

Volume 6 Number 5 October-November 2011

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The Journal of Pulmonary Technique

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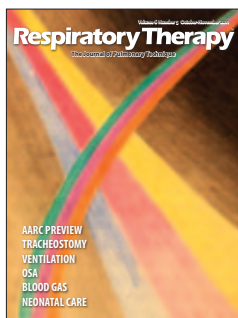


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Vol. 6 No. 5
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Editorial

RESISTANCE TO CHANGE – Lack of “Champion-Clinicians” Hold Back Medical Advancements

Vivian Wright

Remember how things were a decade ago... your staff, your duties, shifts, medical procedures, hospital policies, the equipment you used, government regulations... even the corporate culture was different back then. There's been much change and many advancements within your facility and healthcare in general.

Hard to believe 10 years has flown by...or did the past decade drag by? Does it matter? It should matter because you have been practicing in what many consider one of the most exciting decades in modern medicine. It has been a decade that has seen countless medical advances. If it feels as if the past decade dragged by, perhaps you're in the wrong career or maybe you've lost your passion, your motivation. On the other hand, if the decade passed so quickly you wonder where the last ten years went, congratulations, you adapt to and welcome change.

Yet one thing hasn't changed over the past ten years...previous 120 months...last 3,600 days: your patients. They blur one into another. Admissions, discharges, re-hospitalizations, discharges, admissions...and they keep coming – their illnesses, their diseases, their chronic conditions, even their pain blurs. Or does it?

It certainly matters to each patient and to their loved ones. They are acutely aware when a clinician views them as just another a blurred face. You can't hide it, it's in your eyes, in your walk and it's in your touch. However, when “their” nurse, RT or physician sees them as an individual, a clinician's dedication radiates as “quality care.” When the patient is the recipient of the clinician's knowledge, experience and compassion, there is no doubt in the patient's mind that their nurse, respiratory therapist or doctor is on his or her game. They know they are getting the very best you have to give and the best modern medicine has to offer.

Life is synonymous with change. Change within the healthcare environment results in advancements which lead to improvements for healthcare professionals, patients, caregivers as well as improvements in our entire healthcare system.

Whether it's adding an orphan product or device which may improve a process, or replacing a protocol step with an enhanced step, why would a clinician stand in the way of “something new” or “a promising change?” Why, when the purpose of “new” and/or “change” is to enhance the patient's quality of care, expand clinician knowledge, enhance clinical expertise, lead to additional innovations, create new jobs, bring value to one's facility as a whole, why do so many clinicians resist “new or change” and the exciting possibilities that may result?

Sadly, many clinicians' mantra is, “It'll increase my work load”, “...it's fine the way we've always done it,” “I don't have time as it is,” “they've been cutting the budget there's no way they'll hire more staff.”

Resistant clinicians find excuses why they don't champion a product or idea up the chain of command to a supervisor or product review board, even when the clinician clearly sees the benefits of a new product. “If they don't like it, it'll reflect badly on me!” “It takes too much time.” “It's a lot of work,” and “What am I going to get out of it?”; “I just do my job and stay under the radar,” “That's not my job.”

Of course not all clinicians are resistant to change, sometimes change is not at all determined by individual resistance or acceptance. On occasion, union leaders decide whether an Administration request for integration of new procedures or operation of new equipment by member-clinicians meets with union approval. If union approval
Continued on page 42...

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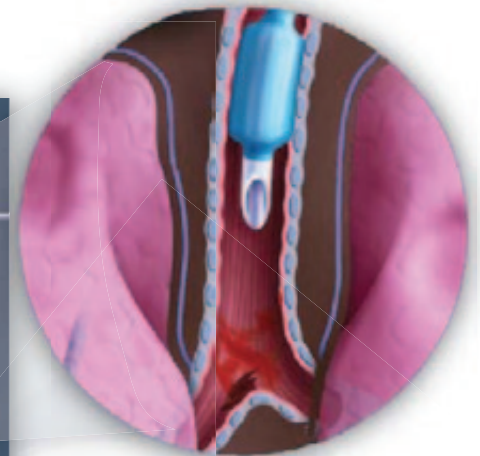
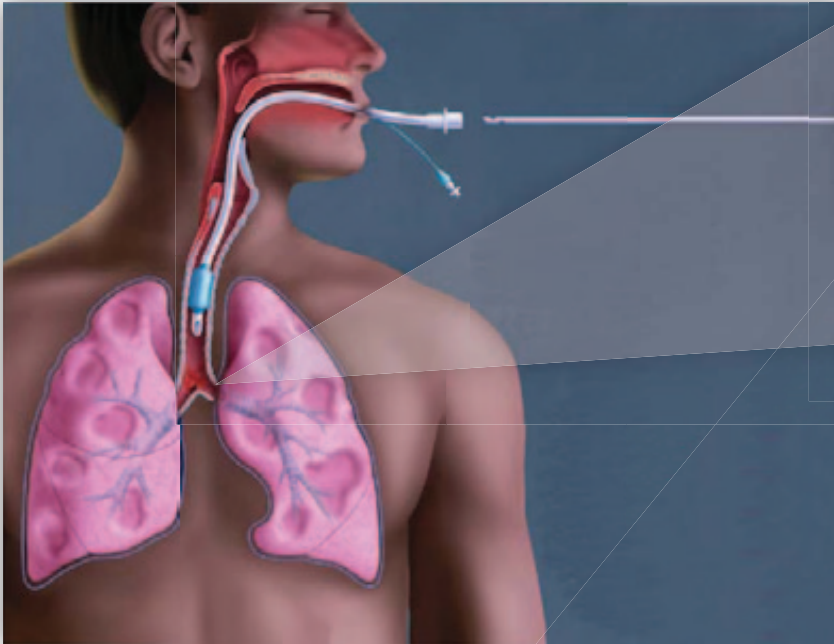


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News

□ October-November 2011

RESPONSIBILITY

Doug Farrago, MD, in *Authentic Medicine Journal*, writes: “We need to stop paying fees for the process of treatment and instead reward the successful results of that treatment.’ This is what the Director of Medicaid in Arkansas is saying. Recognize it? You should. It is parroted over and over again from every administrator in this country. It sounds great. Learn it. You will hear it a million times. Until one day the whole philosophy crumbles. Why? Because medical treatments do not exist in a vacuum. It is not that simple. It is not just putting in an equation and having a computer spit out the answer. Treat someone’s diabetes too well and he has an hypoglycemic episode because he forgot to eat lunch. He hits his head and gets a subdural hematoma. Or... over-aggressively treat a presumed pneumonia

in a ER setting only to set off a bad case of C. Diff. Even better, concentrate on the ‘successful’ treatment of those measures for which you are being graded to the detriment of those you are not and that person commits suicide due to his or her severe case of depression. Read that first line again. You will hear this happy horse**** over and over again. It comes from those who are remora living off the medical system. They never actually see or treat patients. They are not doctors (the few who were quit their regular jobs years ago). They are businessmen and politicians and administrators. The quickest and easiest way to save money in the healthcare system is to remove them. Here is that line again: ‘We need to stop paying fees for the process of treatment and instead reward the successful results of that treatment.’ How would this work, by the way, for the field of psychiatry? I rest my case.” *Authentic Medicine Journal* was formerly *Placebo Journal* and can be found at placebojournal.com, though as we went to press, the journal was no more.

TROOPS IN TROUBLE

The Huffington Post reported that some soldiers have returned from Iraq and Afghanistan with constrictive bronchiolitis, possibly caused by inhaling toxic material. Researchers at Vanderbilt University Medical Center said their analyses can’t show how common the condition is in the troops nor positively identify its cause. But 28 of the 38 diagnosed soldiers in the analysis had been exposed to a sulfur mine fire near Mosul, Iraq, in 2003. The researchers suggested that the soldiers inhaled sulfur dioxide, a known cause of constrictive bronchiolitis. Dust storms and the burning of waste in pits may also have played a role. The soldiers were evaluated between 2004 and 2009. The diagnoses were made after lung biopsies. At least half

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the soldiers have left the service with a disability rating. The researchers said they have counted nine more cases since 2009.

WAR IS HACKING

A recent study offers a comprehensive overview of respiratory illnesses in the Persian Gulf region, many due to war. Pulmonary diseases in the area include bronchial and pleural diseases, respiratory tract infections and neoplasms, as well as chest traumas caused by traffic accidents. According to the WHO, in 2008 there were 114,000 deaths caused by TB; 407,000 from respiratory infection; 25,000 attributed to lung, trachea and bronchus cancers, and 160,000 associated with respiratory disease such as COPD. The report said this number likely surpasses all other regions of the world. Major categories covered in the review include environmental factors, infections, genetic-idiopathic diseases, sleep disorders, lung malignancies, pleural diseases, and miscellaneous respiratory conditions. Contributing to respiratory illnesses are extreme temperature changes, chemical ammunition resulting in "desert-storm pneumonitis," water pipe smoking, and pregnancy-related complications. Another contributor is the large immigrant population.

HACKED?

The Huffington Post reports that medical equipment such as monitors may be susceptible to hacking. The report is based on the experiences of a diabetic who is also a security researcher, who figured out a way his insulin pump and monitor could be hacked. Medical equipment can now transmit health info to both the patient's devices and doctors, and in some instances can be controlled off-site by physicians. Attacks have been

demonstrated against pacemakers and defibrillators. Medical device makers say the possibility of hack attacks is remote, but security professionals say, if it can be done, someone will try it. According to HuffPo, "The hacking fears come on top of human errors and technical glitches tied to medical devices. The US Food and Drug Administration has identified software and design errors as critical concerns in investigating hundreds of deaths potentially linked to drug pumps... the FDA [has said] that any medical device with wireless communication components can fall victim to eavesdropping." Medical devices can be hacked because their information is typically not encrypted.

iNO in ARDS

Jeff Borink, BS, RRT, of Hamilton Medical, writes in the company newsletter: Inhaled Nitric Oxide (iNO) is a pulmonary vasodilator that selectively dilates blood vessels in lung segments that are actively participating in gas exchange at the alveolar-capillary level. This can lead to improved ventilation-perfusion matching, thereby improving oxygenation. iNO was first discovered for medical use in the mid-to-late 1980s. Since that time, iNO has been utilized in many randomized clinical trials on patients with Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS), or those with hypoxemic respiratory failure, and its use remains controversial. A recent systematic review of the literature, performed by Arash Afshari et al, set out to determine whether or not the use of iNO improves mortality in patients with ALI and ARDS. Fourteen randomized clinical trials involving 1,303 participants were included in their analysis comparing iNO with placebo or no intervention at all. They were unable to identify any beneficial effect of iNO on outcomes. Although iNO had a

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statistically significant but transient effect on oxygenation, it showed no statistically significant effect on mortality in these patients. In addition, use of iNO had no statistically significant effect on duration of mechanical ventilation, ventilator-free days, and length of stay in the intensive care unit and hospital. Therefore, they concluded that despite signs of initial improvement in oxygenation with the use of iNO, it does not appear to improve survival and should not be recommended for these patients. In addition, it may be harmful for these patients as it may cause kidney function impairment. (Author's note: This review does not address use of nitric oxide in neonatal population nor adult care cardiac use.) [Reference: Afshari A, Brok J, Moller AM. Inhaled nitric oxide for acute respiratory distress syndrome and acute lung injury in adults and children: a systematic review with meta-analysis and trial sequential analysis. *Anesth Analg*. 2011 Jun;112(6):1411-21.]

NO DIFFERENCE

A comparative study at Royal Children's Hospital, Australia, found that bronchoalveolar lavage for treating CF in infants that obtains and cultures fluid samples from the lungs was no more effective than standard diagnostic procedure. The five-year study included newborns diagnosed with cystic fibrosis from screening programs across 8 Australasian cystic fibrosis centers. Eighty-four infants received BAL-directed treatment and 86 received standard therapy based on oropharyngeal cultures. No statistically significant between-group differences were observed. The average total CF-CT scores for BAL-directed therapy were 3.0% and 2.8% for the standard therapy groups. The researchers concluded, "BAL-directed therapy provided no clinical, microbiologic, or radiographic advantage and led to an increased risk of predominantly mild adverse events as a direct result of bronchoscopy as well as disadvantages such as the need to fast prior to the procedure, exposure to anesthesia, and potential perioperative anxiety." They did note that BAL was likely best used on young children whose conditions are deteriorating rapidly. Information is from Medical News Today, written by Anne Hudsmith, copyright Medical News Today.

IN YOUR HEAD

Asthma may be in your head, according to researchers at Harvard Medical School, whose study found that the power of the placebo effect versus albuterol inhalers

left asthma patients thinking that real and fake drugs were equally effective. The results convinced patients they were breathing better even if they hadn't taken a real drug and hadn't actually improved. Researchers studied 39 asthma patients who were randomly assigned to be treated with an albuterol asthma inhaler, a placebo inhaler and a sham acupuncture treatment, and underwent sessions of treatment with nothing. They were exposed to each approach and their exhaling ability was tested over 12 interventions. The albuterol inhaler improved exhaling by 20%, while the other methods improved it by 7%, overall. When questioned, the subjects said both inhalers and the sham acupuncture improved their breathing by about the same amount, the albuterol inhaler by 50% and the fake inhaler by 45%. The false acupuncture made them feel better by 46%, while they thought doing nothing only improved their breathing by 21%. Researchers said healthcare providers should test actual lung function instead of asking patients for self-assessment. Information for the above is from Medical News Today, by Sy Kraft, copyright Medical News Today.

TWO YEARS OF GASPING

One-fifth of patients with pulmonary arterial hypertension suffer with it for more than two years before being correctly diagnosed and properly treated, according to a new national study of 2,493 patients by researchers at Intermountain Medical Center in Murray, UT. The study found that more than 21% of patients with PAH had symptoms for over two years before being diagnosed and beginning treatment. Patients under 36 years old were most likely to receive a delayed diagnosis. Those who had previously been diagnosed with common respiratory disorders were also likely to have a delayed diagnosis. How come? Researchers noted that PAH symptoms like shortness of breath, fatigue, swelling, and chest pain, are also indicative of common disorders like asthma. Also, younger patients are more active and notice symptoms when they're subtler, but because the symptoms are less severe, physicians may be less likely to order testing for PAH. In addition, the researchers noted, young patients are more likely to be uninsured and thus less likely to seek treatment.

PIPE UP

The first successful transplantation of a synthetic tissue engineered windpipe has been performed on a patient

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suffering from late stage tracheal cancer at the Karolinska University Hospital in Huddinge, Stockholm, by professor Paolo Macchiaroni and colleagues. The doctors designed and built a nanocomposite tracheal scaffold and produced a bioreactor to seed the scaffold with patient's own stem cells. The patient wasn't put on any immunosuppressive drug, since the trachea was regenerated using the patient's own cells, and the body did not show any signs of rejection. The patient's tumor had grown to 6 cm and extended to the main bronchus, completely blocking the trachea. With this type of transplantation, there's no need to wait for a suitable donor. Information for the above is from Medical News Today, written by Anne Hudsmith, copyright Medical News Today.

FAT, NOT FATAL

Obese adults undergoing surgery develop respiratory insufficiency and ARDS less frequently, and if they do, it's less likely to be fatal, according to researchers at the Hospital for Special Surgery. In fact, researchers said, obesity might be protective for such patients. The researchers used a large national database of 9 million patients to identify patients who underwent common surgical procedures and had a high risk of leading to RI/ARDS. They found that 5.48% of patients had a diagnosis of obesity, with an incidence of RI/ARDS at 1.82% among obese patients and 2.01% among non-obese patients. In-hospital mortality was significantly lower in obese patients, 5.45% vs 18.72%. Also, the need for mechanical ventilation was lower in obese than non-obese patients (50% vs 55%), as was in-hospital mortality in those requiring intubation, 11% vs 25%. The researchers conjectured that obese patients may have

more energy stores and better nutritional status to help them through an acute illness, and that fatty tissue may have some advantageous effect when patients are in a high inflammatory state, acting as a sink for inflammatory proteins or cytokines, thus neutralizing them. Another hypothesis was that doctors were typically more vigilant with obese patients, because they worried that these patients might have more health problems, so they paid more attention to taking care of potential problems.

INFO SHARING

The Global Allergy and Asthma Patient Platform, GAAPP, is a newly formed international initiative aimed to fight the rapidly proliferation of asthma and allergies, and to ease management of the diseases for patients, founded in Istanbul, with offices in Vienna. The GAAPP is an umbrella organization to cross-link patient self-help and patient initiatives worldwide. Its objective is to share expertise, coordinate campaigns for increased public awareness and organize support programs for patients in underprivileged countries. Patient initiatives in more than 20 countries have already joined the platform.

BAD FOR EVERYONE

Traffic pollution is particularly bad for asthma sufferers, and may affect fetuses, too, according to a research study by Dr Mohammad Shamsain of Cairo. He tested the lung functions of 1,397 children, aged 7-10, and measured air pollution levels in Cairo, one of the world's most traffic-congested cities. Of course, he found a high prevalence of asthma, wheezing, eczema and hay fever symptoms. He noted that he had identified that pollutants such as nitrogen and sulphur dioxide as well as particle matter



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25 YEARS OF SLEEP DIAGNOSTICS EXCELLENCE Since 1987 AF451 Issue1

from vehicle exhausts and road dust is linked to the onset of asthma. The risk can start from the time a child is in the womb, as the placenta does not offer protection to mothers exposed to pollutants. Pollutants entering the fetal circulation system have a significant impact on growth and development; there have also been cases of babies born with retardation, morbidity and low birth weight. Children in homes near roads with heavy traffic also have increased risk of new-onset asthma, incidence of wheeze, risk of recurrent dry coughs, hospitalization and school absenteeism. Shamssain noted that one preventive step was for people in polluted areas to eat more fruit and vegetables and to take vitamins A and C, for their antioxidant effects on the respiratory system. He noted that dietary supplementation with suforaphene reduces inflammatory responses, especially to diesel exhaust particles.

GIN MILL

The last in a series of cotton gins in the US Cotton Belt are being tested as the fieldwork for a major four-year cotton gin dust sampling by the USDA. Researchers noted that the EPA computer models and dust samplers likely overestimated the distance gin dust travels and the concentrations of the smallest particles. For the study, the exhaust from each gin's dust control devices is sampled, and outside dust is measured by 126 ambient air samplers surrounding each gin.

CHEAPER!

Pediatric researchers at the University of Alabama at Birmingham have developed an effective, inexpensive way to help breathe life into children in developing countries, with a modified device for adults that can safely be used for low-cost, low-maintenance, low-concentration oxygen therapy in infants and small children. The device blends compressed oxygen and compressed air to provide accurate and precise concentrations and flow rates. Researchers said, "Use of these blenders in developing countries is hindered by multiple factors, including cost, maintenance and lack of local availability of compressed air. The system allows delivery of the exact oxygen concentration by pulling air from the environment using a commercially available device." Researchers said theirs was the first demonstration that air-blending devices can accurately and precisely deliver set oxygen concentrations at flows lower than those for which they are nominally designed, if used with the proper delivery systems.

PROTECTION

Infection with the gastric bacterium *Helicobacter pylori* provides reliable protection against allergy-induced asthma, according to immunologists from the University of Zurich. Their work confirms the hypothesis that the dramatic increase in allergic diseases in industrial societies is linked to the rapid disappearance of specific micro-organisms that populate the human body. The researchers reiterated that the rapid rise in allergic airway disease is attributed to air pollution, smoking, the hygiene hypothesis and the widespread use of antibiotics. The hygiene hypothesis states that modern hygiene measures have led to a lack of exposure to infectious agents, which is important for the normal maturation of the immune system. In their study, the researchers pinpointed the specific disappearance of the gastric bacterium *H. pylori* from Western societies. According to estimates, around half of the world's population might be infected with the bacteria. The affliction often has no symptoms, but under certain conditions can cause gastritis, gastric and duodenal ulcers, and stomach cancer. Consequently, *H. pylori*

is often killed off with antibiotics as a precaution, even if the patient does not have any complaints. Working with infected mice, the researchers found that early infection impairs the maturation of the dendritic cells and triggers the accumulation of regulatory T-cells that are crucial for the suppression of asthma. Mice that had been infected early also lost their resistance to asthma-inducing allergens if *H. pylori* was killed off with the aid of antibiotics after the sensitization phase. This confirms that the increase in allergic asthma in industrial nations is linked to the widespread use of antibiotics and the subsequent disappearance of micro-organisms that permanently populate the human body.

BLEEDING

The journal CHEST presented a new study suggesting that the use of combination antithrombotic therapy may increase the risk of clinically relevant bleeding in patients with atrial fibrillation (AF). Researchers compared outcomes in 3,728 patients with AF receiving anticoagulation and 848 patients with AF receiving combination antithrombotic therapy. Patients receiving combination therapy had a 2.3-fold increased risk of clinically relevant bleeding.

TRADITIONAL

A traditional medicine long used in Korean, So-Cheong-Ryong-Tang (SCRT), can alleviate asthma-like pulmonary inflammation by suppressing chemokines or proteins, according to researchers from Boston University School of Medicine. To elucidate the mechanism of how SCRT modulates allergic response, the researchers evaluated the immunomodulatory effects of SCRT in a murine model of asthma induced by a house dust extract containing cockroach allergens and endotoxin. They found that SCRT treatment significantly reduced airway hyper-reactivity as measured by both whole body plethysmography and direct measurement of airway resistance. They also reported that the immune response of pulmonary inflammation was significantly inhibited by SCRT treatment as demonstrated by reduced plasma IgE antibody levels and improved lung histology, and that SCRT significantly reduced the number of neutrophils in the bronchoalveolar fluid, and also significantly reduced the BAL levels of CXC chemokines.

LUNG MACHINE

A purpose-built machine used for the first time worldwide by Sahlgrenska University Hospital in Sweden is being used to assess and treat the function of donors' lungs before transplantation. While the lungs of many donors are of good quality, some can swell on account of the fluid that gathers in them, rendering them unsuitable for transplantation. The new machine allows doctors to get rid of the swelling and so make them fully functional. Lungs taken from the donor are first cooled at the donor hospital. On arrival at the transplant center the donor lungs are hooked up to the machine. After being slowly re-warmed they're ventilated so that they can be assessed. If, after three to four hours' treatment they're in good condition, they're cooled once more before transplantation. Four people have been given these newly-treated lungs, and the recipients were doing great. The researchers noted that with the use of the machine, they could probably increase the number of lung transplants by 20 to 30%.

BREATH MILK

Babies fed on breast milk up to the age of six months have a lower risk of developing asthma-related symptoms in early childhood, according to researchers at the Erasmus Medical

Center in The Netherlands. Their findings showed a link between duration of breastfeeding and number of wheezing periods, and revealed that asthma-related symptoms appear earlier in children who are breastfed for fewer months or who are also given other milk or solids in the first four months. The researchers looked at the effect of breastfeeding duration and the introduction of other liquid and solid food on 5,368 children, and at medical data about the children at subsequent yearly intervals. Compared to children who were breastfed for 6 months, children who had never received breast milk had an increased risk of wheezing, shortness of breath, dry cough and persistent phlegm in their first 4 years. Children who were never breastfed had 1.5 times higher risk of phlegm and wheezing. Inclusion of solids in the diet during the first four months was also linked to more wheezing, shortness of breath, dry cough, and phlegm in the early years. Information above was from an article by Catharine Paddock, PhD, for Medical News Today, copyright Medical News Today.

IPF + GERD

Patients with IPF who are also treated for GER appear to live longer than IPF patients who are not treated for GERD, according to researchers at the University of California, San Francisco. Researchers looked at data from 204 patients, finding GER symptoms in 34%, and patient- or physician-reported history of GER in 45%. When they were diagnosed with IPF, half of patients reported that they were being treated for GER with medication. Eleven patients reported having undergone surgical treatment for GER. Patients who had undergone or were undergoing treatment for GER had a significantly improved survival time in comparison to those who had not been treated. Researchers said their study demonstrated that the use of GER treatment was associated with a lesser degree of fibrosis and longer survival time. They theorized that GER treatment suppressed the acidity of gastric contents and thus reduce the injury caused by microaspiration. The surgical procedure to reduce GER appeared to have an additional benefit over medication alone in the study.

SPRAY AWAY

Children with OSA using fluticasone furoate nasal spray were found to produce lower amounts of specific inflammatory cell proteins that trigger their condition, according to researchers from the University of Chicago Medical Center and Pritzker School of Medicine. The researchers wanted to find out what effect intranasal corticosteroid therapy might have on inflammatory cytokines in adenoid tissues and set up a study involving 24 participants aged from 2 to 12 years who were having their tonsils and adenoids surgically removed for OSAS. One group received 55µg of fluticasone furoate nasal spray once a day for two weeks, another group got no intranasal treatment. After the patients' adenotonsillectomy, their adenoids were weighed to find out whether two weeks of treatment had had any effect on the size of tissue. The researchers reported that there was no statistical difference in adenoid weight between the treatment and non-treatment groups. Levels of spontaneous IL-6 production in the treatment group were found to be significantly lower than in the non-treatment group. Spontaneous IL-6 regulates cell growth and differentiation and is secreted by T-regulatory cells. The authors concluded that the reduction of IL-6, a proinflammatory cytokine, in adenoid tissue obtained from children with obstructive sleep apnea syndrome treated with fluticasone furoate nasal spray, could contribute to the

clinical efficacy of this class of medications in the treatment of childhood obstructive sleep apnea syndrome. Information is from an article written by Christian Nordqvist for Medical News Today, copyright Medical News Today.

A BIG PLAN

England's health service announced a major plan to address respiratory diseases, particularly COPD. The UK has the second highest mortality rate from COPD and asthma in Europe, with 3 million COPD cases and 4 million people being treated for asthma. One in eight adults aged over 35 has COPD that has not been diagnosed, and more people are admitted to UK hospitals as emergency cases for COPD than for any other condition. The new program, Outcomes Strategy for COPD and Asthma, will attempt drive improvements in outcomes for patients through an approach that coordinates the efforts of the National Health Service, patients, and social care and voluntary organizations. The program's objectives are to improve awareness of good lung health, reduce the number of people with respiratory disease and improve the quality of life for those diagnosed.

SMOKING AND BABIES

A study by the University of Liverpool found that babies admitted to hospital with bronchiolitis from a household where a parent smokes are twice as likely to need oxygen therapy and five times as likely to need mechanical ventilation, regardless of the family's socioeconomic status. Over the winter months, about 25 in every 1,000 babies are admitted to a hospital with bronchiolitis and 10% need a ventilator. The relationship between household tobacco smoke and risk of developing bronchiolitis in infants is well recognized, as is the relationship between deprivation and smoking, but until now it was difficult to describe the independent contributions of tobacco smoke exposure and deprived socioeconomic status upon severity of bronchiolitis.

BACK TO SLEEP

Respiratory Therapy's e-book of sleep articles is now available on Amazon. Three hundred pages of informative articles culled from leading international journals cover all aspects of sleep therapy. It is available for only \$9.98 from amazon.com, and is downloadable to all applicable Kindle e-book media. Visit amazon and type: RESPIRATORY-THERAPY-SLEEP-2011-ebook.

SLEEP NEWS

DON'T BE STILL, MY HEART

Obstructive sleep apnea may cause changes in blood vessel function that reduces blood supply to the heart in people who are otherwise healthy, according to researchers at the University of Birmingham, but researchers found that 26 weeks of CPAP improved blood supply and function. The researchers noted that even healthy patients with sleep apnea showed abnormalities of small and large blood vessels, as well as impaired blood supply to the heart muscle, and that these could improve with CPAP therapy. This study was the first to show blood vessel abnormalities in sleep apnea patients. Researchers looked for changes in blood vessel function in 108 participants who were otherwise healthy.

DRIFTING AND DRIVING

The American Sleep Apnea Association (ASAA) announced plans for its 2011 Sleep Apnea & Multi-Modal Transportation Conference (SAMTC) on November 8-9 at the Sheraton

Baltimore City Center. Co-sponsored by the Federal Motor Carrier Safety Administration (FMCSA) and the Federal Railroad Administration (FRA), the conferences will focus on the role of OSA management within the major modes of transportation, including air, rail, ground and maritime. Conference topics and speakers will hone in on operational considerations pertaining to OSA diagnosis and treatment which ultimately affect fitness, certification, and related workplace issues. Contact the American Sleep Apnea Association, sleepapnea.org.

SLEEP ON THE LEFT

Women who sleep on their right side during their last night of pregnancy have twice the risk of stillbirth, compared to women who sleep on the left, according to researchers at the University of Auckland. Still, the risk is small, according to the researchers. The risk of stillbirth was also found to be higher among women who got up during the night to go to the bathroom once or less on their last night of pregnancy, as well as those who regularly slept during the day during their last four weeks. Researchers interviewed 155 women who gave birth to a stillborn baby, all of whom had been pregnant for at least 28 weeks, and compared answers to a control group of 310 women. The women were asked about their sleeping positions during pregnancy, and their sleep and waking patterns during their last month, as well as the night before they believed their baby had died. They also reported on whether they snored and how often they got up during the night to go to the toilet. The women who slept on their right side or on their backs on the last night of their pregnancy were more likely to have a late stillbirth compared to women who slept in other positions. Women who frequently got up to go to the toilet at night on their last night before giving birth were less likely to experience a late stillbirth than those who got up once or less. The researchers conjectured that restricted blood flow to the fetus when a mother lies on her back or right side for long periods may help explain this association. Due to the sampling size and percentage results, other researchers noted that there was no need to alarm mothers by warning about right-side sleeping. Information for the above is from an article by Christian Nordqvist in Medical News Today, copyright Medical News Today.

APNEA AND PREGNANCY

Women with severe sleep apnea had the highest incidence of adverse pregnancy outcomes, driven by a higher incidence of gestational diabetes and early preterm birth, according to researchers at Chicago's Northwestern University. The researchers identified 150 women who had received a sleep evaluation by overnight polysomnography. Eighty-seven percent of the women were overweight or obese at delivery, with a body mass index of 25 or more. Seventy-two percent had undergone the sleep study within three years of their delivery. The analysis assessed the associations between sleep apnea and three adverse pregnancy outcomes: pregnancy induced hypertension, gestational diabetes, and early preterm birth at 34 weeks or less.

BRACING

Children with enlarged tonsils and adenoids who wore an oral appliance for six months experienced more favorable craniofacial growth, enlargement of pharyngeal dimensions, and improved breathing and snoring during sleep, according to researchers at the University of Sao Paulo. Forty children waiting for an adenotonsillectomy were enrolled for the study, all of them with snoring, tonsil and adenoid enlargement, and dental malocclusion. Twenty four were treated with the Bioajusta

X dental appliance and 16 were controls. The researchers evaluated the craniofacial growth in children with enlarged tonsils and adenoids, after dental appliance (Bioajusta X) treatment, and compared the prevalence of snoring before and after treatment. Use of the dental appliance helped normalize respiratory function and sleep.

JUST LISTEN

The analysis of breathing sounds while a person is awake may be a fast, simple and accurate screening tool for obstructive sleep apnea, according to researchers at the University of Manitoba. Their results showed that several sound features of breathing were statistically significantly different between participants with obstructive sleep apnea and healthy controls. In an analysis that combined two significant sound features, the presence or absence of OSA was predicted with more than 84% accuracy. Sound analysis also allowed for the stratification of OSA severity. Researchers noted that people with OSA tend to have a narrower and more collapsible pharynx with more negative pharyngeal pressure, which creates greater resistance when breathing through the nose. Breathing sounds are directly related to pharyngeal pressure, making sound analysis a viable diagnostic option for OSA. The pharyngeal pressure in people with OSA during wakefulness is usually more negative than that in the non-OSA group. The researchers studied 35 patients with varying severity levels of OSA and 17 controls. The subjects were instructed to breathe through their nose at their normal breathing level for at least five breaths and then breathe at their maximum flow level for another five breaths. Then the process was repeated as they breathed through their mouth with a nose clip in place. The breathing sounds were picked up by a microphone. The data were digitized and then analyzed.

NEWS FEATURE

Modified Endotracheal Tubes – Do They Make a Difference?

Carl Sprow, RCP

The author is with Hamilton Medical. This article is from Hamilton's Newsletter.

Nosocomial pneumonia is a complication for the Intensive Care Unit (ICU) patient and is the most common infection. The intubation process, introduction of the endotracheal tube into the airway, aspiration of contaminated secretions, and mechanical ventilation are all factors that play a role in this complication. Ventilator associated pneumonia (VAP) accounts for 80 to 90% of nosocomial pneumonia in ICU patients. Patients are at the greatest risk for VAP during the first few days of mechanical ventilation and the risks continue to grow the longer the patient is on the ventilator.

The following are known to help with the prevention of VAP:

1. Implementation of basic infection control practices by the staff coming into contact with the patient.
2. Good oral hygiene (ex should be practiced Q4 hours and prn).
3. Keeping the patient properly positioned in bed (ex head of the bed at 30 degrees or greater).
4. G.I. prophylaxis.
5. Removing the endotracheal tube as soon as possible (ex

sedation vacation to assess if the patient can be weaned towards extubation).

Today there are several different endotracheal tube (ETT) designs that are available to help reduce the mechanism leading to VAP. One ETT design allows subglottic suctioning to be performed. This can be done with either intermittent or continuous suctioning to prevent micro aspiration of secretions. Subglottic suctioning may increase the risk of drying out and causing trauma to the mucosa. Another ETT design utilizes a cuff composed of polyurethane or silicone which helps prevent aspiration and may reduce early incidence of pneumonia. Antibacterial coated ETTs are designed to help limit the bacterial colonization on the lumen of the ETT. Some ETT designs have also changed the shape and inflation features to reduce the amount of secretions that build up on the lumen of the tube.

Of course, there are the costs associated with each of the modified ETTs. Depending upon the style of the tube, modified ETTs can range in price from \$30-\$100 per tube. This increased cost would be worth the investment if modified ETTs are proven effective in reducing VAP. However, there is still insufficient evidence in regards to how well the various tubes work, and what risks factors are involved with each.

VAP is a costly nosocomial infection that is directly related to the introduction of the ETT into the airway. A wide spectrum approach to the prevention of VAP that incorporates infection control practices, oral hygiene, proper patient positioning, and removal of the ETT as soon as possible, is likely the most effective approach to VAP prevention. Modified ETTs may play an additional role in helping to prevent VAP, but further studies are needed to prove the efficacy on patient outcomes and safety. The jury is still out. [Reference: Steven Deem MD and Miriam M Treggiari MD PhD MPH. New Endotracheal Tubes Designed to Prevent Ventilator – Associated Pneumonia: Do They Make a Difference? Respiratory Care August 2010 Vol. 55 No 8.]

PRODUCTS

HOME GROWN

Royal Philips Electronics has introduced the HomeLox portable liquid oxygen system. The innovative system enables oxygen users to generate and store the liquid form of oxygen in the home setting. The HomeLox system offers users the long-lasting and lightweight characteristics of traditional liquid systems, while freeing them from difficulties of filling and dependence on deliveries associated with conventional systems. Home oxygen is a critical, life-sustaining medical treatment prescribed to nearly 1.5 million Medicare patients. It includes a liquid oxygen generation and storage unit that remains in the user's home, and a lightweight and long-lasting portable device, GoLox. HomeLox generates liquid oxygen by converting room air into oxygen, and then chilling and converting it to liquid form using a proprietary refrigerant along with standard refrigeration technology found in industrial and household applications. The liquid oxygen is stored within the HomeLox unit until transferred to GoLox for portable use. The system also features a new hands-free clean filling process. To fill the GoLox portable device, the user simply places the unit on top of HomeLox, turns and locks the unit, and pulls the filling lever. The hands-free process helps reduce freezing, overfilling, and under filling. For homecare providers, the system reduces cost and complexity. Contact philips.com/homelox.

TEAM EFFORT

CareFusion and ResMed announced a five-year agreement providing CareFusion the exclusive right to distribute the ResMed Stellar 100 and 150 non-invasive ventilators (NIV) and their related accessories into the US institutional healthcare market. As a result, CareFusion will have a more competitive offering in the institutional NIV market, which is expected to grow by more than 6% annually. For ResMed, it provides a timely introduction of its new ventilation products via CareFusion's long-standing relationships with US hospitals, long-term acute care and skilled nursing facilities. CareFusion will also market and sell the Stellar 100 and 150 related accessories, including tubing and filters. The Stellar ventilators are small, quiet, and versatile, with both invasive and non-invasive applications. They use ResMed's leading leak-compensation algorithm, TiControl and on-screen waveforms for managing leak and patient-ventilator synchrony, two common problems that occur when administering non-invasive ventilation in an institutional setting. It is also portable with a built-in rechargeable battery. The ResMed Stellar 100 and 150 were cleared by the Food and Drug Administration (FDA) earlier this year. Contact resmed.com or carefusion.com.

SLEEP WITH ALICE

Philips Respironics has introduced the Alice 6 in-lab sleep diagnostic systems, the new members of the Alice diagnostic family. The systems include the Alice 6 LDE for routine sleep studies and the full-featured Alice 6 LDx base station with either the LDxS or LDxN head box. The Alice 6 systems are designed to help sleep lab managers better meet their business and clinical challenges, regardless of the size of their lab. The Alice 6 LDE system incorporates the base set of channels needed for routine polysomnographic testing and incorporates an easy-to-understand and intuitive head box. The Alice 6 LDx system offers full-featured flexibility and two head box options of either 19 EEG (the LDxS) or 32 EEG inputs (the LDxN) for when more advanced EEG studies are needed. Both head boxes are designed with easy-to-identify and easy-to-connect inputs. The Alice 6 LDE and LDx systems provide up to 500Hz recording, continuous impedance recording, and meet AASM standards. The Alice 6 systems are powered by Sleepware G3 sleep diagnostic software, designed to help lab managers better meet their workflow needs and offer lab staff a richer, more productive experience. Contact philips.com.

KEEP ON THE GRASS

Grass Technologies offers its Portable Sleep Screener: The SleepTrek3 six-channel type III compact, lightweight, portable sleep screener is designed for patients in the comfort of their home. After overnight recording, data is reviewed at the sleep lab. A comprehensive report and analysis of the study is then produced by the Grass Software. Easy to set up, SleepTrek3 records airflow, snore, respiratory effort, body position, pulse rate, and SpO₂. Its internal rechargeable battery records 12+ hours. SleepTrek3 includes sensors, cannulas, pouch, home carry case, rechargeable battery, Patient Quick Reference Guide, and software. The company also offers its Gold Standard Electrodes: Genuine Grass electrodes are the Gold Standard with unsurpassed recording clarity, long life and dependability. Available in a "tangle free" material ideal for sleep labs, every Grass electrode is made of the finest materials and is precision crafted using an exclusive 12-step manufacturing process. The superior quality electrodes assure reliable, accurate recordings for PSG and EEG. Each and every Genuine Grass Electrode is

tested for mechanical and electrical properties to ensure high performance – we guarantee it for one full year. Grass products are designed, manufactured, sold and supported by Grass, pioneer in EEG/PSG since 1935.

NEURO-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 ± 13.2 (50.2% improvement); Mean ODI Reduction from Screening to Week 12 of 19.3 ± 15.8 (54.3% Improvement); Mean HI Reduction from Screening to Week 12 of 15.2 ± 13.2 (46.1% improvement); Mean ESS Reduction from Screening to Week 12 of 5 ± 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 ± 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 its pioneering sleep apnea device, the aura6000. 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 aura600 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.

ON THE CUFF

The Journal of Critical Care has published in its June 2011

edition the findings of a clinical study on mechanical ventilation titled, "A Polyurethane Cuffed Endotracheal Tube is Associated with Decreased Rates of Ventilator-associated Pneumonia."

The purpose of the study was to determine whether the use of a polyurethane-cuffed endotracheal tube (Microcuff, Kimberly-Clark Corporation, Roswell, GA) would result in a decrease in ventilator-associated pneumonia rate. The study was conducted by researchers at the University of Michigan, and partially supported by Kimberly-Clark. The authors of the study replaced the conventional endotracheal tube with a polyurethane-cuff endotracheal tube in all adult mechanically ventilated patients throughout their large academic hospital from July 2007 to June 2008 and compared the rates of ventilator-associated pneumonia before, during, and after the intervention year. They found that "Ventilator-associated pneumonia rates decreased from 5.3 per 1000 ventilator days before the use of the polyurethane-cuffed endotracheal tube to 2.8 per 1000 ventilator days during the intervention year. During the first 3 months after return to conventional tubes, the rate of ventilator-associated pneumonia was 3.5/1000 ventilator days. Use of the polyurethane-cuffed endotracheal tube was associated with an incidence risk ratio of ventilator-associated pneumonia of 0.572. In statistical regression analysis controlling for other possible alterations in the hospital environment, as measured by rate of tracheostomy-ventilator-associated pneumonia, the incidence risk ratio of ventilator-associated pneumonia in patients intubated with polyurethane-cuffed endotracheal tube was 0.565." The authors concluded: "Use of a polyurethane-cuffed endotracheal tube was associated with a significant decrease in the rate of ventilator-associated pneumonia in our study." Contact khealthcare.com/VAP.

MAP VS VAP

Kimberly-Clark Health Care recently launched its KimVent Multi-Access Port (MAP) Closed Suction Systems. The new system features a compact rotating manifold with multi-access ports, allowing clinicians to perform suctioning and other procedures, such as bronchoalveolar lavage, bronchoscopy or MDI drug delivery, while maintaining a closed ventilator circuit. Designed in collaboration with respiratory therapists, the KimVent Multi-Access Port (MAP) Closed Suction System addresses requirements for VAP prevention best practices from the AARC, as the system maintains a closed ventilator circuit while allowing for multiple procedures to take place. In addition, the system provides a suction capability with a completely closed airway circuit, thus preventing dangerous environmental contaminants that could potentially cause VAP, enhancing care for both the patient and the caregiver. It also fulfills recommendations as part of a VAP prevention bundle strategy. Key features of the KimVent Multi-Access Port (MAP) Closed Suction and the MAP Catheter include:

- New rotating manifold remains in place for the life of the ventilator circuit, allowing for replacement of the catheter without opening the vent circuit.
- Lock mechanism that locks the catheter into the manifold and stays connected, clean and isolated, and the new sleeve tether prevents the over-retraction of the suction catheter.
- Ability to perform multiple procedures.

Contact khealthcare.com/VAP.

ALLIES

Ambulatory Monitoring, Inc has entered into a strategic alliance with Clinilabs, a full service contract research organization that provides early-phase and specialty clinical drug development services to industry. AMI provides equipment for monitoring physiological functioning in ambulatory subjects. The company's Motionlogger Actigraphs were the first commercial devices for

long-term continuous 24-hour monitoring of activity and sleep and have been validated through use in hundreds of studies in numerous clinical populations. AMI's activity monitors can be applied in clinical trials and therapeutics for sleep, motor activity, psychiatric, pain, hyperactivity, dermatologic and cardiovascular disorders, among others. AMI also provides the original PVT-192 Psychomotor Vigilance Task Monitor (PVT), the dominant assay used in sleep deprivation studies. This alliance brings together AMI's instrumentation with Clinilabs' core laboratory, a leading provider of centralized data management for multicenter clinical trials. Clinilabs' core laboratory aggregates and processes ECG, PSG, EEG, and EMG data for clinical studies, offering pharmaceutical companies centralized services that standardize data obtained in multicenter trials. Centralized actigraphy has been offered jointly by Clinilabs and AMI since 2005, paving the way for this strategic alliance. Contact ambulatory-monitoring.com or clinilabs.com.

INTEGRATED

Maquet Critical Care and Aerogen, Ireland, have announced the release of their partnered product, an integrated unit which provides state of the art nebulizers for the Maquet SERVO-i ventilator. Maquet has been a long term distribution partner for Aerogen. Maquet and Aerogen have jointly created this product which can fit neatly into the Maquet ventilator, enabling the user to benefit from the advanced Aerogen OnQ micropump technology. The Aerogen technology in the form of the Aeronex Solo nebulizer allows drugs to be nebulized into a fine particle mist that can be absorbed through the lungs while maintaining drug integrity. The aerosol is based on a vibrating mesh which, when powered, acts as a micropump creating predictable sized droplets enabling targeted drug delivery to the lungs. The technology offers an alternative to the existing nebulizer offerings. This unique technology allows for the caregiver to nebulize suspensions and solutions, without heating or degrading the drug. Recently, Aerogen began work on an integrated solution for the SERVO-i ventilator, which will enable users to replace the existing nebulizer with the high efficiency Aeronex nebulizer. The integration will enable caregivers to control the Aeronex nebulizer directly from the user interface, providing ability to nebulize in both intermittent and continuous modes. The integrated product is available to new SERVO-i customers and can be retrofitted into the SERVO-i's currently in use. The Aerogen integration is available for purchase through Maquet dealers. The unit can be installed before purchase or retrofitted by a Maquet service engineer.

TREATMENT APPROVED

Novartis announced that the FDA has approved once-daily Arcapta Neohaler (indacaterol inhalation powder) 75 mcg for the long-term maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Arcapta is not indicated for acute deteriorations of COPD or to treat asthma. The decision makes Arcapta, formerly known as QAB149, the first once-daily therapy in the long-acting beta₂-agonist (LABA) class to be approved in the US for maintenance treatment of airflow obstruction in COPD patients. Arcapta 75 mcg was studied in 641 COPD patients in two key Phase III trials lasting 12 weeks. Results at week 12 showed that Arcapta significantly improved lung function at 24 hours compared to placebo. Lung function improvements were seen five minutes after the first dose and consistently maintained over 12 weeks. Arcapta also significantly reduced the need for

patients to use daily rescue medication. Additionally, Arcapta improved health-related quality of life compared to placebo, as measured with the St George's Respiratory Questionnaire (SGRQ). The SGRQ is widely used in clinical trials to measure symptoms, activities, and impact of COPD on daily life as reported by patients. The clinical trial program supporting US submission evaluated safety in 2,516 patients who received Arcapta for at least 12 weeks at doses of 75 mcg or more, with results supporting the safety and tolerability profile of Arcapta. The most common adverse reactions in 449 patients taking Arcapta 75 mcg (ie those reported in more than 2% of patients and with higher incidence than placebo) were cough, nasopharyngitis, headache, nausea, and oropharyngeal pain. Contact www.novartis.com.

TAKING CARE

GE Healthcare announced that the University of Colorado Hospital (UCH) has installed the new CARESCAPE Monitor B850, the company's latest advance in bedside patient monitoring, to help enhance clinical decision-making in the NICU. Deployed in UCH's 50-bed NICU and Neonatal OR, the CARESCAPE Monitor B850 enables access to critical patient information from any bedside monitor anywhere in the unit. Additionally, UCH leverages the CARESCAPE Monitor B850 care area-specific monitoring features for more accurate NICU clinical measurements, and to help support its goal of aggressively addressing common premature infant complications. With the CARESCAPE Monitor B850, UCH staff can flex monitoring capabilities up or down depending on the patient's needs. Visual alarming can replace sounds to reduce disruptive bedside noise, helping support a developmentally appropriate environment. Large displays and remote controls enable caregivers to view monitoring screens from across the patient room. When an alarm occurs, nurses can remotely view the clinical information without leaving the patient's side, helping streamline workflow and making it easier to care for their patients. The monitors can help parents watch their baby's clinical status, while the infant remains in an enclosed environment. Using Masimo technology, caregivers can measure both preductal and postductal saturation. The monitor's trending capabilities help make it easier for clinicians to track respiratory and oxygen saturation status during a bradycardia episode occurring within the prior 72 hours. Masimo technology provides enhanced sensitivity for SpO₂ measurements. Oxygen saturation measurements help clinicians determine when patients can be weaned off ventilators. The CARESCAPE Monitor B850 is a key component to the platform of GE Healthcare technologies used at UCH. The hospital has also implemented CARESCAPE Patient Data Module, a portable device that enables continuous monitoring during patient intra-hospital transport. GE Healthcare DINAMAP helps support patient care further by enhancing the accuracy of NICU blood pressure measurements. Its clinical algorithms account for patient movement and low blood pressure rates characteristic of premature infants, and its non-invasive measurements reduce the pain and discomfort caused by traditional invasive techniques. UCH is also the first hospital to leverage InSite, a GE Healthcare remote diagnostic and repair service, with the CARESCAPE Monitor B850. Contact gehealthcare.com.

ERROR-FREE

Up to 75% of test errors occur in the preanalytical phase. Radiometer presented free information about avoiding these errors at the recently held AACC 2011 Clinical Lab Expo in

Atlanta. The company presented info about how its 1st Automatic can help manage the preanalytic phrase. Radiometer noted: “1st Automatic combines analyzers, samplers and data management to ensure the right result for the patient at the right time, while improving operator safety and sample integrity.” Contact radiometer.com and visit AvoidPreanalyticalErrors.com.

CF PROGRESS

Vertex Pharmaceuticals Incorporated announced the final results from its pivotal Phase 3 STRIVE study that evaluated VX-770, a medicine in development that targets the defective protein that causes cystic fibrosis. STRIVE was designed to evaluate VX-770 among 161 people 12 years or older with a mutation known as G551D in the CF gene. Approximately 4% of people with CF have at least one copy of the G551D mutation. STRIVE evaluated 161 patients 12 years or older who received at least one dose of either VX-770 as a single 150 mg tablet (n=83) or placebo (n=78) twice daily. Data from the study showed rapid improvements in lung function (FEV₁) that were sustained through 48 weeks among those who received VX-770, compared to those treated with a placebo. Significant improvements in all key secondary endpoints were observed among people who received VX-770 compared to placebo. The results showed a mean absolute improvement in lung function of 10.6% through week 24 and 10.5% through week 48. VX-770 is a medicine in development for people with cystic fibrosis who are 6 years or older and have at least one copy of the G551D mutation. Contact Vertex Medical at (877) 634-VRTX (8789).

EMERGENCY PLANNING ROUNDTABLE

CareFusion

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

The CareFusion LTV ventilator offers both invasive and noninvasive modes of ventilation in pressure control, pressure support, volume control and spontaneous breath types for patients from 5kg to adult. The patient presets for quick initiation of ventilation is a proven feature to assist with a simple and effective emergency set-up. The oxygen conserve feature reduces oxygen consumption when the time and place of care require it to extend the sometimes scarce resource of oxygen during transport or emergencies, and may be turned off when oxygen resources are again in full supply.

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?)

CareFusion can provide in person educational CE programs ranging from two to six hours. We also have in-service DVDs regarding the LTV ventilators, quick guides, and setup guides for the initial setting up of the ventilator and use of NPPV. There is a downloadable operator's manual emergency setup cards and in-service training videos on the CareFusion website at: <http://prepare.carefusion.com>.

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

For over 10 years, the LTV ventilator has been used for transport across the United States and international transport, including military transport. In addition, CareFusion's LTV ventilators have

been used in several disaster relief efforts including the 2009 Haiti earthquake; Hurricane Katrina and the 2007 Minneapolis interstate 35W bridge collapse and the recent 2011 Japan earthquake and tsunami. In addition, the CDC has purchased LTV 1200 ventilator as the primary ventilator for the US Strategic National Stockpile; 36 states have made the LTV 1200 ventilator the choice for their emergency preparedness plan.



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

The LTV products have 510(k) clearance from the FDA and meet the following: • Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety; • UL 60601-1, 2003 First Edition; • CAN/CSA C22.2 No. 601.1-M90; • IEC 60601-1; • Medical electrical equipment Part 2: Particular requirements for the safety of lung ventilators – critical care ventilators IEC 60601-2-12: 2001 (Second Edition); • Compliant with Shock and Vibration requirements of MIL-STD-810F; • Full compliance with the requirements of RTCA/DO-160F Section 20, Category S, and Section 21, Category M.

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

There is no published life span for any of the LTV ventilators at this time. The operator's manual outline recommends functional checks that should be completed on a regular basis; these do not have to be performed by a trained bio-med/tech. Every two years or 10,000 operating hours, the ventilators need to have preventive maintenance performed by one of CareFusion's service centers or factory trained field technician. There are six locations across the US that are authorized to perform preventive maintenance, along with warranty and non-warranty repair of CareFusion LTV ventilators. CareFusion also provides a training template.

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

The LTV ventilator is reusable; patient circuits are available in either single use or reusable. The CDC and several state homeland security offices purchase resupply kits from CareFusion. The resupply kit contains patient circuits, HMEs and closed- suction catheters in three patient sizes.

SLEEP ROUNDTABLE

CareFusion

What sleep products you offer?

CareFusion offers a wide-ranging product line that provides diagnostic and therapeutic devices including SomnoStar, Nox T3 and Tiara Medical products.

What is the range of the product's applications?

CareFusion sleep products can be used both in the sleep lab and a patient's home. SomnoStar diagnostic PSG system assists in diagnosis of a full range of sleep disorders in patients ranging from neonate to adult. Nox T3's unique design offers users a portable sleep monitor for home and unattended studies. The Tiara Medical catalog includes multiple therapy interfaces including the Advantage Series, Sleep Net masks, PureSom CPAP and other CPAP accessories.

Talk about the use of your products in sleep lab, home, and/or hospital.

For more than 25 years, CareFusion has been a leader in bringing sophisticated and comprehensive solutions for the sleep market. For example, SomnoStar has the ability to distinguish a wider variety of sleep disorders and determine effective treatment modalities using our direct integration of Calibrated Flow Volume Loops. Because of the close relationship between sleep apnea and heart dysfunction, the Heart Rate Variability Graph provides a deeper analysis of a patient's cardiac function throughout the entire night in a one-page report. In addition, with the incorporated LabManager Microsoft Word report generator, interpretations can be created in a matter of minutes. Service is also an important facet of CareFusion's portfolio, with 24-hour live tech support through Registered Polysomnographic Technicians.

In addition, the NOX-T3 device's design is small and lightweight, which may increase comfort for children and adults. Unlike other screeners with limited software, the NOX-T3 device has the functionality of a full-fledged sleep software and can navigate, score, review, report and export the sleep data. CareFusion sleep diagnostic equipment can be interfaced to a facility's EMR using V-Link, our HL-7 solution. This interface allows bi-directional flow of ADT data that ensures accurate patient information and billing. In addition to the EMR feature, users have the ability to remotely access their sleep data. Physicians can score and interpret studies anywhere with Internet access.

Discuss reimbursement as it applies to your product and where it's used.

Reimbursement is always an important aspect to any successful lab. CareFusion's sleep products meet or exceed the American Academy of Sleep Medicine. SomnoStar's ability to collect full Polysomnography, MSLTs, MWTs, and calibrated respiratory inductive Plethysmography, allows the user to bill all of the sleep related CPT codes. The Nox T3 is also positioned in the home sleep market to offer users a wider range of patients to test. Standard features such as actigraphy, Pulse Transit Time, RIP and FDA approval for patients two years and older, make the T3 an attractive product for sleep professionals.

Philips Respironics

Tell us about the sleep products your company offers.

Philips Respironics offers a complete range of sleep diagnostic and therapy products, services and programs that support sleep labs and homecare providers in treating patients across the care continuum. Our products help to facilitate the identification, diagnosis, titration, treatment, and compliance management for sleep disorders. We are focused on building these solutions with our customers. Our products are designed to meet their varying needs and the needs of the patients they serve. We are working together with our customers to increase the number of patients who are comfortable with and adhere to their PAP therapy over the long term. The evolution in comfort of CPAP includes improvements in both masks and devices. Finding the right mask for the patient is critical to therapy success. For a more comfortable mask experience, materials and design are the biggest factors. Gel mask features are soft and flexible and conform to a patient's facial structure. These features enable the mask to be more comfortable on the face and create a better seal so that mask leaks can be minimized. Over the past few years a new category of minimal contact masks including pillows and direct seal cushions has been introduced, to remove the bulk and claustrophobic feeling patients may experience with other styles of masks. The newest addition to our range of nasal, pillows and full-face masks is GoLife for Men. When designing GoLife for Men, we listened to what sleep therapy providers, clinicians, and male patients told us they wanted in a nasal pillows mask, and that was stability and simplicity. As a result, GoLife for Men takes the complexity out of achieving successful nasal pillow therapy for male patients. And soon, a GoLife for Women mask will offer the same customized features designed for a female patient's face. Both masks are designed so that used together with Philips Respironics System One Resistance Control, they help to deliver improved PAP therapy and comfort. Like our mask portfolio, our PAP systems also have improved over time. Enhancements include the delivery of humidification, flexibility with expiratory pressure, smart ramps that detect flow changes and other comfort features. The enhanced System One device now provides dramatically quieter, intelligent sleep therapy. System One matches the patient's breathing cycle for increased comfort, due to the patented, flow-based Flex technology. With advanced detection, it continuously monitors activity to recognize when therapy needs are changing. It also provides higher target relative humidity levels. The humidity control minimizes the nuisance side effect of rainout. New technologies such as System One Resistance Control enhance the way the device and a specific mask deliver comfortable therapy. This is an excellent example of how we're building solutions with our customers. As further support for therapy success, Philips Respironics offers a 30-day Mask Satisfaction Promise Program to help get patients fitted with the mask that will work best for them. All of our products are backed by industry-leading after-sales support and customer service.

How do your products enhance patient compliance and ease of use?

We are entering a new era in sleep therapy. Technology is enabling a higher level of care for patients while helping to streamline business operations that benefit the clinician. The most recent developments in CPAP treatment help improve compliance by giving providers and care team members faster and easier access to patient therapy data so that they can

intervene more quickly and effectively. Data can be transferred automatically via a modem into a web-based system, such as EncoreAnywhere, where providers, labs and physicians can view data, communicate to other members of the care team and make pressure adjustments remotely. With this faster flow of information, enhanced and more efficient protocols are being implemented to enable a higher level of care for more patients, which ultimately leads to better compliance.

What training and education do you offer in the use of your product for healthcare providers?

Philips Respironics offers a variety of education and training resources for clinicians to help patients achieve positive treatment outcomes. Resources include self-directed written and web-based tutorials or face-to-face instruction. Clinicians learn key concepts and practical applications in the area of sleep medicine that they can apply to their daily activities or to the care of their patients. Clinicians can earn continuing education credits as required by their states to maintain credentials. As in most life-impacting disease management situations, caregivers play an important role in helping patients get the most out of their sleep apnea treatments. Philips Respironics provides extensive materials in written, audio/video and web-based formats to help educate the patient, caregiver and family on the condition and treatment, including tips for use and the need for regular replacement of accessories to maintain comfort and performance of therapy. The materials are available for distribution to caregivers or people using Philips Respironics equipment. Co-morbidities such as heart disease, diabetes, hypertension, stroke and post-operative care continue to be an area of focus for sleep researchers. Education is critical. There are studies that show positive trends in conventional management of these co-morbidities when OSA is effectively treated. We believe that efforts to educate physicians and patients on the need to treat OSA should extend to the medical specialties where co-morbid conditions exist.

Discuss any issues relevant to cost-control/reimbursement.

The combination of our products, technology and programs helps to ensure that patients are compliant with sleep therapy and that providers are equipped with the tools they need to address the challenges of cost-control and reimbursement. We place a great value on understanding the challenges facing clinicians and patients, and we work to provide tools and solutions to help them deal with these challenges. For example, enhancements to our System One sleep therapy platform, coupled with our web-based patient data management system, EncoreAnywhere, and our wireless modems for monitoring, have been very well received in the market. In the last decade, we've gone from looking at data on the machine to a web-based system, where the device stays in the patient's home, and information is bi-directionally transferred daily for easy access and intervention anytime, anywhere by the entire care team.

AARC PREVIEW

Aerogen

Booth 327

What new products will you be presenting?

We are very excited to be exhibiting our Continuous Nebulization Tube Set (CNTS). The continuous nebulization tube set is an

accessory to the Aeroneb Solo nebulizer system and is intended to enable safer continuous infusion of liquid medication for aerosolization into the Aeroneb Solo nebulizer, while reducing the risk of a potential misconnection of a feed-line from another source. The tube set accessory has been designed to incorporate non standard, over sized luer connectors, ensuring that the risk of misconnection with standard luer connectors such as those in use in IV and enteral applications is eradicated. Additionally, the tube set has a unique blue coloration that immediately helps distinguish it from other tube sets typically found in the clinical setting.

What products will you be featuring that are of particular current importance, and why?

Aerogen has developed the continuous nebulization tube set to eliminate any potential risk of misconnection between different luer connectors. Aerogen is committed to patient safety and is constantly working on improving the working environment for both respiratory therapists and patients.

Why should AARC participants visit your display?

RTs should stop by our booth (#327) if they want a hands on demonstration of our unique CNTS system. Aerogen provides the most technically advanced nebulizers on the market today with the Aeroneb Solo and Aeroneb Pro systems. RTs can learn more about how to improve the quality of ventilated patients' lives through the use of our highly efficient nebulizers. We will demonstrate how our nebulizer range saves RTs valuable time as our products operate without changing patient ventilator parameters therefore not setting off ventilator alarms and can be refilled without interrupting ventilation. It may change the way you nebulize forever. AARC offers us an excellent opportunity to meet with Aeroneb users and hear about their experiences and needs with the technology.

Asmatx, Inc

Booth 815

What new products will you be presenting?

The Alair Bronchial Thermoplasty System.

What products will you be featuring that are of particular current importance, and why?

The Alair Bronchial Thermoplasty System: Bronchial Thermoplasty (BT) delivered by the Alair System is a non-drug procedure for severe asthma in adults whose asthma is not well controlled with inhaled corticosteroids and long-acting beta agonists. BT is a new bronchoscopic procedure that delivers radio frequency energy to the airway wall, minimizing excessive airway smooth muscle (ASM). Reducing ASM decreases the ability of the airway walls to constrict and narrow during an asthma attack. The Alair System was FDA approved in April 2010.

Discuss educational/training materials you'll be promoting at the convention.

Procedure animation will be available for attendees to understand how the treatment works and view testimonials by physicians and patients who share their experiences with bronchial thermoplasty.

Why should AARC participants visit your display?

Participants are invited to visit our booth for more detailed

information and education on this new procedure for severe asthma. Procedure animation and patient and physician testimonials are available.

Bunnell Incorporated

Booth 727

What products will you be featuring?

Bunnell Incorporated is celebrating 25 years in the ventilator industry. The Life Pulse High-Frequency Jet ventilator has passed the test of time. Its therapeutic flexibility makes it an indispensable tool in many NICUs. Jet pulse technology, passive exhalation, and an adjustable I:E ratio makes this high-frequency uniquely effective. The “WhisperJet” patient box with sound reduction technology is the most timely product Bunnell will feature at the 2011 AARC Conference in Tampa, FL. The most recent sound reduction upgrade has lowered the sound output from 56 to 41 dB.

What educational/training/support materials will be available?

Bunnell has developed a three booklet pocket reference set that explains *What* high-frequency ventilation is, *Why* the Life Pulse is uniquely effective, and *How* the Life Pulse is used to care for patients. The Life Pulse HFV Training DVD will also be available at the AARC. The DVD contains a complete in-service video, a patient management video, an alarms and troubleshooting video and more. It contains everything you need to understand how the Life Pulse works and how to use it. The DVD is organized, for your convenience, into chapters so you can focus in on the information that is important to you. All of these training materials and much more are available on the Bunnell website, www.bunl.com.

Why should our readers visit your display?

The number one reason neonatal clinicians should stop by the Bunnell booth is to hear how quiet HFV can be, just 41 dB. Noise in the NICU has become an important topic of research and debate. Bunnell is committed to continuous improvement and our new “WhisperJet” proves it. Stop by Booth # 727; hearing is believing. Whether you currently use HFV or not, our clinical specialists can answer all your HFV questions. Stop by and give us a try.

Discovery Labs

Booth 1139-1141

Through our work in developing aerosolized KL4 surfactant therapies, Discovery Labs has become an innovation leader in creating technologies to improve the delivery of aerosol medicines. Two key drug delivery technologies include our proprietary patient interface technology, and the capillary aerosol generator (CAG) device, a high output aerosol generation technology. Both of these technologies will be highlighted at this year’s AARC.

Our patient interface technology, AFECTAIR, is a disposable medical device intended to improve delivery of aerosolized medication to patients requiring positive pressure ventilatory support. Discovery Labs is targeting initial commercial introduction of AFECTAIR in 2012, and multiple recently completed studies with AFECTAIR have been submitted for presentation at AARC.

A study in an acute lung injury preclinical model utilizing aerosolized KL4 surfactant, AFECTAIR, and the CAG technology has also been submitted for presentation at AARC. Come by our booth at AARC to get more information regarding Discovery Labs and our drug delivery and KL4 surfactant technology.

Dräger

Booth 101

What new products will you be presenting?

Dräger has completely revolutionized its portfolio of mechanical ventilation products. In addition to the Evita Infinity V500, Babylog VN500, and Carina, the Savina 300 will make its debut at this year’s congress.

What products will you be featuring that are of particular importance and why?

The Babylog VN500 represents the latest technology that is an infant-specific ventilator. Long awaited by many neonatal clinicians, the Babylog VN500 offers a platform that specializes in the needs of very small infants. The Evita Infinity V500 offers a wide range of IT connectivity options as well as advanced clinical features to improve safety and workflow. The Savina 300 is the latest innovation in chronic/acute care that has the versatility to meet many challenging workplace demands in and out of the ICU, recovery room, emergency room, or skilled long term facility.

Discuss educational/training materials you’ll be promoting at the convention.

An educational DVD discussing the topics of respiratory monitoring including gas exchange, biomarkers, work of breathing, and use of respiratory monitoring systems will be available while supplies last. Our clinical booklet series including Non-Invasive Ventilation, Protective Lung Ventilation, Modes of Ventilation, and Spontaneous Breathing will also be readily available.

What speakers will your company be working with or featuring?

Stop by the booth to see the theater schedule for the latest topics in mechanical ventilation featuring customers and our staff of clinical applications specialists.

Why should AARC participants visit your display?

Dräger will be showcasing the latest advances in technology. The booth will again be fun-filled and a great venue to reconnect to colleagues. In order to thank you all for the work you do everyday at the bedside, Dräger will also be proudly sponsoring the AARC’s opening reception.

Fisher & Paykel Healthcare, Inc

Booth 1011

Fisher & Paykel Healthcare, Inc will feature our Nasal High Flow System at the 2011 AARC 57th Annual International Respiratory Congress and Exhibition. The combination of Optimal Humidity with the Optiflow nasal cannula allows a greater level of respiratory support than traditional oxygen therapy, delivering high flows up to 60 lpm comfortably and effectively to meet a patient’s inspiratory demand. There are four key benefits of the Fisher & Paykel Nasal High Flow System: delivery of up to 100%

oxygen more accurately, washout of anatomical deadspace, positive pressure through the respiratory cycle and optimized mucociliary clearance.

The central component of our Nasal High Flow System is the Optiflow Nasal Interface. Optiflow is a soft silicon wide bore cannula that eliminates jetting with high gas flows for added comfort and assured compliance with the therapy. Optiflow has the added benefit of allowing the use of Optimal Humidity to maximize mucociliary clearance and increase tolerance of high gas flows without condensation and water jetting proximal to the patient's nasal airway.

The Optiflow Interface Series also includes a Tracheostomy Adapter. High flow systems set to deliver body temperature and saturated gases via a tracheostomy adapter helps mimic normal physiologic conditions of lower airway mucosa and ensures patient airway mucosa and secretions remain normal. Data from reports for both children and adult patients with long term tracheostomy shows that providing Optimal Humidity (gas conditioned to 37° C and 100% Relative Humidity) results in a reduction in secretion volume, suctioning frequency and tracheostomy tube changes, thereby reducing exacerbations and improving outcomes and quality of life.

The latest addition to the Fisher & Paykel Nasal High Flow System is Airvo. Airvo is a stand-alone flow generator for hospital and home use with a built in humidifier that can deliver blended gas flows up to 45 lpm and humidified to Optimal Humidity conditions. Airvo is an ideal device for delivering Nasal High Flow therapy in a wide variety of settings for long term oxygen, to supplement pulmonary rehab and exercise tolerance, for long term non-ventilator dependant tracheostomy patients and a variety of other applications.

Visit the Fisher & Paykel Healthcare, Inc AARC Exhibition booth 1011, to try Optiflow to experience the comfort and ease of use of the components of our Nasal High Flow System (wear Optiflow and see if you can guess what the set flow rate is). Also be sure to ask about Fisher & Paykel Evaqua breathing circuits for adult/ped and infant ventilation as well as our circuit and mask interfaces for NIV applications. Fisher & Paykel Healthcare will also feature the latest in OSA mask, nasal and oral interfaces and the new ICON OSA CPAP range of world leading clinical technologies for treating Sleep Apnea. ICON is stylish on the outside and smart on the inside, with ThermoSmart, SensAwake, Auto-Adjust and InfoSmart technologies.

Fisher & Paykel Healthcare, Inc – Neonatal

Booth 1011

What new products will you be presenting?

Fisher & Paykel is launching its first complete Bubble CPAP System including the new FlexiTrunk CPAP Interface and new CPAP Nasal Masks. Also, see the first humidified infant resuscitation system using the MR850 respiratory humidifier. The Neopuff Infant T-Piece Resuscitator facilitates the delivery of warm humidified gas to help protect the pulmonary epithelium and reduce heat and moisture loss especially during prolonged resuscitation. Conditioning cold, dry gas to body temperature and saturated with water vapor can help reduce the risk of an inflammatory response occurring in the infant's airway.

What products will you be featuring that are of particular current importance, and why?

Fisher & Paykel Healthcare, Inc understands and appreciates the critical role respiratory therapists undertake in infant care. This is the reason Fisher & Paykel is dedicated to improving patient care and outcomes for over 20 years. We are introducing Toby's Journey through the F&P Infant Respiratory Care Continuum from Neopuff Infant T-Piece Resuscitation to Optiflow Nasal Cannula for Nasal High Flow therapy, and also learn more about the launch of our new products. The first complete Bubble CPAP System will be presented along with our new FlexiTrunk CPAP Interface and new CPAP Nasal Masks.

Discuss educational/training materials you'll be promoting at the convention.

Come and experience hands-on training with the Neopuff Infant T-Piece simulator using the new Ergonomic T-Piece Resuscitation Circuit and our Resuscitation Masks. Fisher & Paykel Healthcare will be giving out Ergonomic T-Piece Resuscitation Circuit Kits to all visitors.

Why should AARC participants visit your display?

Attendees are invited to experience all of the above-mentioned demonstrations and hands-on stations. Please join us at the AARC Conference in Tampa at Booth 1011 for a complete review and demonstration of all Fisher & Paykel Healthcare products and experience the F&P Infant Respiratory Care Continuum. Please visit our website at www.fphcare.com for more information.

Hamilton Medical, Inc

Booth 217

What new products will you be presenting?

Hamilton Medical is pleased to once again be showcasing our patented Intelligent Ventilation technologies to the attendees of the AARC and introducing members to the latest advances in the field of ventilation. In addition to our flagship G5 and C2 ventilation systems, the newest generation ventilation platforms and accessories from Hamilton Medical will be front and center for hands-on demonstrations from our top rated Clinical Support Team.

What products will you be featuring that are of particular current importance, and why?

With a focus on reduced length of stay and increased patient safety, Hamilton Medical will feature our cornerstone closed loop ventilation technology, Adaptive Support Ventilation (ASV), our unique lung recruitment tool (PV Tool) and our one of a kind user interface. ASV is our closed loop mode that automatically implements lung protective ventilation strategy based on patient's measured pulmonary mechanics and continuously evaluates, promotes and supports spontaneous respiration from complete control ventilation through spontaneous breathing trials without the need for operator intervention or mode changes. PV Tool is our automated pressure volume tool to determine optimal PEEP and/or for use as a Recruitment Maneuver and determination of LIP and UIP for bi-level ventilation. All of our ventilation platforms have an award winning interface that is consistent across all ventilators, making competencies for the staff simple and reducing the chance of error, regardless of the ventilator in use or the application. Our Intelligent Panel allows the clinician to enter patient information,

choose modes, breath types and enter changes. Additional graphic displays include the Dynamic Lung, Ventilator Status Panel and Wean Screen and optional volumetric End Tidal CO₂ OR side stream End Tidal CO₂ monitoring is offered only by Hamilton Medical.

Discuss educational/training materials you'll be promoting at the convention.

Hamilton Medical places a high value on education. To supplement our simulation CDs, reference cards and internet based WebEx training; Hamilton Medical will have on-line, Hamilton Medical IntelliUniversity, available for all Hamilton Medical customers. An introduction to this invaluable educational resource will be provided by our Advanced Clinical Team.

Why should AARC participants visit your display?

Hamilton Medical has experienced record growth in 2011 and has held the top composite score for all ventilator manufacturers, as rated by MDBuyline, for the past five years. We have introduced three new ventilation products in the past 3 years and have released 6 new products to the European market by the end of 2011 with the intent that most will be available by early 2012 in the United States. Come see firsthand the difference Hamilton Medical ventilation technologies can make in your facility.

Hill-Rom

Booth 1111

What new products or services do you plan to exhibit?

We will be introducing a new booth experience that is designed to engage the customer in the overall clinical experience, highlighting the continuum of care that Hill-Rom has to offer.

What products will you be featuring?

Hill-Rom will have booth representatives available to demonstrate and instruct participants on home and acute care products. Stop by and view our updated website and new patient stories.

Discuss educational and training materials.

We will have booth representatives directing traffic into the booth and guiding customers to their area of interest. We will have technical and clinical information available on interactive kiosks throughout the booth as well as information available with booth representatives directly. Customers visiting our booth will be able to demonstrate all of the various therapies exhibited.

Why should AARC participants visit your display?

To see the Hill-Rom Progressive Mobility approach to therapy – mobilizing your patients and helping to reduce length of stay, easily and safely. Hill-Rom technology lets you guide patients through each step, improving pulmonary function while reducing critical care costs. The result is better outcomes for both you and your patients—which matters most to us.

Invacare

Booth 1223

What new products will you be presenting?

Invacare HomeFill DS Oxygen System and Invacare Perfecto₂ DS Stationary Oxygen Concentrator.

What products will you be featuring that are of particular current importance, and why?

Invacare HomeFill DS Oxygen System/Invacare Perfecto₂ DS Stationary Oxygen Concentrator, Invacare XPO₂ Portable Oxygen Concentrator, Invacare SOLO₂ Portable Oxygen Concentrator. Non-delivery oxygen technology provides the means to drive success in the respiratory business while offering patients independence.

Discuss educational/training materials you'll be promoting at the convention.

Marketing collateral such as brochures, tri-folds and videos. Key personnel will be available to provide on-site product in-services.

What speakers will your company be working with or featuring?

Joe Lewarski, Vice President of Clinical Affairs.

Why should AARC participants visit your display?

Invacare is the industry leader in home oxygen and respiratory therapy. We are expanding our broad and comprehensive line of oxygen products and will be showcasing those innovations. We will highlight how these products enhance patient care and improve quality of life.

Kimberly-Clark Health Care

Booth 133

What new products will you be presenting?

From the global leader in closed suctioning for over 25 years, Kimberly-Clark Health Care will be presenting the KimVent Multi-Access Port (MAP) Closed Suction System with Ballard Trach Care Technology. The new system features a compact rotating manifold with multiple access ports, allowing clinicians to perform suctioning and other procedures, such as bronchoalveolar lavage, bronchoscopy or MDI drug delivery, while maintaining a closed ventilator circuit.

What products will you be featuring that are of particular current importance, and why?

Kimberly-Clark Health Care will feature a Closed Suction System that provides multiple access for multiple procedures, with one closed circuit. With KimVent Multi-Access Port (MAP) Closed Suction System, clinicians can perform suctioning and other procedures such as bronchoalveolar lavage, bronchoscopy, or MDI drug delivery while maintaining a closed vent circuit, recognized as a best practice in the prevention of VAP, reducing the risk of cross-contamination, and to maintain ventilation and oxygen therapy throughout the suctioning procedure, preventing approximately 50% of the lung volume fall observed when suctioning after disconnection from the ventilator. To provide easy access for conducting a mini-BAL without opening the ventilator circuit, the KimVent MAP Closed Suction System was designed for use with the Kimberly-Clark KimVent BAL Cath Bronchial Aspirate Sampling Catheter, used to safely sample a patient's lower respiratory tract secretions, giving physicians the data they need to make an accurate lung infection diagnosis in order to prescribe a targeted antibiotic treatment. In addition, the KimVent MAP Closed Suction System includes the only extended-use catheter that retracts within a unique, isolated and vacuum-sealed turbulent cleaning chamber, creating turbulent cleansing action that results in an 89% cleaner catheter tip compared to a standard closed suction system.

Discuss educational/training materials you'll be promoting at the convention.

We plan to showcase a videotaped version of a clinically-accredited series of live VAP Workshops that Kimberly-Clark Health Care has been sponsoring in partnership with the American Association of Respiratory Care (AARC). The three-hour continuing education workshops, Best Practices in VAP Management: Becoming the Resident Expert, were held in conjunction with the Michigan, Colorado, Wisconsin, Minnesota, and Virginia state societies throughout 2011. The workshop was taped in August at AARC's production studios, and planned for online distribution through AARC's website in October. During this VAP workshop, respiratory therapists learn the importance of becoming the resident expert in their department about best practices in VAP prevention through details around how VAP affects hospital and patient care costs, along with providing the necessary components for leading, planning and implementing a successful VAP prevention program.

Why should AARC participants visit your display?

AARC participants should visit the display to learn how the KimVent MAP Closed Suction System can enable them to suction and perform multiple airway procedures without opening the circuit.

MEDGRAPHICS

Booth 211

What new products will you be presenting?

Medical Graphics Corporation, St Paul MN, will be presenting the BreezeConnect HL7 Interface, which provides bidirectional communication with your facility's Electronic Medical Record system. Test results and interpretations can be automatically uploaded to the patient record providing rapid, system wide access to diagnostics enhancing the quality of care. Download of patient demographics and physician orders through the interface saves time and reduces errors by eliminating manual re-entry of data. The BreezeConnect HL7 Interface offers a flexible business solution that increases productivity, convenience and cost savings.

What products will you be featuring that are of particular current importance, and why?

Featured products from MEDGRAPHICS include the Platinum Elite Plethysmograph and the Ultima Cardio₂ gas exchange system. These systems lead the way in the diagnosis of cardiorespiratory diseases which affect millions of people.

Why should AARC participants visit your display?

MEDGRAPHICS is a leader in cardiorespiratory diagnostics. Participants visiting our booth will experience the latest innovations in hardware and software, and how we can provide the best solutions for their diagnostic needs.

Mercury Medical

Booth 532, 534, 536

What new products will you be presenting?

Mercury Medical will be exhibiting Neo-Tee, the industry's first disposable Infant T-Piece Resuscitator with Built-In Pressure Relief and Color-Coded Manometer on the Tee.

What products will you be featuring that are of particular current importance, and why?

The new Neo-Tee will be very important as hospitals begin changing their protocols for safer and more affordable infant resuscitation solutions. The Neo-Tee infant T-Piece resuscitation single-patient-use device allows practitioners to deliver required volumes for neonatal lung expansion with simultaneous patient monitoring of airway and/or PEEP pressures. The new Neo-Tee affords the clinician more consistent PIP and PEEP pressure. Additionally, there is no "bag" to squeeze so the clinician will not experience bag squeezing fatigue. Furthermore, the Neo-Tee includes a built-in pressure relief valve as an added safety measure when releasing high ventilatory pressures over 40 cm of H₂O. The stay-put PEEP valve allows for quick and easy gas flow adjustments, when needed. The adjustable PIP controller, which regulates pressure, is much smaller and compact than competitive capital equipment. Neo-Tee does not require cleaning and it's completely disposable. As compared with expensive capital equipment, Neo-Tee will be affordable for any hospital (small or large) to incorporate at every NICU, L & D and ED bedside – or just about anywhere since the Neo-Tee can also be used efficiently during transporting infant/patients.

Discuss educational/training materials you'll be promoting at the convention.

Full product training will be offered at our booth by Mercury Medical Product Specialists. We will supply Neo-Tee product information brochures with specifications and hand out free samples. The samples will be provided by fully trained sales representatives who will give full product in-servicing at the attendees' facilities.

Why should AARC participants visit your display?

While our new Neo-Tee is truly unique, Mercury is also a leading manufacturer of resuscitation products that command the number 1 market position for infant CPR resuscitation bags. Mercury pays special attention to customer needs and develops high-quality products to meet those customer requirements. Mercury's slogan, "Your Need...Our Innovation!" sums up the company positioning. AARC participants should visit our display to get a first-hand view and advantages of Neo-Tee, the industry's first disposable infant T-Piece resuscitator with built-in pressure relief and color-coded manometer on the Tee.

nSpire Health, Inc

Booths 111 & 113

What new products will you be presenting?

nSpire Health will be introducing HDweb rapid remote physician review and nSight streamlined PFT testing software.

What products will you be featuring that are of particular current importance, and why?

In addition to our full line of respiratory care products, nSpire Health will feature the new HDweb application, HDnet connectivity, and enhanced nSight PFT testing software. 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.

Why should AARC participants visit your display?

Stop by our booth to learn how nSpire Health can put you back in control of your day, interpreting patient tests in under a minute!

Oridion Capnography

Booth 611

What new products will you be presenting?

The Oridion Capnostream 20p bedside monitor with capnography provides a continuous, accurate measure of the adequacy of ventilation along with the earliest indication of airway compromise. The Capnostream 20p is the next generation of the Capnostream 20 monitor, the first monitor to feature the Integrated Pulmonary Index (IPI). The IPI algorithm utilizes the real-time measures and interactions of four parameters (etCO₂, respiratory rate, pulse rate, and SpO₂) to provide an uncomplicated, inclusive assessment of the patient's respiratory status. Displayed as a single index from 1 to 10, IPI simplifies respiratory assessment, facilitating more timely interventions to improve patient outcomes. With its Microstream measurement technology, the CS20p produces crisp, mainstream-quality waveforms and allows monitoring for all populations, from neonate to adult, both intubated and non-intubated, across all hospital environments, including post-operative opioids on the general floor. Designed for ease of use, the CS20p monitor features a large, easy-to-read display and requires no individual patient calibration and no expensive external sensor subject to damage. The Capnostream 20p features the new microMediCO₂ OEM capnography module. More rugged and smaller than ever before, the micro module can be designed into the smallest host monitoring systems. The CS20p meets the requirements for waveform capnography in the new 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.

What products will you be featuring that are of particular current importance, and why?

Non-intubated consumable solutions: Oridion has developed a series of non-intubated consumable solutions for all patient types in all clinical settings. The evolution of these consumable solutions has created a new generation of capnography: non-intubated capnography that works. The development of the Smart CapnoLine Plus allows for monitoring of patients who may switch between mouth breathing and nose breathing. The special features of this unique cannula include: • Patented Uni-junction design assures oral and nasal sampling even at low tidal volumes, with minimal dilution of the CO₂ waveform during O₂ delivery; • Unique O₂ delivery system (up to 5 l/min) enables effective oxygen therapy and may reduce the O₂ drying effect on patients' sensitive mucus membranes; • Built in hydrophobic filter prevents moisture from entering the monitor while maintaining the laminar flow and excellent waveform; • The filter design and small diameter of the circuit (1.0 mm I.D. microbore tubing) improve accuracy and response time, allowing low flow rates for monitoring neonates; • Ideal under masks for accurate CO₂ monitoring during CPAP, bi-level device or NPPV and high flow rate O₂ delivery therapy; • For adult, pediatric, and neonate patients.

Discuss educational/training materials you'll be promoting at the convention.

The Oridion Knowledge Center offers free, accredited online continuing education courses for respiratory therapists and nurses. These programs provide comprehensive learning modules related to using etCO₂ monitoring in various clinical settings, and how it may increase patient safety in these clinical environments.

Why should AARC participants visit your display?

AARC participants will be able to experience in person what clinical studies have demonstrated for years: that non-intubated capnography is the earliest indicator of respiratory distress. During the "Ventilatory Challenge," participants hold their breath, simulating an apnea. Immediate recognition of the apnea is witnessed in the capnography waveform with an alarm following, while the pulse oximeter continues to display normal values. Participants will see firsthand that it takes pulse oximetry two to four minutes to respond to respiratory distress and is not an adequate measurement of ventilation. Participants will receive a free t-shirt with an opportunity to win an Apple iPad.

Passy-Muir Inc

Booth 419/421

What new products will you be presenting?

This year at AARC, Passy-Muir Inc will present the new Passy-Muir Cleaning Tablets. The New Cleaning Tablets for Passy-Muir Valves are made from a detergent used for other medical supplies because it is biodegradable and leaves no residue on the valves as do some commercially available soap. The Passy-Muir Cleaning tablets are sold in a convenient one month supply of 30 tablets. Free samples will be provided.

What products will you be featuring that are of particular current importance, and why?

Pocket T.O.M. : The Pocket T.O.M. is a more portable pocket-sized version of our popular Tracheostomy T.O.M. Tracheostomy Teaching and Observation Model. The new Pocket T.O.M. displays the same cutaway view of the upper aero-digestive tract and anatomy with tracheostomy, and can be easily taken to the bedside for patient education. It is great for spontaneous staff teaching as well. The Pocket T.O.M. includes model, cuffed tracheostomy tube, syringe, 3 Passy-Muir Valves, and simulated nasogastric tubing. It can be easily cleaned between patients.

Discuss educational/training materials you'll be promoting at the convention.

At AARC, the Ventilator Instructional Tracheostomy Observation (VITO) mannequin will be featured to demonstrate the ventilator application of the Passy-Muir Valve. This simulated ventilator demonstration will aid clinicians in the understanding of the important aspects of ventilator application. Early Passy-Muir Valve placement may result in a faster weaning and shorter length of stay for the tracheostomized and ventilator dependent patient. Passy-Muir, Inc has always held education and clinical support for professionals and patients to be of primary importance. Our latest FREE web-based continuing education opportunities will be featured, along with the new, pocket sized quick reference guide.

What speakers will your company be working with or featuring?

This year, the clinical team from Madonna Rehabilitation Hospital will present: "Pulmonary Management of the Spinal Cord Injured Patient in the Rehabilitation Hospital Setting." This presentation will identify the four primary pulmonary impairments of a high spinal cord injury and demonstrate the role of the Passy-Muir Valve in their prevention and treatment. Rebecca Wills, BA, LRCP-NPS, Pulmonary Program Manager will discuss the use of the Passy-Muir Valve in successfully weaning patients with SCI from the ventilator and/or tracheostomy tube. She will also explore the vital role that the Passy-Muir Valve plays in life-skills training, vocational pursuits, access to community resources and the promotion of self-advocacy for ventilator and/or trach dependent individuals with a spinal cord injury.

Why should AARC participants visit your display?

The Passy-Muir Tracheostomy and Ventilator Swallowing and Speaking Valve is a small device with a huge impact on the lives of tracheostomized and ventilator dependent individuals. Respiratory care professionals are key players in helping these individuals maximize their potential in all environments of health care. A visit to the Passy-Muir, Inc booth will help provide the respiratory professional with the knowledge and tools needed to make that difference in the tracheostomized person's life and care, and will help the respiratory therapist advance as a primary partner in tracheostomized patient outcome management.

Philips Respironics

Booth 401

Philips Respironics brings a patient's journey from the hospital to the home to the forefront at AARC 2011 with its solutions pathway—an interactive showcase of the latest advances for diagnosing, treating and managing long-term respiratory and sleep-disordered breathing illnesses. Attendees will walk through the unique patient-care model and progress from diagnosis to therapy and ultimately to compliance. Products on display in the pathway will include the HomeLox portable liquid oxygen system, the Alice 6 sleep diagnostic systems, both System One's REMstar Pro with AutoIQ CPAP and BiPAP autoSV Advanced devices, the OptiChamber Diamond valved holding chamber, and GoLife and TrueBlue patient interfaces. On the critical care side of the business, new product releases include VentAssist for the Respironics NM3, the NIVO nebulizer system for the AF531, and the Bronchoscopy elbow for the AF531 and PerforMax. These technologies connect the care team to vital patient information and illustrate Philips Respironics' integrated solutions. The booth will also feature knowledgeable speakers, product experts and other educational resources for clinicians.

As the provider of diagnostic sleep testing and PAP therapy equipment for NBC's *The Biggest Loser*, Philips Respironics is pleased to sponsor a series of presentations at AARC entitled "Diagnosis and Treatment of OSA: Lessons learned from *The Biggest Loser*." Ashley Johnston, a contestant from that show's ninth season and Brett Hoebel, the show's trainer from Season 11, will speak on the unique management of obstructive sleep apnea during the production of the reality show. Ashley will also be in the Philips Respironics booth signing autographs and speaking about her personal experience with our products.

Philips Respironics, a global leader in the sleep and respiratory

markets, is passionate about improving the quality of people's lives with solutions designed around the needs of customers and patients. That's why we align with caregivers to establish healthier living and healthier practices. Philips Respironics first considers the needs of our customers, their patients and caregivers and then introduces simpler and more intuitive innovations that consistently revolutionize the areas of sleep, oxygen therapy, ventilation and respiratory drug delivery. As a result, Philips Respironics is recognized worldwide as a pacesetter and as a valuable ally in better sleep and breathing.

Teleflex

Booth 301

What new products will you be presenting?

We will be featuring the Teleflex ISIS HVT Endotracheal Tube and will take this opportunity to provide a preview of some new Hudson RCI Respiratory Products focused on Infection Protection.

What products will you be featuring that are of particular current importance, and why?

The Teleflex ISIS HVT comprehensive endotracheal tube has an integrated suction port and a separate suction line which allows for subglottic secretion removal when needed. This convertible design allows the Teleflex ISIS HVT to meet the needs of patients requiring short or long term intubation, without the need to change tubes for access to subglottic secretion removal, a VAP reduction strategy. [Coffin S, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. *Infect Control Hosp Epidemiol.* 2008;29:S31-S40.] Additionally, we will be featuring the ConchaTherm Neptune heated humidifier. Focused on delivering heated humidification to meet multiple patient needs, the Neptune can be used across the care continuum, from neonates to adults, for applications including invasive ventilation, NIV, and heated, humidified high-flow oxygen nasal cannula therapy.

Why should AARC participants visit your display?

In addition to the in-booth clinical education, we will be featuring products which provide better access to best respiratory practices including VAP prevention strategies.

Thayer Medical

Booth 233

What new products will you be presenting?

Thayer Medical will be presenting its new addition to the existing MiniSpacer MDI adapter family. The addition, recently cleared by the FDA, is a configuration with 15mm O/D x 15mm I/D connections – part number 1543. All adapters in the MiniSpacer MDI adapter family now include extended nozzles that accommodate the pMDI dose counters.

What products will you be featuring that are of particular current importance and why ?

Thayer Medical changed the design of its MiniSpacer MDI adapters for compliance with the international standard for conical connectors. This modification, conformity with the FDA recognized international standard, results in a higher quality part and a tighter interference fit between the components of the patient circuit and the MiniSpacer MDI in-line actuator product.

Why should AARC participants visit your display ?

In addition to the enhancements to the MiniSpacer MDI adapter family, Thayer Medical will feature its innovative MDI holding chamber – the LiteAire. The LiteAire is the only dual-valved, holding chamber constructed of paperboard. It is offered in a dispenser box of twenty-five individually packaged devices allowing for easy access and storage. It is re-usable for up to a week for single patients and is ideal for PFT labs, emergency departments and in-patient floors. The LiteAire is a low-cost, alternative to plastic holding chambers in many environments. Generous quantities of LiteAire samples will be provided to qualified clinical sites. Participants should also visit the Thayer Medical booth to learn about the cost-savings available with the originally designed, US manufactured, Valved Tee family of ventilator circuit components.

Vortran Medical Technology 1

Booth 311

What products will you be presenting?

Vortran Medical Technology 1, Inc manufactures and markets a patented line of fully automatic disposable respiratory devices for patients in the hospital and other market segments (EMS, post acute and home care). Our latest advances in product development and applications provided for an addition to the VAR-Plus Models product line. In addition to the VAR-Plus PC Model with an entrainment feature for an FiO₂ delivery option of 50% or 100%, the *new* VAR-Plus PT Model features an FiO₂ delivery of 100% only. Both the VAR-Plus Models PT and PC offer our customers three packaging configurations. Our new VAR-Plus Model to be featured at the AARC convention is of particular importance because the VAR-Plus PT and PC Models are manufactured with a modulator diaphragm eliminating tilting asymmetric friction and spring force effect as with the RT/RC piston modulator, suitable for both pediatric and adult patients (body weight 10 kg and above).

Discuss other recent developments.

Because of this recent development, two of the older VAR Models, and related packaging configurations were discontinued effective, September 1, 2011. After this date, the RT and RC Models are available for purchase until our inventory is depleted, or by January 1, 2012, whichever is sooner. We have made suggestion for the appropriate VAR-Plus Model to replace the two older RT and RC Models to be discontinued. Both of the suggested replacement VAR-Plus Models are less expensive than the RT/RC Models, suitable for both pediatric and adult patients (body weight 10 kg and above), and are manufactured with a modulator diaphragm eliminating the tilting asymmetric friction and spring force effect as with the RT/RC piston. Of course, Vortran will continue to support all VAR Model RT/RC users, but encourages the user to transition to the suggested replacement VAR-Plus Model as soon as possible. To assist customers in this transition, users may be eligible for a sample evaluation of the suggested replacement VAR-Plus Model to evaluate the improved operational characteristics and performance.

Discuss educational/training materials.

Vortran utilizes various avenues for education and training through media, on-site visits, tradeshow, industry publication advertising, and our network of specialty dealer representatives to communicate key education and training messages. Our message promotes and heightens the clinician's awareness of our

Educational Module Sponsorship for FREE online continuing education units at no charge to medical professionals, an interactive CDROM which contains a multi-media presentation for PC platform of all Vortran products, and our website at <http://www.vortran.com> with up-to-date information on clinical research, company policy and statement, and PDF format of product brochure and user guide.

Why should AARC participants visit your booth?

The AARC convention presents a well-seasoned clinician's affair, climaxing three days of hard work with many topics. Vortran being a small manufacturer realizes speaker sponsorship would enhance relationships, but we prefer the lighter side in State Society meeting themes. This permits a more affordable financial arrangement necessary for speakers, and we are included in deciding the select topics for the appropriate occasion. We encourage AARC participants to visit the Vortran display located at booth #311 so they may interact with product demonstrations for all Vortran products, obtain educational materials providing the opportunity to secure free CEUs, creating an experience of touch, sight, and sound, and we believe this will create a lasting impression on participants so that our brand, our products, and our offers are burned into their minds long after the tradeshow ends.

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is received, member-clinicians proceed with the Administration request incorporating the new procedures or new equipment into their daily routines or protocols.

Whether it be resistant clinicians or union disapproval of a "new or changed" procedure or product, loved ones – mothers, sons, spouses, are forced to suffer hour after hour, day in and day out with a problem that could be erased or drastically reduced with a "new or changed" product, device or procedure that is being held back from use on the floor or unit until a clinician-champion or union leadership is ready to embrace change.

For clinicians resistant to change the answer could simply be because making a decision to champion a new product, procedure or device, that may offer benefits to the patient, isn't worth the risk if they don't perceive it to be as industry changing as for example, the discovery of penicillin. If this reasoning is the case, we are denying the patient quality of care and denying ourselves as medical professionals, personal, professional and industry wide advancement.

Another explanation for resistance and the lack of "champion-clinicians" is possibly due to the culture in which some clinicians practice. Until recently, evidence-based medicine (EBM) and evidence-based practice (EBP) were not part of the medical profession's focus, in fact, EBM and EBP are today key concepts to change; however they are not yet status quo either in the halls of higher learning nor universally practiced in our current healthcare system. "EBM/EBP recognizes that many aspects of healthcare depend on individual factors such as quality and value-of life judgments, which are only partially subject to scientific methods. EBP, however, seeks to clarify those parts of medical practice that are in principle subject to scientific methods and to apply these methods to ensure the best prediction of outcomes in medical treatment, even as debate continues about which outcomes are desirable."¹

EBM and EBP will be further encouraged indirectly through the

FDA Office of Orphan Products Development (OOPD), whose mission is in part to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. Through initiatives such as this, the FDA along with CMS are in fact discouraging the “resistance to change” attitude throughout all levels of our healthcare system.

Acceptance of new innovative products and changes in patient care are painfully slow in the healthcare profession. Perhaps because of that fact, CMS is now requiring immediate attention and action from the healthcare profession, encouraging improvement in patient transitions and tracking reduction and ultimate prevention of re-hospitalizations.

A report published in 2001 from the Committee on Quality of Healthcare in America observed that “scientific knowledge about best care is not applied systematically or expeditiously to clinical practice.”² Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.”³ A decade after these words were written these statements remain true in 2011.

Innovative products and ideas result out of necessity, frustration and often desperation when first-hand experience produces unsatisfactory results. With the thought, “there has to be a better way” the goal is increased efficiency. Clearly it’s about taking a fresh look at an old problem. Whether a new product or idea offers minor improvements or major improvements, improvements bring change and with change advancement is possible.

Consider advancement of the auto industry. Although the auto industry has had more than 35 years, (from the 1970s oil crisis to 2001), to bring alternative fuel vehicles to the market, the hybrid was only introduced in 2001. In other words, it took 25 years for auto makers to *combine* the 125 year old gasoline powered technology with the 169 year old electric golf-cart technology. The reality is an “alternative” type vehicle was invented *first*, with the 1769 steam powered vehicle, sixty-six years later it was followed by the electric vehicle, (in 1832) and finally, fifty-three years later (in 1885) the gasoline fueled vehicle was invented.⁴

The computer industry has been far more productive yet didn’t have the luxury of over a century of prototypes to refer to. The first computer was invented around 1936. In seventy-five years the computer has evolved from a speed of 1Hz and 64-word memory to the amazingly powerful portable feather-weight tablets we can’t live without today.

From pharmaceutical companies to DME (Disposable Medical Equipment) manufacturers, it is apparent that while it takes 7 to 12 years for a product to gain acceptance in the US, in countries such as Israel, Australia, Canada and many European and Asian countries, clinicians are encouraged to introduce new products and changes to their employers resulting in significantly less time for products to gain acceptance. There seems to be a collective effort in these countries to welcome new improvements in the quality of care they provide and embrace new product development in their healthcare systems.

Meanwhile, for new (trial) knowledge to become policies and procedures and incorporated into practice it takes an average of 17 years.⁵ The reality is, your facility’s “new” policies and

procedures are actually on average 17 years old. With that in mind, current RT students may see today’s new trial knowledge become policies and procedures in their 15th year as a respiratory therapist.

How much time is lost during those 7, 12 and 17 years to “making its way through the system?” How long does it take a product, policy or procedure to go from introduction to practice in your facility? How many weeks, months, years does that procedure languish on desk after desk? How many patients have come and gone from your floor in that time, patients who may well have benefited from that one procedure, that one little product or device?

There has been much published in the past few years identifying specific approaches and an abundance of successful strategies for reducing readmissions. What those articles leave out is the most important element that facilitates successful reduction in readmissions... you, the clinician. Everything you do for the patient, goes home with the patient. Anything you don’t do, comes back to you as a readmission or results in mortality. It is just a matter of time before respiratory therapists will be encouraged to seek out and ensure the best prediction of outcomes in respiratory treatment even if the debate continues about which outcomes are desirable.

Some experts contend that the will to adopt successful strategies is lacking. Lack of will ultimately harms patients. “This isn’t necessarily about implementing a protocol, but about leadership at the organizational level to make transitions of care a priority,” said Dr Amy Boutwell, Director of Health Policy and Strategy at the Institute for Healthcare Improvement. “At thousands of hospitals across the United States, transitions are absolutely an afterthought. There is very rarely a systematic approach to handing the care over to the next provider in the community. What we see is that it’s not so much about the ideas as it is the intention and the motivation. That’s where the results are found.”⁶

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Vivian Wright is President of Wright Solutions LLC. This editorial was provided by Wright Solutions LLC.

The Wright Face and Tracheostomy Nebulizing Mask

David Chen, Chad Villanueva

The Wright Face and Tracheostomy Nebulizing Mask is manufactured by Wright Solutions LLC, a company owned and operated by sisters Vivian Wright and Vicky Gates. The Mask is designed to perform the essential task of humidifying the airways of tracheostomy patients. This report discusses how the device was conceptualized and created, the purpose behind humidification and the advantages to using this product over other conventional methods of humidification.

Origins

The founder of Wright Solutions and creator of the mask, Vivian Wright, invented the device out of necessity. This story was taken from the company's website.¹ In the fall of 2000, Vivian's then boyfriend, Dean Wright, was battling head and neck cancer. Dropping everything that she was doing, Vivian transferred from Arizona to Florida to help Dean through months of radiation and chemotherapy. As the disease progressed, Dean eventually needed to have a tracheostomy put in place. Dean's airway needed humidification through nebulization. His mouth, nose, and tracheostomy had to be nebulized separately for 30 minutes each, five times a day. The laborious process took five hours from Dean's daily activities. Because of the painstaking process, he began to comply less with the procedure. The 30 minute requirement was cut in half, then he cut it down to once per day, and eventually he completely stopped nebulizing his nose and mouth.

By the time Vivian and Dean got married, on June 26, 2001, Dean was already experiencing labored breathing because of thick mucous in his mouth and trach. This is a normal reaction to lack of humidity in the airway. Finally, on an airplane flight, a piece of dry epithelial tissue from Dean's airway got into his tracheostomy tube and created an airflow obstruction. He was in serious respiratory distress for most of the flight, and it was lucky he survived. After landing, he was checked into a hospital where he received a 48-hour nebulization treatment. This was the event that motivated Vivian to invent the Face and Tracheostomy Nebulizing Mask.

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She crafted the first prototype from various materials which included twine, electrical tape, masking tape, and elastic bands. She also utilized extra medical tubes, hoses, and a pair of spare face and tracheostomy collars to finish the job. Vivian found a way to connect all materials and thus the Wright Mask was born.

The mask allowed Dean to nebulize his upper and lower airways simultaneously. This cut his nebulizing regimen in half, and he would have 2 1/2 hours more to spend with Vivian. Because of his compliance with the therapy, his nasal, oral and tracheal mucosa stayed moist and healthy, thus making his secretions thinner and easy to expectorate.

Dean made Vivian promise to patent her invention so that other people with the same condition could benefit from it. After Dean died in March 2002, Vivian spent all her time developing and perfecting the mask. Now, Vivian and her twin sister Vicky manage this corporation so that they can provide a means for trach patients to have a better quality of life, in Dean's memory.

The Wright Face and Tracheostomy Nebulizing Mask Delivery System:

- Enables the user the humidify the upper airway and tracheostomy simultaneously
- Uses less tubing than conventional masks
- Is adaptable for hospital and home use
- Encourages patient compliance
- Reduces medical costs of nebulizing
- Saves time
- Is physically comfortable
- Improves quality of life



Significance of Humidification

The primary goal of humidification is to maintain a normal physiologic condition in the lower airways. Proper levels of heat and humidity help ensure normal function of the mucociliary transport system.² The upper airways – the nose, pharynx and trachea, primarily serve the purpose of heating and humidifying inspired air.³ Once the upper airways are bypassed by an artificial airway (eg tracheostomy tube), normal physiological humidification of inspired air ceases. This is why constant humidification through a nebulization regimen is necessary. In

the case of trach patients, wherein the upper airway is separated from the lower airways by the tracheostomy tube cuff, separate humidity administration through nebulization of the nose and mouth via an aerosol mask should be performed. A tracheostomy collar attached to a nebulizer would be responsible for delivering humidity to the lower airway via the tracheostomy.

Benefits of Nebulization and Humidification for Trach patients:¹

1. Thins secretions and mucus, making it easier to expectorate
2. Makes coughing easier
3. Keeps the stoma, the upper and lower airways moist and healthy

Advantages of the Wright Mask over traditional treatments

The problem with the conventional humidification procedure is that it is a laborious daily procedure, especially for long term tracheostomy patients. Along with all other life issues they have to deal with, they have to add a tedious process that requires up to five hours of treatment. Most patients do not have the emotional discipline and physical endurance to comply with the procedure. As a result, most trached patients decrease or end their nebulizing regimen. At the very least, they suffer a dry nose, dry mouth and dry sinuses. Their mucus becomes thick, stringy and difficult to expel. With dry tissue, it becomes painful to gag, choke and cough out mucus. All of these increase the probability of life-threatening mucus plugs.⁴ The key to preventing this is continuous humidification through regular nebulization of the airways.

Previously, the only way for trach patients to actually humidify their tracheostomy, nose and mouth was to mimic what is done in a hospital setting. According to Dr Eugene N. Myers, Distinguished Professor and Emeritus Chair of Otolaryngology of the University of Pittsburg School of Medicine, “the traditional procedure is very awkward to use in the home setting.”⁴ The conventional nebulization process takes 15 steps, two mask set-ups, and a one hour treatment time, done five times, which totals 5 hours per day.⁴ Thus, trach patients have a high probability of not complying with the treatment. The Wright Mask is a solution to remedy this situation. The Wright nebulizing process only takes eight steps, one device and 30 minutes of treatment, which cuts the total treatment time by half to 2 hours and 30 minutes.⁴ Dr Myers further states, “The Wright Mask Delivery system is a big improvement especially for home use... If the patients feel more comfortable and they’re getting along better, then they’ll be more compliant with the treatment.”⁴

Economic Contribution

Proper humidification directly impacts a patient’s health, but it also has an economic value. Consistent use of the Wright Mask delivery system should reduce the need for hospital inpatient humidification treatments. Recent statistics on non-operating room therapeutic procedures on nose, mouth and throat show that the annual patient cost for the treatments is \$6,081.00.

	Other non-operating room therapeutic procedures on nose, mouth and throat
Total number of discharges	12,950
Length of Stay, days (mean)	3.5
Charges, \$(mean)	18,510.00
Cost, \$ (mean)	6,081

*12,950 patients were admitted to community hospitals for “other non-operating room therapeutic procedures to nose, mouth and throat in 2007” (from HCUP 2007 National Statistics)⁴

This means that if tracheostomy patients are compliant with their humidification treatments, they could maintain a healthier airway and avoid hospitalization and treatment, and potentially save approximately \$6,081 in medical expenses.

In summary, the Wright Face and Tracheostomy Nebulizing Mask makes is more convenient to maintain a regular humidification regimen, especially for those who do this at home. This increases patient compliance to the treatment, making the airways healthier, reducing re-hospitalization and ultimately providing the patient with a better quality of life. This is a fitting purpose in memory of Dean Wright, whose life inspired the creation of this device.

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So What is the Difference?

Ray Braxton, RRT; Paul Garbarini, RRT

As a member of a leadership team conducting an interview of a candidate for a staff respiratory therapist position, I [Ray Braxton] have been known to ask the question: “So tell me the difference between a pressure control (PC) breath versus a pressure support (PS) breath?” After what seems like several minutes the typical response is: “Well, a PC breath is a control breath with a set rate and a PS breath is a spontaneous breath with no set rate.” We in the respiratory care profession speak a special language that comes from our formal training and years of experience as respiratory therapists. When we use the word control in explaining a mode of ventilation, we usually infer that set variables such as volume, pressure, flow and/or time are controlled, and usually at a set frequency. On the other hand, when we use the word spontaneous we usually infer that the patient initiates or triggers each breath and has control on how the breath cycles to expiration.

At this point in the interview conversation, I generally give an example of a patient who is on a PC-IMV mode of ventilation with intermittent PS breaths and identical pressure settings. I draw identical pressure-time scalar tracings on a piece of paper representing each breath type asking the applicant to distinguish between which breath is PC versus PS. The following screen shot taken from a Hamilton G5 ventilator depicts this situation.



Can you distinguish between these two breath types from this screen shot taken from a test lung simulation on PC-SIMV mode? As you can see, the pressure and flow scalar tracing are very similar in shape and duration with a set pressure setting of 15 cm H₂O for both PC and PS breaths. In this example the 1st and 3rd breath are PC breaths with a set inspiratory time of 1.2 seconds. With a set frequency of 20 breaths per minute, the timing window (sometimes referred to as “total phase time” or “total cycle time”) becomes 3 seconds. The interval between the 1st and 2nd along with the 3rd and 4th breath is approximately 2.5 seconds. Therefore, the 2nd and 4th breaths are patient triggered PS breaths as indicated by the triangle shaped marking below the pressure scalar tracing time line.

The cycle to expiration for the PS breath occurs once the inspiratory flow (not expiratory) drops to some percentage of the initial peak inspiratory flow, or absolute flow rate. So pressure support breaths normally are flow cycled. On the Hamilton ventilators, this flow cycle setting for spontaneous breaths is called the Expiratory Trigger Sensitivity (ETS) setting. In this case, flow reaches the set ETS setting, which is set at 10%. The lesson learned here is that a PC breath cycles to expiration based on a set inspiratory time, and the PS breath cycles to expiration primarily based on the ETS setting. This is the answer that I was seeking with my first question to the applicant. Other terminology examples for the flow cycle setting on other ventilators include “Esens” (PB), “PSVcycle” (Avea), “End Flow Level” (GE), and “Inspiratory Cycle Off” (Servo).

This leads me to my next question for the applicant: “In what clinical situations are adjustments to the ETS setting needed?” This often leads to another period of silence from the applicant. Usually, their response is: “Well, I usually leave it set at its default setting of 25%.” The value of setting the ETS appropriately cannot be over-emphasized. There are clinical situations that the patient presents when the RT needs to turn the ETS setting up or down and not just leave it on its initial startup setting. On the next page is an example of what happens to a PS breath when there is a significant leak in the system, and an ETS setting of 5%. Notice, the 1st and 2nd breaths are PC breaths that cycle to expiration after a set inspiratory time of 1.2 seconds. The 2nd breath is a PS breath with a prolonged inspiratory phase of nearly 3 seconds, which could lead to asynchrony for the patient.

The authors are with Hamilton Medical, Inc. This paper is from Hamilton’s newsletter.



This is a common situation that the RT faces when setting the patient on a mode with PS breaths when there is a leak around an endotracheal tube (ie uncuffed ETT) and/or air leaks from chest tube placement. In this example, a higher ETS setting is required to establish synchrony with the patient's breathing. This situation occurs frequently when providing mechanical ventilator support to a pediatric or neonatal patient. This is a skill that most RTs working with pediatric and/or neonates acquire. Each brand of ventilator also has secondary cycling criteria to terminate a spontaneous/pressure support breath if the flow cycle criteria is not met. Typically, if the pressure support setting is exceeded by 2-3cm H₂O, the breath will cycle off. This is often the case when the patient is actively exhaling prior to the ventilator cycling into expiration, and can be identified by a spike at the end of the pressure-time scalar tracing or waveform (see example on the right). This is a sign that the flow cycle needs to occur earlier in the breath. Additionally, each ventilator has an absolute limit on inspiratory time for spontaneous breaths. This is 3 seconds for Hamilton ventilators, but it can also be adjusted to shorter times in pediatric and neonatal application, as well as non-invasive application.

Another example of when an adjustment in the ETS setting is needed can be seen when placing a patient with advanced chronic obstructive pulmonary disease (COPD) on PS mode. In the example above right, the patient is grunting himself into expiration on each breath as detected by the pressure spikes at the end of the pressure-time scalar tracing. This imposes work on the patient to breathe during the expiratory phase of the breath, and is an example in which a PS breath may be cycled to expiration by the creation of pressure spike of 2-3 cm H₂O above baseline. In this situation, the ETS setting should be adjusted to a higher % setting until there are no longer pressure spikes detected. This may require increasing ETS to as high as 70%-80% in some cases of advanced COPD.

In COPD patients with long "emptying"/expiratory times due to long time constants, the ETS/flow cycle criteria often needs to be adjusted to let the breath cycle off at a higher inspiratory flow level. This is because it takes much longer for inspiratory flow to drop. So even if the patient is not actively exhaling or "grunting" to cycle off the breath, adjusting the ETS/flow cycle criteria is often necessary to allow for more expiratory time to reduce air trapping/autopenp.

Most mechanical ventilator manufacturers will incorporate as many as 3 to 5 conditions in which a PSV breath will cycle to expiration. A review of the operator's manual for a specific mechanical ventilator will usually provide this information. It is important to understand precisely how the flow cycle criteria is set for each ventilator. For example, with Hamilton ventilators, the "ETS" is expressed as a percent. So if one increases the ETS setting from 25% to 70%, the PSV breath will cycle off sooner as inspiratory flow only has to drop to 70% of the initial inspiratory flow vs down to 25% of the initial flow. A practical way to view adjustment of the flow cycle criteria is that by adjusting this setting you are adjusting the inspiratory time for spontaneous/pressure support breaths.

Adjustments to the ETS may also be essential to successful non-invasive/mask ventilation with a mechanical ventilator in which leaks are routine. In the presence of leaks, it may be necessary to increase the ETS setting to allow the breath to cycle off sooner. Some ventilators, such as the latest Hamilton ventilators, now incorporate automatic leak compensation algorithms which can adapt both the inspiratory flow trigger and expiratory flow termination criteria to compensate for leaks, therefore minimizing the need to make manual adjustments in this scenario.

Today's modern mechanical ventilators generally all come equipped with some level of graphic monitoring. The ability of the RT to interpret the scalar tracings and loops provided and fine-tune the adjustments such as ETS are a part of the art of practicing respiratory care. Hopefully, the previous explanations and examples will be helpful for those who may be faced with a clinical question during an interview such as being asked to provide a more detailed distinction between a PC versus a PS breath.

Case Study – Best Practice

Automated ABG Specimen Handling, Documentation at Kaiser Permanente San Diego: how a marriage of IT and clinical systems improved patient safety, documentation

Margaret Mulligan, BA, BSN, RN

Clinicians can waste little time or resources when they need to make decisions based on an arterial blood gas (ABG) sample analysis. To ensure accurate results for such decision-making, it is imperative that preanalytical factors be as standardized and finely calibrated as is humanly possible. For example, variations in technique in the areas of patient and specimen preparation (such as mixing – or not mixing – the blood for 2 minutes);¹ specimen time (from bedside to analyzer), as well as specimen handling and analyzing can all affect the lab results. Once ABG results are available, they need to be reported quickly and accurately.

When time is of the essence and accuracy is essential, clinicians need a cost-effective and robust system that allows delivery of results to physicians and other providers. These providers must be able to act on those results with confidence. This case study will discuss how one RT (respiratory therapy) group addressed these issues.

Kaiser Permanente in San Diego, CA, is a 392-bed facility. It is the sole Kaiser Permanente hospital in the area, and it serves more than 500,000 members in San Diego County. Various staff members (including a 24-hour, 365-days-per year RT department) process 2,033 ABG samples each month. To cover this need, Guillermo Friederichsen, RRT, manager, neurology/pulmonary, and respiratory care services, has a staff of 4 assistant directors and 66 RRTs (registered respiratory therapists). The department also works closely with 24 physicians and 3 nurse practitioners.

As a result of a process and safety initiative that started in 2007, Kaiser Permanente San Diego began using the 1st Automatic system, sales distribution by Radiometer America (Westlake, OH) in August 2009. This system consists of the safePICO sampler, ABL series analyzers and IT modules, which allow bedside data entry/retrieval, and interface to Kaiser Permanente's EPIC client, "Health Connect."

How, why they did it

Improved accuracy of clinical results and specimen handling were among the most important goals in the implementation of the system, according to Friederichsen. So was the RT lab's credibility. "As a CLIA-certified lab, our department is examined individually by Joint Commission and the College of American Pathologists," he said. "As a result, the accrediting bodies look at

every single ABG analyzer in our facility. This led us to conclude that we needed a system that could meet their standards – and ours."

Even though the Kaiser Permanente respiratory department is independently certified as a CLIA laboratory, the process of bringing a new system online necessarily involved other functional areas of the hospital. "In our presentation to management, we focused on a number of key benefits to the institution, particularly critical result turnaround and reporting, and overall accuracy," said Friederichsen. Project outcomes and goals had to support the overall clinical and quality measures and mission of the institution. The implementation process comprised four steps:

1. Making a capital request
2. Project manager teams and review
3. Budget talks
4. Board review and approval (consisting of physicians, administrators, others)

"We felt that the 1st Automatic system's potential would allow us to present a best-case scenario [as a cost-to-benefit analysis]," said Friederichsen. "However, it is important to emphasize that I did not present this case [to management] as a plan to save money. The plan and presentation were designed to show how we would improve processes, such as the prevention of transcription errors. The planned system was also projected to improve work flow for the RTs. Most important, however, we wanted to report results quickly and accurately and without errors."

As a backdrop to this planning process, it is worthy to note that the Joint Commission's laboratory accreditation program addresses two essential patient safety goals: patient identification and improved reporting and communication among caregivers.² Moreover, the Joint Commission standards "emphasize the results a laboratory *should* [emphasis added] achieve, instead of the specific methods of compliance."³ Execution, then, is left to labs and clinicians. In addition, the "standards highlight the essential nature of laboratory services on the actual care and service delivery processes that contribute to and support the overall health care delivery system."³ These standards, along with two other overriding Kaiser Permanente-related (internal) factors, drove the change, Friederichsen said.

The factors were:

1. Going to an electronic order entry system. Kaiser Permanente

Margaret Mulligan is a writer in Cleveland. This article was provided to Respiratory Therapy by Radiometer America.

uses the EPIC system for computerized physician order entry (CPOE). “[Within this system] we needed a way to improve work flow,” said Friederichsen, because “there was no interface between the ABG instruments and our computerized order-entry system.”

2. Safety. “Manual entry of information could compromise the accuracy and safety of information,” he added.

Quality improvement

Since Kaiser Permanente’s RT department has its own CLIA license, “we undergo a level of scrutiny that other entities in the organization do not have to endure,” said Friederichsen. And, according to Ted Fuertes, RRT, RCP, RPFT, assistant department administrator, respiratory services, “We all know that our tracer methodology, ie, order/sample/results, had better be accurate and fast.”

As an example, “In a 2007 Joint Commission survey, we were cited for lagging report times on critical ABG values,” said Fuertes. “For a time, I had to report monthly to the Joint Commission’s Accreditation and Licensing Committee, where I kept track of average reporting times and noted outliers. In 2009, after we used the 1st Automatic, there were zero recommendations. In fact the surveyor ‘called out’ 1st Automatic, and made a point of mentioning the system on her summation.”

Lessons learned

What lessons can be learned from the process of getting a new system approved and running smoothly? According to Friederichsen:

1. Safety is the priority. When you are looking to make a change, make patient safety the priority, he advised. “You must avoid sentinel events [that are] related to malfunctioning equipment,” he said.
2. Accurate documentation = safety. “We fought for accurate documentation,” said Friederichsen. “I told the [executive] committee that inaccurate documentation creates a tremendous vulnerability for the organization.”

Fuertes also added these pieces of advice:

1. Support. You’ll need IT support and senior management buy-in.
2. Bar codes. Departments need printers for bar codes (be sure to acquire bar codes for operator IDs also).
3. Server space. The Kaiser Permanente RT department has its own server (for ABGs and the pulmonary function systems).

“You probably won’t need [your own server],” said Fuertes, “but you’ll want to ensure that you have some sort of server space within your IT infrastructure.”

4. Wireless scans. Do you have a wireless scanner? “The Bluetooth scanner has made a difference,” said Fuertes. “Wireless scanners let you capture PID [patient identification data] before and after draws.”

It is unusual for an RT department to have their own server, of course. Fuertes explained that the “RT departmental server was originally purchased in 2006 for another IT product (Kaiser Permanente’s old ABG system) and then we upgraded to the Radiometer platform. We secured approval for the Radiometer IT product [because of our unusual setup],” he said.

One issue that the IT department may raise is whether the 1st Automatic application shortcut can reside on the desktop, added Friederichsen. “We got buy in and approval from IT by explaining that the 1st Automatic system is a piece of biomedical equipment,” he said. “The icon you see on the bedside desktop is a shortcut to our server. Only the RTs can access it. And the application only runs within the KP network so data only passes within the security framework our network provides.”

Metrics—before and after

In two years of use, has the system truly improved accuracy and safety? The accompanying table shows some of the key metrics and how they changed with the Radiometer system.

Critical result reporting/transcription errors. Two key metrics are worthy of note: critical result reporting times, which have been brought down to 15 minutes or less, and transcription errors have also been reduced significantly. While volumes of ABGs have gone from 2,025 in 2007 to 10,454 in 2010, reporting, labeling and handling have greatly improved in that same period. For example, in the past (before use of this system) up to 25% of samples were not labeled, and now the process is automatic. Turnaround time has also improved over the period by 28%.

Needle sticks. Between 2007 and 2009 there were 2 needle sticks in 35,000 draws by the RTs. The needle sticks were related to staff training, where the staff didn’t “listen for the click” of the Radiometer ABG syringe. While the syringe initially presented a learning curve, “we feel this syringe is better,” said Friederichsen. “Cost was not a factor, as the Radiometer syringe
Continued on page 51...

Table 1. Metrics before and after 1st Automatic implementation at Kaiser Permanente San Diego

Process/Metric	Before	After
Requisition creation	4 people	1 person
Specimen labeling	RT affixes to syringe	Already on syringe
Reading of label	RT manually reads	Bar coder scan at bedside
Pt information (med record number, diagnosis, vent settings)	RT manually input	Bar coder scan at bedside (may have to input some settings the first time)
Operator information	Initials on lab slip	Bar coder scan at bedside
Critical reporting time	Variable	Less than 15 minutes
Patient data edits	68 (in 2008)	5 (after 2009)
Sample errors	Possible	Extremely unlikely
Chain of specimen custody	Variably secure	Secure
Integrated with CPOE	No	No, but capability is there

Source: Data compiled for Respiratory Therapy.

Applying Transpulmonary Pressure in the ICU

Tom Piraino, RRT

Patient case overview

A 65-year old morbidly obese male (BMI 55.5 kg/m²) with obesity, hypoventilation and severe COPD was intubated for respiratory failure, secondary to pneumonia. He received a tracheostomy after 10 days of ventilation and was transferred on the 22nd day of invasive mechanical ventilation to St. Joseph's Healthcare facility to utilize our bariatric CT scanner to rule out abdominal sepsis.

The patient was sedated and apneic on arrival with ventilation settings as follows: Positive end-expiratory pressure (PEEP) of 10 cmH₂O, pressure assist control of 20 cmH₂O above PEEP, respiratory rate of 20 bpm, inspiratory time of 1.0 seconds, FiO₂ of 1.0. Initial blood gas analysis was pH 7.16 PaCO₂ 50 mmHg PaO₂ 215 mmHg HCO₃ 17 mmHg SaO₂ 0.99. Hemodynamically, the patient was hypotensive and required norepinephrine to maintain an acceptable blood pressure.

Initial patient management

The first 12 hours of ventilation at our facility were challenging. The patient's ventilation requirements had increased to the following: Pressure assist control of 32 cmH₂O above PEEP, respiratory rate was 30 bpm, inspiratory time of 1.0 seconds, PEEP of 12 cmH₂O and FiO₂ of 0.5. Blood gas analysis on these settings was pH 7.17 PaCO₂ 47 mmHg PaO₂ 63 mmHg HCO₃ 16 mmHg SaO₂ 0.9.

Method and management using esophageal pressure manometry

To determine Transpulmonary Pressure (P_{tp}), an esophageal balloon was inserted into the patient. It was suspected that the patient might not have had the PEEP level needed to achieve a normal end-expiratory transpulmonary pressure (P_{tp}PEEP > 0 cmH₂O). The esophageal balloon catheter was inserted to a depth of 60 cm and gentle compression of the abdomen was done to confirm placement. The catheter was then pulled back 40 cm and cardiac oscillations were present, and the waveform was clearly different than before. (Figure 1). With the patient sedated and paralyzed using a neuromuscular blockade, an expiratory hold was done to obtain a stable transpulmonary reading. The resulting P_{tp} value was -12 cmH₂O. To achieve a

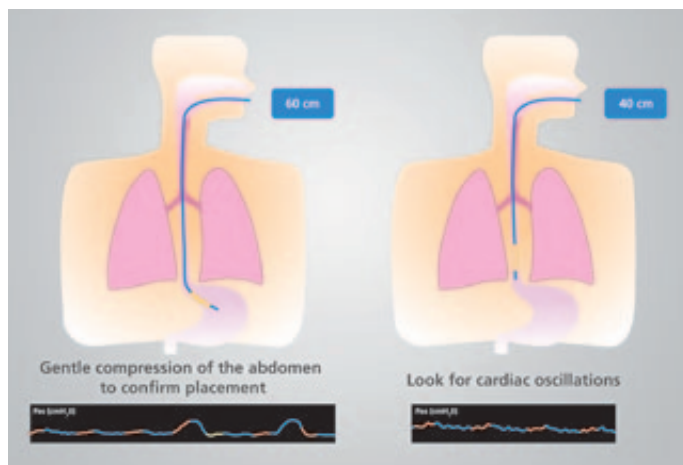


Figure 1. Insertion of the esophageal balloon.

transpulmonary pressure close to what would be physiologically normal (P_{tp} ≥ 0 cmH₂O), the PEEP was increased from 12 cmH₂O to 24 cmH₂O.

Patient response

The 48-hour trend of PaO₂/FiO₂, respiratory system compliance and peak airway pressure are shown in Figure 2. The blood pH improved as a result of HCO₃ increasing to a normal level. The respiratory rate and peak airway decreased significantly despite the CO₂ level remaining 45-47 mmHg over 48 hours. The PaO₂/FiO₂ ratio increased significantly from 126 to 370 as PEEP was titrated, according to P_{tp}, from an initial increase to 24 cmH₂O, and then to 18 cmH₂O 48 hours later.

Improved outcome

The use of esophageal pressure manometry to determine P_{tp} and set PEEP in this patient resulted in an individualized lung protective strategy. The end-result was improved oxygenation, improved ventilation (lower minute ventilation required), improved respiratory system compliance and peak airway pressure below the limitations recommended by literature. The patient was returned to the sending facility 2 days later with a PEEP of 18 cmH₂O, FiO₂ of 0.30, PC of 12 cmH₂O and a respiratory rate set at 22 bpm.

Supporting research

A study by Behazin et al found that obese patients have higher pleural pressures than non-obese patients when sedated and paralyzed for surgery.³ This causes tidal breathing to occur at a

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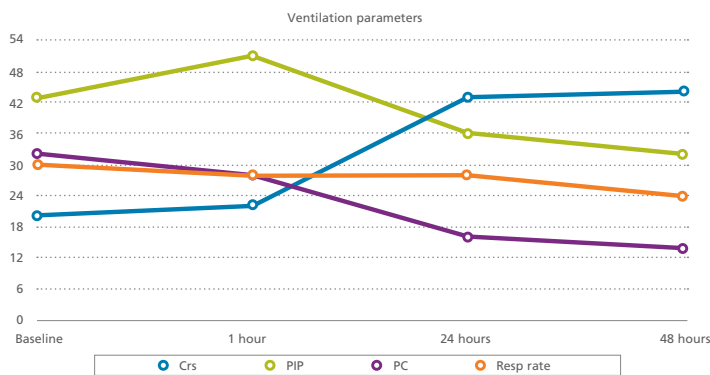


Figure 2. The 48 hour respiratory trend.

lower FRC, lungs are less compliant and airways are prone to collapse during exhalation. It was also concluded that the pleural pressures were variable, and not predictable by BMI, making the measurement of Pes and Ptp a valuable clinical tool. The level of PEEP required to maintain a Ptp > 0 in this sedated patient was slightly higher than the normal range for surgical patients with BMI levels > 38. The cause of this patient's elevated pleural pressure may have been due to his fluid requirements secondary to hypotension caused by his sepsis. In my experience, I have seen clinicians be less concerned with elevated PIP in obese patients assuming that the size of the patient implies that they don't "feel" the pressure. This study helps demonstrate that when PEEP is set optimally, high PIP may not be necessary.

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Best Practice...continued from page 49

was actually more expensive, but we chose to use it due to the improvement in safety."

When looking at broader issues and data sets for outside quality and accreditation, there have been other improvements resulting from the streamlining of the ABG process, noted Marion Yerxa, RN, Assistant Administrator Quality and Patient Safety and Donna Lupinacci, MSN, Medical Center Compliance Officer.

Indirect metrics that may not be solely based on ABGs can still yield useful data on quality care. For example, Kaiser Permanente self-reports data to CalHospitalCompare.org.⁴ Kaiser Permanente's "superior" score for "respiratory complication prevention" reflects the fact that their clinical processes yield a prevention score that is above the state average (Kaiser Permanente is at 97% versus the California state average of 92%).⁴ As an internal benchmark, Kaiser Permanente's score has gone from 95% a year ago to 98% in the past survey year.⁴

Physician/provider perspective

Marvin C. Weiss, MD, PhD, medical director, respiratory therapy and ICUs, was an early advocate within the Kaiser Permanente system for integrating technologies such as bar coding to the bedside and beyond. "I could see that the integration of patient data, preanalytical issues, and reporting of results would improve reporting and decision-making," he said.

Next steps

The Radiometer system has improved accuracy of preanalytical activities as well as allowing for faster reporting of results. The next step is to integrate the system with the electronic medical record (EMR), which is Health Connect, sometime in 2012.

On a larger scale, plans to rollout 1st Automatic to the 12 other Southern Cal hospitals "is in its infancy stage," notes Friederichsen. "Our Riverside location is probably the closest, since they are seriously looking at the PICO syringes, based on our experience with them, particularly the fact that they are pre-barcoded and they provide automatic mixing. Their administrator recently asked for more data and information on our workflows for our 1st Automatic system."

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Product Study: air-Q

The air-Q intubating laryngeal airway is a supraglottic airway device which may overcome some limitations inherent to the classic laryngeal mask airway for tracheal intubation. The authors of a study published in *Pediatric Anesthesia* reported on a series of cases with patients with anticipated difficult airway in whom the air-Q device was used successfully as a conduit for fiberoptic intubation.*

Background

The laryngeal mask airway has been demonstrated to be effective as a conduit for tracheal intubation in pediatric patients with a difficult airway. Though the LMA has undergone advancements to facilitate tracheal intubation in adults, the authors note that such advancements were not previously available for application to children. The advantages of LMA-assisted tracheal intubation are ease of placement, reliable alignment of the glottic opening, the ability to continuously oxygenate and ventilate the patient, and minimizing disconnection time from the breathing circuit. The air-Q intubating laryngeal airway supraglottic airway device has been designed to overcome the limitations of classic LMA for tracheal intubation. Its advantages include: a shorter, more curved shaft, an easily removable airway adapter, lack of a grill in the ventilating orifice, and the ability to remove the laryngeal airway after tracheal intubation with or without a stabilizing rod. The authors present several cases of patients with anticipated difficult airway in whom the air-Q was successfully used as a conduit for fiberoptic intubation.

I. 2-Year Old With Hurler's Syndrome

A 2-year-old boy with Hurler's syndrome was to undergo ventriculo-peritoneal shunt revision. Two months before the revision, the boy had been difficult to ventilate after inhalation induction. A Cormack and Lehane Grade IV was noted upon direct laryngoscopy. A number 2 classic LMA was placed revealing a C&L II view of the glottis through a fiberoptic bronchoscope, and the patient was successfully intubated with a 4.0 uncuffed TT via the LMA. A new supraglottic revealed a limited oropharyngeal space secondary to mucopolysaccharide deposits resulting in a mouth opening of 12 mm. Intramuscular

ketamine was administered, and IV access established. When positive pressure ventilation was adequate, paralysis was instituted with rocuronium. A size 1.5 air-Q ILA was inserted with a leak pressure of 24 cm H₂O followed by fiberoptic-assisted tracheal intubation with a 4.0 mm ID cuffed TT.

II. 2-Year Old With Large Bilateral Maxillomandibular Dysplastic Mass

A 2-year-old girl with a large bilateral maxillomandibular dysplastic mass presented for excision. CT scans revealed an expanding fibrous mass involving both the maxilla and the mandible. Previous records documented easy mask induction and placement of a 1.5 LMA for the CT scans. The girl's mouth opening was now less than 2 cm. Inhalation induction was performed with sevoflurane in oxygen, and PPV was instituted. IV access was obtained and paralysis was established with rocuronium. An air-Q ILA size 1.5 was placed with a leak pressure of 26 cm H₂O and the patient was intubated with a 4.5 ID cuffed TT over a fiberoptic scope.

III. 6-Year-Old With Treacher-Collins Syndrome

A 6-year-old boy with Treacher-Collins syndrome was to undergo dental extractions. For a previous mandibular distraction surgery, mask ventilation was noted to be easy and an oral fiberoptic intubation was successfully accomplished, although difficult secondary to a large epiglottis. Airway examination revealed a mouth opening of 13 mm with significant micrognathia. Anesthesia was the same as described above for patient II. An air-Q ILA size 1.5 was placed without difficulty, with a leak pressure of 30 cm H₂O and the patient was intubated with a 5.0 ID cuffed TT using a fiberoptic scope.

IV. 7-Year-Old With Goldenhar Syndrome

A 7-year-old boy with Goldenhar syndrome was scheduled for mandibular extraction. Prior history was significant for easy mask ventilation, but limited visualization by direct laryngoscopy and difficult tracheal intubation. Airway examination revealed a limited mouth opening of 15 mm and micrognathia. The patient was sedated with 70% nitrous oxide in oxygen and an IV was placed. Anesthetic induction was achieved with propofol. An air-Q ILA size 2 was placed with a leak pressure of 26 cm H₂O and the patient was intubated with a 5.5 ID cuffed TT and a fiberoptic scope.

V. A 16-Month-Old Girl With Hunter's Syndrome

A 16-month-old girl with Hunter's syndrome presented for magnetic resonance imaging of the brain and spine. At age 10 months she was found to have limited visualization upon direct laryngoscopy. She was a difficult intubation and was intubated with a fiberoptic scope with a 3.5 uncuffed TT through a no. 1.5 LMA for a ventriculo-peritoneal shunt placement. Airway examination revealed a limited oropharyngeal space due to mucopolysaccharide deposits. A size 1 air-Q ILA was placed with

*All information in this article was originally published in a different form and is from the paper "The new air-Q intubating laryngeal airway for tracheal intubation in children with anticipated difficult airway: a case series," by Narasimhan Jagannathan, MD; Andrew G. Roth, MD; Lisa E. Sohn, MD; Thomas Y. Pak, DO; Sapan Amin, MD and Santhanam Suresh, MD. FAAP. The authors are with the Department of Pediatric Anesthesiology, Children's Memorial Hospital, Northwestern University's Feinberg School of Medicine, Chicago, IL. The authors thanked Dr. Daniel Cook of Cookgas, USA for his support. The original article is © 2009 The Authors, *Pediatric Anesthesia* 2009, © 2009 Blackwell Publishing Ltd. The paper was provided to this journal by Mercury Medical, manufacturers of the product discussed. For the complete article, please visit the website of *Pediatric Anesthesia* or Google the title of the article.

a leak pressure of 28 cm H₂O and the patient was intubated with a 4.0 mm ID cuffed TT using a fiberoptic scope.

Securing the Airway

All patients received 10 mcg/kg of IV glycopyrrolate to minimize secretions. The air-Q was deflated and inserted using a rotational technique. The cuff of the air-Q ILA was inflated according to the manufacturer's instructions: Size 1 required <3 ml, size 1.5 required <5 ml, and size 2 required 5–10 ml. The authors' goal was to achieve a minimum leak of 20 cm H₂O while staying within the manufacturer's guidelines for cuff inflation. Leak pressures were obtained by auscultation over the anterior neck while observing the ventilator manometer during a positive pressure breath. Subsequently, mechanical ventilation of about 10 ml/kg using pressure-limited ventilation was instituted. The airway adapter of the air-Q ILA was removed prior to proceeding with a fiberoptic-assisted intubation. A TT was loaded on to the fiberoptic scope prior to insertion into the trachea. The patients were ventilated through the TT still within the air-Q to verify bilateral breath sounds and end-tidal carbon dioxide. The air-Q ILA was easily removed without the aid of a "pusher" or stabilizing rod after intubation. Removal of the air-Q ILA required removal of the TT adapter, deflation of the air-Q ILA, downward traction on the TT, and distal control of the TT with the forefinger and thumb, while withdrawing the laryngeal airway. All patients were successfully extubated over an airway exchange catheter.

Summary

Classic LMA has some limitations when it is used as a conduit for intubation. The shaft of the LMA can be as long as the TT, making it difficult to maintain control of the TT while removing the LMA. Either a long tracheal tube, a double tracheal tube assembly, or a stabilizing rod is required to overcome the length of the LMA. Shortening the shaft of the LMA or leaving the LMA in place for the duration of surgery have also been suggested to minimize these potential risks. The airway connector of the LMA is not wide enough to allow passage of the cuffed TT pilot balloon. This would result in the pilot balloon "hanging up" within the shaft of the LMA and potentially breaking upon attempted withdrawal of the LMA. When using disposable LMAs, the grill may have to be cut to permit a larger or cuffed TT when compared with its nondisposable counterpart.

The air-Q ILA has several key structural differences from the classic LMA and thus has the potential to overcome the above limitations. Since the shaft of this airway is much shorter and curved, enough of the proximal TT is still above it, allowing for removal of the air-Q without the aid of a stabilizing rod. The air-Q ILA can be easily removed with a specially designed removal stylet to prevent dislodging the TT. In the cases outlined above, the authors were able to remove the air-Q ILA without the use of this stylet to stabilize the TT in the larynx. The airway connector of the air-Q ILA is easily removable, eliminating the potential area where the pilot balloon of the TT can get stuck. The air-Q doesn't have a grill, and pediatric sizes 1, 1.5, 2, and 2.5 can accommodate up to cuffed TT sizes of 4.0, 5.0, 5.5, and 6.0 mm ID. This issue is clinically applicable in patients with a limitation in mouth opening in whom only smaller laryngeal airways may fit, while the placement of a size-appropriate cuffed TT is needed. The authors found the rotational insertion technique of the deflated air-Q ILA to be the most successful. Prior to conducting this case series, they placed several air-Q ILAs in children with normal airways and found this to be easiest. In all

patients the TT was inserted into the trachea on the first attempt with no decrease in oxygen saturation. An AEC was placed through the TT prior to extubation as a means to re-intubate if needed. The AEC was removed when the patient exhibited adequate respiratory effort, facial grimacing, and hip flexion. There were no postoperative airway complications in any of the patients.

The air-Q ILA is available in sizes 1, 1.5, 2, 2.5, 3.5, and 4.5 for single use and sizes 2.0, 2.5, 3.5, and 4.5 for reusable use. Sizing of the pediatric air-Q ILA, as for the LMA, is weight-based. A size 1 is designed for patients <5 kg, size 1.5 for 5–10 kg, size 2 for 10–20 kg. In the case series presented here, various cuffed TT sizes can be placed through the same size air-Q ILA as seen with patients I through III, above. The patients demonstrated that a smaller than weight-based size air-Q ILA can be used without compromising ventilation parameters and to allow for tracheal intubation with an appropriately sized cuffed TT. This would not have been possible with an equivalently sized classic LMA. The shaft of the classic LMA does not permit passage of a larger diameter TT or the pilot balloon of a cuffed TT. While the use of the air-Q may not improve the view when used in conjunction with a flexible fiberoptic scope in the presence of blood and secretions, the alignment with the glottis anatomy may allow for increased success in the use of a "light guided" or blind technique for intubation. When intubating neonates, if a continuous ventilation technique is employed, a standard bronchoscope adapter will add length to the shaft of the air-Q ILA, necessitating the use of a stabilizing rod. Once the air-Q ILA airway connector is removed, the bronchoscope adapter will no longer be able to be connected to the shaft.

The authors concluded: "We believe the use of the air-Q ILA may be a well-suited alternative to the classic LMA in children with difficult airways, especially when a cuffed TT is desired. In these patients with restricted mouth opening, this airway offers many advantages over the traditional LMA-assisted intubation... This device may prove to be a valuable tool in the management of a difficult pediatric airway."

Endnote

In a correspondence in a subsequent issue of the journal in which the aforementioned air-Q study appeared, the respondents wrote: "By way of contribution to this debate, we report the successful use of the ILA in two pediatric patients with a predicted difficult airway and discuss solutions to some practical problems we have encountered in our early experiences with this device." Their first patient was ideally suited for a supraglottic device-assisted technique. The size 2.5 device gave a good airway seal at pressures that allowed easy positive pressure ventilation. A stylet helped to overcome a problem particular to pediatrics, where the ETT can be contained entirely within the shaft of an LMA. The stylet effectively lengthens the ETT to sufficiently allow continuous retention of control of the ETT throughout withdrawal of the ILA over the ETT, which is helpful in reducing the risk of accidental extubation. While the note's authors agreed that the ILA could be withdrawn over the ETT without extending the ETT because of the short, hyper-curved style, they noted that this was awkward. Tube hold-up at the ILA exit caused some difficulty. The authors noted that they did not adequately lubricate the lumen of the ILA airway. With better lubrication, they did not have this problem during subsequent intubations through the device. By contrast, in another case, *Continued on page 56...*

Use of Nasal EPAP for the Treatment of Obstructive Sleep Apnea in Adult Patients: A Guide for Respiratory Therapists

Glenn Adams, MD; Dennis Hwang, MD; Laurie Skinger, RPSGT, RRT; Gary Lavalette, RPSGT, CRT; Lucy Gonzalez, RPSGT, RRT

Summary

This guide is based on research and clinical practice experience regarding the use of nasal Expiratory Positive Airway Pressure (EPAP) [Provent Therapy] to treat obstructive sleep apnea (OSA). In clinical practice nasal EPAP has been used in: (1) patients with mild, moderate or severe OSA who have rejected or are non-compliant with prescribed CPAP; (2) newly diagnosed mild/moderate patients without significant co-morbidities; or (3) CPAP compliant patients looking for alternatives to current therapy or for travel. Follow-up polysomnography or portable monitoring is needed to verify efficacy. Regular follow-up is recommended to assess the patient for compliance and signs and symptoms of OSA.

1.0 Introduction

Nasal EPAP is a novel treatment of OSA (Figure 1). The device consists of a small valve attached externally to each nostril with hypoallergenic adhesive designed for single-night use. 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

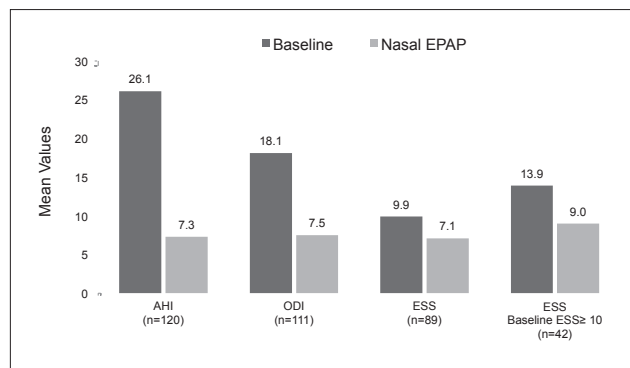


Figure 1. Nasal EPAP device. Single use valves are externally attached to each nostril and sealed with adhesive.

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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.

The effectiveness of nasal EPAP has been validated through five published clinical trials¹⁻⁵ demonstrating statistically significant and clinically meaningful reductions in the apnea-hypopnea index, oxygen desaturation and daytime sleepiness as measured by the Epworth Sleepiness Scale (ESS). Figure 2 below presents a pooled data subgroup analysis⁶ of nasal EPAP responders from the five published studies.



(AHI reduced >50%)
p<0.001 for all groups

Figure 2. Pooled Data Subgroup Analysis of Nasal EPAP Responders

This paper is intended to provide suggested guidelines for patient selection, acclimation support and efficacy verification when using nasal EPAP for the treatment of OSA.

2.0 Methods

The guideline outlined on the next page is based on published nasal EPAP literature and clinical practice experience. While this guide outlines a recommended protocol for nasal EPAP, the treating physician is the one best suited to identify those most appropriate for EPAP therapy and to determine method of follow-up care.



Figure 3. Suggested Guidelines for Nasal EPAP Use in OSA Patients.

Figure 3 summarizes a suggested pathway for patients considered for treatment with nasal EPAP therapy. More detailed recommendations are provided in section 3.0.

3.0 Recommendations

3.1 Diagnosis and Baseline Evaluation

An OSA diagnosis must be made and the severity of disease determined before evaluating treatment options. Either in-laboratory polysomnography (PSG)⁷ or portable recording⁸ are recommended to confirm the diagnosis.⁹ Both modalities provide objective results (AHI/RDI, ODI) that can be compared to results following the initiation of nasal EPAP treatment. The diagnostic criteria for OSA include the PSG or portable monitoring findings as well as clinical signs and symptoms.

3.2 Patient Selection

Nasal EPAP may be considered for the following patients:

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

At this time, there is no data to predict which patients will be most effectively treated with nasal EPAP based on specific patient characteristics.

3.3 Initial Therapy Use and Acceptance

During an office consultation, a trained practitioner or designee should instruct each patient how to properly apply the nasal EPAP device, and refer the patient to the Instructions for Use booklet. An in-office demonstration of Provent application may be helpful.

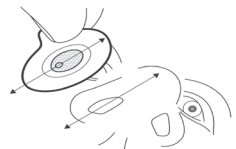
Instruct patients to:

1. Start with a clean, dry face. Stand in front of a mirror.

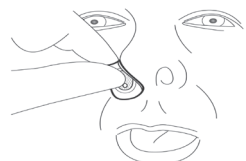
2. Grasp the small tab to peel the device off the backing.



3. Align the plastic portion of the device with your nostril to ensure correct placement.



4. Drop your upper lip downward (as if shaving the mustache area).



5. Apply and press down gently on the adhesive to create a seal. Ensure there are no air leaks. Use the thumbs or fingers to completely cover the oval mesh over both nostrils and gently exhale through the nose to confirm that no air is escaping past the adhesive.



6. Repeat device application on other nostril. Breathe through the device to feel it working.

The following points should be shared with patients to set their expectations regarding acclimation:

1. The device works by making it harder to breathe out.
 - This creates pressure which keeps your airway open.
2. Breathe out through your mouth when awake and attempting to fall asleep.
 - You'll naturally breathe out through the device when you fall asleep.
3. It may take time to get used to wearing the device.
 - Give it a few days; you should feel a lot better.
4. You may take it off (if necessary).
 - If you wake up during the night and feel uncomfortable, open your mouth and try to fall back asleep. If unsuccessful, just take the device off your nose. Try to sleep with it the next night.

Follow-up with the patient after the first night(s) of device use to provide coaching and encouragement may enhance the acclimation process.

3.4 Effectiveness Confirmation

After patients acclimate to nasal EPAP during the initial evaluation period, they should undergo an assessment of effectiveness to ensure a satisfactory therapeutic benefit. It is

suggested that the same methodology used for OSA diagnosis be used for effectiveness verification in order to readily compare the outcomes. As noted in section 3.1, these verification methods include in-lab PSG or portable recording to obtain objective results.

A specially-designed nasal cannula from Ventus Medical can be used to securely attach to the nasal EPAP device to allow for standard measurement of nasal airflow via nasal pressure during a PSG or portable monitoring (Figure 4).



Figure 4. Nasal Cannula Attached to EPAP Device.

A retrospective review of clinical practice data¹⁰ suggests that adjunctive therapy such as the use of positional therapy or chin straps may augment the effectiveness of nasal EPAP. During an in-lab PSG, this can be evaluated by the technicians monitoring the sleep study.

Positional therapy may be considered when non-supine AHI values with nasal EPAP reach therapeutic levels but AHI values in the supine position are not completely therapeutic.

Chin straps may be evaluated for patients who, while wearing nasal EPAP, continuously vent through the mouth thus preventing the creation of the required nasal expiratory pressure to help keep the airway open.

3.4 Prescription and Device Use

Patients with demonstrated efficacy may be given a prescription for nasal EPAP by a licensed health care practitioner. Nasal EPAP devices are intended for a single night of use and should be discarded after wearing. Patients may use nasal EPAP as a primary therapy or some may opt to continue with CPAP and use nasal EPAP for travel. As with CPAP therapy, if nasal EPAP is used as a primary therapy, optimal therapeutic effect will be achieved only with consistent nightly use.

3.5 Follow-up

Patients should be scheduled for periodic follow-up office visits to assess patient compliance with nasal EPAP as well as to evaluate signs and symptoms of OSA.

4.0 Conclusions

This guide was developed based on the current nasal EPAP clinical literature and clinical practice experience. Nasal EPAP may be used to treat all severities of OSA and effectiveness

must be confirmed with an in-lab PSG or portable monitoring. Device use training and acclimation coaching are key elements to achieve patient acceptance of the therapy. Patient selection and effectiveness assessment with nasal EPAP are ultimately the responsibility of the prescribing physician.

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Product Study: air-Q...continued from page 53

the authors of the correspondence encountered no difficulty passing the 3.5 cuffed endotracheal tube past the distal aperture of the size 1 ILA. The only problem encountered was an inability to pass the pilot balloon through the ILA lumen. This was handled by cutting off the pilot balloon. Using a 4.0 uncuffed endotracheal tube would have obviated this problem. They noted that the technique of inverting a stylet designed for a larger ETT worked very well but didn't routinely recommend it because of the theoretical risk of having the end of the stylet advance too far into the endotracheal tube such that it becomes difficult to remove. The correspondents noted: "In summary, we have used a novel supraglottic airway device, the air-Q ILA, as a conduit for fiberoptic intubation in two difficult intubation scenarios." The correspondents are: Kawshala Peiris, Mike Traynor and Simon Whyte, with BC Children's Hospital, Vancouver.

Chronic Cough and Obstructive Sleep Apnea in a Community-Based Pulmonary Practice

Krishna M. Sundar, Sarah E Daly, Michael J. Pearce, William T. Alward

Abstract

Background: Recent reports suggest an association between unexplained chronic cough and obstructive sleep apnea (OSA). Current guidelines provide an empiric integrative approach to the management of chronic cough, particularly for etiologies of gastroesophageal reflux (GERD), upper airway cough syndrome (UACS) and cough variant asthma (CVA) but do not provide any recommendations regarding testing for OSA. This study was done to evaluate the prevalence of OSA in patients referred for chronic cough and examine the impact of treating OSA in resolution of chronic cough.

Methods: A retrospective review of chronic cough patients seen over a four-year period in a community-based pulmonary practice was done. Patients with abnormal chest radiographs, abnormal pulmonary function tests, history of known parenchymal lung disease, and inadequate followup were excluded. Clinical data, treatments provided and degree of resolution of cough was evaluated based on chart review. Specifically, diagnostic testing for OSA and impact of management of OSA on chronic cough was assessed.

Results: 75 patients with isolated chronic cough were identified. 44/75 had single etiologies for cough (GERD 37%, UACS 12%, CVA 8%). 31/75 had multiple etiologies for their chronic cough (GERD-UACS 31%, GERD-CVA 5%, UACS-CVA 3%, GERD-UACS-CVA 3%). 31% patients underwent further diagnostic testing to evaluate for UACS, GERD and CVA. Specific testing for OSA was carried out in 38/75 (51%) patients and 33/75 (44%) were found to have obstructive sleep apnea. 93% of the patients that had interventions to optimize their sleep-disordered breathing had improvement in their cough.

Conclusions: OSA is a common finding in patients with chronic cough, even when another cause of cough has been identified. CPAP therapy in combination with other specific therapy for

cough leads to a reduction in cough severity. Sleep apnea evaluation and therapy needs to be considered early during the management of chronic cough and as a part of the diagnostic workup for chronic cough.

Background

The revised ACCP guidelines provide a step-wise approach for managing patients with chronic cough.¹ These guidelines recommend basing the etiology of chronic cough upon clinical opinions derived from historical information and therapeutic interventions.¹ Considerable variations therefore result in the management of chronic cough. Variations in management also stem from the diagnostic workup used to ascertain the cause of cough² and also from the occurrences of multiple etiologies of chronic cough.³ Recent reports have suggested an association between chronic cough and obstructive sleep apnea (OSA).⁴ There is also evidence that treatment of sleep apnea can improve chronic cough.⁵ Despite the lack of any specific guidelines on testing for OSA in patients with chronic cough,^{6,7} the impact of treatment of OSA is being noted in community-based pulmonary practices where chronic cough is most frequently encountered.

This study was undertaken to evaluate current strategies in approaches to chronic cough in non-smokers without known parenchymal lung disease in a large community-based pulmonary clinic. Besides evaluating treatment regimens and diagnostic testing, the impact of diagnosis and treatment of sleep apnea on the course of chronic cough was also assessed.

Methods

A retrospective review of medical records of patients seen in the Utah Valley Pulmonary Clinics in Provo and American Fork between 2005 and 2009 was done. Charts with diagnoses of "cough" and "bronchitis" were reviewed for cough lasting longer than 8 weeks. Since this study was confined to the evaluation of chronic cough in non-smokers without parenchymal lung disease, patients with abnormal chest X-rays, any prior smoking history, history of asthma requiring maintenance therapy, history of chronic parenchymal lung disease were excluded. Also patients that were not compliant with follow-up visits were excluded. Patients with only "normal" spirometry were included. Pulmonary function tests were conducted and interpreted based on the Intermountain Thoracic Society standards.⁸

Following above exclusions, 75 patient records were identified and reviewed for clinical data, diagnostic workup and therapeutic interventions. Clinical data obtained included demographic information, cough duration, comorbidities, etiologies for chronic cough, treatments provided and ancillary laboratory, radiological, and physiological workup. Patient records were specifically

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reviewed for mention of details regarding concomitant or pre-existing evaluation for OSA. Details regarding sleep history, physical exam pertinent to sleep apnea (pharyngeal crowding, neck circumference more than 17" in males and 16" in females, moderate to morbid obesity) were looked for.

Polysomnography was done based upon pulmonologist's decision to pursue testing for OSA based upon findings of sleep history, physical exam consistent with a possibility of sleep disordered breathing and results of overnight oximetry. For patients undergoing polysomnography, the severity of sleep apnea was estimated based on the calculated apnea-hypopnea index.⁹ Treatments and effects of therapy for chronic cough at the initial and following visits were reviewed. Improvements in cough were ascertained based on self-reported assessments of cough during followup visits.

Waiver of consent for the study was obtained from the Intermountain Office of Research. Part of the study findings were presented in an abstract form during CHEST 2009, San Diego, USA.¹⁰

Results

Patient records were reviewed from 8 different American Board certified pulmonologists. The number of included patients varied from 1 to 23 patients per provider, with a mean of 9. Patient characteristics, duration of cough, body mass index and co-morbidities are as shown in Table 1. Out of 75 patients, 44 patients had a single diagnosis for chronic cough at the time of the first visit with gastro-esophageal reflux disease (GERD) being the most common etiology (37%) followed by upper airway cough syndrome (UACS) (12%) and cough variant asthma (CVA) (8%) (Table 1). One patient was diagnosed and treated only for OSA. 31/75 (41%) patients had multiple diagnoses for chronic cough with the combination of GERD-UACS being the commonest followed by GERD-CVA and UACS-CVA (Table 1). Two patients received therapy for all three causes – UACS, GERD and CVA at first visit.

GERD was the commonest etiology for chronic cough (irrespective of whether diagnosis was made as part of single or multiple etiologies) followed by UACS and then CVA. Proportion of patients with diagnoses of GERD, UACS and CVA (single or multiple diagnoses of cough) were 76%, 48% and 19% respectively. In 39% of patients, there was a history of an upper or lower respiratory tract infection at the onset of cough although this occurred more than 8 weeks before the patient presented to the pulmonary clinic. 5/75 patients had stoppage of angiotensin-converting enzyme inhibitors as a part of their management of chronic cough.

The investigative workup for these patients is detailed in Table 2. Two patients underwent methacholine challenge testing with one test demonstrating bronchial hyperreactivity. All chest CT scans performed were normal. Sinus radiographs or CT scans were ordered in 10 patients with 3 showing evidence of sinusitis (Table 2). ENT referrals were made in 4 patients. Two patients underwent upper gastrointestinal endoscopy with one undergoing 24 hour pH monitoring (Table 2).

67 patients in this study came as referrals from primary care providers (5 patients were self-referred to clinic). Two patients were referred from an ENT specialist and 1 from a gastroenterologist. Most if not all had been tried on multiple

Table 1: Patient demographics, comorbidities and etiology of chronic cough.

Patient characteristics	N = 75
Age in years (mean ± SD)	57 (± 14)
Female:Male ratio	1.5
BMI kg/m ² (mean ± SD)	
Overall	32 (± 8)
Male	31 (± 5)
Female	33 (± 9)
Duration of cough in weeks (mean ± SD)	
Overall	127 (± 274)
Male	55 (± 101)
Female	175 (± 337)
Comorbidities	
Hypertension	25 (33%)
Diabetes mellitus	9 (12%)
Rheumatoid arthritis	1 (1%)
Known sleep apnea	13 (17%)
Coronary artery disease	1 (1%)
ACE-I therapy	10 (13%)
Single diagnoses for cough	43/75 (57%)
GERD	28 (37%)
UACS	9 (12%)
CVA	6 (8%)
Multiple diagnoses for cough	31/75 (41%)
GERD & UACS	23 (31%)
UACS & CVA	2 (3%)
GERD & CVA	4 (5%)
UACS, GERD & CVA	2 (2%)

Abbreviations: BMI - Body mass index, ACE-I - Angiotensin converting enzyme inhibitors.

previous therapies including those for GERD, CVA and UACS. Despite this all patients were tried on therapeutic interventions based on the clinical impression of the treating pulmonologist. No patient underwent additional workup beyond chest X-rays and PFTs at the time of the initial visit. Initial and subsequent therapies were guided entirely by pulmonologist's empiric diagnosis of etiology of cough and therapeutic responses to rendered therapies. Although this approach broadly followed the outlines of the pathway for the management of chronic cough in the ACCP guidelines, there were variations from this pathway based on intention to pursue therapy based upon the perceived etiology. Percentage of improvement with different initial therapies for GERD, UACS and CVA was 82%, 56%, 83% respectively. In the groups with multiple diagnoses, initial therapies were successful in 78% of the UACS-GERD group, 50% of the GERD-CVA group and 100% of the UACS-GERD-CVA and UACS-CVA groups. Inhaled steroid therapy was done in 19% of patients and oral steroids were given in 4% of patients. 12 patients received empiric macrolide therapy in conjunction with other therapies that improved cough in 7 patients. Significant variations were noted in the proportion of patients treated for GERD, UACS and CVA between different providers.

A sleep history was elicited in 55% of the patients (Table 2). This included history of duration of sleep, sleep quality, daytime somnolence, history of snoring and apneic spells. The decision to elicit history pertinent to the diagnosis of OSA varied amongst providers. A sleep history was consistently elicited in pulmonologists who were American Board certified

Table 2: Investigative workup for etiology of chronic cough and sleep-apnea specific workup in patients with chronic cough

INVESTIGATIONS PERFORMED	N (%)
Pulmonary Function Tests	
Spirometry	70/75 (93%)
Diffusion capacity	60/75 (80%)
Lung volumes	44/75 (59%)
Methacholine challenge testing	2/75 (3%)
Six-minute walk test	1/75 (1%)
Radiologic studies	
Chest X-ray	54/75 (72%)
Chest CT scan	10/75 (13%)
Sinus imaging	10/75 (13%)
Endoscopic studies	
Bronchoscopy	0/75
Upper GI endoscopy	2/75 (3%)
24 hour pH monitoring (Bravo* pH probe)	1/75 (1%)
Laboratory studies	5/75 (7%)
SLEEP APNEA RELATED WORKUP	
Sleep history obtained	41/75 (55%)
Abnormal	36/75 (48%)
Screening overnight oximetry	6/75 (8%)
Abnormal	6/75 (8%)
Polysomnography	38/75 (51%)
Sleep disordered breathing	33/75 (44%)
No OSA (AHI < 5)	4/75 (5%)
Mild OSA (AHI 6-15)	6/75 (8%)
Moderate OSA (AHI 16-30)	6/75 (8%)
Severe OSA (AHI >31)	14/75 (19%)
Periodic limb movement disorder	1/75 (1%)
Sleep efficiency (mean)	89%
Arousal index (mean)	17
Oxygen saturation (mean)	91%
Lowest oxygen saturation (mean)	78%

Abbreviations: OSA - Obstructive sleep apnea; AHI - Apnea hypopnea index.

* Bravo pH capsule with delivery system (Medtronic, Inc. Minneapolis, MN, USA)

in Sleep Medicine as well. Similarly details regarding historical aspects pertaining to OSA were variable. All six patients that underwent screening oximetry had abnormal studies. 12 patients had previously known OSA that was inadequately treated out of which 3 patients were not on any CPAP due to non-compliance with previously tried CPAP therapy. 34/38 patients had abnormal polysomnographies with 33 being diagnostic for OSA. Out of these 33 patients, 16 patients had initiation of CPAP therapy and 11 patients had re-titration of their CPAP therapy. Improvement in cough was noted in 25/27 (93%) patients that had initiation of new CPAP therapy or re-titration to optimal CPAP pressures. CPAP therapy was initiated or re-titrated in 18/27 of patients

following the first visit, 6/27 following the second visit and 3/27 of patients thereafter. Patient characteristics, duration of cough, concomitant diagnoses, and comorbidities of patients who were diagnosed with OSA during evaluation for chronic cough is shown in Table 3.

Discussion

The development of guidelines for evaluation and management of chronic cough represents a major milestone in the history of treatment of this common health problem.¹ Chronic cough accounts for 3.6% of outpatient physician visits in the US and is the commonest complaint for which medical attention is sought in the US.¹¹

Current guidelines emphasize empirical management of GERD, UACS and CVA depending on historical information gathered in favor of these diagnoses. This is based on the fact that a number of studies have consistently shown that UACS, GERD and CVA account for the majority of cases of chronic cough in the nonsmoker.^{12,13} However, there is no understanding of the pathobiologic mechanisms by which these conditions lead to cough. Neither is there a defined pathological substrate that triggers cough from these conditions. This has led to difficulty in associating the results of investigative testing for UACS, GERD and CVA with the occurrence of cough. In addition, the common occurrence of these predisposing conditions in chronic cough patients and the lack of reliable tests to link GERD and UACS to cough results in therapeutic interventions being the mainstay for the diagnosis and resolution of the cough.

This study explores current approaches towards chronic cough in community-based pulmonologists from a single center in the United States. There has been a paucity of studies from North America on chronic cough evaluating current diagnostic and therapeutic trends over the last decade. This retrospective study evaluates management patterns of chronic cough over a time period overlapping and following the revised ACCP guidelines. Not surprisingly, it continues to show the same preponderance of etiologic diagnoses, namely GERD, UACS and CVA in patients with chronic cough and a tendency towards treating multiple etiological diagnoses during the initial visit. As reflected in the guidelines, the etiological diagnoses for chronic cough were based on therapeutic interventions despite the fact that a number of these referred patients underwent similar therapeutic interventions prior to evaluation by the pulmonologist.

The extent of therapeutic testing for chronic cough has been debated upon.¹⁴ In this study, invasive testing for GERD, non-acid reflux disease, abnormal esophageal motility and testing for sputum eosinophilia was limited or lacking. The lack of a standardized protocol for evaluating sputum eosinophilia resulted in empiric therapy for CVA in a number of patients. Testing for OSA in patients with chronic cough has been recently recommended.⁵ OSA is a common condition increasing in prevalence with age and body mass index¹⁵ and therefore, likely to occur in a significant proportion of patients with chronic cough. Even though chronic cough has been reported to be a presenting symptom of OSA, no large prospective studies evaluating for OSA in chronic cough patients exist.

A major finding of this retrospective study was the impact of concomitant evaluation and treatment for OSA. OSA has been reported in prior case reports of chronic cough and one case series of four patients that resolved their cough with treatment

for OSA.^{16,17} In our current study, 44% patients with chronic cough were found to have OSA and following optimization of nocturnal positive pressure therapy, improvement or resolution of cough was noted in 93% of the patients. Since therapy for OSA was done in conjunction with other therapies for chronic cough in all but one patient, it is not clear to what degree the treatment for OSA had impact on the resolution of chronic cough. Despite this, the evaluation for OSA in the management of chronic cough requires important consideration given the increasing number of reports reporting improvement in cough with treatment of OSA. OSA can lead to or has been associated with GERD, asthma symptoms and upper respiratory complaints, all of which underlie the “pathogenic triad” leading to more than 95% of chronic cough.¹⁸ OSA has been shown to be associated with airway inflammation that can contribute to chronic cough. In a study performed in Sweden, the number of patients with chronic bronchitic symptoms that were found to have sleep-disordered breathing was up to 14-29%.¹⁹ Other studies on patients with OSA have shown an increase in exhaled nitric oxide values and other markers of inflammation on sputum analyses.^{20,21} A number of OSA patients can present with bronchitic symptoms and demonstrate bronchial hyperreactivity.^{22,23} Treatment of OSA has been shown to improve other known disorders of airway inflammation, especially asthma and COPD. Whether this is as a result of lessening gastroesophageal reflux that is common with OSA²⁴ or due to improvement in airway inflammation is unknown.

As compared to other series, the diagnosis of unexplained cough was not given to any of our patients. A significant incidence of unexplained cough has been noted in different series.²⁵ Interestingly the profile of patients reported for unexplained cough patients fits in with those patients in our series that improved with specific therapy for OSA.²⁵ A number of these patients start out with a post-infectious cough that fails to resolve despite multiple therapies directed at GERD, UACS or CVA. Whether OSA can perpetuate cough by impairing resolution in patients with acute bronchitis needs to be evaluated in future studies. OSA can potentially contribute to abnormal esophageal motility²⁶ and an enhanced cough reflex,¹⁶ both of which have been shown to contribute to or perpetuate cough.

This study is limited by a retrospective design, non-standardized protocol and data collection with only 55% of subjects being screened for OSA. Despite this a significant number of patients were found to have OSA. Whether this high prevalence of OSA in our chronic cough population is due to some kind of referral bias or due to a higher body mass index of patients is not clear. The majority of cough patients came from primary providers who considered possible etiologies for chronic cough as outlined in the ACCP guidelines but failed to ascribe any relationship between the possibility of sleep-disordered breathing and the cough. Henceforth a number of these patients were not evaluated for possibility of sleep-disordered breathing or if they had known OSA, the possibility of inadequately treated OSA contributing to cough was not entertained. Although only half the patients underwent workup for OSA and this was expected to reduce the estimate of OSA-cough in this population, the prevalence of OSA encountered in this study is nevertheless very high (44%). The majority of patients undergoing sleep apnea-related workup had an elevated BMI that makes obesity a confounding factor in this study purporting a link between OSA and chronic cough. Ascribing a relationship between chronic cough and OSA in obese subjects may also carry an overlap bias given the common

Table 3: Characteristics of patients diagnosed with OSA.

Patient characteristic	N = 33
Age (mean ± SD)	57 (± 13)
Female:Male ratio	1.3
BMI kg/m ² (mean ± SD)	
Overall	35 (± 7)
Male	33 (± 4)
Female	36 (± 8)
Duration of cough in weeks (mean ± SD)	
Overall	88 (± 262)
Male	23 (± 26)
Female	136 (± 341)
Comorbidities	
Hypertension	12 (37%)
Diabetes mellitus	7 (21%)
Known sleep apnea	12 (37%)
Coronary artery disease	1 (3%)
ACE-I therapy	6 (18%)
Single diagnoses for cough	
GERD	17/33 (52%)
UACS	2/33 (9%)
CVA	0
Multiple diagnoses for cough	
GERD & UACS	10/33 (30%)
UACS & CVA	0
GERD & CVA	1/33 (3%)
UACS, GERD & CVA	2/33 (6%)

Abbreviations: OSA - Obstructive sleep apnea; BMI - Body mass index; ACE-I - Angiotensin converting enzyme inhibitors.

occurrence of these problems and the linear relationship between obesity and OSA. However, the majority of obese patients in this study improved their cough following CPAP therapy and since resolution of cough remains the sine qua non for the diagnosis of the etiology of cough,⁶ further prospective studies researching the link between chronic cough and OSA will have to be designed factoring in the contribution of obesity. In addition, treatment for OSA can improve the contribution from multiple etiologies especially GERD that improves with the treatment of OSA. This study was also confined to the evaluation of cough in non-smokers without parenchymal lung disease. A number of recent studies have shown a high prevalence of OSA in patients with interstitial or airway lung disease.^{27,28} Treating OSA early on in patients with parenchymal lung disease may not only offer the potential of impacting the course of the underlying lung disease but also the potential for amelioration of the cough seen in these disorders.²⁹

A small number of patients in this study received macrolides that were effective in 70% of those treated. Azithromycin used for up to 12 days improved cough in subsets of patients that also received PPIs. Macrolides have been shown to have beneficial effects on lower respiratory tract inflammation in a number of diseases ranging from asthma to post-transplant bronchiolitis.³⁰ Whether resolution in cough following macrolide therapy is due to its salutary effects on lower-respiratory tract inflammation or due to effects on sinus inflammation needs to be proven.

Conclusions

This retrospective evaluation of management of patients with chronic cough in nonsmokers found that GERD, UACS and CVA continued to be the commonest etiologies for chronic cough. A significant proportion of patients had multiple etiologies for their chronic cough and specific diagnostic workup was limited. Clinicians primarily relied on the results of therapeutic interventions in cases with single or multiple etiologies for chronic cough. A number of patients improved with therapy of OSA that was given in conjunction with other therapies for chronic cough. The impact of OSA in occurrence and perpetuation of chronic cough needs to be evaluated prospectively in future studies of chronic cough.

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Bosentan Role in Severe Refractory Pulmonary Hypertension in an Extremely Low Birth Weight Infant

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Abstract

Pulmonary hypertension (PH) is one of the known complications of bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD) in extremely low birth weight (ELBW) infants. The incidence of secondary complications of BPD and CLD is increasing as the survival of extreme low birth weight neonates is improved in modern neonatal intensive care units. Pulmonary hypertension (PH) in infants can be devastating and can result in long-term morbidity and mortality. An infant with PH can be a therapeutic challenge in the emergency room with mild URI or even during a relatively benign surgical procedure. The treatment options for PH in neonates are very limited due to lack of large randomized controlled trials. Available therapeutic data comprise animal studies, case reports and few studies in pediatric and adult population. Sildenafil and iNO has been used for the treatment of PH. There is some promising evidence for the use of Bosentan as a treatment modality. Bosentan is an active, dual endothelin (ET) receptor antagonist, which helps to decrease pulmonary vascular resistance. We describe a case of severe PH in an ELBW with BPD who had pulmonary hypertension crisis after bilateral inguinal hernia repair and was treated with Sildenafil, iNO and Bosentan. We have successfully used Bosentan in this patient without any adverse effects with significant clinical improvement.

Introduction

As neonatal medicine is growing with emerging new techniques and improved management strategies, survival of extremely low birth weight (ELBW) infants has increased. Though the overall mortality for ELBW infants has decreased over the past decade, their survival is associated with significant morbidities.¹ One of the most common complications is bronchopulmonary dysplasia (BPD), which affects approximately 40% of ELBW infants.² BPD is associated with other conditions related to prematurity, which include pulmonary hypertension (PH), growth failure, metabolic disease of prematurity, neurodevelopmental impairment and retinopathy of prematurity.

One of the most challenging complications of BPD is pulmonary vascular remodeling leading to PH. Over the past decade,

different strategies have evolved to manage PH.⁴ Although use of oxygen, inhaled nitric oxide (iNO), sildenafil and prostacyclin has helped to improve survival, neonatologists still continue to encounter cases where these strategies are either minimally successful or fail to improve the patient's condition. With this in mind, neonatologists are constantly striving to improve treatment regimens.

Bosentan is an active, dual endothelin (ET) receptor antagonist with effects on both ETA and ETB receptors. Blocking these receptors has shown to decrease pulmonary vascular resistance in adult and pediatric populations.^{5,6,7} We report case of a 5-month-old ELBW infant with severe, life-threatening PH, which was treated with Bosentan in addition to iNO and sildenafil. To our knowledge there is only one reported case of Bosentan use for pulmonary HTN secondary to BPD for patient less than 1 year old.²¹

Case

Our patient is a Hispanic male born at 26 weeks' gestation with severe IUGR (birth weight 390 g) via C-section for late decelerations with oligohydramnios. Mother did receive one course of antenatal steroids. He was intubated in the delivery room and received surfactant. On DOL 11, his chest Xray showed cystic lucencies consistent with pulmonary interstitial emphysema. Subsequently, he was changed to high frequency jet ventilation (HFJV). On DOL 44, he was extubated to nasal synchronized intermittent mandatory ventilation (nSIMV), and 8 days later to nasal continuous positive airway pressure (nCPAP). During this hospitalization, he underwent PDA ligation on DOL 10. Head ultrasound showed no intraventricular hemorrhage. TORCH infection workup was negative.

The patient underwent bilateral laser treatment for his retinopathy of prematurity (ROP) and bilateral inguinal hernia repair on DOL 150 (5 months). Following these procedures, patient had persistent respiratory distress. An echocardiogram showed PH with pulmonary artery pressure of 58mm Hg. At that time, sildenafil was started at 0.25 mg/kg/dose Q6hours. Two weeks later, sildenafil was increased to 1mg/kg/dose Q6hours. A second echocardiogram showed improved pulmonary arterial (PA) pressures with mild right ventricular dilation. Five days later, the patient began requiring increased oxygen. A third echocardiogram showed worsening PH.

The patient was then referred to our institution at 5-½ month of life (CGA 48 wks, weight = 3.64 kg) for management of

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refractory PH in the setting of BPD. He was maintained on high flow nasal cannula (HFNC) at 3L/min. His medications included Aldactazide, Sildenafil, L-albuterol and Budesonide. Echocardiogram showed equal pulmonary and systemic pressures. His sildenafil dose was increased to 2mg/kg/dose Q6hours. The following day, it was increased further to 3mg/kg/dose Q6hours. Throughout the first 4 days, he remained on high flow nasal cannula, 3L/min at 100% FiO₂.

On day 5 of admission, patient was placed in an oxyhood with 100% FiO₂ along with 3L/min nasal cannula for persistent desaturations, tachypnea and increased work of breathing. B-type natriuretic peptide (BNP) level sent and was high at 670. Due to this, sildenafil dose increased to 4mg/kg/dose Q6hours. The following day, the patient continued to decompensate and was intubated for hypoxic respiratory failure. He was transitioned from SIMV to High Frequency Oscillatory Ventilation due to decreased lung volumes and pulmonary edema. Inhaled nitric oxide was started at 20ppm. He became hypotensive, required multiple normal saline boluses, milrinone, and epinephrine drips. Fentanyl and versed drips were started for sedation. Septic workup was initiated with blood and urine cultures and ampicillin and cefotaxime were started. Chest x-ray showed right upper lobe infiltrate, concerning for aspiration pneumonia. His antibiotic coverage was changed to gentamicin and piperacillin/tazobactam. Echocardiogram pre- and post-nitric oxide showed equal pulmonary and systemic pressures, with an estimated PA pressure of 71mm Hg. Three days later, the patient was extubated to nCPAP, continuing on iNO. By the following day, he was taken off pressors, and his iNO was weaned by 5ppm every 12 hours to level of 5ppm. Repeat echocardiogram showed persistent PH with estimated PA pressures of 55-60mm Hg. Two days later, he was weaned to high flow nasal cannula (2 L/min) with 100% FiO₂ and given four doses of Furosemide 1mg/kg Q12hrs for pulmonary edema. Despite being on iNO at 5ppm and on maximum Sildenafil dose at 4mg/kg/dose Q6, repeated echocardiograms demonstrated persistent PH with elevated RV and PA pressures and septal deviation along with significant TR. After discussion with cardiology and parents, Bosentan was started at 1 mg/kg/dose (3mg) twice a day. This dose was extrapolated from adult and pediatric dosing data based on the patient's age and weight.^{5,8,9} Liver function tests obtained prior to starting Bosentan and during therapy remained normal. Nitric oxide was weaned by 1ppm every 24 hours until it was discontinued 5 days later. Two days into the nitric oxide wean, the Bosentan dose was increased to 1.3 mg/kg/dose (4mg) twice

a day. The patient was then weaned to 1L/min nasal cannula with 100% FiO₂. Adding Bosentan in the management regimen helped to improve clinical status in 2-3 days and six days later a repeat echocardiogram showed improved PA pressures (figure 1). He was then weaned to 0.5L/min NC, only requiring 1L/min during feeds and physical therapy. Baby was discharged home on Bosentan, Sildenafil and Aldactazide. Patient has slow but gradual improvement of respiratory status and has shown no adverse effects of Bosentan including no abnormalities of liver function tests at follow up visits to pulmonary hypertension clinic up to 9 months of life.

Discussion

Pulmonary hypertension (PH) is a devastating entity that is characterized by an increase in pulmonary vascular resistance (PVR), which can lead to progressive deterioration, right heart failure, and death. Common etiologies include congenital heart anomalies, parenchymal lung disease like BPD and idiopathic pulmonary fibrosis.⁹ PH and chronic pulmonary vascular changes are expected complications of BPD in young infants and children. Therapies available currently include oxygen, iNO, oral Sildenafil and parenteral Prostacyclin. These therapies are suboptimal and may be unsuccessful in treating these patients. Recently, oral endothelin receptor blockers and phosphodiesterase-5 inhibitors have been used successfully for pediatric patients who have PH secondary to BPD.¹⁰

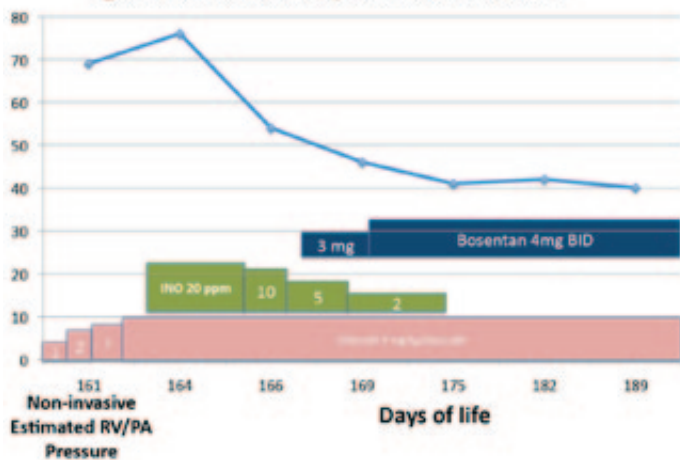
Endothelin-1 is a smooth-muscle mitogen and a potent vasoconstrictor. PH is associated with the loss of endothelin B-mediated vasodilation and increased endothelin A-mediated vasoconstriction.^{11,12,13} Experimental studies have shown that intrauterine blockage of endothelin A-receptor resulted in a decrease in pulmonary artery pressure, right ventricular hypertrophy and distal muscularization of small pulmonary arteries.¹⁴ In experimental models of pulmonary hypertension, endothelin receptor blockade caused sustained improvement in hemodynamics and oxygenation.¹⁵ Endothelin-1 may play a major role in the pathophysiology of PH.

Bosentan is an antagonist of both endothelin-1 receptors A and B. This dual effect on both endothelin receptors results in diminishing or eliminating the inflammatory, fibrotic and proliferative effects of endothelin-A.^{5,8} Bosentan may have immediate effects on pulmonary circulation. In an experimental newborn lamb model with PPHN, endothelin-A receptor antagonist effect resulted in markedly decreased pulmonary vascular resistance.¹⁵ Bosentan has also been shown to prevent and reverse developing hypoxic PH in rats.¹⁶ It has been successfully used in both pediatric and adult populations.

Bosentan has been used successfully and safely in pediatric and adult patients and has been shown to reduce PVR and pulmonary arterial pressure.^{5,6} One study in pediatric patients with congenital heart disease emphasized the use of Bosentan to reduce PVR in PH.⁷ There have been case reports describing the use of Bosentan in smaller children with secondary PH due to BPD.¹⁸ Bosentan has been shown to be safe at 1 yr follow up study done in 2002.¹⁴ Administration of intravenous Bosentan can cause dose dependant fall in total PVR within hours.¹⁷ The pharmacokinetics, safety and efficacy of bosentan are very similar in pediatric PH patient as compared to adults.⁸

There are two documented cases in the literature reporting the use of Bosentan in neonates with PPHN¹⁹ and another case

Fig 1: Trend of estimated PA pressure and Medications



report demonstrating use of Bosentan for PH in the presence of congenital heart defect ie TOGA.²⁰ In the past there is only one reported case of Bosentan use for PH secondary to BPD for patient less than 1 year old.²¹ Bosentan was started in that particular case at 9 month of age concomitant to Epoprostenol use. The dose administered was higher at 3mg/kg/dose BID compared to our case where we used lower dose at 1 mg/kg/dose BID. Use of Sildenafil in that case was at 12 month of age in an attempt to wean Bosentan and Epoprostenol. Sildenafil was started in our patient at 5 months of age, was maximized prior to starting Bosentan while patient was on iNO. Our patient showed decrease in estimated pulmonary pressure to half systemic pressure with the use of Bosentan. In our case, Bosentan was well tolerated and the diagnostic laboratory tests including liver function remained normal at follow-up visits.

Conclusion

In conclusion, we believe that this case supports the use of Bosentan as an adjunct treatment for neonates with refractory PH in the setting of BPD. Although Bosentan is not currently used as a standard adjunct therapy, it may be useful in the newborn population with PH due to its beneficial effects shown in this case report. Further studies are warranted to assess the efficacy, pharmacokinetics, and pharmacodynamics of Bosentan use in neonates. In addition, we need to establish criteria for the selection of patients who will benefit from Bosentan use. Studies are also required to evaluate whether Bosentan use is superior in isolation or as an adjunct with other agents like Sildenafil and iNO.

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Treatment of Pneumothorax in Newborn: An Old Simple Approach Revisited

Heather Hang Duong, MD, BSc; Koravangattu Sankaran, MBBS, FRCP(c), FCCM

Abstract

Spontaneous pneumothorax occurs as frequently as 0.7% in all newborns. A significant number of pneumothoraces resolve spontaneously with medical treatment. The management of symptomatic pneumothorax is generally with a tube thoracostomy, which at times requires mechanical ventilation resulting in prolonged hospital stay and permanent scar on the chest. Pneumothoraces can also occur as a complication of respiratory distress syndrome and or mechanical ventilation. In such cases tube thoracostomy is routinely done further increasing hospital stay and discomfort to the neonate. However, in selected cases simple needle decompression may be all that are needed in alleviating symptoms and pneumothorax thereby reducing hospital stay, pain and scar formation. An illustrative case will be presented with detailed description of the techniques along with chest radiographs showing resolution of pneumothorax.

Introduction

Spontaneous pneumothorax occurs as frequently as 0.7% in all newborns.¹ The incident is higher in infants with underlying lung conditions such as hyaline membrane disease and in infants requiring positive pressure ventilation.

It is well accepted that tube thoracostomy is required in neonates requiring ventilation because mechanical ventilation could prolong resolution and or induce further air leak. The needle decompression is used as an emergency procedure for tension pneumothoraces while bridging placement of a traditional tube thoracotomy. Recently improvements in insertion with the Seldinger technique lead to less and less requirement for the tube thoracostomy. However needle aspiration is not generally attempted for complete resolution of pneumothorax. Further, needle aspiration technique has not been revisited in neonate since a 1978 case report by Wung et al.² The technique was performed on a 30 week old infant on positive pressure ventilation when no skilled staff was available to place a chest tube. The verres needle (16-gauge) connected to water seal by venous tubing was placed into the 3rd intercostal space at the mid axillary line. Eventually, a tube thoracostomy replaced the needle. Obviously the intentions, equipment and techniques were different and probably caused more harm.

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Case

Our patient is a late preterm male (36 week + 5 days) admitted to the Royal University Hospital NICU for development of respiratory distress at 10 minutes of life. Mom is a 31 year old G2P1 with a medical history of essential hypertension and mild asthma. Her medication included methyldopa and intermittent use of ventolin. During this pregnancy, she had per vaginal spotting at 10-14 weeks and threatened preterm labor at 28 weeks. She is GBS positive; the rest of her serology was negative. She was induced for hypertension with artificial rupture of membrane for clear amniotic fluid. She received adequate intrapartum antibiotic coverage. Baby had nuchal cord wrapped twice which was slipped over and a true knot. Apgar score was 7 and 8 at 1 and 5 minute, respectively. He required minimal resuscitation at birth. NICU was consulted at 10 minute of life for grunting and pallor. His heart rate remained above 100 and perfusion improved after receiving a bolus of normal saline.

His initial chest X-ray revealed mild ground-glass appearance which did not warrant intubation and surfactant therapy (Fig-1). He was placed on NCPAP at +6 and 25-35% O₂. Repeat chest X-ray at 24 hours of birth revealed increased opacification in the right upper lobe (Fig-2). He was placed on empiric antibiotic treatment for query pneumonia and his feed was held. Blood culture and tracheal secretions were sent and were negative for bacterial growths after 48 hours. He continued to show signs of respiratory distress - grunting, mild in drawing and nasal flaring. Repeat Chest X-ray at 36 hours of age revealed left pneumothorax and evidence of hyaline membrane disease (Fig-3). He was intubated and received a dose of surfactant. Chest decompression by needling was proposed in this case as a simple approach to pneumothorax even in a mechanically ventilated patient mostly because of the size of air leak and O₂ requirement.

Technique

Equipment required for the procedure included a 23 gauge butterfly needle attached to a three way stop-cock and 20 ml syringe. The patient had already received fentanyl for intubation and thought to have adequate analgesia. He was placed in supine position exposing the side of chest where air leak was observed on the X-ray. The third intercostal space at the mid axillary junction was landmarked for site of needle insertion. Under sterile conditions the chest was cleaned with chlorhexidine. The primary operator stabilized both hands on the patient's body while driving the needle slowly through the third intercostal space above the rib. A second operator is instructed to operate the stop cock to withdraw air. Thirty-nine ml of air was removed

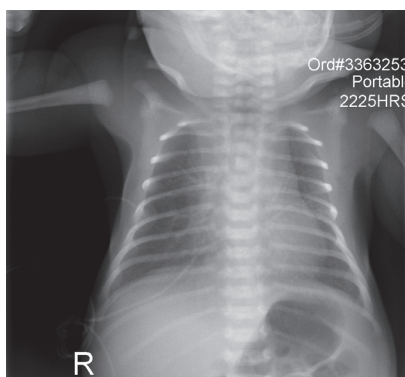


Fig. 1: Chest X-ray on admission.



Fig. 2: Chest X-ray at day of life one.

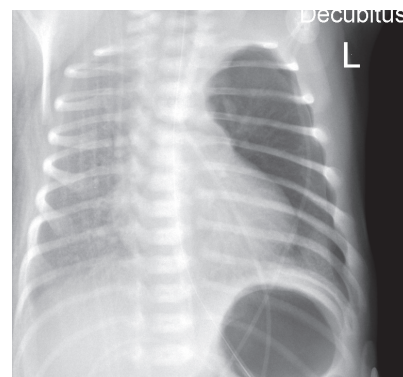


Fig. 3: Chest X-ray – lateral decubitus position. Left pneumothorax is more evident.

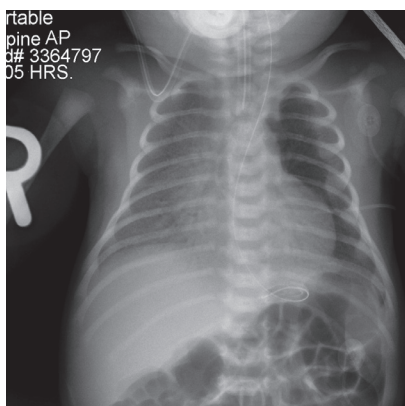


Fig. 4: Chest X-ray for visualization of residual pneumothorax.

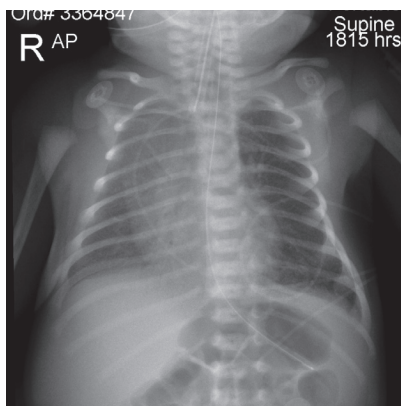


Fig. 5: Chest X-ray after 1 dose of surfactant and two needle decompressions.

from the first needle aspiration. Chest X-ray was repeated (Fig-4) revealing a smaller residual pneumothorax. A repeat needle decompression at the 2nd intercostal space mid-clavicular junction was performed and withdrew 7 ml of air.

Repeat chest X-Ray revealed complete resolution of pneumothorax (Fig-5). The patient's symptoms improved significantly. He received two more doses of surfactants and was extubated to room air on day 6. His respiratory status remained of no concerns and he was discharged home a few days later.

Discussion

Improvement in our patient's symptoms is attributed to both administration of surfactants and relief of pneumothorax. Although chest tube thoracostomy is the recommended procedure, carries its own risks and complications. Reported complications include lung injury, phrenic nerve paralysis, chylothorax, and hemorrhagic pericardial effusion.³ A study published by Litmanovitz et al reported management of pneumothorax without initial chest-tube placement in select group of ventilated neonates.³ These groups of infants were more mature, were on lower ventilator setting and had better blood gases at the time of the pneumothorax. The study reported fourteen infants treated initially with needle aspiration although six received subsequent management with chest tube.

There are many advantages to needle aspiration. It is a short procedure; requires minimal instrumentation; is relatively cheap; is easy to master; causes less injury; and requires minimal

sedation and post-procedure pain management as compared to placing a chest tube and produces no scar.

Our patient's clinical status improved after needle decompression and surfactants so that he did not require a chest tube. If there is small amount of trapped air detected it can be managed with medical treatment. In selected cases needle decompression is a safe and simple alternative approach to tube thoracostomy and may avoid pain and suffering and scar.

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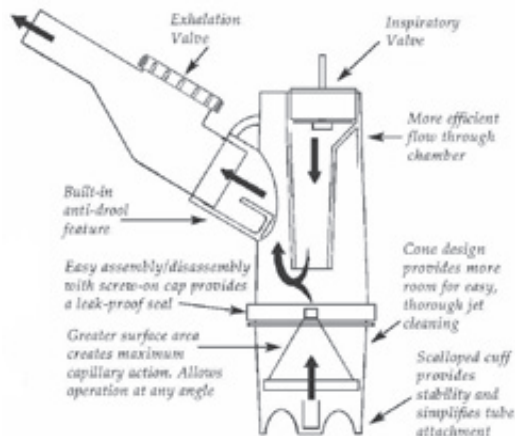
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