don't think very many people from the team have quit because of the patient, or because the patient saw them as useless. The family itself has labeled them as useless" (2/RN). • "You're caught in between the two roles of being a professional and being a friend. In every role, you're caught somewhere in between. You have no clear role in relation to anything. In everything we do. We don't actually decide anything. And in this way you're caught between the patient and the parents" (5/Social Educator).

### Who decides?

The HCP's working directly with the patient expressed enormous frustration with regard to who decided on the medical treatment. Was this the specialized hospital, the patient, the family, the community health administration, or the HCP in question? The HCP's believed they possessed the competence to make the professional decisions but had to eventually consult with the family, and many times compromise on their decisions with persistent family members who had become experts in care. The disagreements and obscurity surrounding these decisions especially affected the unlicensed carers; therefore, the respondents suggested that the boundaries for what the families should be involved in needed to be clarified. Many of the respondents thought it was very unfortunate that some family members were employed as part of the health care team, leading to the double role of both caring family member and care provider. This was often the source of conflicts, eventually ending up in the resignation of a HCP; therefore, most of the respondents proposed that family members should not be employed as part of the health care team.

Quotation examples "who decides?": • "She (the wife) claimed rights she did not have. This was because it was in her home, so she had a completely different role than the other employees coming from the outside. And because of this, she became a type of informal leader and did the decision-making" (3/RN/Communal Director). • "Who decides? God only knows. I have been fighting with them for years. In the end, it was always them" (4/RN/previous leader). • "What I thought was very unfortunate was to employ family members as part of the health care team, because this became a very difficult role. She went and checked anything she was unsure about. And it was very difficult to be controlled in work-related situations. And this quickly turned into conflicts" (3/Critical Care RN).

### How much can we take?

The majority of HCP's experienced conflicts with families while working in the patient's home. Some felt harassed, but believed there was a limit to how much one could get involved. In these situations, the HCP could not distance themselves because the patient's condition demanded them to be constantly present. All of the respondents knew the reasons the previous HCP had resigned. This was not because they did not enjoy working with the patient, rather the mental burden of being alone in these situations, without the possibility to reach out for support from fellow coworkers. Quotation examples: "how much can we take?": • "Where do we draw the line? I tell the family member that I do not accept the way you behave when you are here together with your spouse. So, you were caught in the middle... the family member had his or her spouse in the home, while I had to care for my employees" (1/RN/nurse manager). • "Those at work deserve a good work environment as well. Finding the threshold of where the limit goes. But I have been blamed for crossing this line many times" (2/licensed vocational nurse). • "If only the family had a little different attitude, another way to cooperate. I've thought about this many times. If the relationship with the family were different, then I think those eight years with the patient could have been pure bliss" (2/RN/Communal director).

### Discussion

This study has illustrated that caring for HMV patients with complex needs represents a wide range of immense challenges for community health services. The respondents in this study described the dilemma of being a guest in the patient's home and having to behave accordingly. Being in this position can create

obstacles when providing care, as confirmed by previous studies.<sup>6</sup> Similar to previous research,<sup>8</sup> our study also highlights how considerable family member involvement as informal carers and experts challenges the role and authority of HCPs. Understandably further frustration is experienced when family members are employed as part of the care team for loved ones. This type of system is apparently exclusive to Norway, as we did not find similar descriptions in the literature review. In this study, these relationships had a distinctly negative influence on the HCPs professional and psycho-social work environment when working in the patient's home. As a consequence of this, the study revealed that many of the HCPs could not continue working in the patient's home and eventually quit. This same phenomenon is also described in another study.<sup>9</sup> HCP recruitment was difficult, either because potential job seekers did not picture themselves with such a unique type of care or because they had heard how difficult it is to work in the patients' homes. Whereas it is important that HCPs have competence tailor-made for this special patient group,<sup>1,19</sup> the communities we studied often recruited unlicensed carers. The high turnover rate and lack of competent and experienced HCPs led to constant focus on recruitment and training of new employees. These challenges stand in contrast to what HMV patients describe as imperative to live a good and active life: competent HCPs and continuity in care.<sup>11</sup> In our study, the respondents cited how the lack of continuity and competence among HCPs also had a negative impact on the family members. It increased the burden on family members because they had to step in and do much of the work themselves or they could not trust the caregiver, especially when the family was not present. These issues have been documented in other studies.<sup>20-22</sup>

What can be done to reduce the consequences related to the challenges revealed in this study and what proposed solutions do the respondents in this study suggest? Similar to the findings from previous research,<sup>8</sup> the results from this study emphasize the need for dialogue regarding the boundaries of family member involvement in this type of technically advanced care. If the solution includes limiting the involvement of family carers, something we sensed that the respondents in this study wanted, this will probably prove difficult for the families to accept. Family carers are aware that their competence level may well exceed that of the other carers and that their expertise is important for the well-being and survival of the ventilator-dependent patient.<sup>4</sup> Additionally, finding an alternative to family carers could be difficult because professional support for this type of specialized care is not always readily available,<sup>20</sup> which was also the case in the communities we studied. Instead, the HCPs should recognize the family members' competence and be willing to learn from them.<sup>4</sup>

Initiatives to improve the HCPs professional and psychosocial work environment seem to be important to ensure continuity and competence. Several studies have pointed out the importance of supporting the family carers' emotional and psychosocial needs.<sup>12,23-25</sup> Our study identifies this same need in the HCPs and supporting the families' emotional and psychosocial needs should be done systematically, which was not being done in the communities we studied.

The respondents in our study recommended that this complex group of HMV patients should be treated together in an assisted-living facility to avoid the challenges associated with caregivers working alone in the patients' homes. This recommendation corresponds with a recent statement from the Norwegian Direc-

tor of Health, which implies that communities should not have the responsibility or obligation to care for these types of patients in their homes because of the enormous challenges associated with its provision.<sup>26</sup> The respondents argued that this would improve the work environment by strengthening both the social and professional work cultures. By working with several patients an increased variation in work would be achieved, which could prevent employee burnout and reduce turnover rates. Reduced employee turnover rates could lead to increased competence, something that would most certainly benefit the patient. The respondents defended the use of assisted-living facilities by claiming that the community health care services' role in decision-making and setting limitations and guidelines would be strengthened, which would reduce costs. Another benefit was the possibility for family members to live a more normal life by relieving them of some of the workload associated with caring for an HMV-dependent family member. Despite these benefits, the respondents believed both the patients and the families would strongly oppose to the idea of not having the right to live in their own homes. Patients and parents of HMV-dependent children want to live at home.<sup>11,20,27</sup> It gives the HMV patient a feeling of freedom and security,<sup>28</sup> even though it can be stressful for patients and families to have an unfamiliar health care worker in their homes.<sup>1,11,29</sup>

Fulltime HMV care can be considerably expensive<sup>30</sup> and disagreements and obscurities of the financial responsibilities are described,<sup>13,31</sup> Because of large regional differences in the provision of HMV,<sup>32</sup> some communities carry a much heavier financial burden than others. In the present study, expenses were never mentioned as a problem or as a source of the challenges the municipalities described. This is probably because health care financing varies from country to country and because the Norwegian health care system, including both specialized hospitals and community health care services, is publicly financed. In addition to public financing, the Norwegian government has developed special funding for community health care services caring for complex HMV-dependent patients. Despite the availability of financial support, the Norwegian Director of Health has recently signaled a possible reduction in the provision of fulltime-monitored HMV because of the high demand for HCP resources thereby generated. No literature was found to support that this is a prioritization other countries are also considering.

Possible limitations: The sample in this study was small, as in most qualitative studies. Despite this limitation we believe this study draws an accurate picture of the current situation in Norway. We believe the results of this study may have transferability to other types of advanced in-home treatment, such as tracheostomies, dialysis, parental nutrition, and intravenous medications. One must take into consideration that the results of this study may not be transferable to other countries because of the differences in treatment, delegation of responsibilities, organizing, and financing of HMV. Neither the patients nor the families have validated the results of this study because we focused only on the experience of HCPs. However, we recently conducted a study involving all the five communities used in the present study to investigate the experience of family members of HMV patients with complex needs. Interestingly, we found that there is a large gap between family members' expectations and what the community health care services are able to provide, even when almost unlimited resources are available.

## Conclusions

This study illustrates how home care for ventilator-dependent patients with complex needs presents a wide range of immense challenges for community health care services, both at administrative level and for the health care personnel in direct contact with the patient and his or her family. These challenges can have a negative impact on community HCPs' work environment and the community health care services' provision of professional care. The results of this study point towards the need to define the roles of family caregivers and HCPs, and also to find solutions to improve their collaboration. A debate considering whether family members should be formally employed as carers for loved ones is also needed. The work environment of HCPs in patient's homes must be improved to ensure the necessary competence and quality of care. Specialized hospitals should allow community health care services to be more involved in both the adaptation of HMV and long-term follow-up care. The study also shows the need for more dialogue concerning eligibility requirements, rights, and the limitations for patients in the provision and use of HMV in private homes. Further research exploring the experience of HCPs in other countries caring for individuals dependent on continual care and highly advanced technology is needed.

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# Use of the Passy-Muir Valve for Weaning in Long Term Acute Care Hospitals

Julie Kobak, MA, CCC-SLP; Linda Dean, RRT

With the aging of the baby boomer population and advances in critical care, the population of adult patients requiring prolonged acute mechanical ventilation is steadily rising. Based on an analysis by Zilberberg and Shore (2008), the number of cases is expected to more than double from 250,000 in the year 2000 to over 600,000 by the year 2020. Furthermore, it is projected that these patients will require approximately 13 million hospital days with annual hospital costs of over \$64 billion.

Hospitals will have a difficult time meeting the nearly 140% growth in demand for ICU beds. In recent years, long term acute care hospitals (LTACH) have emerged as a novel care model for patients recovering from severe acute illness and requiring prolonged mechanical ventilation. The number of LTACHs has been increasing at a steady rate of approximately 8.8% per year in response to the demand for specialized acute care (Kahn, et al, 2010).

As soon as patients reach the door, one of the primary objectives of LTACHs is weaning them from mechanical ventilation. Clinicians as well as administrators are actively trying to identify and develop strategies and weaning protocols that will result in more efficient care delivery and patient outcomes. Madonna Rehabilitation Hospital in Lincoln, Nebraska has developed a multi-disciplinary team model which incorporates use of the Passy-Muir Swallowing and Speaking Valve to facilitate weaning and decannulation (Windhorst, Wagoner, & Harth, 2009). This hospital's protocol includes a standing order that, within 48 hours of admission, every tracheostomized and ventilator-dependent patient is co-evaluated by the respiratory therapist and the speech language pathologist for placement of the Passy-Muir Valve.

The multidisciplinary team has developed a flow chart for assessment and treatment including objective criteria for Passy-Muir Valve tolerance. Use of the valve is a critical step in weaning because it enables the clinicians to assess communication, voice, swallowing, and ability to manage secretions. Even some of the most medically complicated patients have been successful using the valve in-line, including those on full ventilator support.

The Passy-Muir Valve has numerous clinical benefits. Dr Sean Barry, Medical Advisor to Respiratory Therapy Department at Madonna Rehabilitation Hospital, reported that the Passy-Muir Valve facilitates the ability for patients to relay to their

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The authors are with Passy-Muir, Inc, which provided this article.



Figure 1: Rebecca Wills, BA, LRCP-NPS, places the Passy-Muir Valve in Marvin Gearhart's ventilator circuit at Madonna Rehabilitation Hospital, Lincoln, NE.



Figure 2: Carrie Windhorst, MS, CCC-SLP evaluates Mr. Gearhart's ability to swallow liquids with the Passy-Muir Valve in-line.

care providers their needs in a timely manner which results in better patient care. Carrie Windhorst, MA, CCC-SLP, speech-language pathologist, explained that the valve helps redirect airflow to make a more normal closed respiratory system that allows the vocal cords to vibrate, giving patients their voice and speech to communicate. This leads to less frustration, improved confidence, and a better quality of life. In addition, the Passy-Muir Valve also restores sensation  
*Continued on page 57...*

# Nasal Expiratory Positive Airway Pressure (EPAP) for the Treatment of Obstructive Sleep Apnea: A Review of Clinical Studies of Provent Therapy

Rajiv Doshi, MD; Philip Westbrook, MD

## Abstract

Nasal EPAP (Provent Therapy) represents an important, new treatment option for many patients with obstructive sleep apnea (OSA). A series of peer-reviewed published articles have demonstrated clinically and statistically significant reductions in apnea hypopnea index (AHI), oxygen desaturation index (ODI) and sleepiness as well as high patient acceptance and compliance. This review is intended to provide healthcare providers an overview of the available clinical data to support use of this new class of therapy. The mechanism of action of nasal EPAP and patient selection recommendations are also discussed. Finally, the role of the healthcare provider in helping the patient to acclimate to nasal EPAP is highlighted, along with recommendations to optimize patient acceptance of the therapy.

## Introduction

Obstructive sleep apnea (OSA) is a common medical condition that can be associated with a variety of symptoms and morbidities. OSA frequently results in excessive daytime sleepiness, which is associated with an increased risk of motor vehicle accidents.<sup>1,2</sup> OSA has also been linked to hypertension, stroke, congestive heart failure, cardiac arrhythmia and depression.<sup>3-6</sup>

The gold standard treatment of OSA, continuous positive airway pressure (CPAP), is effective for any severity of OSA as long as the patient remains compliant with therapy. However, CPAP therapy can be cumbersome, noisy and uncomfortable and many patients either cannot tolerate CPAP at all, or only use it sporadically. It has been reported that 46 to 83% of patients with OSA are non-adherent to CPAP treatment.<sup>7</sup> Thus, while CPAP is highly efficacious in a laboratory setting, it is not used regularly at home by a large proportion of patients. Additionally, one recent study showed that 94% of patients who had rejected CPAP were interested in new treatment options.<sup>8</sup> These data underscore the need for alternative therapies.

Response to non-CPAP therapies is typically either expressed as the percentage of patients who achieve  $\geq 50\%$  AHI reduction or who achieve an AHI of less than 10. The basic treatment principle of OSA is to maximally reduce the AHI, recognizing that achieving an AHI of less than 10 may not be possible in all patients, especially those with severe OSA. In these cases,

a partial AHI reduction may be better than non-treatment. Furthermore it is recognized that OSA is a chronic disease that must be treated by the patient over that patient's lifetime. Thus a goal of successful treatment is to prevent as many breathing disturbances as possible which requires both efficacy and utilization. A treatment that prevents 100% of the abnormal events in the laboratory but is used by the patient only half of sleep time may be considered only 50% effective.

Recently, nasal EPAP has become broadly available for patients with OSA. The earliest use of EPAP to treat OSA dates back to 1983 when Mahadevia et al demonstrated that the passive application of 10cm H<sub>2</sub>O of EPAP could significantly improve the apnea index and oxygen desaturation index.<sup>9</sup> More recently, a series of well designed prospective studies have demonstrated the efficacy of nasal EPAP for the treatment of OSA.

The only FDA cleared nasal EPAP product indicated to treat OSA is known as Provent Therapy (Ventus Medical, Belmont, CA) [Figure 1]. The device has been evaluated in multiple published studies and has been shown to be clinically effective in treating mild, moderate and severe OSA. The device consists of a small valve attached externally to each nostril with hypoallergenic adhesive. The valve acts as a one-way resistor, permitting unobstructed inspiration. During expiration, the airflow is directed through small air channels, increasing the resistance. This increased resistance during expiration creates EPAP which is maintained until the start of the next inspiration. Whereas CPAP provides positive pressure during both inspiration and expiration, EPAP only creates pressure during expiration.



Figure 1. Provent Sleep Apnea Therapy (Courtesy Ventus Medical)

## Nasal EPAP Mechanism of Action

OSA is traditionally thought of as an inspiratory disease. However, it is important to note that the closure of the upper airway has its origins at the end of expiration, when the pressure in the airway is zero. Morrell et al showed that upper airway cross sectional area progressively decreased in the four breaths

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prior to an obstructive apnea, with this area being smallest at end-expiration. Their conclusion was that this expiratory narrowing made it more likely for the airway to completely collapse during the subsequent inspiration.<sup>10</sup> Provent nasal EPAP creates increased expiratory pressures which are maintained through the end of expiration and until the start of the subsequent inspiration [Figure 2].

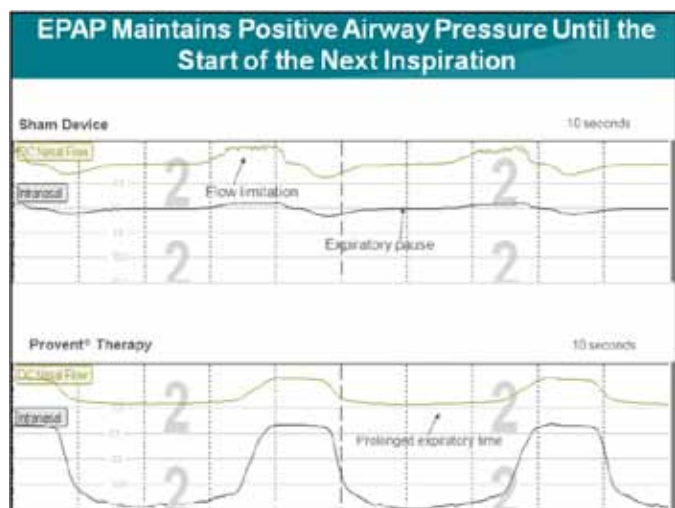


Figure 2: These PSG waveforms demonstrate Provent nasal EPAP's effects on breathing. The top panel shows an untreated subject (wearing a sham device). The bottom panel shows the same subject wearing Provent nasal EPAP. Both nasal air flow (inspiration up, expiration down) and intranasal pressures (in cm H<sub>2</sub>O) are shown. When Provent device is not worn, there is clear inspiratory flow limitation. Intranasal pressures remain about zero during most of the expiratory time---showing a clear end-expiratory pause. In contrast, with Provent nasal EPAP, expiration is prolonged and there is positive intranasal pressure of at least 10 cm H<sub>2</sub>O maintained until the start of the next inspiration. The end-expiratory pause has been eliminated. (Courtesy Ventus Medical).

The exact mechanism through which nasal EPAP treats OSA is still unclear, but several mechanisms appear most likely:

- 1) Positive end-expiratory pressure (PEEP) leading to increased end-expiratory lung volumes (or FRC) that increases longitudinal traction on the pharynx, rendering it less collapsible ("tracheal tug").<sup>11</sup> Indeed, the role of increased lung volumes in decreasing the compliance of the upper airway has been well described in the literature.<sup>12</sup>
- 2) Dilatation of the upper airway by EPAP which carries over until the start of the next inspiration.<sup>13</sup>
- 3) Mild hypercapnia due to hypoventilation which would lead to increased respiratory drive to the upper airway.<sup>13</sup>

It is possible that a combination of more than one of these mechanisms may be responsible for the therapeutic benefit of nasal EPAP.

The first clinical study intended to help elucidate the mechanism of Provent nasal EPAP was conducted by Colrain et al.<sup>14</sup> This study demonstrated that the benefits of the Provent device were due to EPAP, since a similar sham device did not lead to reductions in either AHI or ODI. In a larger study by Patel et al, the authors concluded that those patients who were able to generate and sustain positive end expiratory pressures were more likely to exhibit a therapeutic response.<sup>13</sup> They concluded that the primary mechanism of action was likely related to increased FRC (functional residual capacity) leading to a

tracheal traction mechanism, though they cited the possibility of a carryover effect of pressures from end-expiration into the subsequent inspiration as well as increased CO<sub>2</sub>.

A follow up study by the same group<sup>15</sup> concluded nasal EPAP resulted in significant hyperinflation (higher end-expiratory lung volume) during wakefulness, that there was a trend toward expiratory upper airway dilatation which appeared to carry over into inspiration and that there was significant hypoventilation and hypercapnia induced both while awake and asleep. Additional mechanistic studies are ongoing and will provide additional insights into the mechanism of action of Provent nasal EPAP.

### Review of Provent Therapy Clinical Studies

Provent Therapy has been studied in a series of prospective clinical studies. Several are highlighted below:

#### A novel nasal expiratory positive airway pressure device for the treatment of obstructive sleep apnea: a randomized controlled trial<sup>16</sup> –Berry RB, Kryger MH, Massie CA. [SLEEP 2011; 34:479-485]

250 OSA patients from 19 centers were enrolled in this prospective, multicenter, parallel-group, sham controlled, randomized double-blind trial with three month follow up. Patients were enrolled and randomized to a sham or Provent group. During the first week of treatment, patients underwent 2 in-lab PSGs on non-consecutive nights (one device-on, one device-off in randomly assigned order). After three months of treatment, patients underwent another two in-lab PSGs with the device on and device off. Outcomes included a comparison of the difference in the AHI between device-on and device-off nights in the Provent and sham groups at week one and at three months.

Using an intent-to-treat analysis, at three months the percentage decrease in the median AHI was 42.7% in the Provent group compared to 10.1% in the sham group (p<0.0001). Treatment effect by severity is shown in Figure 3. Provent nasal EPAP reduced the median AHI from 8.8 to 3.9 in mild OSA patients (p<0.001), from 20.5 to 8.4 in moderate OSA patients (p<0.001) and from 48.2 to 18.9 in severe OSA patients (p<0.001). At month three, treatment success (defined as at least a 50% reduction in the AHI or an AHI of less than 10) was achieved in 50.7% of patients in the Provent nasal EPAP group. Based on patient self-report, the median percentage of nights the EPAP device was used for the entire night was 88.2%. There were no serious device related adverse events reported. The authors concluded that Provent nasal EPAP is an effective treatment alternative for a substantial percentage of the OSA population.

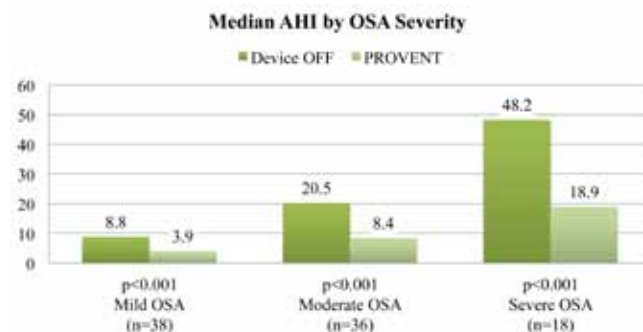


Figure 3. AHI reduction by OSA severity<sup>17</sup>

**A convenient expiratory positive airway pressure nasal device for the treatment of sleep apnea in patients non-adherent with continuous positive airway pressure**<sup>18</sup> –Walsh JK, Griffin KS, Forst EH, et al. [Sleep Medicine 2011;12:147-52]

This study focused on OSA patients who were non-adherent to CPAP. Most patients had moderate to severe OSA, with over half of the patients having a baseline AHI  $\geq 30$ . A total of 59 patients with OSA who refused CPAP or used CPAP for less than 3 hours per night were provided the Provent nasal EPAP device, of which 47 patients (80%) tolerated the device. Patients then underwent baseline sleep studies and 43 of these patients met enrollment criteria. Of these 43 patients, 24 (56%) met efficacy criteria based on AHI and symptom response. The responding patients continued on the device for 5 weeks, followed by a final in-lab PSG to verify ongoing efficacy. The mean baseline AHI in these patients was 31.9 which decreased to 16.4 at 5 weeks. The Epworth Sleepiness Scale improved from a baseline of 12.3 to 8.7 ( $p=0.001$ ). Device use was reported an average of 92% of all sleep hours. This study in non-adherent CPAP patients demonstrated that nasal EPAP can lead to improvements in AHI and sleepiness, along with a high degree of treatment adherence.

**A multicenter, prospective study of a novel nasal EPAP device in the treatment of obstructive sleep apnea. Efficacy and 30-day adherence**<sup>19</sup> –Rosenthal L, Massie CA, Dolan DC, et al. [Journal of Clinical Sleep Medicine 2009;5:532-37]

This multicenter prospective study was specifically designed to assess adherence over a 30 day period, and also evaluated efficacy based on serial in-lab PSG studies. A total of 34 patients with OSA underwent a 30 day trial of the Provent nasal EPAP device. Patients kept a daily log and weekly phone calls were conducted by study staff. Participants reported using the Provent nasal EPAP device all night long for 94.4% of the possible nights during the in-home trial. The 30 day study demonstrated a significant improvement in AHI ( $p=0.001$ ) and symptomatic improvement as measured by Epworth Sleepiness Scale ( $p<0.001$ ) and Pittsburgh Sleep Quality Index ( $p=0.042$ ). Percentage of the night spent snoring was also reduced significantly ( $p=0.013$ ). The authors concluded that treatment with nasal EPAP was well tolerated and accepted by patients in the study.

**A pilot evaluation of a nasal expiratory resistance device for the treatment of obstructive sleep apnea**<sup>20</sup> –Colrain IM, Brooks S, Black J. [Journal of Clinical Sleep Medicine 2008;4(5):426-433]

Colrain et al were the first to publish clinical results of the Provent nasal EPAP device. Thirty patients (24 with OSA, 6 with primary snoring) underwent 2 nights of in-lab PSG, with and without the EPAP device with the order of nights counterbalanced to minimize first night effect. The studies were scored blind to treatment condition. The AHI ( $p<0.001$ ) and ODI ( $p<0.01$ ) both significantly decreased, and the percentage of the night spent above 90% saturation ( $p<0.05$ ) increased significantly with device use. The observed duration of snoring significantly decreased ( $p<0.001$ ) with nasal EPAP use.

**Predictors of response to a nasal expiratory resistor device and its potential mechanisms of action for treatment of obstructive sleep apnea**<sup>13</sup> –Patel AV, Hwang D, Masdeu MJ et al [Journal of Clinical Sleep Medicine 2011;7(1):13-22]

This study sought to provide data to better understand the potential mechanisms of action of Provent nasal EPAP. Twenty patients with OSA underwent 3 in-lab PSGs including diagnostic, therapeutic (Provent), and CPAP studies. Intranasal pressures,  $PCO_2$ , closing pressures (Pcrit), and awake lung volumes in different body positions were also measured. There were significant reductions in AHI ( $p<0.05$ ) and RDI ( $p<0.0001$ ) with Provent nasal EPAP compared to the diagnostic study. No significant predictors of therapeutic response were found. Successful treatment of breathing events was associated with creation and maintenance of elevated end expiratory pressure. The authors concluded that Provent nasal EPAP can treat sleep disordered breathing across the full spectrum of severity.

**Long term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea**<sup>21</sup> –Kryger MH, Berry RB, Massie CA [SLEEP Abstract Supplement, 2011 (34):A118]

This 13 center study was an extension of the three month (Berry et al) study and designed to evaluate the long-term effectiveness of Provent nasal EPAP after 12 months of follow-up. 41 patients from the Provent arm of the three month study who met adherence and efficacy criteria were continued on therapy and returned for in-lab PSG after 12 months of treatment. Results from these 12 month PSGs were compared against their baseline results. Median AHI was reduced from 15.7 to 4.7 (baseline device-off versus month 12 device-on). The AHI (median) reduction was 71.3% ( $p<0.001$ ). Percentage of time snoring was reduced by 74% ( $p<0.001$ ). The Epworth Sleepiness Scale decreased from  $11.1\pm 4.2$  to  $6.0\pm 3.2$  ( $p<0.001$ ) over the twelve months of study. The median percentage of nights patients reported using the device the entire night was 89.3%. The authors concluded that Provent nasal EPAP significantly reduced the AHI and snoring and improved daytime sleepiness after 12 months of treatment. Long-term compliance was deemed excellent.

Additionally, several retrospective studies demonstrating the acceptance and efficacy of Provent nasal EPAP were recently presented at the 2011 Annual Meeting of the Associated Professional Sleep Societies:

**Retrospective cases series analysis of a nasal expiratory positive airway pressure (EPAP) device to treat obstructive sleep apnea in a clinical practice**<sup>22</sup> –Adams, G. [SLEEP Abstract Supplement, 2011 (34):A146]

This retrospective analysis was completed to evaluate patient acceptance and AHI reduction using Provent nasal EPAP in a real world clinical practice. OSA patients (with AHI  $>10$ ) received 10 nights of EPAP devices for in-home evaluation. Patients that acclimated returned for efficacy confirmation using standard in-lab PSG. During these treatment PSGs, adjunctive therapy such as positional therapy or chin straps was used, when necessary, to optimize treatment effect. 151 patients sampled nasal EPAP and 131 were in the analysis group. Of the analysis group, 75% acclimated to the device. The median AHI was reduced from 25.8 to 4.2 ( $p<0.001$ ). A treatment AHI  $<10$  was achieved in 80.7% of all patients and 90.6% of those with mild/moderate OSA. The author concluded that Provent nasal EPAP achieved statistically significant improvements in AHI and that treatment acceptance was excellent.

**Nasal EPAP as a major therapeutic option in a clinical sleep center setting<sup>23</sup>** –Hwang D, Becker K, Chang J, et al. [SLEEP Abstract Supplement, 2011 (34):A146]

This analysis reported a single clinical sleep center's (Kaiser Permanente, Fontana, CA) experience using Provent nasal EPAP as a treatment option for OSA patients who were intolerant of CPAP. Patients underwent a clinic orientation session, in-home acclimation trial, and portable monitoring to confirm effectiveness. A total of 94 OSA patients were offered nasal EPAP; 86 patients (91.5%) continued with in-home evaluation. 36 (41.9%) returned for a nasal EPAP post-test study using portable monitoring. Among those completing a post-test, AHI was reduced from 22.7 to 8.9 ( $p < 0.00001$ ) and ODI 4% from 21.8 to 12.1 ( $p = 0.002$ ). Treatment response rate for mild, moderate and severe OSA patients was 63.6%, 70.0%, and 38.5% respectively. The authors concluded that Provent nasal EPAP is an important therapeutic option for the treatment of OSA.

**Clinical efficacy of a nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea<sup>24</sup>** – Massie C, Hart RW. [SLEEP Abstract Supplement, 2011 (34):A146]

This retrospective analysis included OSA patients in a community based sample that were treatment naive, or had previously tried and rejected CPAP. Of patients offered Provent nasal EPAP, 64% had rejected CPAP, 32% were treatment naive and 4% had tried non-CPAP therapies. In the 70 patients in which follow up was completed, 41 (59%) accepted therapy after an initial trial period. An additional 11 were continuing with Provent nasal EPAP therapy based on subjective symptom response and repeat physician evaluation. PSG data for 30 patients with paired PSG data sets revealed a treatment success of 80% (24 patients). Treatment success was defined as a decrease in AHI  $\geq 50\%$  or an AHI  $< 10$ . Median AHI was reduced from 17.1 to 4.9 ( $p < 0.001$ ) and there was a trend toward lower Epworth scores [7.2 to 5.5 ( $p = 0.07$ )]. The authors concluded that the Provent nasal EPAP device is both an effective and well tolerated treatment option for mild to moderate OSA patients or for patients who have rejected CPAP.

**Responder Analysis**

A pooled analysis of the data from the first five published Provent nasal EPAP studies<sup>17</sup> shows that 57% of patients in the analysis are responders (defined by AHI improvement  $> 50\%$ ) and another 11% of patients are partial responders (defined by AHI improvement of 30-50%) [Figure 4].

**Pooled Analysis of Provent Therapy Responders (published studies)**

Response to Provent Therapy

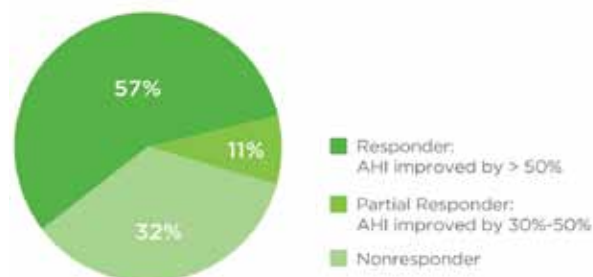


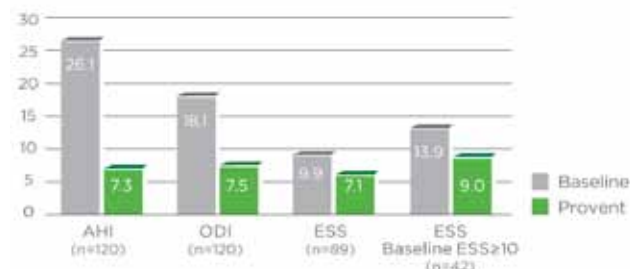
Figure 4. Pooled analysis of Provent Therapy Responders, based on data from the first five published studies<sup>17</sup>

It is important to note that patients in clinical practice should confirm efficacy of the Provent nasal EPAP device since response can vary from patient to patient, as the pooled analysis confirms. In-lab PSG or portable monitoring are preferred. A specialized Provent cannula that snaps onto the nasal EPAP device may be used and can interface with standard PSG and portable monitoring equipment [Figure 5]. The use of confirmatory testing is helpful in quickly assessing which patients are receiving adequate treatment response. Responders to Provent nasal EPAP have an average of 72% reduction in AHI, with a mean treatment AHI of 7.3 [Figure 6].



Figure 5. The Provent nasal cannula can be used with in-lab PSG or portable monitors

**Mean Apnea Hypopnea Index (AHI), Oxygen Desaturation Index (ODI) and Epworth Sleepiness Scale (ESS) in Responder Subgroup**



**Mean AHI by Severity in Responder Subgroup**



Figure 6. Mean AHI, ODI, and ESS in a responder subgroup, based on pooled data from the first five published Provent nasal EPAP studies<sup>17</sup>

**Real World Implications**

Recommended patients for Provent nasal EPAP include:

- 1) Patients (mild, moderate or severe) who have rejected or are non-compliant with prescribed CPAP
- 2) Newly diagnosed mild/moderate OSA patients without significant co-morbidities
- 3) CPAP compliant patients looking for alternatives for travel

As noted previously, CPAP is considered the gold standard treatment for OSA and is associated with an excellent response rate based on reductions in AHI. However, many patients are



not tolerant of or compliant with CPAP and alternative therapies must be considered. OSA treatment alternatives include Provent nasal EPAP, oral appliances and various surgical interventions. Each of the alternative OSA therapies requires confirmatory testing to determine efficacy. However, a trial of Provent therapy requires minimal investment compared to a custom oral appliance (averaging >\$1000 per appliance) or surgical intervention. Finally, real world compliance of Provent nasal EPAP can be tracked by monitoring the frequency of refills.

### The Importance of Acclimation

It may take several days for patients to acclimate to wearing and breathing through the Provent nasal EPAP device. The healthcare provider plays an important role in setting acclimation expectations for the patient as well as providing important recommendations to facilitate acclimation. These include:

- 1) Informing the patient that the first few nights using nasal EPAP may be difficult, but that it improves over the ensuing days
- 2) Suggesting the patient remove the device during initial nights if he/she has difficulty sleeping with the device
- 3) Instructing the patient to breathe through the mouth while awake and falling asleep
- 4) Letting the patient know it may take up to ten nights or more to acclimate to the device

### Summary

Multiple clinical studies of Provent nasal EPAP have been published including a large sham-controlled randomized trial. These studies have consistently demonstrated that the device is associated with excellent compliance and highly significant reductions in AHI in patients with mild, moderate and severe OSA, including patients who have previously failed CPAP. Snoring reductions and improvements in sleepiness have also been consistently demonstrated across these studies. Provent nasal EPAP represents an important new treatment option for patients with OSA and the healthcare providers who care for them.

### Disclosures

Dr Doshi is the Chief Scientific Officer of Ventus Medical. Dr Westbrook is the Chief Medical Officer of Ventus Medical and Advanced Brain Monitoring, a manufacturer of portable sleep recording equipment.

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# Public Health Emergency Preparedness and Response Communications with Health Care Providers

Debra Revere, Kailey Nelson, Hanne Thiede, Jeffrey Duchin, Andy Stergachis, Janet Baseman

## Abstract

**Background:** Health care providers (HCPs) play an important role in public health emergency preparedness and response (PHEPR) so need to be aware of public health threats and emergencies. To inform HCPs, public health issues PHEPR messages that provide guidelines and updates, and facilitate surveillance so HCPs will recognize and control communicable diseases, prevent excess deaths and mitigate suffering. Public health agencies need to know that the PHEPR messages sent to HCPs reach their target audience and are effective and informative. Public health agencies need to know that the PHEPR messages sent to HCPs reach their target audience and are effective and informative. We conducted a literature review to investigate the systems and tools used by public health to generate PHEPR communications to HCPs, and to identify specific characteristics of message delivery mechanisms and formats that may be associated with effective PHEPR communications.

**Methods:** A systematic review of peer- and non-peer-reviewed literature focused on the following questions: 1) What public health systems exist for communicating PHEPR messages from public health agencies to HCPs? 2) Have these systems been evaluated and, if yes, what criteria were used to evaluate these systems? 3) What have these evaluations discovered about characterizations of the most effective ways for public health agencies to communicate PHEPR messages to HCPs?

**Results:** We identified 25 systems or tools for communicating PHEPR messages from public health agencies to HCPs. Few articles assessed PHEPR communication systems or messaging methods or outcomes. Only one study compared the effectiveness of the delivery format, device or message itself. We also discovered that the potential is high for HCPs to experience “message overload” given redundancy of PHEPR messaging in multiple formats and/or through different delivery systems.

**Conclusions:** We found that detailed descriptions of PHEPR

messaging from public health to HCPs are scarce in the literature and, even when available are rarely evaluated in any systematic fashion. To meet present-day and future information needs for emergency preparedness, more attention needs to be given to evaluating the effectiveness of these systems in a scientifically rigorous manner.

## Background

Public health emergency preparedness and response (PHEPR) involves activities directed at preventing possible emergencies and planning to ensure an adequate response and recovery if an emergency occurs. The public health system itself is a complex network of organizations and individuals that work together for the benefit of the public's health. These entities include public health agencies at local, state and federal levels, public safety agencies, emergency managers, academia, business, communities, the media, and the healthcare delivery system.<sup>1</sup> As one component of the PHEPR system, information contributed by health care providers (HCPs) to public health is aggregated, analyzed and used by public health agencies, in part, to inform early event detection and situational awareness.<sup>2</sup> Figure 1 illustrates a simplified transfer of information from HCPs to public health which is aggregated, analyzed and used to inform public health alerts and advisories which are sent to HCPs.

The importance of the transmission of HCP information to public health, particularly for notifiable condition reporting, has been well-documented.<sup>2-5</sup> HCPs serve a critical role in public health's recognition and control of communicable diseases as illustrated by West Nile Virus<sup>6</sup> and SARS;<sup>7</sup> influenza and influenza-like illness;<sup>8</sup> foodborne illnesses;<sup>9</sup> and illnesses associated with intentional release of biologic agents such as anthrax.<sup>10-11</sup> In public health responses involving bioterrorism, HCPs have an especially important role since they will likely report such cases of unexplained or unusual illness to state and local public health officials who, in turn, may be able to conduct investigations and identify specific epidemiologic patterns or characteristics potentially indicative of bioterrorism.<sup>12</sup>

During an emergency situation health care providers (HCPs) are depended on to prevent excess deaths, treat the injured, and mitigate suffering.<sup>13</sup> To do this, and given that individuals will seek medical care in multiple locations during an emergency, HCPs need to be aware of public health threats and emergencies, issue guidelines and updates, and facilitate surveillance.<sup>14</sup> On September 11, 2001, when telephone and paging systems failed, the New York City Department of Health and Mental Hygiene

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successfully used email and fax to distribute public health broadcast alerts to all NYC emergency departments, commercial and hospital laboratories, infection-control programs, and select providers.<sup>15</sup> In an emergency, effective communication will not only depend on the information/message, but on the type of communication system or tool, the delivery format, and the robustness of the system.

While timely, efficient, and effective communications between public health and HCPs is an important part of public health emergency preparedness and response (PHEPR), most publications concerned with this exchange have emphasized the HCP-to-public health component. Yet, it is well-established that the “return” of information to HCPs is also significant. We conducted a systematic literature review to investigate the systems and tools used by public health to generate PHEPR communications to HCPs, and to identify specific characteristics of message delivery mechanisms and formats that may be associated with effective PHEPR communications.

## Methods

Three questions guided this literature review: What public health systems exist for communicating PHEPR messages from public health agencies to HCPs?; Have these systems been evaluated and, if yes, what criteria were used to evaluate these systems?; What have these evaluations discovered about characterizations of the most effective ways for public health agencies to communicate PHEPR messages to HCPs?

Table 1 lists the subject terms and keyword terms identified for key concepts for the search. To ensure retrieval of different types of PHEPR messages we included both health alerts (messages of the highest level of importance that warrant immediate action or attention) and health advisories (messages that provides key information for a specific incident or situation, such as a guideline change, and might not require immediate action). We also included as search terms any system, communication method or device that facilitated these communications. Public health literature is reported to be poorly indexed in bibliographic databases and dispersed across a wide variety of journals and other sources, as well as across many disciplines.<sup>16</sup> We included “grey” or non-peer-reviewed literature sources<sup>17</sup> to ensure wide coverage of less accessible materials such as government reports and conference proceedings (Table 2).

The exact search terminology used was tailored for each database as appropriate to its structure and thesaurus to ensure a high degree of sensitivity (Table 3). The Web of Science database was used to conduct cited reference searches of relevant articles. In addition, we hand-searched (known as snowball sampling) the reference lists of relevant articles and the tables of contents of the following journals: Journal of Homeland Security and Emergency Management, Disaster Medicine & Public Health Preparedness, and American Journal of Disaster Medicine. The review was limited to publications in the English language and to materials published between 01/2000 through 01/2011. All search strategies were recorded at each step. Citations from database searches were downloaded into the EndNote bibliographic reference program (www.endnote.com/) or manually entered as needed. Duplicates were removed. Figure 2 illustrates the identification, screening, eligibility and inclusion numbers, and rationale for excluded materials in our search and selection process.<sup>18</sup>

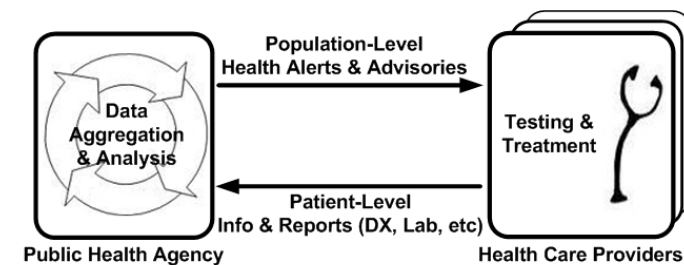


Figure 1.

Articles were included if they described systems or tools for public health agencies to communicate PHEPR messages to HCPs or included an evaluation of these systems or tools. Data extracted from the articles included: purpose, location, organization or agency involved, HCP population, method(s) of communication, and type of evaluation performed, if conducted. If an evaluation was performed, the outcomes were extracted.

## Results

Of the initial set of 42 full-text articles assessed for eligibility, 11 were excluded once read as they only described systems that sent PHEPR messages to health departments (n=6) or were opinion articles (n=5). Data extraction from the final 31 articles resulted in identification of 25 different systems, with one article describing more than one system. Overall, the final 31 articles contained information on the purpose of the system or tool (100%), location of the system (100%), public health organization or agency involved (100%), targeted HCP population (100%), and method(s) used by public health to communicate PHEPR messages to HCPs (100%). Eleven articles (covering 9 systems) included a description of the evaluation used with the system. Type of evaluations included comparative,<sup>19</sup> interviewing,<sup>20</sup> surveying,<sup>21-22</sup> retrospective,<sup>23-24</sup> formative,<sup>25</sup> and an assessment following a simulation exercise.<sup>26</sup> One article reported a causal relationship could be “inferred” between the dissemination of health advisories and HCP reporting and testing<sup>27</sup> and two reported receiving feedback but did not detail method.<sup>28-29</sup> The remaining articles (65%) either did not mention an evaluation or did not contain enough information to determine if an evaluation had been conducted.

Of the 25 systems and tools documented, the majority (96%) were North Americabased. The location of the systems included: 40% state-level, 32% city-level, 16% country-level, and 8% regional, with one international system (4%). Only one tool was designed to provide PHEPR messages to veterinarians; the remaining targeted HCPs in hospitals, emergency departments and/or outpatient clinical settings. The majority of systems used email (64%) to deliver PHEPR messages. Systems also delivered messages by phone, including cellular (36%); fax (36%); pager (28%); SMS text messaging (16%); handheld devices such as PDAs or Blackberry® (16%); other devices such as radios (16%); messaging through an electronic medical record system 12%; and “social media” (4%). Some systems also posted the PHEPR message to a web site (24%) for passive consumption. A majority of systems used more than one method (60%) for delivering messages. Only 4 systems were described in sufficient detail to determine that each method was attempted sequentially as opposed to redundant messages being delivered through all devices and formats. Table 4 (additional file 1 table S1) lists each messaging system or tool included in the final retrieval set and indicates type of evaluation conducted where applicable.

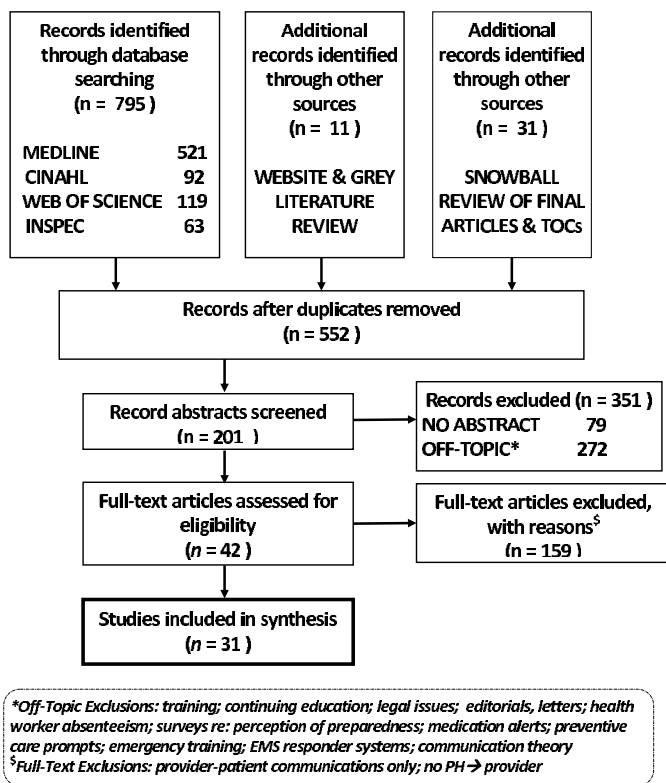


Figure 2.

## Discussion

After conducting a systematic search, we identified 25 systems or tools currently being used to communicate PHEPR messages from public health to HCPs. Of the 9 systems that reported an evaluation, only 2 provided sufficient detail of methodology used. During a Q fever outbreak, two public health alert faxes were sent asking physicians to submit serum samples on any patient meeting a clinical case definition of Q fever and an association with the area where the outbreak occurred. By examining laboratory reports, Van Woerden et al (2006) found a statistically significant difference between the number of patients tested for Q fever in the target population after the alerts had been sent as compared to a comparable two-week period one year before.<sup>19</sup> Another study retrospectively examined recommended public health agency actions communicated to HCPs through a pop-up in an electronic health record in comparison with lab orders and treatment guidelines and found that a causal relationship “could be inferred” (although with no detail to document this inference) between the alert and a change in HCP behavior.<sup>27</sup> Other system evaluations lacked adequate detail to determine the extent of evaluation activities. Prior to developing GermWatch, a system focused on communicating advisories regarding respiratory viral pathogens and pertussis, Gesteland et al (2007) conducted a formative evaluation of the feasibility and sustainability of the system.<sup>25</sup> However, formative studies, though useful in the planning and early development phases of a system, need to be followed up with an evaluation focused on identifying changes in outcome or performance measures, results, or effectiveness criteria that can be confidently attributed to the system rather than other factors and conditions. While reports of retrospective evaluations of ProMED, a global outbreak surveillance system,<sup>23-24</sup> the messaging tools used in conjunction with a TOPOFF exercise,<sup>26</sup> and a survey of homeless service providers during the SARS outbreak in Toronto<sup>20</sup> identify problems and propose measures to counteract problematic communications

issues between public health and HCPs, the reports lacked the detailed methodology or results that are needed to assess the rigor of these evaluations.

One of the most widespread strategies in the US for public health agencies to communicate to HCPs on both national and local levels is through the CDC’s Health Alert Network (HAN) program which communicates information about infectious disease outbreaks and public health implications of national disasters within its health alerts, advisories, and updates.<sup>14, 29-30</sup> Given its wide coverage, we were surprised to find so few studies attempting to systematically verify that HAN messages are received, processed, and/or acted upon by the intended recipients outside of public health agencies. As a result, in part, of current studies of the 2009 H1N1 outbreak, we are now learning that PHEPR messages may not be reaching their targeted audiences. For example, results of a cross-sectional survey of health departments, physicians, and pharmacists in Kentucky regarding information dissemination and receipt during the early H1N1 outbreak found that deficiencies exist in the effectiveness of public health PHEPR communications to HCPs. While 81% of responding local health departments (LHDs) rated their capacity to disseminate information to HCPs as very good or excellent, only 52% of surveyed physicians and 16% of surveyed pharmacists reported receiving any information about H1N1 from a LHD. Seventy-four percent of pharmacists were not aware of their LHD’s emergency plan in the event of an influenza outbreak.<sup>31</sup>

In conducting this review we discovered that there are multiple sources from which HCPs may receive HAN communications. CDC not only sends messages to state and local public health agencies that then disseminate to HCPs, but clinicians can also sign up to receive HAN messages directly through the CDC’s Clinician Outreach Communication Activity (COCA) as well as through any of the 176 COCA partner organizations that pass on or post COCA-generated notices of new and updated CDC information on emerging health threats.<sup>21-22</sup> While any PHEPR situation presents challenges in communicating about uncertainties, collaborating across and within organizations, and communicating timely messages,<sup>32</sup> every additional messaging source raises the potential for redundant and conflicting information. COCA disseminates updates bi-weekly (more frequently when there is emergency information or event-specific updates). Excluding HAN alerts, a tally of messages disseminated through COCA from 2008-2010 yielded 140 messages that each contain as many as 7 topical messages.

Avoiding the communication of multiple and redundant messages that can engender “alert overload” in HCPs is important, especially in a public health emergency situation. The HAN system allows HCPs to set a preference for receiving messages but, as mentioned above, if the HCP is receiving messages from different sources the redundancy potential increases. Staes et al (2011) presented an objective analysis of communication between public health agencies, health care organizations, and frontline HCPs during the 2009 H1N1 outbreak. The investigators conducted a cross-sectional survey to understand communication processes between public health and frontline HCPs and found that HCPs received redundant messages; were challenged to keep up with evolving and tailored messages from multiple organizations at a time when clinic volumes, patient concerns, and media exposure were increasing; and were overwhelmed by e-mail volume. The study suggests

that PHEPR messages sent to HCPs be concise and clearly identified.<sup>33</sup>

We found there are numerous formats (email, fax, etc) in which to deliver PHEPR messages to HCPs. When more than one format was available it was not clear if HCPs were given a choice between different ways to receive messages as opposed to receiving redundant messages in different formats or through different delivery systems. Allowing HCPs to set preferences for receiving PHEPR messages might improve response.

Our review has three main limitations: 1) scope and search terms; 2) access to fulltext articles; and 3) lack of data in the included articles. For practical reasons we limited ourselves to materials written in the English language. While we did not limit ourselves to U.S. systems or studies, it is possible that systems of PHEPR messaging to HCPs developed in Europe and Asia may be written in other languages. It is also possible that our search strategy did not cast either a wide or targeted enough net to capture relevant literature. Perhaps modifications to the terminology or concept operators would have yielded better retrieval sets. We were limited to resources accessible through our academic libraries and their inter-library partnerships so may have missed some material. Another limitation is our elimination of articles missing or with uninformative abstracts. Again, it is possible that this omitted key articles from our results. Lack of data was an issue as many articles did not contain sufficient descriptive information. Despite these limitations, our results show that detailed descriptions of PHEPR messaging from public health to HCPs are scarce in the literature and, even when available are rarely evaluated in any systematic fashion.

## Conclusions

This review shows that little is known about the effectiveness of PHEPR communications from public health to HCPs. We also found that by using multiple formats and delivery methods, current systems and tools may be increasing, rather than reducing, communication challenges for HCPs with unnecessarily redundant messages; confusion due to messages that may reflect conflicting federal, state and local guidelines, information and concerns; alert "overload"; and lack of tailored preferences for receiving these important messages. Much has been written about the "astute clinician" who noted an unusual clinical finding and set off the public health alarm concerning the first case of anthrax in Palm Beach County, Florida in October 2001.<sup>34</sup> Given the importance of HCPs in PHEPR, more research needs to be done to further investigate how public health can communicate effectively with HCPs. There are numerous questions about these systems and tools that need to be answered, some basic, such as: Have PHEPR messages been successfully delivered? Were they read and, if yes, can the date or time of their delivery and their content be recalled? Is there an optimal frequency for sending PHEPR messages? What components of a message are most important for the message to be perceived as credible, authoritative, complete? What impact do PHEPR messages have on HCP behavior, surveillance or reporting of suspected or confirmed events of public health interest or PHEPR knowledge?

One example of new research being conducted in this area is the REACH Trial in which the authors are using a randomized, community-based trial method to investigate the effectiveness of various message delivery systems (email, fax, and SMS) for communicating PHEPR messages from public health agencies

to HCPs.<sup>35</sup> The primary aim of REACH is to determine the effectiveness of various message delivery systems (email, fax, and SMS) for communicating PHEPR messages from public health agencies to HCPs and to compare the effectiveness of communication methods between these two groups across diverse communities. This is however, only one effort. To meet present-day and future information needs for emergency preparedness, concentrated attention needs to be given to evaluating the effectiveness of PHEPR systems in a scientifically rigorous manner.<sup>36</sup>

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*Enabling Speech...continued from page 33*

affect the flap valve in any way.

It is very easy to incorporate the Blom Tracheostomy Tube into the ventilator circuit, as the hub is a standard 15 mm connection. Some patients who would be ideal candidates for this device are patients with known or suspected aspiration and patients unable to tolerate cuff deflation. Patients who would not be candidates for this device include patients with large tracheostomas which can't seal around the trach tube or patients with very thick and copious secretions.

It is very easy to see how the use of this device could be a game changer for patients who were unable to communicate before and can do so now with its help. The exhaled volume reservoir is also a needed development as it will help to solve the false low volume alarms that seem to plague many patients who are already able to speak with ventilation through the use of speaking valves.

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# Hypercapnic Cerebral Edema Presenting in a Woman with Asthma: a case report

Ryan R. Joyce, William T. McGee

## Abstract

**Introduction:** Common causes of non-traumatic acute cerebral edema include malignant hypertension, hyponatremia, anoxia, and cerebral vascular accident. The computed tomographic images and data obtained during care of the patient described in this case report provide evidence that hypercarbia can cause increased intracranial pressure and coma without permanent brain injury. Partial pressure of carbon dioxide evaluation for coma is essential to provide faster diagnosis and therapeutic correction in certain common critical disease states. We present the case of a patient in a coma associated with cerebral edema during a typical asthma exacerbation with hypercapnic respiratory failure.

**Case presentation:** An obese 63-year-old African American woman with asthma presented to our hospital with facial swelling and shortness of breath. Immediately following intubation for hypercapnic respiratory failure, she was noted to have a dilated, unresponsive right pupil. An emergent computed tomographic head scan revealed that she had increased intracranial pressure. A neurosurgeon agreed with the computed tomography interpretation and recommended no surgical intervention. The patient's respiratory acidosis was corrected with ventilator management over several hours in the intensive care unit. Nine and one-half hours later a follow-up head computed tomographic scan was read as normal without cerebral edema. At 12 hours, the patient's right pupil was 5mm in diameter and reactive. By 24 hours, her pupils were symmetrically equal and reactive. Her symptoms had improved, and she was extubated. A brain magnetic resonance imaging scan revealed no abnormalities.

**Conclusion:** Alteration of consciousness related to hypercapnia during respiratory failure is not generally thought to be related to cerebral edema. Respiratory acidosis resulting from hypercarbia is known to produce carbon dioxide narcosis and coma, but no current treatment algorithm suggests that rapid hypercapnia correction can be critical to neurologic outcome. To the best of our knowledge, our case is a unique example

of the physiological changes that may occur in relation to arterial carbon dioxide concentration in the normal brain in the setting of typical hypercapnic respiratory failure. Correction of respiratory acidosis reversed the neurologic symptoms and physiology causing cerebral edema and coma in our patient. Rare similar cases have been sporadically reported in the medical literature, typically in children. Our case is also unusual in that rapid deterioration and clinical status were directly observed on simultaneous computed tomographic scans. Had this patient been found unresponsive, or had she had brief respiratory or cardiac arrest, the scan could have been interpreted as global anoxic injury leading to a different therapeutic course.

## Introduction

The correlation between physical examination, laboratory data, and radiographic imaging before and after hypercapnia therapy for respiratory failure provides documentation of changes in partial pressure of carbon dioxide ( $\text{PaCO}_2$ ) and physiology of the brain capable of producing coma and its reversal. Prior cases of this phenomenon have been sporadically reported in the medical literature, typically in children with acute, severe respiratory acidosis without brain imaging or arterial blood gas (ABG) data.<sup>1,2</sup> Cerebral edema is not generally cited as a cause of stupor and coma during typical hypercapnic respiratory failure in an uninjured brain. Our patient's rapid deterioration and clinical status were directly observed, and the computed tomography (CT) findings did not suggest any alternative diagnosis.

## Case presentation

An obese 63-year-old African American woman presented to our hospital with sudden onset of bilateral facial and tongue swelling associated with progressive shortness of breath. Her medical history included asthma, hypertension, congestive heart failure, obstructive sleep apnea, and obesity. She has minor allergies to certain fruits but no prior history of anaphylaxis. Her initial vital signs were blood pressure 127/67mmHg, pulse rate 98 beats/minute, and 100% oxygen saturation on 6L nasal cannula with a respiratory rate of 18 breaths/minute. Immediate therapy in the emergency department included epinephrine, diphenhydramine, and solumedrol for presumed anaphylaxis; intubation; and mechanical ventilation. Extensive laryngeal edema as well as a dilated, unresponsive right pupil were pertinent positive findings on physical examination. An emergent CT scan of her head showed bilateral effaced sulci with both small ventricles and basilar cisterns. These findings were consistent with increased intracranial pressure (ICP) (Figures 1A through 1C). The patient was admitted to the intensive care unit (ICU). Initial

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The authors are with Baystate Medical Center, The Western Campus of the Tufts University Medical School, Springfield, MA. The authors thank Dr. Larry Goodman (Radiology) for his assistance and expertise in analyzing and correlating the CT images. Reprinted from BioMed Central, Journal of Medical Case Reports, © 2011 Joyce and McGee; licensee BioMed Central Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License.

	Time					Day 2 16:34
	Day 1		Day 1		Day 1 12:54	
	03:00	06:43	08:52	10:56		
pH	7.22	7.23	7.41	7.70	7.64	7.42
pCO <sub>2</sub>	85	89	59	29	36	52
pO <sub>2</sub>	109	82	67	84	75	115
HCO <sub>3</sub> <sup>-</sup>	33	40	40	36	39	35
RR	12	12	18	21	16	20
V <sub>i</sub>	600	600	500	500	Varied	Varied
F <sub>i</sub> O <sub>2</sub>	50	50	50	50	40	40
Change made after ABG	Pre-intubation initial CT scan	RR increased to 22 breaths/minute	No change	Spontaneous breathing observed	Follow-up CT scan performed	Extubation

<sup>a</sup>ABG, arterial blood gas; pCO<sub>2</sub>, partial pressure of carbon dioxide; pO<sub>2</sub>, partial pressure of oxygen; HCO<sub>3</sub><sup>-</sup>, bicarbonate; RR, respiratory rate; V<sub>i</sub>; F<sub>i</sub>O<sub>2</sub>, fraction of inspired oxygen; CT, computed tomography.

**Table 1.** Serial data regarding ABGs, ventilator settings, and changes made after ABGs were obtained for the duration of mechanical ventilation, including the initial pre-intubation ABG<sup>a</sup>.

ABG analysis revealed severe respiratory acidosis, which was corrected over the course of several hours (Table 1). During her initial hours in the ICU, she experienced persistent respiratory acidosis despite being on controlled volume ventilation at a rate of 12 beats/minute. Serial ABG analyses were monitored, and he

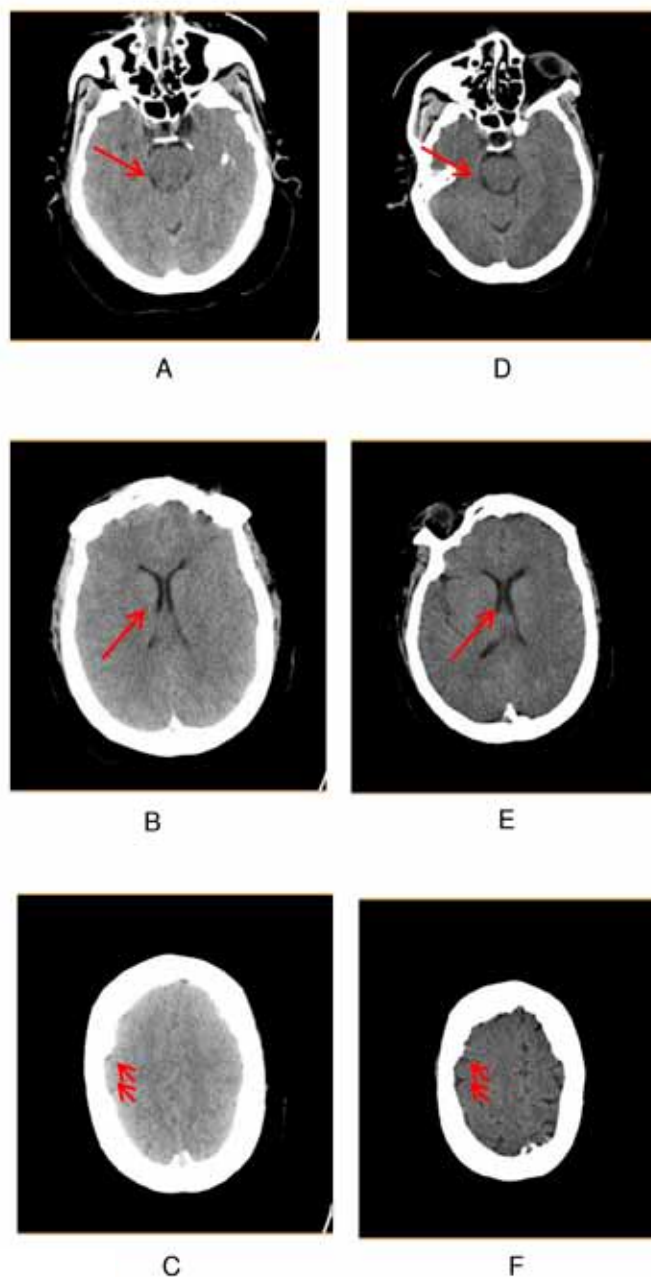
respiratory rate was adjusted as shown in Table 1. A neurosurgeon was consulted, agreed with the CT interpretation, and recommended no surgical therapy. She was continued on scheduled methylprednisolone, diphenhydramine, and albuterol in the ICU as well. Mannitol was not administered, as she had no history or laboratory indications suggesting that an osmotic imbalance was causing her edema. Her physical examination continued to show a dilated, unresponsive right pupil with a pinpoint, yet reactive, left pupil. Disc margins were blurred bilaterally without hemorrhages or exudates. She remained unresponsive.

Eight hours after intubation, the patient's physical and neurological findings were unchanged. Nine and one-half hours later the patient's right pupil was noted to be 5mm in diameter and was now reactive. The left pupil was unchanged. Follow-up head CT performed at this time (Figures 1D through 1F) was normal without cerebral edema.

After 24 hours her pupils had become symmetrically equal and reactive. The remainder of her neurological examination remained normal. She awoke and was extubated. MRI of the brain revealed no pathology. Two weeks following her discharge from the hospital, she was seen in follow-up as an outpatient in our neurosurgery department. She denied having headaches or double vision. Her cranial nerve examination, deep tendon reflexes, and bilateral motor sensory function were normal, as was the assessment of her cognitive function.

## Discussion

Alteration of consciousness related to hypercapnia during respiratory failure is not generally thought to be related to cerebral edema. The severe respiratory acidosis that results from hypercarbia is known to produce CO<sub>2</sub> narcosis with coma.<sup>2</sup> No current treatment algorithm suggests that treatment of hypercapnia in an obtunded patient with hypercapnic respiratory failure is critical to neurologic outcome. In fact, permissive hypercapnia has been recommended to address ventilator-induced lung injury in some cases of respiratory failure.<sup>3,4</sup> The differential diagnosis for a single dilated pupil includes eye or sympathetic trunk trauma, ocular anti-cholinergic or -adrenergic agents, and cranial nerve III injury or compression from intracranial hypertension.<sup>5</sup> In our patient, there was no trauma or use of mydriatic agents. Considering the changes noted on the first CT scan (Figures 1A through 1C), the most



**Figure 1.** (A-C) Pre-CO<sub>2</sub> correction. (A) Basal cisterns. (B) Ventricles. (C) Sulci. (D through F) Post-CO<sub>2</sub> correction. (D) Basal cisterns. (E) Ventricles. (F) Sulci.

likely explanation for unilateral mydriasis was increased ICP causing uncal herniation and unilateral cranial nerve III compression.<sup>5</sup>The elevated concentration of carbonic acid and hydrogen ions from dissolved CO<sub>2</sub> produces dilatation of the cerebral arteries, leading to increased cerebral blood flow and elevation of ICP.<sup>2,6</sup>The direct correlation between paCO<sub>2</sub> causing cerebral vascular dilation has been well-documented in animal models also producing increased ICP.<sup>6</sup>

Brain edema is caused by an increase in intracellular or extracellular water. Damage from ischemia, anoxia, and cytotoxins causes injury to neuronal and vascular cells, leading to cellular swelling.<sup>7</sup> Hypoxia is known to be a direct cause of cerebral edema;<sup>8</sup> however, our patient's initial partial pressure of oxygen saturation suggest that this was not a factor in her condition. Forced exhalation may increase ICP by limiting cerebral venous drainage. Although not specifically observed



or commented upon prior to intubation in our patient, this has been reported as a cause of subarachnoid hemorrhage (SAH) in patients with severe asthma.<sup>9</sup> Once intubated, our patient was deeply sedated, and imaging did not reveal SAH. Hypercapnia and the resultant intracellular acidosis can produce a central nervous system depressive effect by itself.<sup>7</sup> In our patient, however, only elevated ICP explains the dilated pupil and cerebral edema. In this case, cerebral edema and its reversal were directly correlated with PaCO<sub>2</sub>. No other explanation is likely.

## Conclusion

Our patient's scenario provides a unique example of the physiological and anatomical changes that may occur in relation to arterial CO<sub>2</sub> concentration in the normal brain. Treatment was targeted at correction of respiratory acidosis using ventilation management, which reversed the physiology that caused her cerebral injury and led to a good outcome. Over the course of nine and one-half hours, CO<sub>2</sub> correction was documented by both clinical and radiologic improvement in cerebral edema. Cerebral edema should be considered as a cause of obtundation complicating respiratory failure that can respond to CO<sub>2</sub> correction.

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*Passy-Muir...continued from page 44*

and pressures in the airway which improves cough strength, secretion clearance and swallowing safety. Patients begin oral feeding and liberate from tube feedings sooner.

These clinical benefits translate into cost savings. Dr Barry has seen a significant increase in the number of patients with chronic respiratory failure. Considering that cost of care for these patients is two to three times greater than other patients, methods to improve weaning rates are critical. Rebecca Wills, BA, LRCP-NPS, Pulmonary Program Manager at Madonna Rehabilitation Hospital, reported that Madonna Rehabilitation Hospital utilizes a database from the National Association of Long Term Hospitals (NALTH) to benchmark and set their weaning goals. The current standard is to wean at least 50% of ventilator patients completely off the ventilator in less than 20 days. She said that they consistently exceed that goal. For fiscal year 2010, Madonna Rehabilitation Hospital weaned 62% of their ventilator patients in an average of 12.5 days. She concluded that the staff firmly believes that these outcomes are a result of incorporating the Passy-Muir Valve into their patient protocols.

Madonna Rehabilitation Hospital is an exemplary LTACH with dedicated clinicians focused on identifying and implementing practices that not only advance the care of their patients but address the numerous challenges that our healthcare system faces as the population of ventilator patients increases. Learn more about Madonna Rehabilitation Hospital and the Passy-Muir Valve, by visiting the video section of [respiratorytherapy.ca/magazine.html](http://respiratorytherapy.ca/magazine.html).

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*Editorial...continued from page 4*

strong capacity to predict human efficacy.' A majority of drugs that enter Phase III also fail. These failures are caused in large part by the failures of the preclinical animal modes to predict human responses. The other oft-overlooked factor is that animal models have misled scientists into taking wrong research paths and have perhaps kept treatments off the market. In my own field of anesthesiology there are distinct differences in drug response among species. Furthermore, animal testing has failed to prevent tragedies like the death of a gene transplant recipient and the morbidity of the six volunteers. [A researchers stated,] '... the rest of the scientific community had to learn the hard way that what you've learned from animals will not necessarily predict what's going to happen in humans.'

"One reason for [such] failures is that humans vary considerably in their response to drugs and even diseases, thus expecting a different species to predict human response is naïve. The question thus arises: Why do scientists use animals when so much research exists that can and should be performed with humans or human tissue? Much of the failure of basic research can be attributed to the use of animal models.

"Why isn't there more human tissue available for study? I believe there is a critically important reason.

"I want to contrast the ease of working through the regulatory framework for animal-based research, (approval from the local IACUC), with the difficulty of the parallel regulation involved in clinical research (approval from the local IRB). I believe this is one major reason scientists choose to work with animals instead of performing clinical research—the regulatory hurdle is simply much lower.

"Several features of the IRB system as currently configured impose costly burdens of administrative activity and delay on observational health services research studies, and paradoxically decrease protection of human subjects. Central review with local opt-out, cooperative review, or a system of peer review could reduce costs and improve protection of human subjects.

"Promotions in academia (at least in the USA) are based on the number of papers published. One cannot publish clinically-based research while waiting for the local IRB to approve a protocol. It is my experience that one can receive IACUC approval and accomplish a great deal of research in the time it takes to get a single protocol IRB-approved. But, not only is the IRB process very time-consuming, it is also very costly. Dollars that could be spent on research are unnecessarily channeled into IRB preparation cost and these expenditures almost never improve the research. Anecdotally, our department has hired a professional just to handle IRB submissions because of their difficulty.

"The current IRB is an absolute hindrance to medical advancement. The situation as it exists is causing scientists to use animals in research rather than work with human models because of the large discrepancy in regulatory ease between the two types of research. Based on discussions I have had with scientists in my university and other universities where I have been a visiting professor and or collaborator with other scientists, this problem is real and is pushing many academics away from human research. Even translational research, when based on animal studies, has been problematic... Translational

research is based on the premise that in vivo animals studies can be translated to humans but animal models themselves have a poor record of predicting human disease outcome.

"Research should be conducted comparing the length of time and number of changes required between the two review panels. Comparison could be made between the first application and final approved application. The applications could then be submitted to third party review panels for review and judging. Surveys could be performed among young physicians contemplating research careers in an attempt to ascertain why the physicians choose to study animals or humans. Follow up surveys could also be attempted five years later to see how the plan played out. Nevertheless, this introduction offers a reasonable, testable and novel explanation for current thinking among physician-scientists.

"As long as animal-based studies are funded to the neglect of human-based studies and animal-based studies reward the research institution with high overhead costs, there will be pressure to migrate toward animal studies. In order for a long-term satisfactory solution to be reached, the funding process as a whole must be addressed. That being said, we should not wait for a perfect solution before implementing a better system. Standardizing IRBs would be such a step in the right direction. The National Cancer Institute's (NCI's) Central Institutional Review Board [for instance] functions as a central review board to conduct a single review for the NCI's multisite phase III oncology trials. They found that CIRB affiliation was associated with faster reviews, fewer hours of research staff effort, and a savings of money."

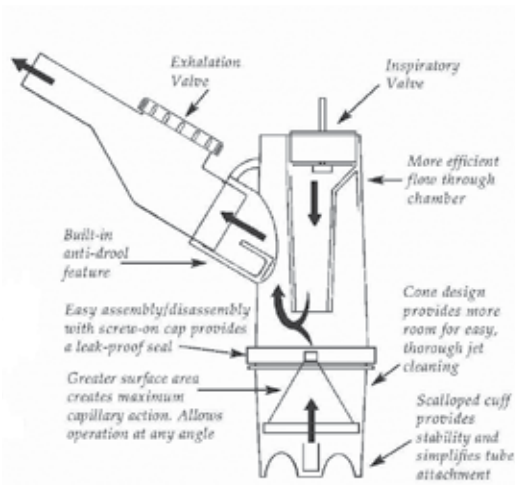
\*This editorial is mostly verbatim or redacted from the article "The Institutional Review Board is an Impediment to Human Research: The Result is More Animal-Based Research, Mark J. Rice, Philosophy, Ethics, and Humanities in Medicine, © 2011 Rice ; licensee BioMed Central Ltd, an open access article distributed under the terms of the Creative Commons Attribution License.

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