

Volume 5 Number 6 December-January 2010/2011

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The Journal of Pulmonary Technique

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The Journal of Pulmonary Technique

Vol. 5 No. 6

December-January 2010/2011

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Editorial

Holiday Cheer

The blog codeblog.com recently featured the following item. A nurse asked: What do you do with the Christmas trees off flow-meters? Why do you take them off? Codeblog replied:

1. Take them off the flow meter, add some beads, and you can make a kick-ass ID badge lanyard.
2. A naughty little addition to that voodoo doll you made.
3. As well, Christmas/fir trees for your kid's miniature doll house yard.
4. They go for about a buck apiece. They're always in demand. I think patients steal them and sell them on the black market.
5. Respiratory Therapy hoards them.
6. Add a little ball on top, some wings on the back, a little halo: instant green angel finger puppet.

Okay, so the real reason we take them off the oxygen flow meters is so that we can put them on the portable oxygen tanks when the patient goes off the unit. Why don't all the portable oxygen tanks have them? I don't know. See above.

The other reason we take them off is because when someone is on a high rate of oxygen (my own personal threshold is about 4L/min) we like to add humidity so the flow doesn't dry the patient's nose so much. Adding the humidifier requires us to take the adapter off the flow meter so that we can screw the water bottle directly on to it. The little green tree gets set down and the next RT that goes into the room scoops it up. It's like a compulsion for them. Kind of like RNs and pens.

For more see www.codeblog.com.

PPS: I would like to point your attention to the first in a series of legal articles by our senior editor, Carol Brass, on page 16. Her premiere feature discusses major legal changes impacting respiratory care providers as a result of the Health Insurance Protection and Accountability Act, rules about keeping electronic health records, the stimulus act, and the Health Information Technology for Economic and Clinical Health Act.

PPS: I just want to remind you that submissions to the journal are always welcome. Since we are an independent journal with in-house editorial review, we can accommodate a wide range of articles and subjects, from formal clinical papers to case studies, to anything of interest to RTs and related disciplines. And, as such, we can tell you right away if your submission has been accepted, and typically run it in the upcoming issue. Feel free to contact me for details. Finally – PPS? – we've started putting our past issues on Amazon, available for downloading, in "book" form onto Kindle and other electronic media. Happy holidays.

Les Plesko
Editor



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Published six times each year by
Goldstein and Associates, Inc.

10940 Wilshire Blvd., Suite 600
Los Angeles, CA 90024 USA

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Design & Production <http://accugraphics.net>

Circulation, Coverage, Advertising

Rates: Complete details regarding circulation, coverage, advertising rates, space sizes, and similar information are available to prospective advertisers. Closing date is 45 days preceding date of issue.

Change of Address notices should be sent promptly to Circulation Department. Provide old mailing label as well as new address. Allow two months for change.

Editorial Contributions will be handled with reasonable care. However, publishers assume no responsibility for the safety of artwork, photographs or manuscripts. All submissions may be emailed to s.gold4@verizon.net. Every precaution is taken to ensure accuracy, but the publishers cannot accept responsibility for the correctness or accuracy of information supplied herein or for any opinion expressed. Editorial closing date is the first day of the month preceding month of issue.

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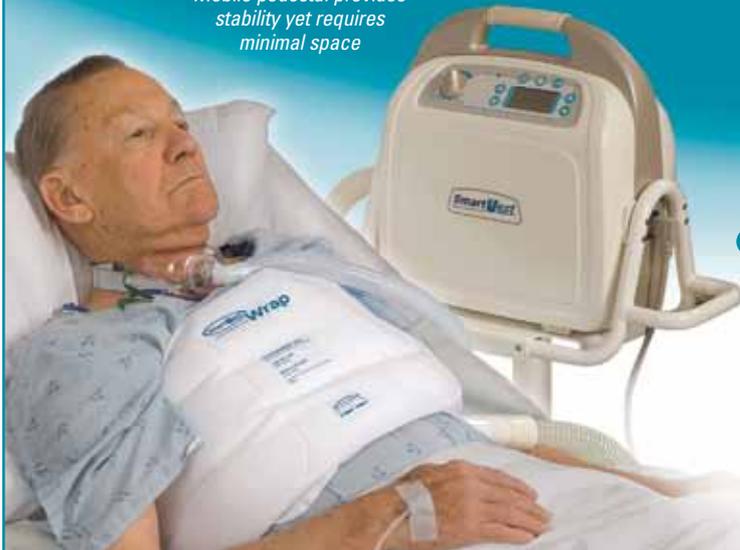
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News

□ December-January 2010/2011

CORRECTION

In the article Saccharine Transit Time Test is Dependent on the Day Period in Nonsmokers, by Nakagawa, et al, which ran in the August/September issue, the author affiliation should have read: Goto, Torres and Santos are with UNICID, São Paulo, Brazil.

WHAT HELPS US HURTS US

While neutrophils fight infection, their enzymes can damage surrounding tissue, according to a study by Imperial College London and the the University of Alabama at Birmingham. In the lung, neutrophils attack the collagen and knock out PGP fragments. In turn, more neutrophils arrive to battle the resultant infection. Researchers also showed that chemicals found in cigarette smoke can exacerbate this process, modifying PGP in a way that increases its ability to recruit more neutrophils and protecting it from degradation, and inhibiting the performance of LTA4H. Patients with COPD typically have persistent neutrophils in the lungs. The researchers said their work has implications for the development of new drugs aimed at treating acute and inflammatory diseases, but cautioned that pro-inflammatory inhibitors could cause lung damage.

GASPI

A study at Duke University said about half of respiratory care patients don't benefit from oxygen therapy, and among those who do, it doesn't matter whether they get pure oxygen or room air. The researchers noted that offering oxygen for shortness of breath has become a standard of care, without any proof of the therapy's efficacy. Clinical guidelines recommend oxygen for hypoxic patients, but for better breathers, giving oxygen is merely an act of compassion, the researchers said. They studied 239 patients randomized to receive oxygen or room air for a week to see if it eased their breathing. The participants had COPD, and some had lung cancer or heart failure. Half of the patients in both groups reported that the interventions offered some degree of relief and both treatments led to equal improvement in shortness of breath, usually within three days. The researchers said it was clear that "air rushing near the nose" helps some people, but that "the same level of relief might be accomplished using a small fan... It would certainly be less cumbersome and less costly... We are not suggesting that physicians abandon medical gas therapy... but this study tells us that it is not the oxygen itself that is making the difference, and if treatment is not improving symptoms after a few days, then it's ok to stop treatment and try something else."

BMC NEWS: Shared Support Membership

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MEMORIAL SCHOLARSHIP

SUNY Upstate Medical University alumnus, Robert Councilman, RRT ('85) passed away suddenly at age 46 due to a massive heart attack. A memorial scholarship was established through the help of his long-time friend and fellow alumnus Ed Coombs, MA, RRT-NPS, director of marketing for Respiratory Care Systems at Dräger Medical, Inc and Joseph Sorbello, MSEd, RT, RRT, chair of the Department of Respiratory Therapy Education at SUNY Upstate. Dräger assisted this scholarship drive through a monetary donation to the Foundation for Upstate Medical University Health Professions Alumni Association. The Association's Joseph Sorbello commented, "The gift will help promising students while remembering Bob as a compassionate patient advocate." The scholarship is scheduled to be given to a deserving student in September 2011. For more information, please contact the Foundation at (315) 464-4416 or www.foundationforupstate.org/chpalumni.

FAT VIRUS

Researchers at UC San Diego are suggesting that obesity may be triggered by a viral infection of adenovirus 36. AD36 causes various types of infection in humans, including respiratory, eye and gastro-intestinal infections and has been linked to obesity in animals and humans, though not much is known about the link. The study included 124 children, half of whom were obese. Nineteen of the kids tested positive for AD36, and 15 out of 19 were obese. The researchers cautioned that the study doesn't necessarily establish a cause and effect relationship between AD36 and obesity. Information for the above appeared in Medical News Today, copyright Medical News Today.

DRUG FOR ASTHMA

Tiotropium bromide, used to treat COPD, when added to low doses of inhaled corticosteroids, is more effective for controlling asthma than doubling the corticosteroid dosage, and is as effective as adding salmeterol, according to researchers at the Wake Forest University Baptist Medical Center. Tiotropium relaxes smooth muscles in the airways in a different manner from beta agonists, and thus could aid those who don't respond to other treatments. The study involved 210 adults resistant to low dose inhaled corticosteroid treatment. Tiotropium bromide improved day-to-day lung function and increased the

number of days with no asthma symptoms. By way of example, doubling corticosteroids gave patients 19 asthma-free days, and tiotropium plus low-dose corticosteroids gave them 48 days. For more info go to clinicaltrials.gov (NCT00565266). Information is from Medical News Today, copyright Medical News Today.

WHOOPIING UP

As of late September, the California Department of Public Health had confirmed just over 4,000 cases of pertussis, beating the previous records of cases reported in 1955 and 1962. Eleven percent of the patients needed hospitalization, and more than half of those were children. Nine deaths were reported, eight of whom didn't receive a vaccination. Babies were hardest hit, followed by young children and adolescents. Reported by Medical News Today, copyright Medical News Today.

OVER THE COUNTER

An FDA advisory committee has recommended not scheduling over the counter medicines containing dextromethorphan, in light of evidence that 40 million US households use such medications for treating coughs. Almost all cough suppressants currently contain dextromethorphan. The advisory committee did recommend education about cough-suppressant abuse, and called for limiting bulk purchases to FDA-registered manufacturers, and limiting teen access to the drug. Recreational doses between 100 and 200 mg have a euphoric effect and cause hallucinations, while larger doses can cause profound alterations in consciousness and out-of-body experiences.

FLU-FRIENDS

Who and where your friends are can predict when and where you'll catch the flu, according to researchers at Harvard. According to the principle of the "friendship paradox," the friends of any individual are more popular than that person. For example, if you ask high school students to name one friend, they'll typically name a person of higher social ranking. Or, at an art gallery opening, many people, if asked to name a friend at the event, will name the highest-ranking person, that is, the artist. Researchers applied this paradox to predicting the spread of infectious disease. They analyzed the 2009 flu epidemic in 744 students, asking 319 to name 425 additional friends. These 425 friends had flu symptoms two weeks before the original 319. The "friends" group showed flu symptoms 46 days before the epidemic's peak. What all this means is that if you ask a random group to name their friends, then track and compare the groups, you can predict epidemics before they strike the greater population. See Social Network Sensors for Early Detection of Contagious Outbreaks, PLoS ONE 5(9). The above information is from a report in Medical News Today by Sy Kraft, California State University, Northridge, copyright Medical News Today.

USELESS

Chest physiotherapy seems to have no effect on acute bronchiolitis, according to researchers in France who conducted a study on 500 children. The physiotherapy technique increased exhalation and assisted cough, but didn't reduce time to recovery. The researchers concluded, "Our results did not support the recommendation that chest physiotherapy be routinely performed in hospitalized infants with acute bronchiolitis."

VACCINATION UPDATE

Infants who received PCV-7 at 2, 4, and 11 months were more likely than unvaccinated controls to wind up with respiratory

pneumococcal disease. The increase of antibiotic-resistant strains of pneumococcal serotype 19A is now the leading cause of the respiratory disease, and the increase in serotype 19A disease has become associated with PCV-7 immunization programs. Researchers at University Medical Center Utrecht looked at the association between PCV-7 vaccination and serotype 19A pneumococci in 1,003 newborns followed up to two years before PCV-7 was widely used. The researchers demonstrated the facilitating role of PCV-7 in nasopharyngeal acquisition of serotype 19A, and warned that other similar serotypes may be the next to proliferate.

IMMUNE

More than half of the US is probably immune to the H1N1 virus, according to scientists at the NIH. The US population is believed to be immune because they've been exposed to the virus, or have been vaccinated. The researchers said that as such, the virus will probably die out unless it adapts and changes. However, they said, anything could happen. As such, they urged vaccination for everyone older than six months. Reported and copyrighted by Medical News Today; original article by Christian Nordqvist. For the full report see Morens, et al, "The 2009 H1N1 Pandemic," mBio vol 1 no 4, e00211-10.

BREEDING GROUND

Daycare is a breeding ground for viruses, particularly for lung conditions associated with preemie birth, according to researchers at Johns Hopkins. Researchers interviewed the parents of 111 children ages 3 and under with chronic lung disease of prematurity (CLDP) about their child's daycare attendance, infections, symptoms, emergency room visits, hospitalizations and use of medications. The kids with CLDP who attended daycare (22 out of the 111) were nearly four times more likely to end up in the ER with serious respiratory symptoms than those who didn't attend daycare, were twice as likely to need corticosteroids, and were more than twice as likely to need antibiotics, and they were nearly three times more likely to have breathing problems at least once a week. Among the 22 children with CLDP who attended daycare, 37% went to the ER for worsening symptoms since their last day in daycare, compared to 12% of children who didn't attend daycare. More than 15% of those who attended daycare were hospitalized for viral illness, compared to 6% among those who didn't. Thirty-nine percent of the daycare kids needed corticosteroids and half required antibiotics, compared to 19% and 26%, respectively. More than half of the children in daycare had respiratory symptoms in the week before their visit, compared to 29% percent of those not in daycare. CLDP develops in about a quarter of babies born at or before 26 weeks of gestation.

WHACK AND WHEEZE

Patients with asthma who are exposed to violence in their community are at an increased risk for an asthma-related hospitalization or a trip to the ER, said researchers at the University of Pennsylvania. The study tracked 397 adults living in an inner city community who had moderate to severe asthma for six months. Participants were interviewed to determine socio-demographics, asthma status, asthma-specific quality of life, depressive symptoms, social support, and exposure to community violence. To define exposure to community violence, patients were asked, "in the past 6 months did you witness any violence in your neighborhood." If they responded "yes," they were asked to be specific about the type of violence they'd been exposed to. This was followed by monthly updates and records

were kept of subsequent ED visits and hospitalization. Nearly a quarter of the group were exposed to violence, and these had twice the number of hospitalizations or ED visits for asthma as those who weren't exposed to violence. Young people were more exposed and visited the ED more often.

BAD COP

An NYPD cop has been accused of doing nothing to help a girl on her way to the hospital for an asthma attack because he said he didn't know CPR. The mom was driving her daughter to the hospital when she crashed into another car. She asked a policeman nearby for help. The cop on the scene was accused of doing nothing, leaving the girl to die. The NYPD said all its officers know CPR and suspended the officer. The cop told the media that he didn't feel confident enough to use his CPR skills. When the mom reached the hospital, the policeman drove away and didn't report the incident. The above is from a story by Christian Nordqvist, copyright Medical News Today.

INJURY TO INSULT

Mold spreading across post-Katrina New Orleans caused severe asthma attacks in children, according to researchers at the National Center on Minority Health and Health Disparities. Researchers found that 80% of children with asthma in New Orleans, after Katrina, were sensitive to mold, 30% higher than children in other US cities. New Orleans has reported the highest childhood asthma death rate in Louisiana. As such, the Merck Childhood Asthma Network pledged \$2 million to a program that helps families manage their kids' asthma. The HEAL program partnered 184 asthmatic children with health education specialists who helped them manage asthma and gave guidance on mold cleanup.

WAKE UP CALL

Nurses are moving into anesthesiology, according to several recent studies highlighted by The Institute of Medicine, which recommended repeal of the supervision rule. A recent study, No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians, examined nearly 500,000 individual cases in 14 states that removed the federal physician supervision requirement for nurse anesthetists between 2001 and 2005, and revealed that patient outcomes did not differ between the states that do not require physician supervision and states that do. Further, the study confirmed that there are no differences in patient outcomes when anesthesia services are provided by CRNAs, physician anesthesiologists, or CRNAs supervised by physicians. Another study, Cost Effectiveness Analysis of Anesthesia Providers, considered the different anesthesia delivery models in use in the US, including CRNAs acting solo, physician anesthesiologists acting solo, and various models in which a single anesthesiologist directs or supervises one to six CRNAs. The results show that CRNAs acting as the sole anesthesia provider cost 25% less than the second lowest cost model. Alternatively, the model in which one anesthesiologist supervises one CRNA is the least cost-efficient model.

PRODUCTS

SLEEP SUPPORT

Philips Respironics and biopharmaceutical company, Cephalon Inc are supporting efforts to bring untreated sleep apnea to the forefront of discussion among primary care physicians (PCP). As the program enters its second year, Cephalon joins the device

maker in responding to educational grant requests to fund a series of independent continuing medical education (CME) activities on this important topic. The education providers' goal of educating 7,200 clinicians was surpassed in the first year with more than 7,800 participants. Prior to participating in the program, 40% of surveyed clinicians felt confident in recognizing the signs and symptoms of sleep apnea. After participating in the CME program, 85% felt confident in their ability to assess and recognize sleep apnea signs and symptoms. For the new program year, the educational activities have expanded to 24 US cities. The first series of OSA CME activities will be conducted at Primary Care Education's Best Practices in Primary Care seminar, accredited by Primary Care Network. OSA education will also be conducted at Pri-Med's Conference & Exhibitions with those programs accredited by pmiCME. The programs run from October 2010 through June 2011. This year's goal is to educate 10,200 clinicians. The activities have been designed with the objective of improving understanding in identifying, treating and managing patients with OSA. They are available to primary care, family practice and internal medicine physicians, nurse practitioners and physician assistants. [Source: Young T, Peppard E, and Gottlieb D. Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med* 2002; 165:1217-1239.] For information about Primary Care Education's Best Practices program contact www.primarycare.com or call (877) 594-1770. For Pri-Med's Conference & Exhibitions contact www.pri-med.com or call (877) 263-5127, or contact resmed.com, philips.com, or cephalon.com.

EASY TO SWALLOW

News from Passy-Muir's "Talk Muir" newsletter, about "Swallowing.": It was not long after David Muir invented the Passy-Muir Tracheostomy & Ventilator Swallowing and Speaking Valve that researchers began studying the positive effects the valve has on swallow function. Today the Passy-Muir Valve is an essential component to dysphagia treatment with the tracheostomized and ventilator dependent population. In June 2010, Passy-Muir, Inc was invited to support an inaugural conference, "Integrative Neural Systems Underlying Vital Aerodigestive Tract Functions." This conference, held at the University of Wisconsin in Madison, brought together leading clinical and academic researchers from the fields of swallowing, voice, speech, respiration and sleep. Passy-Muir continues to offer free CEUs for a number of its webinars in the Swallowing Series. Also offered are full-day seminars on relevant topics. The Passy-Muir newsletter link provides information about these seminars, as

well as user spotlights, profiles of users, and information from clinical specialists. Contact passy-muir.com.

MAJOR EXPANSION

Fluke Biomedical announced a major expansion of service options for its customers across the United States. New CarePlans extended-warranty packages, as well as onsite and mobile services, offer priority services to ensure a new level of convenience for users of Fluke Biomedical best-in-class medical test and safety equipment. Gold, silver and bronze CarePlan packages offer comprehensive priority service and support, including extended warranties, priority bench service, expedited shipping, loaners, VIP technical support, productivity consultation services, educational training and more. Fluke

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CLINICAL STUDY

ImThera Medical, Inc announced interim results from its OSA European clinical study. For the study, ten patients have been surgically implanted with ImThera's aura6000 hypoglossal nerve neurostimulation device for treating Obstructive Sleep Apnea (OSA). The target population for ImThera's neurostimulation device is moderate and severe OSA patients who are non-compliant with or cannot tolerate Continuous Positive Airway Pressure. ImThera is releasing information on data from six patients who have had their calibrations and multiple polysomnography (PSG) studies to date. These patients have used the Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy at home for three months or longer. Four additional patients were implanted in September and their results will be reported at a later date. The six patients vary in age, body mass index, and OSA severity. All patients had a baseline apnea hypopnea index (AHI) of 30 or greater (range 32 to 80). Patients' Oxygen Desaturation Index (ODI) had a range of 12 to 76. The primary objectives of the European Clinical Study conducted at the Université Catholique de Louvain, Belgium, were safety, 50% or better reduction in the AHI, and 50% or better improvement in the ODI. Interim results of the study are clinically significant and very encouraging for short-term data. The interim data indicates that AHI has been reduced by an average of 73% and ODI has improved by an average of 77%. On average, arousals have been reduced by 50%. "These early results are very promising. We have seen a significant reduction in sleep related disordered breathing (decreases in apneas and hypopneas), resulting in much higher oxygen levels during sleep, and in better sleep characteristics. Patients are using the treatment every night at home, and they seem happy with the daytime effects. We see continuous reduction of their AHI over time. In addition, they appreciate the freedom the system gives them during sleep compared to the constraints of CPAP. We are confidently awaiting final data," said Professor Dr Daniel Rodenstein of the Université Catholique, and principal investigator of the European clinical study. The aura6000 is based on ImThera's proprietary THN Sleep Therapy, delivering neurostimulation to key muscles of the tongue during sleep. ImThera's aura6000 system takes, on average, seventy-five minutes to implant surgically. It offers one of the world's smallest implantable and rechargeable stimulators and does not require additional sensors to function. The aura6000 is not for sale in the US. Contact imtheramedical.com.

FDA CLEARANCE

Radiometer America announced that Radiometer's next-generation, cassette-based analyzer, the ABL90 FLEX, received 510(k) clearance from the US Food and Drug Administration. The ABL90 FLEX analyzer is the latest addition to the company's blood gas line, offering speed and high-throughput in a compact instrument. Contact radiometeramerica.com.

NAME CHANGE

Sleep Solutions, the pioneer and largest national service provider of home sleep tests for obstructive sleep apnea (OSA), has

changed its name to NovaSom, Inc, a Delaware corporation. The company changed its name to better reflect its history and commitment to providing the most accurate and cost effective home tests on the market for the diagnosis of obstructive sleep apnea (OSA). Historically, expensive and uncomfortable laboratory testing has been a barrier to diagnosis for many patients. Now the NovaSom Home Sleep Test provides affordable testing in the privacy and comfort of the person's natural sleep environment, making it easier for people at risk of OSA to be tested. NovaSom provides sequential night testing which overcomes the single night snapshot of traditional test methods, for a more accurate picture of sleep disordered breathing patterns. The company provides the resources that primary care physicians need to identify people at risk for OSA and determine appropriate candidates for both in-home and laboratory tests. NovaSom has a field-based medical education force and has made significant investments in CME and non-CME educational programs aimed at primary care. It has a large client care team and offers live clinical/technical support, 24 hours a day, 7 days a week, to patients undergoing the home sleep test. The company continues to actively partner with insurance companies to ensure widespread access to NovaSom diagnostic services. Medicare and most major payers cover the test. NovaSom is a Medicare-approved Independent Diagnostic Testing Facility (IDTF) and is fully accredited as an Ambulatory Care Sleep Diagnostic Center by The Joint Commission. The home testing system manufactured and distributed by NovaSom has FDA clearance for the diagnostic evaluation of OSA in adults. Contact www.sleepsolutions.com.

CHALLENGE

Pharmaxis, a global specialty pharmaceutical company focused on therapeutic products for chronic respiratory and immune disorders, announced that it has received approval from the FDA to market its ARIDOL (mannitol inhalation powder) Bronchial Challenge Test Kit, the first new bronchial challenge test in more than two decades. ARIDOL is used for the assessment of bronchial hyperresponsiveness in patients six years of age and older who do not have clinically apparent asthma. ARIDOL should not be used as a stand-alone tool to assess asthma, but as part of a physician's overall assessment of asthma. ARIDOL is a single-use, indirect test that is easy-to-administer, requires minimal preparation time and only a 15% reduction in lung function from baseline. Many clinicians consider an indirect bronchial challenge test to be preferable to direct challenge tests. The ARIDOL test requires patients to inhale increasing doses of dry powder mannitol from a simple, hand-held device, which causes airways to narrow and contract when airway inflammation is present. The doses are contained in capsules that are administered at one-minute intervals until a positive response is achieved or until all the capsules have been inhaled, indicating a negative result. A positive response is indicated when there is a 15% reduction in lung function from baseline compared to a 20% fall required by a methacholine challenge test. The lower the dose required to cause bronchoconstriction, the more severe the bronchial hyperresponsiveness. ARIDOL is a single-use test that requires less preparation time and eliminates reconstitution, use of a nebulizer to administer, clean-up and sterilization. A positive ARIDOL test is complete in approximately 20 minutes, compared to an average of 44 minutes for a methacholine test. A methacholine test requires additional equipment to administer and a designated testing room with ventilation. Tests that use exercise to assess bronchial hyperresponsiveness require special equipment and conditions, and may not be appropriate

for patients with physical limitations. The safety and efficacy of ARIDOL as a bronchial challenge test were verified in two global Phase III clinical trials. Mannitol, the active ingredient in ARIDOL, is a sugar alcohol indicated for the assessment of bronchial hyperresponsiveness in patients 6 years of age or older who do not have clinically apparent asthma. ARIDOL is not a stand alone test or a screening test for asthma. Bronchial challenge testing with ARIDOL should be used only as part of a physician's overall assessment of asthma. ARIDOL is contraindicated in patients with known hypersensitivity to mannitol or to the gelatin used to make the capsules. The product is also contraindicated for patients with medical conditions that may be compromised by induced bronchospasm or repeated spirometry maneuvers. Bronchial challenge testing with ARIDOL should not be performed in children less than 6 years of age. [Reference: Anderson SD, Charlton B, Weiler JM, et al. Comparison of mannitol and methacholine to predict exercise-induced bronchoconstriction and a clinical diagnosis of asthma. *Respir Res.* 2009;10:4; Provocholine (methacholine chloride powder for inhalation) Methapharm Inc. January 2008.] Contact pharmaxis.com.

CONVERSION

Covidien announced that the Thibodaux Regional Medical Center, located in Thibodaux, LA, has converted to Nellcor OxiMax pulse oximetry technology and sensors. Nellcor OxiMax technology incorporates cardiac-based signal processing algorithms which allow clinicians to track blood oxygen levels and pulse rates during challenging situations, such as during signal interference or low perfusion. Clinicians at Thibodaux now have access to multi-parameter monitors with OxiMax technology, as well as Covidien specialty sensors. These sensors include the Max-Fast forehead sensor, which is more responsive than digit sensors for patients with poor perfusion, and the SoftCare non-adhesive sensor line for patients with sensitive skin. Thibodaux is a 185-bed facility in southeast Louisiana offering a wide range of services, including heart surgery, radiation oncology, neurology, neurosurgery, plastic and reconstructive surgery, orthopedics, obstetrics, sleep disorders, and physical rehabilitation. Contact covidien.com.

ILLUMINATING

ILLuminations Webinar Series recently presented: "Avoid Unnecessary Transfusions and Optimize Blood Management in the CVOR." The speakers were John Toffaletti, Professor of Pathology at Duke University Medical Center and Gerard Myers, Cardiovascular Perfusionist at QEII and IWK Health Sciences. The webinar covered the clinical importance of transfusion management, evaluation of POC blood gas measurements, the role of measured total hemoglobin testing in reducing transfusions, and case analysis of oxygenation status testing methodologies. The ILLuminations Webinar series is presented by Instrumentation Laboratory. For more info contact ilus.com/illuminations.

KNOCKOUT

Covidien recently exhibited new medical technologies and showcased products at ANESTHESIOLOGY 2010, the American Society of Anesthesiologists (ASA) Annual Meeting. The company's continued commitment to development of clinical evidence was seen in many of the featured scientific posters and presentations. Products included the INVOS Cerebral/Somatic Oximeter, Nellcor BIS Brain Monitoring, LiDCO monitoring products to guide anesthetic management, and Mallinckrodt

TaperGuard Endotracheal Tubes. Contact covidien.com.

NEW FROM MASIMO

Masimo recently announced several new products at the ASA Annual Conference, including its Halo Index, 2011 Radical-7, and Patient Safety Net remote monitoring and clinician notification system. The Halo Index facilitates continuous global trending and assessment of multiple physiological parameters to quantify changes in patient status. Ranging in value from 0-10, the Halo Index helps clinicians to better assess overall patient condition and predict deterioration in health status. The Radical-7 offers a new way of looking at patient monitoring with rainbow noninvasive measurement capabilities and a color display screen. The Patient SafetyNet system is the only general floor monitoring system proven to help clinicians reduce rescue activations, ICU transfers, and ICU days. Contact masimo.com.

EXECUTIVE PROFILE

Dräger

Describe your respiratory care products.

Dräger offers specialized ventilation platforms for intensive care, neonatal care, chronic care, noninvasive therapy, and emergency/transport. These ventilators are designed specifically to meet the wide-ranging needs of community hospitals as well as tertiary care centers. Our current ventilator line includes our flagship product the Evita Infinity V500, a universal ventilator that can be utilized in the neonatal, pediatric, and adult critical care areas, and the Babylog VN500 neonatal-specific ventilator that can perform both pressure and volume ventilation. Both of these devices received 510(k) clearance in April 2010. Our Carina ventilator provides both invasive and noninvasive ventilation and is well suited for areas outside of the ICU.

Tell us about the latest advances in the area your respiratory product serves.

Both the Evita Infinity V500 and Babylog VN500 have been developed after years of experience and listening to clinicians from all over the world. Aspects of the latest technology focus on methods to improve workflow, clinical performance, ICU safety, and effective use of clinical information. Configurable data displays, smart views, and other closed-loop systems are examples of our latest products to support you and the patients you care for.

Discuss your research and development process including clinical user input.

Dräger is constantly investing in R&D efforts with a goal of improving patient outcomes and facilitating efficiencies for health care professionals. Approximately 7% of revenues are dedicated to research and development. The development of the Evita Infinity V500 which cleared in March, the Babylog VN500, and the release of a new adjunct known as "Auto-Release" during APRV are examples of this commitment. The "Auto-Release" feature automatically adjusts the T_{low} based on the desired percent of peak expiratory flow to be retained. Through customer feedback, Dräger has provided a customizable interface that can match the monitoring needs of the most critical patients as well as those requiring less diagnostic bedside care. Understanding how clinicians use our equipment
Continued on page 55...

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Legislative Watch: HIPAA, HITECH, and EHR Meaningful Use: An Overview of Major Legal Changes 2009-2010

Carol Brass

The sheer number of acronyms floating around the healthcare atmosphere lately could easily give anyone a headache: from HIPAA to HITECH, EHR to CMS, and ARRA to PPACA, the last two years have been a time of significant legal and regulatory changes for healthcare providers. To best understand these changes, keep in mind Congress' overarching goals: encouraging the adoption and meaningful use of electronic health records (EHR) across the US and assuring patients that their personal health information will continue to be protected as medicine enters the digital era.

Background – HIPAA

In 1996, the US Congress enacted the Health Insurance Protection and Accountability Act (HIPAA), and since then few healthcare providers or their attorneys have heard the term “HIPAA” without feeling a slight chill of apprehension. Under HIPAA, certain covered entities, including healthcare providers, both as individuals (eg, nurses) and organizations (eg, hospitals), are responsible for ensuring that patient safety information is kept confidential. Traditionally, physician-patient confidentiality is protected by judicial evidentiary rules developed by state courts, but patient relationships with other types of healthcare providers are not considered legally protected confidential relationships, nor is physician-patient confidentiality privileged at the federal level. Thus, HIPAA is in a sense the federal legislative equivalent of the state physician-patient relationship, extended to entities such as hospitals and hospital employees.

Ultimately, the goal of HIPAA is to assuage patient concerns that the conditions they disclose to their healthcare providers will not be disclosed to outside parties; the rationale is that if patients know their information is protected, they will be comfortable confiding in these healthcare providers and as a result will receive superior healthcare. While this goal is certainly laudable, HIPAA has unfortunately gained a reputation for being overly complex and sometimes harsh in its attempt to protect information. For example, even inadvertent disclosures can be the basis for penalties, regardless of whether any patient was harmed by the disclosure. CVS Caremark recently settled with the FTC for \$2.5 million over allegations that it had improperly disposed of paperwork containing private patient

information in unsecured dumpsters, despite the fact that there was no evidence that any patient had been harmed. Because the potential penalties for HIPAA violations can be quite large, many healthcare providers have adopted extreme measures to safeguard against disclosure of patient information. While this outcome is in some senses a positive one, it is also inefficient in many cases because providers are hesitant to provide care in what may be the most effective way because they fear HIPAA repercussions. As a result, much of HIPAA's impact has been felt in the adoption of overly protective measures by covered entities. In other words, because of the confusing nature of the regulatory structure, some providers have taken extreme measures – often not mandated by the act itself – to ensure compliance. For example, there was great concern after HIPAA's enactment that announcing a patient's name in a hospital waiting room would violate HIPAA protections, and as a result some hospitals cautioned their employees not to do this. However, HIPAA itself provides an exception for actions such as this in 45 CFR 164.502(a)(1)(iii). In response to the widespread concerns, the Department of Health and Human Services itself stated on its website that: “Covered entities, such as physician's offices, may use patient sign-in sheets or call out patient names in waiting rooms, so long as the information disclosed is appropriately limited.” In many similar situations, the confusing regulatory structure has led healthcare providers to take more extreme measures than necessary to protect patient privacy, ultimately at financial expense to healthcare institutions. The reason for this conservative approach is the severe penalties prescribed by HIPAA; for knowing and willful wrongful disclosures of protected health information, individuals could potentially be fined \$50,000 and imprisoned up to a year (and for a disclosure with the intent of selling the information or using it for personal gain, the penalties go up to \$250,000 and 10 years of imprisonment). Even so, few prosecutions have ever actually been made under HIPAA; up until 2008, only 4 cases were criminally prosecuted under HIPAA. As in many other fields of healthcare however, the fear of accruing legal liability has resulted in extreme responses to laws and regulations that go beyond what is required for legal compliance.¹

ARRA and HITECH – What changes now?

The HIPAA regulatory structure, which defines the uses and disclosures for which an authorization is required, the uses and disclosures requiring an opportunity for the individual to agree or object, and the uses and disclosures for which an authorization or opportunity to agree or object is not required remains largely the same at this point. What has changed is

Carol Brass is senior editor of Respiratory Therapy. She is currently in her final year at Columbia University School of Law and plans to enter into a healthcare regulatory practice after graduation. Please note that the author is not an attorney. This article is meant for educational purposes only and is not intended to provide legal advice.

primarily due to the adoption of new legislation under the American Recovery and Reinvestment Act (ARRA). ARRA, otherwise known as the Stimulus Act of 2009, contained within it a section known as the Health Information Technology for Economic and Clinical Health Act (HITECH), as well as sections that expand HIPAA's reach even further into the realm of privacy. These new sections are primarily concerned with two goals: (1) enhancing the existing privacy protections put in place by HIPAA, and (2) creating financial disincentives for organizations that fail to adopt electronic health record systems. ARRA is relevant to healthcare providers, including individual practitioners as well as institutions, in two ways. First, it sets out fairly aggressive new enforcement guidelines for HIPAA breaches. Recall that a HIPAA breach is fairly broadly defined and does not require intent – for example, a respiratory therapist who loses a work Blackberry on the train home may be liable (as well as her employer) if the Blackberry is not password protected at the time of loss, even if the phone is returned to the hospital a few days later. Under ARRA, in certain circumstances, patients must be notified of any inadvertent disclosure of their information, regardless of whether they were harmed by it or not. Further, ARRA suggests that enforcement will become far more stringent; while previously there were only a handful of criminal prosecutions under the HIPAA statute, prosecutions may be a more common occurrence now. Further, certain penalties have now become mandatory. For example, if a disclosure was made and the provider was found to have acted with “willful neglect,” then a penalty will be mandatory. The dollar values for penalties have also been enhanced, and the Act also mandates HHS to conduct audits to ensure compliance with the Act's terms. Recently, responsibility for HIPAA security rule enforcement has been transferred to HHS's Office for Civil Rights. Previously, such enforcement was the responsibility of CMS. Many believe that this switch indicates a future trend towards more rigorous enforcement, as CMS's enforcement of the rule was notoriously lax. Overall, it does appear that these penalties indicate an even stronger commitment by Congress to penalize the unlawful dissemination of private health information.

The second way that ARRA is relevant to healthcare providers is in the electronic health record (EHR) context. The HITECH Act, a section of ARRA, creates new incentives for the adoption and meaningful use of electronic health records. EHR and, more generally, the use of technology in healthcare, have been touted as solutions to many of the problems currently plaguing healthcare institutions. For example, e-prescription technology would ensure that patients do not receive multiple pharmaceuticals that may adversely interact with each other; similarly, electronic health records help ensure that physicians do not forget to ask potentially crucial diagnostic questions when they diagnose their patients. Others feel that utilizing EHR technology hampers physicians' ability to interact with the patient on a personal level and unduly restricts the physician's ability to make notations on charts and perform examinations in a way that intuitively makes sense for each patient.

Regardless of the perceived benefits and downfalls of EHR, the reality is that the HITECH Act has made adoption of EHR virtually a mandate for many hospitals and eligible providers (EPs). HITECH does this by utilizing both a carrot and a stick. Hospitals and EPs that are able to adopt and meaningfully use EHR technology will be rewarded with incentive payment awards for their use of EHR technology. On July 18, 2010, CMS

released its new rules on what constitutes “meaningful use” of electronic health record technology. These rules are quite complex and ultimately it is predicted that many providers will not be able to take full advantage of the incentive payment awards because they simply are not prepared to move to electronic health records technology yet. The Wall Street Journal reported that an American Hospital Association survey of 3,100 members found only 12% currently using electronic records – and only 2% would have met the requirements drafted by the federal government to receive incentive payments. In other words, the vast majority of hospitals that have already adopted EHR would not currently qualify for meaningful use incentive payments. The incentive payments will only be available for a short time: for example, providers enrolled in the Medicare EHR incentive program may not receive incentive payments if they commence use after 2015. After 2015, the carrot turns into a stick, and providers that still have not adopted and begun to meaningfully use certified EHR will be penalized with schedule-based fee reductions. Very generally, for EPs, fee reductions will consist of 1% off each year; in other words, an EP would likely receive a payment adjustment of 99% of the schedule-based fee in calendar year 2015 and 98% in 2016. Given that schedule-based fees and IPPS reimbursements are already the subject of much legislative scrutiny and potential cuts, these percentage cuts may fall on top of fees that have already been reduced significantly. In that case, failure to meaningfully use EHR could be the difference between financial life and death for a healthcare provider that is already financially unstable.

Future Forecast: Stormy Seas Ahead

Many commentators expect that future HIPAA enforcement will be far more stringent than it has been in the past. The passage of the HITECH Act and its more stringent penalties signals a strong Congressional intent to enhance the protections provided for patient safety. Further, the enhanced financial penalties and the mandatory nature of some penalties under HITECH gives the OCR an enhanced incentive to prosecute cases to their completion. Non-compliance with HIPAA will also now endanger a healthcare organization's future ability to receive the reimbursement incentives in place for EHR adoption. One major concern is that provisions of HIPAA that have not been enforced in the past will now be enforced given the more stringent standards and mandatory penalties. As a result, each individual provider's careful compliance with HIPAA rules and regulations is more important than ever.

Reference

- 1 See, eg, The evolution of HIPAA: the only constant is change, Kirsten Ruzic Wild. 12 No. 2 J. Healthcare Compliance 33 (2010).

Respiratory Complications in Medically Fragile Children: Improving Outcomes with High-Frequency Chest Compression Therapy

Jane Braverman, PhD; Rita Kalema, CRT, LRCP

Abstract

The terms “medically fragile” and “medically complex” designate infants and children with severely debilitating, irreversible, often terminal disorders. In this vulnerable population, respiratory complications (RC) associated with poor secretion management contribute significantly to morbidity and mortality, to patient and caregiver distress and to dramatically increased resource utilization and costs. Until recently, the importance of airway clearance therapy (ACT) in preventing or moderating pulmonary illness in this patient population has been underappreciated. For many of these children, ACT with high-frequency chest compression (HFCC) therapy and, if indicated, supplemental cough augmentation, is a practical intervention that has been shown to contribute substantially to clinical, economic and quality-of-life gains in both the institutional and home setting.

Overview

Medically complex children are a largely invisible population. Estimates suggest that 0.2% of Americans aged 18 and under are so disabled that they are entirely dependent upon others for even the most basic self-care activities.¹⁻³ Approximately half of those children reside in an institutional or long-term residential care setting. Others are cared for by their families, frequently with at least some publically funded ancillary nursing assistance. Among the significant proportion that is technology-dependent, a large subset requires intensive respiratory support services that may include mechanical ventilation, tracheostomy care, frequent suctioning, oxygen supplementation and cough assistance.^{3,5-9} Costs of care, direct and indirect, are enormous.^{2,3,10-12}

A recent study of children enrolled in the South Carolina State Medicaid Plan found that 0.22% qualified as medically fragile. Nearly 7% of the program's \$2 billion budget was spent on care for these children.³ Compared to an average annual expenditure of \$ 3,181 per well child in the program, \$69,906 was spent on

care for each medically fragile child. Among the 1,914 children identified as medically fragile, 54% were hospitalized one or more times during 2004 at an average cost of \$16,066 per event. Fifty percent of these children were seen in the ER at least once annually and outpatient visits were disproportionately numerous. With increased survival of very low birth weight babies and severely disabled infants and children, the economic burden of care is rapidly becoming unsustainable. Targeted, well-executed “practice improvement” strategies are urgently needed to alter the trajectory of skyrocketing costs while continuing to provide these children with the humane care they need and deserve.

Treatment Goals

Care for medically complex children should be both supportive and compassionate. For children with life-limiting or profoundly debilitating, irreversible disorders, straightforward information and realistic outcomes expectations lead to more confident treatment and care decisions.⁵ Therapy goals should be modest and focus chiefly upon minimizing physical and emotional suffering and enabling these children to live as meaningfully as possible within the context of their impairments and life cycle stage.^{5,10,11} Effective management plans are predicated upon an understanding of factors contributing to acute and chronic symptoms. Access to the skills and tools necessary for effective symptom relief are critical to care strategies that alleviate distress and prevent progression of symptoms into crises requiring ER and hospital admissions.

Respiratory complications in medically complex children

Children with severe neurological impairment are at major risk for high-impact RCs.¹³⁻¹⁸ That risk is compounded when cognitive deficit is also present.^{18,19} In this category, individuals with severe cerebral palsy (CP), many of whom began life as very low birth weight infants, are the most numerous. CP is a functional neurological disorder affecting more than half a million Americans and is the most common cause of physical disability in children. *Among the one-third of these children identified as severely impaired, respiratory complications are the leading cause of hospitalizations requiring costly high-technology support and of subsequent mortality.*^{5,12,16} Other categories of medically complex patients include those with genetic abnormalities, progressive neuromuscular diseases such as the muscular dystrophies and spinal muscular atrophies and those suffering sequelae of trauma including spinal cord or closed head or anoxic brain injuries.²⁻⁴ Regardless of the primary diagnosis, medically complex children are universally prone to

Jane Braverman is Vice President of Clinical Services at RespirTech, the manufacturer and distributor of a high-frequency chest compression device called the inCourage System. She has been a medical technologist, was formerly an assistant professor of the History of Medicine at the University of Minnesota Medical School, and has worked with HFCC basic and clinical research for the past decade. Rita Kalema is employed as a Director of Respiratory Care by Mission Health, a Minnesota-based group of Skilled Nursing Facilities serving the majority of the State's mechanically ventilated patients placed in SNF care. She has an extensive background in the use of high-frequency chest compression therapy in a variety of clinical settings.

respiratory compromise caused chiefly by pulmonary aspiration and ineffective mucociliary clearance (MCC) function.^{5,7,9,16-18}

Risk factors

Presenting symptoms of aspiration, lung injury and secretion retention range from persistent congestion, coughing, wheezing, gagging and choking to refractory atelectasis, recurrent pneumonia and, ultimately, respiratory failure.^{5,7,9,16-18} Potential risks and consequences must be reviewed thoroughly; healthcare team members working with medically complex individuals are strongly encouraged to assess patients for susceptibility to preventable RCs. Risk factors include:

- Pulmonary aspiration – Aspiration is the most common cause of recurrent pneumonia in children^{5,16-20} Risk for pneumonia is increased fourfold if tracheostomy is present and 10-14 times more likely with overt or silent tracheobronchial aspiration.²⁰ Aspiration is also triggered by excess oropharyngeal secretions, swallowing abnormalities, gastroesophageal reflux (GER) and seizure episodes.^{5,16-20} Mechanically ventilated/artificial airway patients are universally at risk for aspiration.⁶
- Impaired mucociliary clearance (MCC) – MCC dysfunction leads to airway inflammation, mucus obstruction and/or plugging, recurrent infection, and bronchiectasis. Volume loss (atelectasis) and V/Q (ventilation/perfusion mismatch) are early indicators.^{21,22}
- Ineffective cough – Cough inadequacy is usually secondary to weakness of the diaphragm and other respiratory muscles and results in inability to shear and expectorate secretions from the central airways. Musculoskeletal abnormalities such as kyphoscoliosis diminish respiratory muscle performance significantly.^{7,13,14}
- Immobility/quadriplegia – Static positioning promotes pooling and thickening of secretions and chronic atelectasis.^{5,18}
- Poor oral/dental hygiene – Inadequate mouth care increases risk for micro aspiration of bacteria-laden secretions, resulting in recurrent infections and chronic lung disease.¹⁹
- Neuroleptic medications – Side-effects of many medications contribute to decreased control of oropharyngeal secretions, depressed tracheal mucus flow rates and diminished cough clearance.²²⁻²⁴

Understanding the risk factors and pathogenic processes that contribute to RCs is fundamental to anticipating and minimizing their incidence. In addition to rigorous oral hygiene, medication surveillance, patient mobilization and judicious tracheal suctioning, daily ACT with HFCC, and, where indicated, cough augmentation are critically important.

Airway clearance therapy decisions: HFCC vs cough assistance

On the one hand, HFCC therapy, no matter how effective in mobilizing peripheral secretions, will not result in their expulsion without an effective cough flow. On the other hand, cough assist techniques, regardless of their efficacy in stimulating central airway clearance, cannot clear retained or impacted secretions from distal lung regions.³⁸

Because cough assist devices and HFCC devices are often described in the medical literature and almost always in insurance plan coverage policies as airway clearance devices, their physiological effects and intended purposes are easily misunderstood. Indeed, durable medical equipment [CPT] codes for these devices are sequential: E0482 and E0483 respectively. Clarification is needed.

- Cough assist devices enhance clearance of bronchial secretions from *central airways* in patients whose cough function is ineffective. Individuals with ineffective cough are usually those with neuromuscular or neuromotor conditions that affect respiratory and/or bulbar muscle function to such an extent that cough force is inadequate to shear accumulated secretions for final clearance. Cough assist machines work by gradually applying a positive pressure to the airways and then shifting rapidly to a negative pressure. The patient may use a mouthpiece, mask, or tracheal tube adapter to connect to the machine. The rapid shift in pressure simulates a natural cough, producing a high expiratory flow rate, shearing secretions from the central bronchial walls.^{7,25-27}
- HFCC devices clear bronchial secretions from the most peripheral to larger airways. HFCC is administered by means of an inflatable jacket or vest connected by hoses to an air pulse generator. During therapy, rapidly pulsating compressive forces are applied externally to the thorax, thereby generating oscillating forces within the airways that dislodge mucus adherent to the bronchial walls. Each individual pressure pulse generates airflow velocities in the airways of the lungs approaching that of normal cough. The resulting oscillating bursts of air impart shear forces to the mucus layer and have been shown to reduce the viscosity of mucus. HFCC compensates for MCC failure by 1) loosening mucus from bronchial walls, 2) reducing mucus viscosity, and 3) mobilizing mucus cephalad where it can be cleared by swallowing, coughing or suctioning. HFCC-induced cough augmentation is effective except in individuals with very low PCF thresholds.²⁸⁻³⁴

HFCC and cough assistance: one, the other, both or neither?

- No assistive device therapy: Medically complex patients who are able to cough effectively and adequately clear their secretions may do well with minimal interventions. Simple techniques including frequent repositioning and avoidance of slumped sitting are generally sufficient. Poor positioning, especially at mealtimes, may increase respiratory effort and promote reflux.^{5,7,35-37}
- Cough assist alone: In patients whose ONLY airway clearance problems result from ineffective cough, a cough assist device alone may be sufficient. MCC function and the physical characteristics of mucus are healthy and secretions advance normally from peripheral to central airways, but cough is too weak to accomplish final clearance. Expiratory peak cough flow at the mouth (PCF) is used as a measure of cough adequacy. Normal PCF may be as high as 10-12 L/second. PCFs of less than 4.5 L/sec (270 L/min) are associated with increased risk of pulmonary complications from pulmonary infection. PCFs below 2.7 L/sec are generally a threshold for initiating cough assist therapy.^{7-9,25-27}
- HFCC alone: HFCC alone can meet the airway clearance needs of two categories of patients with small airway secretion retention. These include patients with absent or impaired MCC but with normal cough function and also mechanically ventilated patients or those with tracheotomies receiving routine suctioning. Secretions mobilized by HFCC can be cleared from their collection point in central airways by swallowing, expectoration or suctioning alone; supplemental cough augmentation is unnecessary.^{5,7,16,18}
- Both HFCC and cough assist: Children who can neither cough effectively nor mobilize secretions and who *do not* have a tracheotomy require both HFCC and some form of

cough assistance. The devices work in a complementary fashion. HFCC clears mucus from smaller into the larger airways and the cough assist device propels it from the central airways, significantly reducing the need for suctioning. HFCC plus a cough-assist device may be especially appropriate for children with impaired MCC and ineffective cough for whom routine suctioning is undesirable.^{7,16,18,39}

HFCC and medically complex children: studies and clinical experience

“For the last seven years, I have been using high frequency chest wall compression [HFCWC] for a cohort of medically fragile children; I am referring to children with neuromuscular disorders, cerebral palsy, non-CF bronchiectasis and immunodeficient children with recurrent pneumonia. I have informally evaluated medical resource utilization before and after HFCWC and found a dramatic reduction in hospitalization and emergency room visits, need for antibiotics, and an improvement in quality of life during the period of HFCC usage.”⁴⁰

Limitations particular to device testing are acknowledged.⁴¹ The classic randomized controlled model (RCT) that works so well for drug studies cannot be realistically used for device trials. Where medically complex children are concerned, a maze of ethical, legal, medical and economic constraints limit pediatric recruitment for any kind of clinical trial. Despite investigational challenges, published studies of HFCC therapy in medically complex individuals show compelling results consistent with observational evidence reported by individual clinicians and in patient outcomes data.^{40,42-47}

HFCC therapy is used extensively for medically complex children either cared for at home or in residential treatment centers. Several center-based studies conducted in conformance to prevailing ethical standards show that the therapy can substantially reduce pneumonias and resulting hospitalizations in this patient population.⁴²⁻⁴⁶

- Seven children with quadriplegic CP and significant lung disease received HFCC for 12 months. Outcomes were compared with 12 retrospective months of up to 3 X daily chest physiotherapy. All participants had histories of frequent pulmonary infections and were fed by G-tube. Five had tracheostomies and three had active seizure disorder. Post HFCC outcomes were clinically and economically significant: 1) fewer pneumonias (11 vs 23); 2) fewer hospitalizations; (3 vs 9); 3) fewer seizure episodes (43 vs 267) and; 4) markedly improved successful suctioning of pulmonary secretions (10,445 vs 4, 825). Therapy was well-tolerated.⁴²
- In a follow-up 12-month retrospective-prospective observational study involving 11 similar participants, the same investigator obtained statistically significant outcomes for all outcomes: 1) fewer pneumonias (27 vs 52) and; 2) fewer hospitalizations due to pneumonia (3 vs 13). The frequency of effective suctioning was significantly increased ($P < .05$), and seizure events decreased sharply ($P < .05$).⁴³
- Daily HFCC therapy was evaluated in 15 patients with a rare genetic neurological disorder, familial dysautonomia (FD). All had significant secretion-related lung disease. A 12 month retrospective/prospective medical chart review showed statistically significant improvements *per patient* in all measured outcomes including: pneumonias (3 vs 1), hospitalizations (1 vs 0); doctor visits (11 vs 5); antibiotic courses (8 vs 4); antibiotic days (85 vs 34), and absenteeism 32

vs 9 days). Oxygen saturation, forced vital capacity (FVC) and peak expiratory flow rate (PEFR) also demonstrated sustained improvement.⁴⁴

- Hospitalization data for fifteen diagnostically diverse medically fragile children in a residential long-term care facility was compared following at least one year of HFCC therapy with data from a retrospective year of “usual care” manual chest physiotherapy (CPT). After 12 or more months of HFCC, participants showed an aggregate 1) three-fold reduction in total hospital days (21 days with HFCC vs 66 days with CPT) and; 2) elimination of ICU days (0 days with HFCC vs 21 days with CPT). No treatment-associated adverse events were observed.⁴⁵
- A retrospective quality assurance review of 13 children with cerebral palsy (CP) using HFCC for airway clearance therapy for 6-12 months showed significant reductions in high-level healthcare utilization: 8 vs 5 hospitalizations; 5 vs 1 ER visits. Parents reported fewer respiratory illnesses, less antibiotic use, and reduced absenteeism. Treatment adherence and parental satisfaction were high.⁴⁶

Economic implications

HFCC therapy improves quality of life for medically fragile patients. Just as clearly, judiciously used HFCC therapy can substantially impact direct and indirect costs of care.

In a retrospective-prospective 12 month study of 11 individuals with severe cerebral palsy in 2 skilled residential nursing facilities, hospitalizations for pneumonia were compared after a year of HFCC therapy with a year of antecedent CPT therapy. During the one-year study, hospitalizations were decreased from 13 to 3. Average stays were 5 days, 4 in the ICU. Data were obtained from the business offices of 3 regional hospitals with pediatric ICU units serving the study patients.⁴⁷

- The average hospitalization charge was \$8,225.00 [2002 data].
- Costs do not include laboratory, pharmacy charges or physician charges.
- Cost savings for 10 hospitalizations was at least \$82,550.00.

Cost savings quantitatively estimated in this study can be reasonably extrapolated to evaluate economic impact in the observational studies cited above.

Conclusion

HFCC has been shown to contribute substantially to successful management of medically complex children in both home and institutional settings. Overwhelmingly, the preponderance of all morbidity and morbidity-related care costs in this population are attributable to respiratory complications. In a large proportion of these children, impaired ability to mobilize and evacuate bronchial secretions is a direct cause. The role of HFCC in reducing suffering, improving quality-of-life and easing the burden of care is observable. Importantly, keeping children out of the hospital also decreases risk for exposure to hospital-acquired infections. By limiting episodes of aspiration, mucous plugging and respiratory failure, HFCC helps reduce the significant costs associated with high-technology supportive care, emergency, or hospital treatment. Evidence documenting the cost effectiveness of HFCC in this patient population is accruing. As efforts to improve care in these vulnerable individuals intensify, HFCC merits strong consideration for inclusion in routine pulmonary hygiene regimens.

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Improvement in Intra-hospital Transport of Mechanically Ventilated Patients: A Proposed Quality Improvement Project

Tom Bachman

While the intra-hospital transport (IHT) of patients is an essential clinical practice, it has not been thoroughly evaluated from an administrative or clinical perspective. Based on a review of the limited literature, we provide background on the frequency of IHT and its related adverse effects, as well as highlight an opportunity for improvement.

The frequency of transport depends on the size and intensity of the ICU; however some baseline estimates are available. Approximately half of IHTs are for diagnostic tests, most often CT imaging. However, in larger hospitals a significant number are between specialty ICUs.⁶

In one large retrospective review of a US tertiary care center there were 0.72 transports per ICU admission.⁹ Projecting this would indicate there are about 3 million intra-hospital transports of critically ill patients in the US annually. This would suggest that the typical hospital with 20 ICU beds and reasonable acuity might experience the need for a transport nearly every day. In contrast, the largest units report as many as 10 per day.⁶

Many have reported that patients needing IHT are more severely ill and are much more likely to require mechanical ventilation and infusion than their ICU cohort not needing transport. In one large series the need for transport in patients on mechanical ventilation was estimated as 1 per 2.3 ventilator days.⁶ Accordingly the need for more than one transport during an ICU stay is common, and proportional to the length of ICU stay. In this series 25% received 4 or more transports.

There is consensus that adverse events associated with IHT are common, though data is limited and not homogeneous.^{2,10} The reported incidence of adverse events is between 10%-70%, with those with higher incidence also reporting more than a third to be related to equipment mishaps. Problems with gas exchange were frequent: about one in ten transports.^{1,7,10} Kollef found that IHT independently increased the odds (3.8 times) of ventilator-associated pneumonia (VAP), and Waydhas reported a long-term respiratory decline in 12% of IHT patients. While death during IHT is probably rare, there is some data to suggest IHT is related to mortality and morbidity. Szem reported that mortality

appeared higher in a subgroup of high-risk transport patients when compared to patients with comparable severity that were not transported.⁸

Formal organization and staffing of transport teams can improve efficiency.⁵ Further, the availability of medical systems that can easily accommodate transport enhance efficiency and, more importantly, minimize adverse events associated with equipment dysfunction. While the actual labor cost of an IHT is insignificant, it is an unnecessarily inefficient process, with more than 80% of the time wasted.³ One study suggested that the staffing impact in respiratory care in a large center was the equivalent of one FTE.⁶

Over the last decade ventilators have evolved to facilitate ventilatory support during IHT. While shown to be vastly superior to hand-bag ventilation, they have tended to be a compromise. Ventilators used in transport have been either large full-feature ventilators with battery back-up that can be moved or small compact ventilators meant for transport that are equipped with less sophisticated support capability. In most cases the latter are used just for transport, necessitating a switch of the patient's ventilator when transport is required. Opening the ventilator circuit to change ventilators results not only in pulmonary de-recruitment in patients with severe lung disease but also increases the risk of VAP. This is certainly part of the root cause of the reported increased morbidity and mortality.

Next generation, full featured ICU ventilators, designed to facilitate IHT, such as the EnVe (CareFusion, Yorba Linda, CA), are now available. Patients admitted to the ICU with the highest risk of respiratory compromise associated with transport should be targeted based on IHT risk (expected ICU length of stay, severity of lung disease and likelihood of requiring multiple IHTs during their stay). These patients would be placed on the EnVe ventilator system at admission. This approach makes possible the following quality improvements.

We hypothesize the following impact: 1) reduced adverse gas exchange episodes during the transport process, and 2) reduced RT time needed to initiate the transport. We would also expect less respiratory deterioration of these patients and a decrease in the incidence of VAP, both as a result of a limited need to open the ventilator circuit.

Continued on page 47...

Tom Bachman has a long history describing and evaluating new respiratory technologies. His consultancy specializes in indication development and clinical research. He has been a regular contributor to Neonatal Intensive Care and Respiratory Therapy. He can be reached at Tom.Bachman@MCHcares.com. This article was sponsored by CareFusion.



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Tracheostomy Care: The Importance of Humidification at Home

Joann Miller

“The formation of a tracheostomy significantly alters the patient’s respiratory physiology. In bypassing the upper respiratory tract, the patient is more susceptible to changes in humidity and there is a consequential change in the function of the respiratory mucosa. Understanding these changes is fundamental to managing these patients effectively.”¹

In order to reduce and/or prevent the adverse effects of bypassing the upper respiratory tract, the once-effective system for air conduction, warming and moisturizing inspired gases and filtering foreign particles prior to entering the lower airways and the lungs, humidification treatments of the upper airway, especially at home, becomes imperative in managing tracheostomy patients effectively.

Once a tracheostomy is in place, the upper respiratory tract will naturally begin to dehydrate the ciliated mucosa and goblet cells, which will lead to histological changes in the tracheobronchial mucosa, including, destruction of cilia, dehydration to mucous glands, dehydration of upper respiratory epithelium, disorganization of basement membrane, cytoplasmic and nuclear degeneration, desquamation of airway epithelial cells, damage of the lower respiratory epithelium, and the shifting downward of the Isothermic Saturation Boundary (ISB), which puts the pressure of heat and moisture exchange on the lower respiratory tract, which is not a function the lower respiratory tract. Inpatient humidification is a standard treatment in respiratory management. Unfortunately, this is not always the case in homecare treatment.

“For patients undergoing chemo-radiation, particularly for cancers of the throat and mouth, the problem is even more severe,” said Dr Eugene N. Myers, Distinguished Professor and Emeritus Chair of the Department of Otolaryngology of the University of Pittsburgh School of Medicine. “The body normally produces about a quart of saliva each day to aid in digestion and to moisturize the food we eat so we can swallow it. Saliva also keeps mucus membranes moist, so they don’t stick together. Radiation destroys the salivary glands and dries up saliva, and the glands usually don’t regenerate. Chemotherapy

in conjunction with radiation exacerbates these side effects of treatment.”

Dr Myers, who has performed more than 10,000 surgeries on patients with tumors of the head and neck, said a typical dose of radiation is estimated to be about 65 Gy, and treatment destroys about 80% of salivary glands. Add chemotherapy and the dosage goes up to about 80 Gy and destroys 90 to 95% of salivary glands. New radiation machines (IMRT) have been designed to overcome this problem, but the results have not been dramatic.

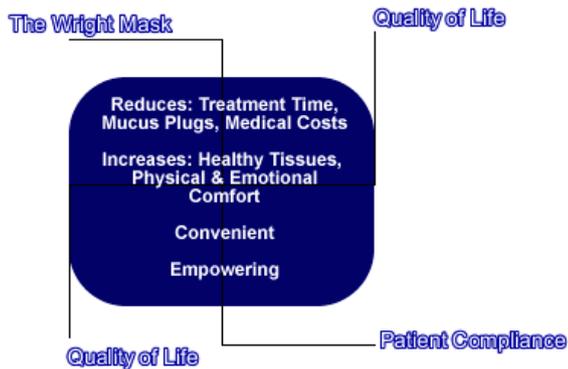
“The swallowing passage, the throat, the pharynx is deprived of this saliva,” Dr Myers said. “It makes it very difficult to swallow. If people have proper moisturization of the mucus membranes, then it is more comfortable and the swallowing may be improved.”

“Trends towards early tracheostomy in intensive care units (ICU) have led to increased numbers of tracheostomy patients. Together with the push for earlier discharge from ICU, this poses challenges across disciplines and wards. Even though tracheostomy is performed across a range of patient groups, tracheostomy care is seen as the domain of specialist clinicians in critical care. It is crucial to ensure quality care regardless of the patient’s destination after ICU.”¹ Further, tracheostomy care does not end with discharge, but rather tracheostomy care must transition from across disciplines and wards to Long Term Care (LTC) or homecare and to the patients themselves. It is at this stage, especially in the homecare of the patient, that humidification of the upper airway is – more often than not – considered a treatment which is no longer needed.

Invisible side effects

As noted above, bypassing the upper respiratory tract requires understanding and managing changes caused by the formation of a tracheostomy. Patients and caregivers must manage a plethora of side effects, not least of which is dry mouth and dry nose. Most tracheotomized patients accept “dry nose and mouth” as just one more uncomfortable side effect of having a trach, which can be temporarily eased with the use of a number of products such as artificial salivas, mucopolysaccharide solutions, saliva stimulants or dentifrices.³ These products temporarily replace some moisture loss but do not replace the once-effective upper respiratory system’s functions, specifically the function of constant humidification and moisturization. Humidification of the upper airway is no less important whether a patient is transitioned home, in LTC or is an inpatient. In fact,

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humidification and moisturization is even more important once the patient is discharged from acute care to home or LTC.

Future Challenges in Respiratory Care

Respiratory care has evolved significantly over the past decade and will continue to evolve especially in the area of tracheostomy care. With the creation and implementation of “trach teams” across disciplines within healthcare centers throughout the world, quality tracheostomy care is becoming the rule rather than the exception. It is estimated that by 2025, more than 1 billion people will be over 60 years of age and many of them will be tracheotomized patients.

One challenge for respiratory clinicians will be to find innovative ways in which to encourage patient compliance prior to transitioning to homecare or LTC. Patient compliance significantly reduces readmissions, thereby lowering healthcare costs while saving valuable clinician time, which can be spent managing new patients, creating new procedures or implementing new innovations.

Another challenge currently facing respiratory care personnel and all healthcare providers is implementing ways in which to improve health outcomes in high-need populations, resulting in “...(A) reducing preventable hospitalizations; (B) preventing hospital readmissions; (C) reducing emergency room visits; and (D) improving health outcomes commensurate with the beneficiaries’ stage of chronic illness...”⁴ as per the Patient Protection and Affordable Care Act requirements.

Innovations – Post Acute Care

One innovative way to ensure that patients humidify their upper and lower airways once they have been transitioned to homecare or LTC, is by providing them with The Wright Face & Tracheostomy Nebulizing Mask (The Wright Mask). The Wright Mask humidifies the upper and lower airways, simultaneously moisturizing the nose, mouth and trachea. As we have seen, humidification of both the upper and lower airways is critical for tracheotomized patients. It is also a known fact that once patients leave the hospital, non-compliance slowly sets in until such time as the patient requires re-admittance due to complications.

The Wright Mask should be considered along with conventional humidification systems by patients and their respiratory team as they begin the transition to homecare or LTC. The Wright Mask is an innovative use of existing conventional masks, specifically a trach mask and an aerosol face mask connected with an adjustable “Tee,” which when attached to a nebulizer and

compressor provides humidification through to the trach, nose and mouth simultaneously.

The Wright Mask is a post acute care product. Since it is a homecare product, patients decide when, where and how long they will sit down for a humidification treatment. As an LTC product, The Wright Mask is a convenient disposable humidification tool which seamlessly continues acute care nebulizing treatments while saving LTC staff valuable time throughout their busy work day.

“The Wright System Mask, combining simultaneous humidification of both upper and lower airways, is likely to become a preferred airway moisturization method due to its time efficiency and comfort,” said Dr Keith A. Candiotti, Chief of the Division of Perioperative Medicine and Vice Chairman of Clinical Research, Department of Anesthesiology, University of Miami Miller School of Medicine.

The Wright Mask was invented to transition a non-compliant re-admission patient into a compliant comfortable patient able to enjoy a higher quality of life at home or in LTC.

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- 3 Artificial Saliva: • Orajel or Vaseline and glycerin swabs • Entertainer’s Secret (KLI Corp) spray • Glandosane (Kenwood/Bradley) spray • Moi-Stir (Kingswood Labs) spray • Moi-Stir Oral Swabsticks (Kingswood Labs) swabs • Optimoist (Colgate-Palmolive) spray • Saliva Substitute (Roxane Labs) liquid • Salivart (Gebauer) aerosol • Salix (Scandinavian Natural Health & Beauty) tablets • V. A. Oralube (Oral Dis. Res. Lab) liquid • Xero-Lube (Scherer) spray Mucopolysaccharide Solutions: • MouthKote (Parnell) spray Saliva Stimulants: • Natrol Dry Mouth Relief lozenges Dentifrices: • Biotene Dry Mouth Toothpaste • Biotene Gentle Mouthwash • Biotene Dry Mouth Gum • Oralbalance Longlasting Moisturizing Gel • Biotene Dry Mouth Kit
- 4 Healthcare Reform Bill H.R. 3590 Patient Protection and Affordable Care Act; pg 26 Sec. 2717 - Ensuring The Quality Of Care; pg 30 Sec. 2718 - Bringing Down The Cost Of Health - Care Coverage; pg 764 Sec. 3024 - Independence At Home - Demonstration Program; pg 775 Sec. 3025 - Hospital Readmissions Reduction – Program; pg 1053 Sec. 3501 - Health Care Quality Improvement - Programs

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Capital Equipment Purchases – Are You Making The Best Decisions? – The Respiratory Therapist – A Hidden Resource.

Catharine Johnson-Tieck, RCP, RRT

With the current fiscal restraints becoming a permanent part of our everyday reality, making the best informed decision when it comes to capital equipment purchases is essential. Getting the “best deal” should not be considered the primary driving force in the decision-making process. Choosing equipment that is inexpensive but incurs excessive costs in time, disposable adjunctive equipment, repair or down time costs, or that just does not deliver everything that you required to meet your clinical goals, can end up wasting your limited financial resources. Tapping into all sources of information as part of the decision-making process is essential. Developing a template or tool to facilitate the process helps eliminate the emotional part of the process. Being caught up in the “pretty blinking lights” and sales rhetoric is always a potential risk.

Often, staff therapists can provide valuable input into the decision-making process. Included as part of your template should be a tool that identifies the purpose or clinical objective that the equipment is supposed to achieve. Therapists can develop a written list of features required in the equipment, how it would be clinically applied, and alternative uses that they could envision (multitasking equipment), decontamination requirements expected, and acceptable size. Once this has been developed, the respiratory therapy staff can investigate (on-line and with in-house demos) what commercial offerings meet their needs and the funding envelope available. In today’s wired world the staff can easily reach out to the national or state groups of respiratory therapists to share their professional experiences and recommendations. Forming an in-house focus group/committee ensures that the staff has a voice in purchasing equipment that meets their needs and facilitates the all important buy-in. A beneficial side-effect is that staff becomes aware of the challenges faced in equipment selection. In fact, providing facility forms and policies governing product evaluation and acquisition can help the staff to take an active role in championing their selection. Once a final selection has been reached, asking one of the staff to be present at the product evaluation committee meeting should be actively considered.

Multidisciplinary strengths

Many of the capital acquisitions by respiratory therapy departments overlap with the scope of other departments/disciplines. A familiar example are mechanical ventilators which nurses, physicians and therapists work with. Involving other disciplines, at least in the early stages of developing the template

for assessment/acquisition, ensures a balanced approach that meets or respects the needs of the other disciplines.

Multiple brands vs single brands – all your eggs in one basket?

Therapists from facilities that utilize multiple brands/models can speak to the challenges and strengths of having different types of equipment from multiple manufacturers. The challenges: maintaining intimate knowledge of each unit and its clinical strengths, weaknesses and idiosyncrasies; noting adjunctive equipment required, emergency troubleshooting, biomedical support of multiple brands, additional costs associated with multiple equipment designs (eg circuits, biomedical costs, flow sensors) and being able to teach equipment operation to new staff and students. The strengths: multiple units offer protection against a single manufacturer’s recalls or failures, offers multiple options to clinical challenges, ensures that staff stay current on the newest applications and helps assure the staff’s role as experts. One of the biggest risks using a single brand/model is that of equipment recall/failure or shortages in adjunctive supplies (eg ventilator flow sensors) – the dreaded “it’s on back order” phenomenon.

Each staff therapist has her or his own experiences to offer; their insight on product selection can often make the difference between buying a “boat anchor” and a really effective, well-appreciated piece of equipment that fulfills the goals set out by the department. Leadership in product selection actually starts with the line staff, multidisciplinary input and the support of cardiopulmonary leadership. From the medical director, department director, vice-president, manager, team leads and staff therapists – everyone is an essential part of product acquisition.

Catharine Johnson-Tieck is President, Innovative Respiratory Concepts.

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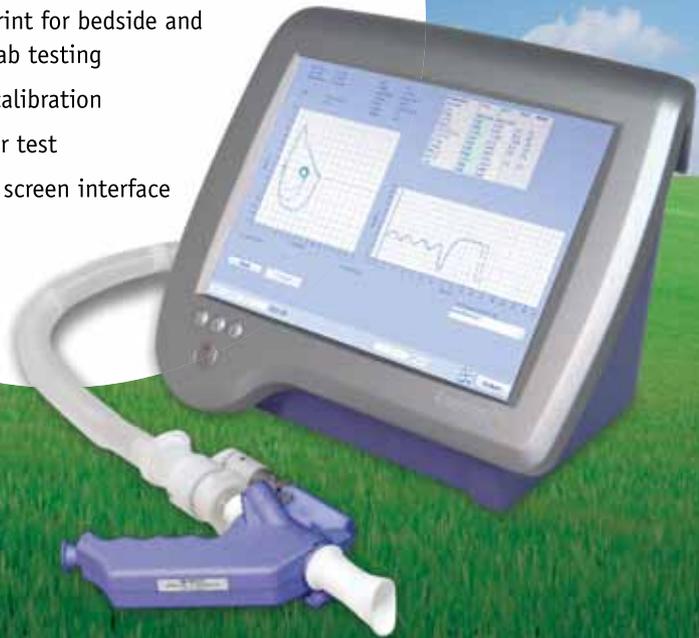
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Helium-oxygen Reduces the Production of Carbon Dioxide During Weaning from Mechanical Ventilation

Gordon Flynn, Gerlinde Mandersloot, Marie Healy, Mark Saville, Daniel F. McAuley

Abstract

Background: Prolonged weaning from mechanical ventilation has a major impact on ICU bed occupancy and patient outcome, and has significant cost implications.

There is evidence in patients around the period of extubation that helium-oxygen leads to a reduction in the work of breathing. Therefore breathing helium-oxygen during weaning may be a useful adjunct to facilitate weaning. We hypothesized that breathing helium-oxygen would reduce carbon dioxide production during the weaning phase of mechanical ventilation.

Materials/patients and methods: We performed a prospective randomized controlled single blinded cross-over trial on 19 adult intensive care patients without significant airways disease who fulfilled criteria for weaning with CPAP. Patients were randomised to helium-oxygen and air-oxygen delivered during a 2 hour period of CPAP ventilation. Carbon dioxide production (VCO_2) was measured using a near patient main stream infrared carbon dioxide sensor and fixed orifice pneumotachograph.

Results: Compared to air-oxygen, helium-oxygen significantly decreased VCO_2 production at the end of the 2 hour period of CPAP ventilation; there was a mean difference in CO_2 production of 48.9 ml/min (95% CI 18.7-79.2 $p=0.003$) between the groups. There were no significant differences in other respiratory and haemodynamic parameters.

Conclusion: This study shows that breathing a helium-oxygen mixture during weaning reduces carbon dioxide production. This physiological study supports the need for a clinical trial of helium-oxygen mixture during the weaning phase of mechanical ventilation with duration of weaning as the primary outcome.

Introduction

Weaning from mechanical ventilation is estimated to account for up to 40% of the total duration of ventilatory support.¹ The

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process of weaning patients therefore has a major impact on ICU bed occupancy with significant cost implication.² Strategies to facilitate weaning have a major potential to reduce use of healthcare resources.^{3,4}

Helium is an inert gas and prolonged administration to animals has demonstrated no adverse effects.⁵ Helium has a lower density and higher viscosity compared with oxygen and nitrogen. Breathing helium leads to a decreased resistance in gas flow, a change from turbulent to laminar flow patterns⁶ and a reduction in the work of breathing. However a change from turbulent to laminar flow patterns is unnecessary for the reduction in the work of breathing which can occur under fully turbulent flow.⁷

Helium-oxygen has been used in clinical situations where upper or lower airways obstruction or disease leads to an increased resistance to flow. Although there are many case reports of successful use of helium-oxygen in these conditions, to date no studies have conclusively demonstrated improved outcomes in these patient groups.⁸

There are limited data regarding the use of helium-oxygen during weaning. Use of a helium-oxygen mixture during weaning with CPAP has been successfully used to improve respiratory distress and improve PaO_2 after cardiovascular surgery in a small study in infants.⁹ In addition, in ventilated patients with airflow obstruction, breathing helium-oxygen during a T-piece breathing trial just prior to extubation resulted in a reduction in airway resistance and consequently a decrease in work of breathing.¹⁰

The aim of this physiological study was to determine whether breathing a helium-oxygen mixture as compared with an air-oxygen mixture during the weaning phase of mechanical ventilation would reduce carbon dioxide production in patients without significant airways obstruction.

Materials and Methods

We conducted a prospective single center, randomized, single blinded, controlled, cross-over study in our 18 bed mixed medical-surgical ICU. Approval for the study was obtained from Research Ethics Committee and the Medicines and Health Regulatory Agency (MHRA). Eligible patients were ready for weaning to CPAP and had to meet the following inclusion criteria; the underlying cause of respiratory failure was improving, pressure support ventilation of less than 10 cmH₂O, no continuous intravenous sedation or inotropes, FiO_2 less than or equal to 0.4 and requiring less than 10 cmH₂O positive end

Table 1

Patient number	Age	Primary reason condition	Secondary reason condition	APACHE II	Status at unit discharge	Length of unit stay (rounded)	Length mechanical ventilation till inclusion
1	21	Status epilepticus or uncontrolled seizures		17	Alive	11	9
2	77	Pulmonary haemorrhage not defined	Thoracic or thoraco-abdominal aortic aneurysm	22	Alive	21	12
3	84	Inhalation pneumonitis (smoke or gases)		19	Alive	11	12
4	44	Pneumonia, no organism isolated	Depression	14	Alive	9	5
5	84	Haemorrhage or haematoma from pelvis, long bones or joints	Fractured ribs	23	Alive	30	12
6	65	Intracerebral haemorrhage	Secondary hydrocephalus	20	Alive	5	2
7	30	Traumatic rupture or laceration of liver	Hypovolaemic shock	16	Alive	17	13
8	68	Lung collapse or atelectasis	Lung abscess	16	Alive	23	6
9	46	Primary (diffuse) brain injury	Lumbar spine fracture or ligamentous injury	25	Alive	27	26
10	47	Primary (diffuse) brain injury	Amputation of limb	15	Alive	10	6
11	72	Primary (diffuse) brain injury	Traumatic subarachnoid haemorrhage	19	Alive	9	7
12	76	Abdominal aortic aneurysm, ruptured	Acute renal failure due to haemodynamic causes	18	Dead	12	7
13	45	Primary (diffuse) brain injury	Pneumonitis due to food and vomit	10	Alive	13	10
14	18	Traumatic myocardial perforation	Anoxic or ischaemic coma or encephalopathy	12	Alive	22	17
15	36	Tracheal trauma or perforation	Traumatic pneumothorax	19	Alive	20	12
16	28	Traumatic subdural haemorrhage	Focal brain injury	9	Alive	10	8
17	58	Chronic obstructive pulmonary disease with acute exacerbation, unspecified		15	Alive	3	1
18	79	Traumatic subdural haemorrhage		28	Alive	6	4
19	67	Pneumonia, no organism isolated	Pleural effusion	24	Alive	12	9
Mean	53.3			17.3		13.9	9.2
SD	21.7			5.0		7.6	5.7
Median							9
IQR							6-12

expiratory pressure. Written informed consent from the patient or assent from their next of kin was obtained.

Respiratory parameters were measured using a near patient main stream infrared carbon dioxide sensor and fixed orifice pneumotachograph connected to a respiratory profile monitor (CO₂SMO Plus Respiratory Monitor, Novamatrix Medical systems, Wallingford, CT) and analyzed using computer software (Analysis plus). The capnograph is barometric pressure compensated with an accuracy of ±2 mmHg (for 0-40 mmHg) and ±5% of the reading (for 41-70 mmHg). The pneumotachograph is a disposable device using differential pressure with an overall accuracy of ±2%. This device was calibrated for the specific fraction of inspired helium and oxygen on an individual patient basis according to the manufacturer's instructions. On initialisation the device performs a zero calibration. The accuracy of the infrared carbon dioxide sensor is further verified

by using a calibration device for carbon dioxide. Furthermore a previous study showed the monitoring device remained stable and accurate over a 48 hour period of continuous monitoring.¹¹ Alveolar minute ventilation, respiratory rate and CO₂ production were continuously recorded by the CO₂SMO plus monitor. Representative base line carbon dioxide production in a 70 kg male is 200 ml/min. An average of a 5 minute period of these parameters was recorded before the start of CPAP as a baseline and at 1 and 2 hours during each CPAP period with the study gases. Systolic and diastolic blood pressure and heart rate were recorded directly by means of an indwelling arterial catheter and electrocardiogram (ECG) attached to a bedside monitor. Arterial partial pressure of carbon dioxide and oxygen were obtained over a 2-hour period from arterial blood gas samples.

Patients were randomly assigned to initially breath either Heliox or air-oxygen mixtures. Patients were blinded to the gas

Table 2

	Baseline	Helium/oxygen after 2 hours CPAP	Baseline	Air/oxygen after 2 hours CPAP	Statistical significance
RR, breaths/min	24 +/- 7	25 +/- 5	26 +/- 6	25 +/- 6	NS
PaCO ₂ , kPa	5.2 +/- 1.0	5.2 +/- 1.0	5.4 +/- 1.1	5.4 +/- 1.2	NS
PaO ₂ , kPa	11.3 +/- 2.1	11.2 +/- 1.8	12.7 +/- 2.3	11.7 +/- 2.4	NS
Minute volume	10.2 +/- 2.8	10.8 +/- 2.5	10.6 +/- 2.3	10.2 +/- 2.4	NS
HR, beats/min	89 +/- 14	89 +/- 13	88 +/- 14	91 +/- 14	NS
SBP, mmHg	128 +/- 27	126 +/- 23	126 +/- 23	130 +/- 27	NS
DBP, mmHg	63 +/- 8	62 +/- 10	63 +/- 11	65 +/- 12	NS
Temperature	37 +/- 1	37 +/- 1	37 +/- 1.5	37 +/- 1	NS

Definitions of abbreviations; RR = respiratory rate; HR = heart rate; SBP = systolic blood pressure; DBP = diastolic blood pressure; NS = non significant. Values are means \pm standard deviation

mixture they received. Data was collected directly to a laptop computer and the researcher and study statistician who analyzed the data were blinded to the gas mixtures. Following baseline measurements, patients received 2 hours of CPAP ventilation (PEEP setting remained unchanged and pressure support set to zero) with helium-oxygen or air-oxygen via an eVent ventilator (eVent Medical Inc, Aliso Viejo, CA). This ventilator was calibrated for the helium oxygen mixture on an individual patient basis according to the manufacturer's instructions. Patients were returned to their pre study ventilator settings for 2 hours, before being given the alternative gas mixture for 2 hours.

The level of CPAP support and FiO₂ were unchanged for individual patients throughout the trial period. The study CPAP trial was defined as unsuccessful and discontinued if the patients developed two or more of the following criteria: respiratory rate >40 breaths/min or rapid shallow breathing index (RSBI) >105; SpO₂ <90% or SpO₂ decrease to >8% from the patients baseline value; HR >140 beats/min or HR changes by >20% from the patients baseline; systolic blood pressure >200 mmHg or <80 mmHg or systolic blood pressure changes by >20% of baseline; deterioration in conscious level, defined as a fall in GCS of >2, or if the patient became agitated/sweating/anxious.

The data were tested for normality and a paired t-test was used to test the treatment effect on within-subject differences. A priori the 2-hour time point was used as a summary measure of treatment effect. The data were expressed as means, standard deviations (SD) and 95% confidence intervals (CI). A p-value of <0.05 was considered statistically significant.

Results

Twenty-three patients were recruited into the study. A total of 19 completed the study protocol and their baseline characteristics are displayed in Table 1. Patients were treated with mechanical ventilation for a median 9 days (inter-quartile range, IQR, 6-12

days). The primary underlying condition was neurological in 8 patients, medical in 4 patients, polytrauma in 6 patients with 1 surgical patient. One patient was recruited with an infective exacerbation of COPD.

Four patients did not have evaluable data and were not included in the analysis. One patient became anxious when commenced on CPAP and withdrew consent (helium-oxygen), in 2 patients the respiratory rates exceeded the protocol within 15 minutes of commencing CPAP and were returned to their pre-study ventilatory support (1 helium-oxygen, 1 air-oxygen) and 1 patient was randomised but developed epileptic seizures just prior to starting CPAP and was withdrawn. Fifteen of the patients were studied on an FiO₂ of 0.3 or less, three patients were on an FiO₂ 0.35 and one patient on an FiO₂ of 0.4. Nine patients received helium-oxygen mixture first compared to ten receiving air-oxygen first.

Compared to air-oxygen, helium-oxygen significantly decreased VCO₂ production at the end of the 2 hour period of CPAP ventilation (Figure 1) There was a mean difference in CO₂ production of 48.9 ml/min (95% CI 18.7-79.2 p=0.003) between the groups. There were no significant differences between baseline and 2 hours CPAP with air-oxygen and helium-oxygen in all other respiratory and hemodynamic parameters measured (Table 2).

Discussion

Our study showed a significant reduction in CO₂ production in patients without significant airways disease. This supports the need for a definitive clinical study of Heliox in weaning from mechanical ventilation to be undertaken. We were surprised by the 19% reduction in CO₂ production seen while breathing helium oxygen although this is in keeping with a 21% reduction in work of breathing shown by Diehl et al in their study.¹⁰

Weaning from mechanical ventilation has a major impact on

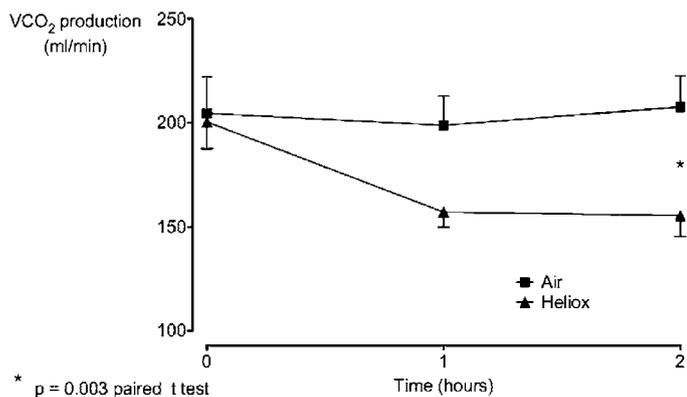


Figure 1

ICU bed occupancy and patient outcome, and has significant cost implications. Strategies to facilitate weaning have a major potential to improve patient outcome and reduce the use of healthcare resources. We demonstrate in this physiological study that patients weaning from mechanical ventilation show a significant reduction in carbon dioxide production when breathing a helium-oxygen mixture. We found that all other respiratory and cardiovascular parameters measured showed no significant changes from baseline values.

In our study we used CO₂ production as a surrogate for the work of breathing. Studies have confirmed that inspiratory muscular work of breathing is proportional to the exhaled volume of CO₂ per minute after allowing a period of time for stabilisation of CO₂.¹²⁻¹⁴ Our findings are consistent with previous studies using helium-oxygen in intubated patients with COPD during controlled ventilation and on pressure support ventilation during the weaning phase of ventilation.^{15,16} These studies have shown a reduction in total, resistive and elastic work of breathing with helium-oxygen mixtures. In spontaneously breathing patients with COPD during a T-piece trial there was a reduction in work of breathing from 1.4 to 1.1 J/L in 13 patients with COPD and a reduction in intrinsic positive end expiratory pressure PEEP_i.¹⁰ Change in flow from turbulent to transitional or laminar by the use of the less dense helium is thought to be a major reason for improvement in gas flow. However, a study by Papamoschou, demonstrated that helium-oxygen does not need to be laminar to improve flow and benefits exist even if flow remains turbulent.⁷ In a study in 18 patients without COPD studied immediately post-extubation, helium-oxygen given for 15 minutes reduced inspiratory effort as measured by transdiaphragmatic pressure changes. A significant subjective improvement in respiratory comfort was also observed. This benefit reversed when patients were returned to air-oxygen.¹⁷ However as patients were already weaned to the point of extubation, no conclusion can be drawn as to whether helium-oxygen improved the weaning phase. A further small study of helium use in infants post-cardiac surgery, during weaning, showed a reduction in CO₂ production and an increase in PaO₂ reflecting a reduction in work of breathing.⁹ Our current study extends these previous data to a group of general adult intensive care unit patients without significant airways disease during the weaning phase of mechanical ventilation. While this physiological study has demonstrated a beneficial but transient effect on CO₂ production with the short-term use of a helium mixture, future studies designed to investigate the effect on duration of weaning would require longer term use of helium mixture.

It is worth noting that helium can interfere with the function of ventilators and in particular, flow measurement devices. It is therefore important that clinicians are aware of the effects helium can have on the equipment they use, and equipment must be compatible with, and calibrated for, use with helium.¹⁸

This study has several limitations. The aim of this physiological study was to measure CO₂ production in patients without documented obstructive airways disease. It is not possible to exclude that a proportion of the patients had unrecognised small airways obstruction. The study is limited by the small number of patients and one patient had a documented history of COPD. Importantly when this patient is removed from the analysis the beneficial effect of helium-oxygen is still significant. In addition, we used CO₂ production as a surrogate for work of breathing. Carbon Dioxide production is one of the indirect calorimetric methods of measuring metabolic rate. Factors other than work of breathing that increase metabolic rate will likely increase CO₂ production. No changes to the physical workload of our patients were made during the study period. Furthermore there was no difference in other measured respiratory and haemodynamic parameters or temperature as shown in Table 2. This indirectly indicates that the change in CO₂ production is likely to indirectly reflect work of breathing. Measurements of trans-oesophageal pressures or pressure-volume loop would have been useful to more directly assess work of breathing but unfortunately these were not available.

In conclusion, our study demonstrated a significant reduction in CO₂ production, as a surrogate measure of work of breathing, in adult patients during the weaning phase of ventilation breathing a helium-oxygen mixture. This provides support for a clinical study powered for duration of weaning as the primary outcome to be undertaken.

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Prediction of Delayed Recovery from Pediatric Community-Acquired Pneumonia

Massimiliano Don, Francesca Valent, Mario Canciani, Matti Korppi

Abstract

Background: If children with community-acquired pneumonia (CAP) do not recover within 48 hours after starting antibiotic therapy, complications are possible and a checkup must be ensured.

Aim of the present study was to evaluate the improvement of pediatric CAP, within 48 hours after starting therapy, in relation to age, etiology, clinical/laboratory characteristics and selected antibiotics.

Methods: Ninety-four children were treated for radiologically confirmed CAP, 64 by oral amoxicillin, 23 by intravenous ampicillin and 7 by other antibiotics. The etiology of CAP was studied by serology, data on more than 20 clinical characteristics were collected retrospectively, and antibiotics were selected on clinical grounds.

Results: After starting of antibiotics, the mean duration of fever was higher in children ≥ 5 than < 2 or 2-4 years of age ($p=0.003$). Fever continued > 48 hours in 4 (4.3%) children and 2 additional children had empyema. Clinical, radiological and laboratory characteristics and serological findings were not significantly associated with the duration of fever. Fever continued > 24 hours in 1 (4.8%) child treated with ampicillin and in 2 (8%) inpatients compared with 19 (28.8%) children treated with amoxicillin ($p=0.007$) and 23 (33%) outpatients ($p=0.0012$), respectively.

Conclusions: Respiratory rate and erythrocyte sedimentation rates were associated with rapid decrease of fever. Anyway, none of the reported characteristics was able to predict treatment failures or delayed fever decrease in children suffering from CAP.

Background

Streptococcus pneumoniae is the most common bacterial agent in pediatric community-acquired pneumonia (CAP) at any age, while *Mycoplasma pneumoniae* is more common

among patients over 5 years of age.¹ The majority, over 90%, of basically healthy, western children with CAP clinically improve with disappearance of fever and reduction of breathing work within 48 hours after the onset of antibiotics, with no significant differences between beta-lactams and macrolides as first-line antibiotics.²⁻⁴ In recent years, pneumococcal macrolide resistance has become an emerging problem,¹ and complications such as empyema and even necrotizing pneumonia have become more common than earlier, particularly complicating pneumococcal pneumonia.⁵⁻⁷ Therefore, most international and national guidelines recommend penicillin, amoxicillin or other beta-lactams as first antibiotic choice for all children with CAP at < 5 years of age, and also in older children if clinical signs and symptoms suggest pneumococcal etiology.¹ The "48 hours rule" has been included in most guidelines:⁸ if symptoms and signs of pneumonia have not started to improve within 48 hours after the beginning of antibiotic therapy, the child must be re-evaluated and treatment must be changed if indicated.

We have recently published our results on the etiology of infection (determined by serological means),⁹⁻¹¹ the severity of illness (assessed by serum procalcitonin and need of hospital care)¹² and the value of clinical features¹³ in differentiating between viral, pneumococcal and atypical bacterial infections in 101 children with CAP confirmed by radiology. In the present paper we report the outcome of these children, in relation to age, etiology, clinical characteristics and first-line antibiotics, with special focus on the improvement within 48 hours after starting therapy.

Methods

Study subjects: During a surveillance period of 15 months in 2001-2002, 101 consecutive, previously healthy children with signs and/or symptoms compatible with respiratory infection (fever $\geq 37^\circ\text{C}$, tachypnea, cough and/or findings of crackles, bronchial breathing or silenced sounds on auscultation) and radiological infiltrations consistent with pneumonia were eligible for the study at the Department of Paediatrics, University Hospital of Udine, Italy.⁹⁻¹³ The exclusion criteria were the neonatal age, chronic infectious and non-infectious underlying diseases, wheezing on auscultation and hospital-acquired pneumonia.⁹ The study was approved by the Ethics Committee of the University of Udine, School of Medicine, and an informed oral consent was obtained from the parents of all children. The time between the beginning of antibiotic therapy and the stable disappearance of fever, always accompanied by a substantial clinical improvement, was estimated from the fever curves of

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Table 1 Duration of fever in 94 children with community-acquired pneumonia, in relation to fever and other clinical signs/symptoms on admission, findings in physical and radiological examination and four serum non-specific inflammatory markers

	< 12 hours (N = 27)	12-24 hours (N = 42)	> 24 hours (N = 25)	p-value
Fever (°C)	38.6 ± 1.3	38.7 ± 0.9	38.6 ± 0.9	0.86 §
Fever >37,5°C (N = 81)	21 (25.9)	39 (48.2)	21 (25.9)	0.19 #
Fever >39,5°C (N = 16)	7 (43.8)	7 (43.8)	2 (12.5)	0.23 #
Cough (N = 84)	26 (31.0)	36 (42.9)	22 (26.2)	0.39 #
Vomiting (N = 29)	8 (27.6)	12 (41.4)	9 (31.0)	0.81 #
Chest pain (N = 15)	3 (20.0)	8 (53.3)	4 (26.7)	0.72 #
Abdominal pain (N = 23)	6 (26.1)	11 (47.8)	6 (26.1)	0.95 #
Respiratory rate *	40.45 ± 11.7	37.5 ± 14.5	30.1 ± 12.5	0.04 §
Tachypnea † (N = 29)	10 (34.5)	15 (51.7)	4 (13.8)	0.31 #
Crackles ‡ (N = 47)	15 (31.9)	20 (42.6)	12 (25.5)	0.83 #
Dullness (N = 11)	2 (18.2)	7 (63.6)	2 (18.2)	0.37 #
Decreased breath sounds (N = 56)	13 (23.2)	27 (48.2)	17 (30.4)	0.16 #
Alveolar infiltration (N = 58)	18 (31.5)	26 (44.8)	14 (24.1)	0.19 #
Pleural fluid (N = 12)	5 (41.7)	4 (33.3)	3 (25.0)	0.74 #
CRP (mg/L)	146.2 ± 131.9	159.3 ± 118.0	102.1 ± 103.3	0.25 §
PCT (ng/mL)	14.1 ± 19.6	10.5 ± 12.9	5.9 ± 14.9	0.18 §
WBC (cells/ μ L)	20363 ± 9846	18343 ± 9148	15669 ± 6612	0.16 §
ESR (mm/h)	81.9 ± 29.3	68.5 ± 31.6	57.6 ± 33.9	0.03 §

Data are presented as means \pm SD or number (percentage). * Data were missing for 18 children; † by age-specific WHO criteria; ‡ fine and medium-sized inspiratory crackles (or rales) included. CRP: C-reactive protein; PCT: procalcitonin; WBC: white blood cells; ESR: erythrocyte sedimentation rate.

§ Analysis of variance; # Fisher's exact test.

the patient records for inpatients, or by asking the outpatients' parents at the pediatrician's visit or by phone 48-72 hours after the diagnosis. In particular, the body temperature was taken in hospitalized patients by the nurses every six hours a day, while the outpatients' parents were specifically required to take and write the body temperature down, at home, at least twice a day, after a brief training in body temperature measuring received by the nurses at the time of diagnosis. In both in- and out-patients the body temperature was taken on the axillary level, by means of standard mercury thermometers, that were supplied to the outpatients' parents by the investigators. The body temperature data were available in 94/101 (93%) children, and they formed the subjects of the present study: their mean age was 4.7 years (range 0.3-14.7 years).

Etiological studies: Streptococcus pneumoniae etiology of CAP was diagnosed by significant increases of IgG antibodies to pneumococcal pneumolysin or C-polysaccharide between paired sera, using enzyme immunoassay (EIA). Non-capsulated Haemophilus influenzae and Moraxella catarrhalis infections were diagnosed by significant increases of IgG antibodies to whole cell antigens using EIA; all cases were mixed infections with viruses or other bacteria. Mycoplasma pneumoniae etiology was diagnosed by significant increases of antibodies in either complement fixation (CF) or EIA serology. Correspondingly, Chlamydia pneumoniae etiology was diagnosed by EIA and/or by micro immunofluorescence (MIF),⁹ and Simkania negevensis etiology by MIF.¹⁰ Viral involvement by respiratory syncytial virus (RSV), human metapneumovirus (hMPV), influenza A and B virus, parainfluenza 1, 2 and 3 virus, adenovirus and cytomegalovirus was studied by EIA in paired sera.^{9,11}

Laboratory and radiological studies: On admission, C-reactive protein (CRP) and procalcitonin (PCT) were measured in serum samples, white blood cells (WBC) and erythrocyte sedimentation

rates (ESR) in blood samples, as described previously.¹² In 2005, three experienced radiologists interpreted the chest radiographs, and the infiltration was considered as alveolar in 63 cases and as interstitial in 38 cases.¹² Pleural fluid was present in 14 cases.

Clinical definitions: Medical history and clinical characteristics were registered in the hospital records of the patients on admission by the medical doctors on duty. In 2006, one of the authors (MD) collected data on over 20 items from these records using a structured case record form, including age, gender, fever on admission, respiratory rate on admission, preceding and presenting clinical signs and symptoms, and findings on physical examination. "Tachypnoea" was defined by the World Health Organization criteria, that are respiratory rate >60 breaths/minute in children aged <2 months, >50 breaths/minute in children aged 2-12 months and >40 breaths/minute in children aged >12 months.¹⁴ "Length of fever" was defined as the period in which a patient became spontaneously (without the use of antipyretic) and steadily non-feverish: the hours elapsed from the time of CAP diagnosis to the time a body temperature >37°C was last recorded. "Delayed recovery" was defined as the combination of those patients with fever for longer than 48 hours and/or those patients who developed a complication, such as pleural empyema or lung abscess.⁸

Pharmacological choices: According to the policy of the hospital, all children with pneumonia diagnosed by chest radiography were treated with antibiotics, and the preferred drugs were amoxicillin for oral therapy and ampicillin for intravenous therapy. Other antibiotics were chosen by the doctors on duty only by specific indications (cephalosporins in case of penicillin allergy, macrolides in case of high suspicion of atypical etiology). Oral amoxicillin was started for 55 children, oral amoxicillin-clavulanic acid for 4 children, intravenous ampicillin for 21 children, oral cephalosporin (cephalexin) for 2

Table 2 Duration of fever in relation to antibiotic treatment (amoxicillin vs ampicillin) and treatment setting (inpatients vs outpatients)

	Amoxicillin (N = 59)*	Ampicillin (N = 21)	p-value	Inpatients (N = 25)	Outpatients (N = 69)	p-value
Hours (h) of fever	25.2 ± 18.6	13.4 ± 11.3	0.012	15.3 ± 13.6	25.8 ± 20.3	0.0056
<12 h	11 (18.6)	13 (61.9)		14 (56.0)	13 (18.8)	
12-24 h	29 (49.5)	7 (33.3)	<0.0001†	9 (36.0)	33 (47.8)	0.0012§
>24 h	19 (32.2)	1 (4.8)		2 (8.0)	23 (33.3)	

Data are presented as means ± SD or number (percentage).

Amoxicillin was administered orally, ampicillin intravenously.

* Four children with oral amoxicillin-clavulanic acid included.

† Age-adjusted comparison between ampicillin and amoxicillin groups: p = 0.0006; age-looking-setting-adjusted comparison between ampicillin and amoxicillin groups: p = 0.0018.

§ Age-adjusted comparison between inpatient and outpatient groups: p = 0.0058.

children, intravenous cephalosporin (ceftriaxone) for 6 children, and oral macrolides for 4 children. Vancomycin was started in one and quinolones in no case. In both in- and out-patients, the first antibiotic dose was given at the time of diagnosis, making so easy the record of the starting time of such therapy.

Acetaminophen, ibuprofen or ketoprofen were allowed and they were the most commonly prescribed antipyretic and analgesic drugs in case of high fever or pain, such as headache, chest pain, arthralgia, referred abdominal pain.⁸

Statistical analysis: In univariate statistical analyses, Fisher's exact test was used for discrete variables and analysis of variance for continuous variables. In multivariate analyses, adjusted for age, linear regression was used for continuous variables and stratified analyses with Mantel-Haenzel chi square tests for discrete variables.

Results

Forty-eight patients (51%) were enrolled during the winter season, from December to March. Seventeen patients were <24 months old, 41 were 2 to 4 years old and 36 were ≥5 years old. Twenty-five children were treated in hospital, and their mean hospitalization time was 5.0 days (range 3-13 days). Bacterial infection was diagnosed in 45 patients; *S. pneumoniae* was found

in 17, *M. pneumoniae* in 25, *C. pneumoniae* in 8 and *S. negevensis* in 5 cases (9 were dual bacterial infections). Viral infection was diagnosed in 38 children, including 15 RSV cases and 5 hMPV cases; 19 were viral infections alone and 19 were mixed infections with typical or atypical bacteria.

After starting of antibiotics, the mean ±SD duration of fever was 23.0±19.2 hours, being 15.6±13.4 in <2 years, 18.9±14.9 in 2-4 years and 31.2±23.1 hours in ≥5 years old children (p=0.003). Fever decreased in 44 (47%) children within 12 hours, in 25 (27%) between 13-24 hours, in 21 (22%) between 25-48 hours, and in only 4 (4%) children after 48 hours. Fever continued for >24 hours in 10/58 (14.7%) children aged <5 years compared with 15/36 (41.7%) children aged ≥5 years (p=0.0154).

No clinical sign or symptom showed any significant association with the duration of fever (Table 1). The doctors assessed 37 patients as "ill-looking" on admission, 19 (51.4%) of which were treated with parenteral antibiotics, that was used in 9 (15.8%) of the 57 "well-looking" patients. From the 37 "ill-looking" patients, only 2 (5.4%) had fever >24 hours vs 23/57 (40.4%) of "well-looking" children (p=0.001). In both groups, *S. pneumoniae* was found in 19% of the cases. Likewise, no finding in physical or radiological examination associated with the duration of fever, except for respiratory rate that was associated with rapid,

Table 3 Clinical characteristics and outcome of the six children with community-acquired pneumonia and delayed recovery

Findings	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
	On admission					
Age (yrs), gender	10, girls	10, boy	7, boy	8, girl	3, girl	3, girl
Fever (°C)	37.5	39.5	39.2	39.5	37.5	40.3
Looking ill	no	Yes	yes	no	yes	yes
CRP (mg/L)	98	270	292	82	202	426
PCT (ng/mL)	0.20	0.54	33.8	0.40	18.4	33.0
WBC (cells/μL)	8.760	18200	31400	16250	27010	31400
ESR (mm/h)	26	132	70	6	94	95
Pneumonia	interstitial	alveolar	alveolar	interstitial	alveolar	alveolar
Primary antibiotics	macrolide	vancomycin	ampicillin	amoxicillin	ampicillin	ampicillin
	In hospital					
Complications	pleural fluid	lung abscess	no	no	empyema	empyema
Fever >48 hours	yes	yes	yes	yes	no	no
Hospital stay	no	7 days	7 days	no	15 days	15 days
Serology	Mycoplasma	none	pneumococcus	mixed*	mixed†	none‡

* Parainfluenza viral, mycoplasmal and pneumococcal serology positive; † influenza A viral and mycoplasmal serology positive; ‡ Group A hemolytic streptococci grew in pleural fluid.

not with delayed fever abatement (Table 1). Elevated ESR was associated with rapid decrease of fever. A similar tendency was seen also for elevated CRP, PCT and WBC, but the results did not reach statistical significance (Table 1).

Ninety-four patients with adequate data available were classified into 4 microbiological groups. The pneumococcal group consisted of all 18 cases with *S. pneumoniae* etiology (including cases with viral and mycoplasmal co-infection). The atypical bacterial group consisted of 27 cases with *M. pneumoniae*, *C. pneumoniae* or *S. negevensis* etiology (including cases with viral co-infection; pneumococcal co-infections excluded). The viral group consisted of 19 viral cases with no pneumococcal or atypical bacterial co-infections, and the 30 cases with no serological findings formed the group of unknown etiology. The serological classification of CAP had no association with the duration of fever, and the result remained negative also in multivariate adjusted analysis (data not shown). Oral amoxicillin was started for 11 patients (61%) of the pneumococcal group, 16 patients (59%) of the atypical bacterial group and 19 patients (63%) of the viral group.

Intravenous ampicillin was more effective than oral amoxicillin or macrolide (Table 2); fever continued >24 hours in only 1 (4.8%), compared with 19 (28.8%) patients treated with amoxicillin ($p=0.007$) or with those 2 (50.0%) treated with macrolide ($p=0.056$). In multivariate analyses, adjusted for age category, fever lasted in mean 11.1 hours less in children treated with ampicillin, than in those treated with amoxicillin ($p=0.001$). The treatment setting was significantly associated with the duration of fever (Table 2). In hospitalized children the duration of fever was shorter than in outpatients; the difference was significant also in the age-adjusted analyses.

Finally, there were 6 patients with delayed recovery; fever continued >48 hours in four >7-year-old children, and two 3-year-old girls were treated for empyema for >2 weeks in hospital (Table 3). On admission, four of these 6 children were "looking ill", and CRP was >80 mg/L in all cases. The other clinical and laboratory findings varied a lot on admission. When the 2 children with empyema and the only child with lung abscess were excluded from the analyses, the mean duration of antibiotic treatment was 7.4 ± 3.1 days in the 90 children with no severe complication. The mean duration of intravenous treatment with ampicillin was 3.3 ± 1.5 days.

Discussion

The main result of the present study was that children with CAP improved well with the recommended treatment by oral amoxicillin or intravenous ampicillin.^{1,8} However, starting with intravenous ampicillin, in this study for three days in average, seemed to be a more effective practice than starting with oral amoxicillin. Different conclusions were reached by a recent randomized clinical multicentre trial in over 1700 African, Asian or South-American children hospitalized for severe CAP, showing an equivalent effect for oral amoxicillin and parenteral penicillin.¹⁵ However, the cases with fever continuing for >48 hours were rather common (19%) in both groups. Instead, our observations are in line with the experiences from UK and Finland,^{4,6,16} where the treatment is often started with intravenous G-penicillin for an average period of one to three days, and then switched to oral amoxicillin. In these studies, over 90% of the children with CAP improved and were non-feverish within 48 hours, usually between 12 and 24 hours after

the first dose of antibiotics.^{4,6} The most recent equivalence study from UK, however, showed that oral amoxicillin and intravenous penicillin were equally effective in 246 children with CAP.¹⁷ In the present study, all patients improved, and delayed improvement assessed by fever still present at 48 hours was low (<5%). In fact, as many as 75% of the patients were non-feverish as early as 24 hours after starting therapy.

Half of the 6 children with delayed decrease of fever had atypical bacterial etiology of infection, in line with earlier studies.^{18,19} Overall, nearly 30% of the children had serological evidence of atypical bacterial etiology, and they improved well with no treatment with macrolides or quinolones. On the other hand, inappropriate selection of first line antibiotic may be the reason why, in the present study, the mean duration of fever was significantly higher in ≥ 5 years old children with high rates of atypical bacterial etiology and treated with macrolides, doxycycline or quinolones according to most guidelines.^{1,8} However, delayed recovery was in no case due to viral infection, refractory to antibiotics, though viral involvement was demonstrated in >40% of the cases. Empyema needing surgical intervention was diagnosed in two children and pulmonary abscess treated conservatively in one child. Pleural fluid was present in one child with pneumococcal pneumonia, but *S. pneumoniae* was not serologically found in the two children with empyema. Thus, the rate of severe complications (3%) was low, in accordance with recent observations from Finland.⁶ On the other hand, empyema and other complications after childhood pneumonia have been on increase in recent years in many countries.^{5,6} The occurrence of severe complications in children with no underlying illness, although rare, stress the importance to make sure that substantial improvement of pneumonia starts within 48 hours by selected antibiotics.⁸

We were not able to find, on admission, any useful clinical, radiological or laboratory factor in predicting delayed recovery or development of complications or, on the other hand, the recovery at the situation in which the treatment is selected appropriately. If non-beneficial outcomes are rare, as was the case in the present prospective study focusing on a wide severity spectrum of CAP, retrospective case-control studies have more statistical power. In a recent case-control study from Finland, duration of fever before admission, tachypnea on admission and pain on abdominal palpation were significant and independent risk factors in multivariate analyses for empyema in children with presumptive bacterial etiology of pneumonia.⁶ In the present study, abdominal symptoms and tachypnea or dyspnea were common, but not predictive for delayed recovery, assessed by duration of fever. In the Finnish study, prolonged fever and persistence of high serum CRP during hospitalization were associated with the development of empyema.⁶ In line, CRP was elevated in all our 6 CAP patients with delayed recovery.

Pneumococcal penicillin-resistance is rare, about 5%, in North Italy, but pneumococcal macrolide-resistance is as common as 25%; the figures are based on the monitoring of bacterial resistance to antibiotics in clinical samples (>600 samples from the Friuli Venezia Giulia region in 2004-2006). The Prospective Resistant Organism Tracking and Epidemiology for the Ketolide Telithromycin (PROTEKT) study²⁰ showed that about 40% of *S. pneumoniae* display multidrug-resistant phenotypes (resistance to three or more antibiotics), with highly variable prevalence rates observed in different countries; in particular, penicillin non-susceptibility and erythromycin resistance were

35.7% and 36.0%, respectively. Currently, no useful and rapid tests for pneumococcal infection are available for children in clinical practice. Determination of pneumococcal antigens in urine samples has been used in adults, but the tests have not been sufficiently sensitive and specific for clinical use in children with low rate of bacteremic pneumonia and high rate of pneumococcal carriage in nasopharynx.²¹ In addition, mixed viral-pneumococcal infections and mixed mycoplasmal-pneumococcal infections are common, and co-infections with *S. pneumoniae* are difficult to diagnose.²²

In the present paper the diagnosis of pneumonia was radiologically confirmed in all cases, a large microbiological test panel was used, and patients represented the whole spectrum of pediatric CAP. The great diversity of etiologic agents in pediatric CAP makes the identification of risk factors difficult, which may result in one antibiotic (ie ampicillin) appearing more effective than another (ie amoxicillin). For example, children who are treated for pneumonia due to an atypical or viral infection by an ineffective empiric agent such as a beta-lactam, more likely will fail to improve within 48 hours, because of less effective therapy, not because of the agent itself. As described by Marchant et al,²³ this is a major confounder in clinical drug treatment and intervention trials.

Conclusions

In conclusion, respiratory rate and erythrocyte sedimentation rates were associated with rapid decrease of fever, but none of the reported signs, symptoms, radiological or laboratory markers was able to predict delayed recovery or development of complications in children with CAP. According to current recommendations, *S. pneumoniae* should be always covered in the treatment of CAP in children, even in the case of proven viral or atypical bacterial pneumonia, as was done in >95% of the cases of the present study. An intravenous induction of antibiotics seemed to increase the efficacy of therapy, though the patients treated intravenously were selected on clinical grounds, and thus they were more severely ill.⁸

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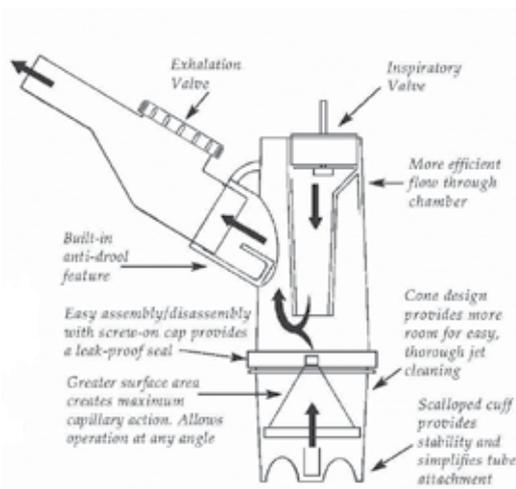


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Assessing Primary Care Physicians' Beliefs and Attitudes of Asthma Exacerbation Treatment and Follow-Up

William Lincourt, Richard H. Stanford, Alicia Gilsenan, Dana DiBenedetti, Hector Ortega

Abstract

Objective: The objective of this survey was to assess adult primary care physicians' and pediatricians' perceptions of asthma exacerbation management, including beliefs concerning the discharge of patients from the emergency department (ED) following asthma exacerbations.

Methods: This was a cross-sectional survey of primary care physicians (PCPs) treating adult or pediatric patients. Surveys were mailed to physicians and included questions on how PCPs define an exacerbation, how they are notified and how they followed-up with their patients who experienced exacerbations.

Results: A total of 189 physicians were targeted in this survey, with 124 (65%) returning a completed survey. The majority of physicians agreed that an exacerbation included worsening asthma requiring a course of oral corticosteroids (83%). However, $\geq 70\%$ of physicians agreed that an exacerbation could also include events which did not require OCS. Overall, 71% of PCPs believed that the majority of their patients' asthma exacerbations were treated in the doctor's office with only 6% believing the majority were treated in the ED. Over 90% of PCPs surveyed said they scheduled a follow-up with their patients "all or most of the time" when notified of an ED visit for an asthma exacerbation. Of the adult PCPs surveyed, 20% said they were never notified when one of their patients received treatment in the hospital because of an asthma exacerbation, whereas only 10% of pediatricians said they were never notified. The majority of PCPs surveyed (79%) indicated that if a controller medication was warranted, the ED staff should initiate treatment at time of discharge.

Conclusions: This study showed that healthcare providers may not share a common definition of an asthma exacerbation. In addition, most physicians believe that the majority of exacerbations are treated in their office or at home. Further, most agreed that if a controller medication was warranted, the ED or urgent care staff should initiate treatment.

Introduction

Asthma exacerbations are often associated with lack of asthma control. They can be severe enough to lead to emergency department (ED) visits or hospital admissions, and even death. Patients who have exacerbations requiring an ED visit, hospitalization, or intensive care unit admission are at greater

risk of exacerbations in the future. In addition, severe asthma exacerbations can occur in patients across the spectrum of disease severity including patients considered to have "mild" asthma. Asthma guidelines indicate that disease awareness education, follow-up care and assessment of appropriate use of long-term controller medications should be priority items in the discharge planning of patients from the ED or hospital. In a study by Singh and colleagues, 31% of patients overall used the ED first when experiencing asthma problems, and 22% reported the ED as their usual source of asthma prescriptions. Even in patients with a PCP, 10% used the ED as their primary provider of asthma medications. Importantly, studies have shown that approximately 70% of patients do not receive controller medications, such as inhaled corticosteroids, on discharge from the ED. The reason for this is not well understood. It may be that ED staff focuses solely on treating the current acute event or physicians assume patients will receive these medications upon follow-up with their PCP. Therefore, we sought to assess adult primary care physician and pediatrician perceptions of asthma exacerbation management, including beliefs concerning the discharge of patients from the ED following asthma exacerbations.

Methods

Study Design: This was a cross-sectional survey of PCPs, conducted from June through August 2008. The final survey was approved by the institutional review board of RTI International.

Study Setting and Population: Physicians from thirty-five adult primary care and 29 pediatric study sites focusing on the delivery of health care that were currently participating in an ongoing observational study were invited to complete the questionnaire. Sites were identified from a proprietary database of more than 2000 US physicians with membership in the Primary Care Network, an organization that provides continuing medical education to its members. Study sites were excluded if they specialized in asthma treatment or had an asthma specialist on staff, or if they had participated in a respiratory-related clinical research study in the previous 3 years.

Study Protocol and Measurements: This survey was administered to physicians as part of the Asthma Control Characteristics and Prevalence Survey Studies. Although physicians from across the country participated in this exacerbation survey it was not the intent to get a geographic representation or random sample of physician responses and we did not stratify results by region or practice dynamics (eg size of practice).

A brief questionnaire was developed by RTI Health Solutions in collaboration GlaxoSmithKline, a maker of inhaled asthma medications, which included questions on how PCPs define

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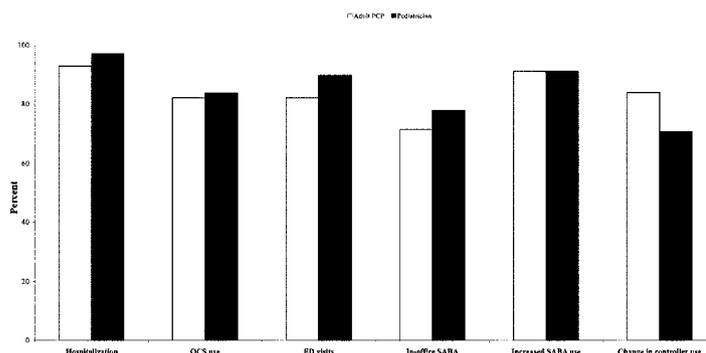


Figure 1. Percent of physicians that agree an asthma exacerbation had occurred when different definitions were provided.

and are informed of their patients' exacerbations, and how they followed-up with patients who experienced exacerbations. Initially, a pilot survey was conducted to cognitively pre-test the questions among physicians (5 PCPs and 5 pediatricians) and to identify any revisions necessary to maximize understanding and ease of completion of the final survey. Based upon feedback from the pilot, modifications were made to the final survey instrument. These changes were minor and included rewording of several questions to increase understanding. The final survey contained a total of 25 questions, 18 of which dealt with issues related to asthma exacerbations and are described in this report. Exacerbations in this survey were identified from a spectrum of options by the physicians such as the need for hospitalization, use of oral corticosteroids, ED visits, increase in rescue medication use; or change in controller medication without a course of oral corticosteroids.

Data Analysis: Descriptive analysis and tables summarizing survey results were produced for the entire sample and also stratified by type of PCP (adult or pediatric). For continuous-type data, the mean, standard deviation, median, minimum, and maximum were generated, whereas counts and percentages were produced for categorical data. Data analysis was performed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

Results

A total of 189 physicians were sent the final survey, with 124 (65%) returning a completed survey. Among the 124 respondents, there were 56 adult primary care physicians and 68 pediatricians. This sample of physicians was geographically dispersed across the US (25% Midwest, 22% Northeast, 25% South, and 28% West).

The majority of physicians agreed that an exacerbation is defined as worsening asthma requiring a course of oral corticosteroids (83%). However, 70% of physicians agreed that an exacerbation could also include events which did not require OCS, but rather, resulted in increased use of rescue albuterol for two or more consecutive days or required an inhaled or nebulized albuterol intervention in the physician's office or prompted the need to change maintenance medications (Fig 1). When asked to rank events most likely to trigger an exacerbation, both adult and pediatric PCPs ranked poor compliance with asthma medication, common cold or flu or allergen exposures the highest. Pediatric PCPs were more likely to rank common cold or flu as the primary trigger while adult PCPs were more likely to rank poor compliance with asthma medication as the primary trigger. When asked about which season Adult PCPs see the most asthma exacerbations, 45% reported winter, 30% reported fall, 23%

reported spring, 0% reported summer, and 5% reported they do not see any seasonal differences. When Pediatricians were asked the same question, 48% reported fall, 39% reported winter, 13% reported spring, 0% reported summer, and 0% reported they do not see any seasonal differences.

Overall, 71% of All PCPs believed that the majority of their patients' asthma exacerbations were treated in the doctor's office. Further, 19% believed treatment usually occurred in the patient's home, 6%, the ED, another 4% in urgent care, and 3% said they did not know. Approximately half of the PCPs (55% of adult PCPs and 43% of pediatricians) said they were notified of their patient's ED visit or hospitalization within a few days of the event, whereas 27% and 49%, respectively, were notified at the time of hospital visit. Only 4% of adult and 10% of pediatric PCPs were notified of an urgent care visit at the time of the event. Approximately 20% of adult and 10% of pediatric PCPs said they are never notified of an ED visit for asthma and became of aware of these events later (Table 1). On the other hand, results show that a large percentage (40%) of adult PCPs said they receive no notification of their patient's visit to an urgent care center for an exacerbation; this percentage is less (29%) for pediatric providers. When adult PCPs and pediatricians were notified that their patient had been treated for an asthma exacerbation in the ED, the majority (91%) required a follow-up visit in the office "all of the time or most of the time." In contrast, only 73% stated that they followed-up through an in-office visit for patients who treated an exacerbation at home. The majority of physicians surveyed (79%) indicated that if a controller medication was warranted, the ED or urgent care staff should initiate treatment at time of discharge.

Discussion

Exacerbations consist of a sustained, often progressive, deterioration in asthma symptoms and airflow obstruction that occurs over hours to days and can last for days to weeks, where additional medications and/or emergency care is often needed. These attacks generally allow time for intervention; however, a few patients have a rapid onset or a severe asthma exacerbation and require immediate medical attention. In this survey most PCPs reported that the majority of their patient's asthma exacerbations were treated in the doctor's office. These findings suggest that the intensity of the exacerbations could have been perceived as not too severe and therefore, required a less aggressive intervention. This could be also a function of the interpretation or definition of an exacerbation. In 2008 the National Health Interview Survey (NHIS) included the following question to their asthma prevalence survey, "During the past 12 month months, have you had an episode of asthma or an

Table 1. How Primary Care Physicians are Notified of ED or Hospital Admissions for Asthma Exacerbations

Method of Information*	Adult PCPs	Pediatricians
Call from the ED	13 (23.2%)	24 (35.3%)
Note, letter, fax or e-mail from the ED	33 (58.9%)	43 (63.2%)
Call from hospital or attending physician	3 (5.4%)	20 (29.4%)
Contact from patient via phone, e-mail or office visit	17 (30.4%)	33 (48.5%)
Do not get notified	11 (19.6%)	7 (10.3%)
Other	0 (0%)	2 (2.9%)

*Sum totals may exceed 100% as respondents were allowed to select all that applied.

asthma attack?" The use of the term "asthma attack" appears to be in recognition of a broader definition of exacerbations that may be less severe but still clinically important. Considering the significant impact these "asthma attacks" have on the patient and the need for a clinical response, perhaps the primary care physician's definition is also appropriate with the modifier of mild or moderate exacerbation. The burden of uncontrolled asthma may be under reported considering that these milder events may not be captured in many epidemiological surveys that track asthma morbidity. Therefore, a broader, common definition of an asthma exacerbation between all health care providers may help the precision for reporting serious episodes of worsening asthma and in turn, increase quality of care for millions of patients with asthma. In addition, patients seen in the sites surveyed may have been more likely not to use the ED for less severe events or for events that occurred during normal office hours.

An interesting difference between responses of adult PCPs and pediatricians was the season when providers observe the greatest number of asthma exacerbations. For adult PCPs, the majority reported winter as being the season when they observe the most exacerbations in their patient population. On the other hand, the majority of pediatricians reported fall as the season when they observe the greatest number. This difference may in fact relate to the start of school in younger asthmatics. PCPs questioned in this survey stated they were usually notified within a few days of an ED visit in the majority of cases, with pediatricians reporting being notified 90% of the time. This number may be an over-estimate since it represents only the events the PCP was made aware of at a later date. Over 90% of PCPs surveyed said they scheduled a follow-up with their patients "all or most of the time" when notified of an ED visit for an asthma exacerbation. Also evident from the data collected was that PCPs are less aware of urgent care visits for asthma than for ED visits or hospitalizations. These results highlight the importance of having consistent communication to allow follow-up with patients in a timely manner and possibly preventing further asthma morbidity.

The majority of physicians surveyed (79%) indicated that, if a controller medication was warranted, the ED or urgent care staff should initiate treatment at time of discharge. National guidelines for the treatment of asthma suggest that sufficient medication be prescribed so that patients may continue treatment until follow-up. Despite the current evidence supporting the role of anti-inflammatory controller agents in the management of chronic asthma, data suggest that few ED physicians prescribe these agents at the time of discharge, perhaps thinking that the patient's primary care physician will address this at follow-up. However, many patients may not see their primary care physician soon enough after an exacerbation, and even when they do, many do not receive inhaled corticosteroids. Also, for many patients with asthma without a PCP, the ED may be their primary source of care. Patients who present to the ED with acute asthma are often under-treated prior to the event, or are non-adherent to their asthma management plan. This was confirmed as most PCPs in our study identified poor medication compliance as a significant trigger for exacerbations. These patients may benefit from a reassessment of their asthma management plan, including starting controller therapy, since it has been found that inhaled corticosteroids initiated at ED discharge were most often continued at follow-up by the primary care physician. Knowing that the majority

of PCPs felt it was acceptable for a controller medication to be initiated in the ED may help remove one of the obstacles and perception associated with prescribing asthma controller medications at discharge. To facilitate continuity of care, ED physicians should also consistently provide summaries of care received and medications prescribed to the patient's PCP.

Limitations: There are some limitations to the present study design and survey methodology. The overall sample was geographically diverse with a response rate of over 60%, however physicians that responded to the survey may not have been fully representative of overall PCP population of the US. Due to the small sample size within each region, we were not able to stratify results by region or practice dynamics (eg size of practice) so it is unknown if any differences exist. Another potential limitation is that the survey was qualitative in nature and written to elicit opinions of the physician based on physician experience and recall. Therefore, further studies would need to be conducted to quantify these findings.

Conclusions

This study showed that healthcare providers may not share a common definition of an asthma exacerbation. In addition, most physicians believe that the majority of exacerbations are treated in their office or at home. Further, most agreed that if a controller medication was warranted, the ED or urgent care staff should initiate treatment.

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Persistent *Chlamydia Pneumoniae* Serology is Related to Decline in Lung Function in Women but Not in Men

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Abstract

Background: *Chlamydia pneumoniae* (C pn) infection causes an acute inflammation in the respiratory system that may become persistent, but little is known about the long-term respiratory effects of C pn infections. Aim: To estimate the long term respiratory effects of C pn with change in forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC) as a main outcome variable.

Methods: The study comprised of 1109 subjects (500 men and 609 women, mean age 28±6 years) that participated in the Reykjavik Heart Study of the Young. Spirometry and blood samples for measurements of IgG antibodies for C pn were done at inclusion and at the end of the follow-up period (mean follow-up time 27±4 years).

Results: Having IgG against C pn at both examinations was significantly associated to a larger decrease in FEV₁ (6 mL/year) and FVC (7 mL/year) in women but not in men. In women the association between C pn and larger FEV₁ decline was only found in women that smoked at baseline where having C pn IgG was associated with 10 mL/year decline compared to smokers without C pn IgG. These results were still significant after adjustment for age, smoking and change in body weight.

Conclusion: Our results indicate that persistent C pn serology is related to increased decline in lung function in women but not in men. This effect was, however, primarily found in smoking women. This study is a further indication that the pathophysiological process leading to lung impairment may differ between men and women.

Background

Chlamydia pneumoniae (C pn) is an intracellular gram-negative pathogen that is detected in 5 to 10% of community-acquired pneumonia and other lower respiratory tract infections.¹

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Most adults are infected at least once during their lifetime, as indicated by seroprevalence of 70 to 80%.² C pn respiratory diseases may manifest as an acute disease or persistent and recurring infection that causes intense chronic inflammation. Growing evidence indicates that inflammation results from cellular responses by non immune cells, including mucosal epithelial and vascular endothelial cells.³ Studies have suggested that C pn may be related to the pathogenesis of wheeze in children,⁴ asthma in adults⁵ and to chronic obstructive pulmonary disease (COPD).⁶ Systemic aspects of COPD include oxidative stress and altered circulating levels of inflammatory mediators and acute-phase proteins. C-reactive protein (CRP) reflects the total systemic burden of inflammation in several disorders and has been shown to up regulate the production of proinflammatory cytokines.⁷ Systemic inflammation is increasingly being recognised as a risk factor for a number of different complications including atherosclerosis, cachexia, anorexia, and osteoporosis, but all of these complications are commonly observed in patients with COPD.⁸ Associations between C pn serology and atherosclerosis⁹ and ischemic heart diseases have been reported, as well as an additive or synergistic effect of other persistent infections on atherosclerosis.¹⁰ These cardiovascular associations with persistent infections may be highly relevant in COPD since ischemic heart disease and stroke are the leading causes of mortality among patients with COPD.⁸

Several studies have reported gender differences in the association between risk factors and pulmonary diseases. In one study of young children a positive serology for C pn was related to wheeze in girls but not in boys.⁴ Other studies have shown gender differences in the association between various other risk factors and changes in lung function such as smoking¹¹ and CRP.¹² Most previous studies on the association of C pn and respiratory diseases have been performed on patient samples from different clinical settings, but large population-based longitudinal studies are lacking. No studies are available on the association between C pn serology and long term changes in lung function. The primary aim of the present research was to study the association between C pn serology and changes in lung function in a longitudinal population study with particular focus on gender differences.

Methods

The Reykjavik Study of the Young: The Reykjavik Study of the Young was conducted in 3 stages between 1973 and 2003 and recruited 2147 participants aged 25-62 years. Stages 1,2 and 3 took part in the years: 1 (1973-1974); 2 (1983-1985); 3 (2001-2003).

Table 1 Characteristics of the participants (% and mean ± SD)

	Men (n = 500)	Women (n = 609)	p-value	All (n = 1109)
Age at baseline	27.9 ± 5.7	27.4 ± 5.4	0.15	27.6 ± 5.6
Smoking history (%)			< 0.0001	
never	41.8	41.5		41.7
ex	23.6	14.1		18.4
current	34.6	44.3		40.0
Pack years between surveys in current smokers	14.7 ± 13.1	17.0 ± 12.5	0.04	15.8 ± 12.9
BMI kg/m ²	23.2 ± 2.8	22.0 ± 3.1	< 0.0001	22.5 ± 3.0
Change in BMI over 10 yrs.	1.5 ± 1.2	1.9 ± 1.3	< 0.0001	1.7 ± 1.3

The present research is based on a subset of the Reykjavik Study of the Young which consisted of a random sample of individuals born in 1940 through 1954 who were living in the greater Reykjavik in 1973. The aim of the study was to compare younger generations to the older ones who were being investigated in the Reykjavik Study^{12,13}

The present study focuses on the pulmonary part of the database, the methodology of which has been described separately.¹³ Only subjects who had participated both at baseline (either stage 1 or 2) and follow-up (stage 3) were included in the present analysis. In addition two serum samples and acceptable pulmonary testing were needed. Altogether 1109 came for the follow-up study in 2001-2003, of whom 962 had come for the first stage in 1973-74 and 147 in 1983-85. The lung function tests included measurements of forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC).

Smoking status was recorded at each survey. Participants were divided into never smokers at baseline, current or ex-smokers, and the number of pack years was calculated. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters.

Serologic methods: IgG antibodies against Chlamydia pneumoniae (C pn) were measured using reagents from the Immuno Biological Laboratories, Hamburg, Germany. Serum samples that gave indefinite results in antibody measurements were classified as seronegative.

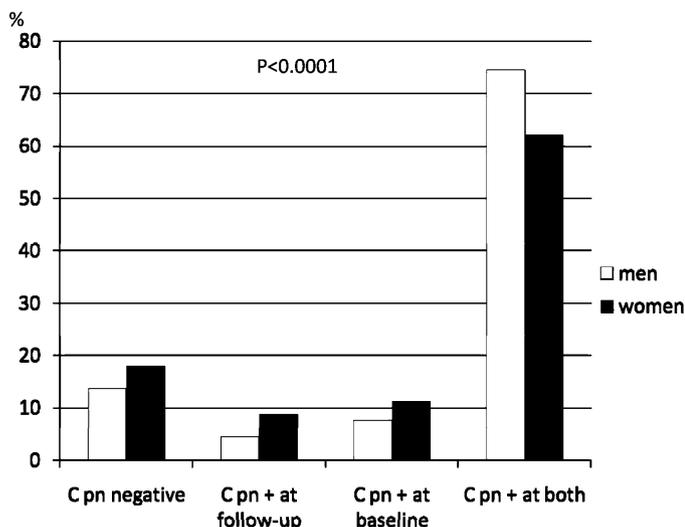


Figure 1. Proportion men and women divided after Chlamydia pneumoniae (C pn) serology at baseline and follow-up.

Statistics: Statistical analyses were performed using STATA 9 software (Stata Corp, Texas). The Chi² test and unpaired t test were used to compare characteristics between men and women. Multiple linear regression was used to analyse the association between lung function and C pn IgG status. A p-value < 0.05 was considered as statistically significant. In these regression analyses change in FEV₁ and FVC from baseline to follow up (mL/year) was used as the dependent variable. The analyses were stratified by sex and the following independent variables were included: age (mean age between the surveys), age², height, BMI, change in BMI and pack years between the surveys.

Results

The characteristics of the study population are presented in Table 1. Women were more likely to be smokers at baseline and had a higher smoking exposure during the follow-up. Women were leaner at baseline but had a larger increase in BMI during the follow-up period. Men were more likely to have IgG antibodies against C pn at both surveys (Figure 1).

C pn serology and change in lung function: Women with C pn positive C pn serology at both examinations had a larger decline in FEV₁ and FVC than women with negative C pn serology, while no corresponding association was found in men. Women that developed positive C pn serology during the follow-up had a significantly larger decline in FVC, whereas the corresponding association to FEV₁ was of border-line significance (p = 0.06) (Table 2). Decline in lung function was associated with an increase in BMI and smoking in both men and women, while a higher baseline BMI was associated with a greater decline in FVC but not in FEV₁.

Interactions: The sex difference in association between change in lung function and C pn serology was statistically significant for FEV₁ (p_{interaction} = 0.04) and almost significant for FVC (p_{interaction} = 0.08). A significant interaction was found between women that were non-smokers and smokers at baseline (p_{interaction} = 0.02). Women that were smokers had a significantly larger decline in lung function if they had a positive C pn serology at the second or at both examinations (Figure 2). No such corresponding interaction was found for men (Figure 3). No interactions were found concerning the association between C pn and FVC. No interactions were found for BMI or birth cohort concerning the association between C pn and change in lung function.

Discussion

The main result of the study was that C pn infections were associated with increased lung function decline. This finding was, however, only seen in women. This study thereby provides further evidence of sex differences in the mechanisms related to decline in lung function. Our study also indicates that C pn may

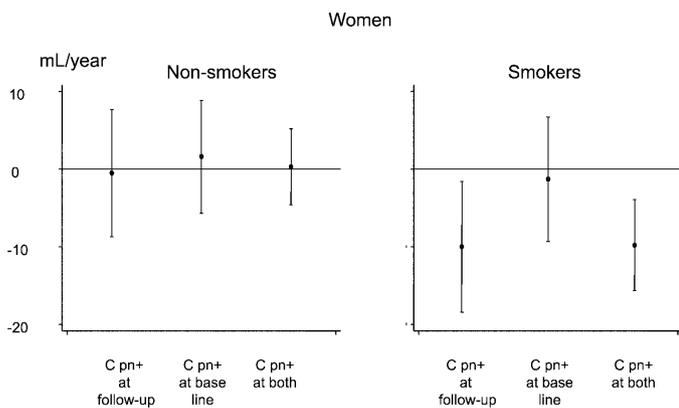


Figure 2. Association between Chlamydia pneumoniae (C pn) serology and change in FEV1 (mL/year) in women that are non-smokers or current smokers. The estimates are adjusted for age, height, smoking (pack years), BMI and change in BMI. Participants that were C pn negative at both surveys are the reference group in each smoking status group.

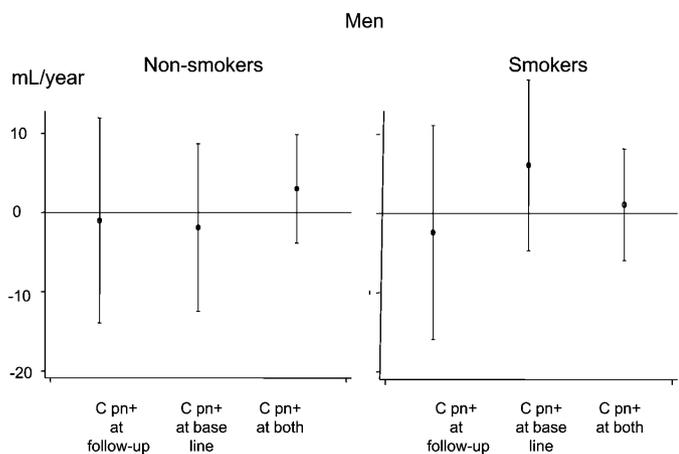


Figure 3. Association between Chlamydia pneumoniae (C pn) serology and change in FEV1 (mL/year) in men that are non-smokers or current smokers. The estimates are adjusted for age, height, smoking (pack years), BMI and change in BMI. Participants that were C pn negative at both surveys are the reference group in each smoking status group.

enhance the lung damaging effect of smoking in women.

The main strength of our study is that it is a population-based longitudinal study with a follow-up of 27 years. A potential weakness is that IgG antibodies measured by ELISA were used as the only indicator of persistent infection with C pn. Previous studies have shown that high levels of IgG antibodies to C pn measured by ELISA do not persist for half a decade after seroconversion without reinfection or reactivation.¹⁴ In young military recruits IgG antibody levels measured by microimmunofluorescence test decrease rapidly after the infection.¹⁵ The microimmunofluorescence test is however not suitable for seroepidemiological studies. Two studies have demonstrated that the ELISA test has comparable sensitivity and specificity to the microimmunofluorescence technique.^{14,16} Another possible weakness is that our study population was not assessed by post-bronchodilator lung function testing and we can not know how much of the decline in FEV1 was due to reversible (asthma) or irreversible airflow obstruction (COPD). The widespread use of postbronchodilator spirometry is mostly

confined to the twenty-first century. The long follow-up time of our study population is, however, unique.

The finding that C pn infections are more strongly related to lung impairment in women than in men fit surprisingly well with data from children where an association between wheeze and C pn IgG was stronger in girls than in boys.⁴ There are several reports on gender differences in the association between wheezing and asthma irrespective of C pn or other infections. The predominant trend reported is a greater incidence of wheezing and asthma in boys with a reversal between ages 10-20 when the incidence becomes greater in females.¹⁷⁻²² Girls are reported to be more vulnerable than boys to the impact of smoking and overweight on respiratory symptoms and lung function.²³ In contrast to the findings in children, Chinn et al found that weight gain had a larger effect in men than in women.¹¹ A stronger association between systemic inflammation and lung function decline in men than in women has also been reported in several studies.^{12,24,25} Several mechanisms have been suggested to explain these gender differences. The sexes may develop their airway disease based on different sex related genetics²⁶ or on different immunological time scales.²⁷ Female sex hormones may also be part of the explanation for the gender difference as there is increasing evidence that sex hormones play a role in lung function development and decline. For an instance, it has been recently reported that girls with an early menarche have lower lung function as adults.²⁸

There are reports on a positive association of C pn and IgA and IgG serology and COPD^{29,30} but negative associations have also been reported.³¹ A causal association between C pn and COPD has, therefore, not been proven and possible mechanisms are not clear.³² In a recent experimental study an intranasal inoculation with C. pneumoniae on day 0 was from day 7 associated with both sustained bronchial hyper-responsiveness and airway inflammation in mice.³³ An association between bronchial hyperresponsiveness and IgA antibodies against C pn has also been found in Swedish population study.³⁴ Acute in vitro experiments of human lung tissue with C pn suggest that C pn plays different roles during acute and chronic stages of pulmonary infection.³⁵

If persistent C pn infections play a significant role in the pathogenesis of asthma, COPD and lung function decline, this opens the therapeutic possibility of useful antibiotic treatment. The data supporting antibiotic therapy are limited, however, as shown in a Cochrane review of macrolide usage in treatment of chronic asthma³⁶ and further long term studies are needed to confirm the possible role of persistent infections in the decline in lung function.

Conclusion

In conclusion, our results indicate that persistent C pn serology is related to increased decline in lung function in women but not in men. This effect was, however, primarily found in smoking women. This study is a further indication that the pathophysiological process leading to lung impairment may differ between men and women.

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Predictors of Pneumococcal Vaccination Among Older Adults with Pneumonia

Paul Krueger, Oona St. Amant, Mark Loeb

Abstract

Background: The incidence of community-acquired pneumonia (CAP) almost triples for older adults aged 65 years or older. In Canada, CAP is a leading cause of hospital admissions and mortality. Although CAP is very prevalent, complications due to CAP may be reduced with the pneumococcal polysaccharide vaccine (PPV). The purpose of this study was to identify predictors of pneumococcal vaccination among community-dwelling older adults with clinically diagnosed CAP.

Methods: A telephone survey was used to collect detailed information from adults aged 60 years and older with clinically diagnosed CAP. This was a community wide study with participants being recruited from all radiology clinics in one Ontario community.

Results: The most important predictors of pneumococcal vaccination among older adults included: getting an influenza vaccine within the past year (OR 14.5, 95% CI 4.27 to 49.0); at least weekly contact with a friend (OR 3.97, 95% CI 1.71 to 9.24); having one or more co-morbidities/chronic conditions (OR 3.64, 95% CI 1.60 to 8.28); being 70 years of age or older (OR 2.56, 95% CI 1.21 to 5.40); having health problems that limited physical activities (OR 5.37, 95% CI 1.49 to 19.3); having little or no bodily pain (OR 2.90, 95% CI 1.25 to 6.73); and reporting having spiritual values or religious faith (OR 3.47, 95% CI 1.03 to 11.67).

Conclusions: A wide range of factors, including demographic, co-morbidity, quality of life, social support and lifestyle were found to be associated with pneumococcal vaccination status among older adults with clinically diagnosed CAP. The findings from this study could inform future pneumococcal immunization

strategies by identifying individuals who are least likely to receive the PPV.

Background

Community-acquired pneumonia (CAP) refers to pneumonia acquired outside of hospitals or extended-care facilities. In Canada, CAP poses a considerable threat to the health of older adults and the incidence of CAP almost triples among those aged 65 years or older. With the pending demographic influx of seniors, the prevalence of CAP is expected to substantially increase, resulting in a greater burden for older adults, their caregivers and the health care system. CAP is a leading cause of hospital admissions and mortality in Canada and with increasing age, there is a corresponding increase in morbidity and loss of independence for older adults. Furthermore, case fatality rates of pneumonia with invasive pneumococcal disease increase sharply from 20% (for person 65 years or older) to 40% (for persons 85 years or older). Seniors with cardiopulmonary disease, poor functional status (such as limitations with activities of daily living), weight loss or recent changes in weight are at increased risk for CAP.

The most common causative pathogen worldwide of CAP is *Streptococcus Pneumoniae*, accounting for approximately 30-50% of all cases. The pneumococcal polysaccharide vaccine (PPV-23) immunizes against 23 strains of the pneumococcus bacteria. PPV is 50-80% effective in the prevention of invasive pneumococcal disease among immunocompetent patients. While the efficacy of the pneumococcal vaccine in preventing pneumonia remains inconclusive, there is evidence that administration of the vaccine can play a critical role in reducing the severity of the disease among older adults. Despite recommendations for uptake of PPV in seniors and a target goal of 80% immunization rate among adults aged 65 years or older by the year 2010 in Canada, immunization rates remain low with only 42% of Canadians over 65 years of age reported being vaccinated. In order to further understand PPV uptake in Canada, where the vaccine is publicly funded, we explored the predictors for pneumococcal vaccination among communitydwelling older adults with clinically diagnosed CAP.

Methods

The Community Acquired Pneumonia Impact Study (CAPIS) was a mixed methods, communitybased study designed to assess the impact of CAP on older adults and their family caregivers. This manuscript reports the findings from the quantitative data, specifically focusing on predictors of pneumococcal vaccination

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among older adults having a clinical diagnosis of CAP. Other qualitative and quantitative findings are reported elsewhere.

Setting: This study was conducted in Brant County, Ontario, a mix of urban and rural settings which includes the city of Brantford and the amalgamated County of Brant (comprised of eight towns and villages). The population of Brant County at the time of data collection was 118,485 with 14% of the population aged 65 years and older. Brant County was selected for this communitybased study because of its moderate size and population demographics. The population of Brant County is predominantly English-speaking, with 86% reporting English as a first language. There were two major community hospitals, eight radiology centers and approximately 80 family physicians at the time of the study.

Recruitment: Study participants were recruited over a 15 month period at the eight x-ray facilities in Brant County. Eligibility criteria included being clinically diagnosed with CAP by a family or emergency room physician, being 60 years of age or older, living in the community (Brant County), presenting for a chest x-ray at one of the community or hospital radiology centres, speaking English, and obtaining informed consent. Exclusion criteria included: cognitive impairment and having hospital or nursing home acquired pneumonia. In order to preserve the health of the participants and prevent participant-burden, x-ray technicians were trained to recruit participants at the time of their x-ray and a trained interviewer telephoned the participants four weeks later. Ethics approval was obtained from McMaster University and the Brant Community Health Care System.

Data Collection: The interviewer collected detailed information including: demographic characteristics (gender, age, marital status, living arrangements (ie number, ages and relationships of people living in the household; owning or renting; type of dwelling), cultural background (ie the ethnic or cultural group most identified as representing their heritage), level of education (categories from none to a university graduate degree), household income (total household income before taxes and deductions in \$20k increments), perceived level of social status (as measured by the MacArthur Scale of Subjective Social Status), employment history (whether currently employed; main occupation when employed); co-morbidities (eg allergies, asthma, chronic bronchitis, diabetes, emphysema, heart disease, cancer and liver disease); lifestyle (eg immunizations (if ever received the influenza and pneumonia vaccines; and the timing either <1 year ago; 1 to 2 years ago; more than 2 years ago), having a family physician, smoking status, exposure to second hand smoke, alcohol consumption (ever in the past 12 months), ownership of pets, nutrition (frequency skipping meals, number of servings of fruits, vegetables, milk products, meal replacements/supplements; difficulty chewing or swallowing; self perceived appetite), spiritual values (rating of how much spiritual values or religious faith plays a role in their life), overall happiness (rating from very unhappy to very happy); quality of life (using the Short-Form-8 Health Survey (SF-8) to collect information on overall health, activity limitation because of health problems, difficulty doing usual daily activities because of physical health, amount of bodily pain, level of energy, limitations of social activities and activities due to personal or emotional problems); functional status (measured using the 10-item Modified Barthel Index which includes grooming, dressing, feeding oneself, transferring from one's bed to a chair, bathing, toilet use, bladder control, bowel control, mobility, climbing

stairs); instrumental activities of daily living scale (measured using the 8-item Instrumental Activities of Daily Living Scale developed Lawton which includes items on meal preparation, mobility beyond short distances, shopping, phone calling, doing laundry, doing household work or handymen work, taking one's medication and money managing); and social support (numbers and types of family relatives, friends, distance to these contacts, frequency of contact, involvement in social and religious networks). Data collection ended March 2004.

Data Analysis: The dependent variable was self reported pneumococcal vaccination status prior to receiving a clinical diagnosis of CAP. The dichotomous outcome variable was created based on participant responses, namely, "ever vaccinated" and "never vaccinated". Based on the literature and clinical experience, two investigators (PK and ML) reviewed the questionnaire for potential predictors to include in the analysis. The potential predictor variables included the above listed demographic characteristics, co-morbidities, lifestyle, quality of life, functional status, instrumental activities of daily living, and social support variables. Data from the telephone interviews were entered into and analyzed using SPSS 17.0 (SPSS Inc, Chicago IL). Descriptive statistics were computed for all variables, including frequency counts, and percentages for categorical variables, or means and standard deviations for continuous variables. For categorical variables, we used the chi-squared test, or when appropriate, Fisher's exact test to determine the significance of potential predictor variables. In addition, unadjusted odd ratios (ORs) and 95% confidence intervals (CIs) are reported for each potential predictor of pneumococcal vaccination. T-tests were used to compare continuous variables between the vaccinated and non-vaccinated patients. A logistic regression analysis was used to identify the best predictors of pneumococcal vaccination status from those variables which had a statistically significant association in the above bivariate analyses or were considered by the investigators to be theoretically significant. A forward selection process was used whereby non-significant variables were removed from the model one at a time. The parameter estimates were reviewed at each step to assess whether the eliminated variable should be kept in the model to control for confounding. Adjusted ORs and corresponding 95% CIs are reported for each variable in the final logistic regression model. The goodness of fit of the logistic regression model was assessed using rho-square statistic. A rho-square value between 0.20 and 0.40 suggests a very good fit of the model. The Cox and Snell (R²) and Nagelkerke (R²) statistics are also reported as estimates of the proportion of variance explained by the final model. A probability level of <0.05 was used to determine statistical significance.

Results

Sample Characteristics: Forty-four potentially eligible patients refused consent to participate and therefore no information was available for these individuals. Of those who initially agreed to participate, 86% completed the telephone interview. The reason for declining was that the patients simply did not want to participate. Of the 195 participants, 95 had x-ray confirmed CAP, and 185 reported on their pneumococcal vaccination status. Among these participants: 62% were female; 66% were aged 70 years or older (mean 72.7 years, standard deviation 6.7); 62% were married or commonlaw; 71% lived with others; 76% owned their homes; 54% completed high school; 68% earned a household income of \$20,000 or more; and 94% had children.

Bivariate Analysis: A total of 58 variables were identified a priori from the telephone interview data as potential predictors of pneumococcal vaccination status. Of these 58 variables, 19 were included in the logistic regression analysis based on either their statistical or theoretical significance (Table 1).

Multivariable Analysis: The 19 variables shown in Table 1 were entered into a logistic regression analysis. The final logistic regression model included seven variables (Table 2): getting an influenza vaccine within the past year (OR 14.5, 95% CI 4.27 to 49.0); at least weekly contact with a friend (OR 3.97, 95% CI 1.71 to 9.24); having one or more co-morbidities/chronic conditions (OR 3.64, 95% CI 1.60 to 8.28); being 70 years of age or older (OR 2.56, 95% CI 1.21 to 5.40); having health problems that limited physical activities (OR 5.37, 95% CI 1.49 to 19.3); having little or no bodily pain (OR 2.90, 95% CI 1.25 to 6.73); and reporting having spiritual values or religious faith (OR 3.47, 95% CI 1.03 to 11.67). The final logistic regression model statistics are reported in Table 2.

Discussion

From our dataset, we identified seven important predictors of pneumococcal vaccination. Those who reported getting an influenza vaccine within the past year were more likely to report having received the pneumococcal vaccine than those who had not. Our results differ from those of Al-Sukhni et al who did not find a statistically significant association between regular annual receipt of the influenza vaccine and the likelihood of pneumococcal vaccination (OR 0.90; 95% CI 0.45-1.79; p-value=0.75). The authors, however, reported that most participants (59%, 92/156) reported receiving the PPV at the same time as the influenza vaccine. The timing of the vaccine (and therefore the opportunity to receive PPV) may be related to the influenza vaccine as a predictor for pneumococcal vaccination. Older adults who reported chatting or doing something with a friend at least once/week were more likely to report having received the pneumococcal vaccine. This finding is in keeping with what may be reasonably expected. A study by Madhavan et al. assessed predictors of influenza and pneumonia vaccination among rural senior adults in the United Kingdom. The authors found that knowing someone with pneumonia was the strongest predictor for the pneumonia vaccination in rural senior adults (p=0.007). Older adults tend to talk about their health and a discussion about influenza and or pneumonia could prompt them to make an immunization appointment with their family physician.

Older adults with one or more co-morbidities were also more likely to report having received the pneumococcal vaccine. A likely explanation for co-morbidities as a predictor for pneumococcal vaccination is that persons with chronic conditions are more likely to access health care services more frequently, allowing for more opportunities to engage with health care practitioners. The evidence related to the role of practitioners and pneumococcal vaccination rates, however, is conflicting. Stehr-Green et al. identified a recommendation by a health care provider as the most important predictor of PPV immunization among older adults. In a study based in the same region as this study (Brantford, Ontario) Krueger et al. found that over half of family and ER physicians surveyed reported CAP to be a very important health concern for their practices.

In contrast, however, a study examining the impact of public vaccination programs in Ontario found that more than 90% of

unvaccinated respondents reported seeing a physician at least once in the previous year, indicating a missed opportunity for vaccination. The authors suggest that this missed opportunity may be related to physicians' on-going uncertainty about the effectiveness of the vaccine.

Older study participants were more likely to report having received the pneumococcal vaccine. This finding is also in keeping with what may be reasonably expected. Since the highest incidence of pneumonia occurs among people >85 years of age (81 cases per 100,000) in Canada, it is more likely that these older patients would be targeted for immunizations by family physicians. Similarly, older adults who identified that their health problems (prior to their bout of pneumonia) limited their usual activities a lot, or prevented them from doing physical activities, were more likely to report having received the pneumococcal vaccine. Again, this could be due to a greater likelihood or frequency of contact with their family physicians.

The finding that older adults with mild to no bodily pain are more likely to have received the pneumococcal vaccine than those with more severe pain may be related to their ability to access health care services. Although few studies have examined the relationship between bodily pain and vaccination status, a study by Groenwold et al. identified bodily pain as a potential unmeasured confounder for immunizations, specifically using the influenza vaccine as an example. The authors found bodily pain to be inversely related to vaccination status. Further research is needed to understand the relationship between bodily pain and the likelihood of immunization. Although somewhat speculative, those with less pain may have less difficulty accessing their family physician or immunization clinic. The finding that older adults who reported having spiritual values or religious faith was an important predictor of pneumococcal vaccination is interesting. Again, although speculative, this finding could be related to social networking. Those who go to church or attend religious outings may be advised to get their immunizations to avoid illness, or have greater opportunity for talking about immunizations than those who do not have this type of social networking. While the relationship between spiritual values and/or religion and vaccination status has not been explored in-depth in the literature, some studies have demonstrated a positive relationship between religion and health promoting behaviors such as healthy eating habit.

Strengths of this study include it being a community-based study that attempted to recruit all older adults who were sent for a chest x-ray to confirm/rule out CAP. In addition, we had a comprehensive data set that allowed us to explore the association between a wide range of demographic, health, lifestyle, quality of life, functional status, and social support variables and whether or not community dwelling older adults received the pneumococcal vaccine. There are several potential limitations of this study. The first is that we only recruited older adults who went for chest x-rays. We therefore missed those who were treated for CAP by their physicians but were not sent for chest x-rays or who were sent but did not go. Self-reported immunization status is another potential limitation. The literature would suggest that the sensitivity of self reported pneumococcal vaccination status is very good but there is more variability with reported specificity. However, one potential reason for the variability in specificity is the validity of the source of the comparison data (ie medical charts). This is particularly important in Ontario where a relatively high

percentage of the population are without a family physician and where older adults have easy access to community immunization clinics outside family physician practices (notices regarding immunization would not be sent to family physicians). The inaccuracy of using medical charts could therefore account for some of the variability in specificity noted in the literature. Sample size was also a limitation of this study, resulting in large confidence intervals. Given the large number of potential predictor variables and the relatively small sample size, another limitation is the chance for Type I error. In defense of this, however, we restricted our analyses to only include meaningful variables that were chosen a priori and our multivariate modeling fulfilled the requirement (1 variable for 10 outcome events) for having reliable parameter estimates. Since this study was done in only one relatively homogeneous community, the generalizability of the findings is another potential limitation. Although we expect the accuracy of the information collected from study participants to be very good, based on the use of reliable and valid instruments, some degree of random error should be expected in studies that collect self reported data retrospectively. However, we don't suspect that recall bias is a weakness of this study. And finally, our definition of CAP was clinically diagnosed CAP versus x-ray confirmed CAP. The decision to use clinically diagnosed CAP versus x-ray confirmed CAP was based on there being no important differences in the characteristics or outcomes of those clinically diagnosed versus those with a positive chest x-ray; the fact that a large percentage of physicians do not send their patients for chest x-rays; and to increase the sample size for this analysis.

Conclusions

In conclusion, this study identified a wide range of factors, including demographic (age), comorbidity (having at least one health condition; amount of bodily pain), quality of life (the extent that health problems limited usual activities), social support (frequency chatting or doing something with a friend) and lifestyle (recent influenza immunization; and the amount that spiritual values or religious faith played a role in life) to be associated with pneumococcal vaccination status among older adults with clinically diagnosed CAP. CAP is a relatively common infection among community-dwelling elderly. Although there are identified comorbidity risk factors for CAP, such as chronic lung disease, one of the most important is age with the "older" elderly being at highest risk. Because the risk of invasive pneumococcal disease increases in this group, for which there is excellent evidence that the vaccine is effective, from a health policy perspective this is indeed the group that should be targeted for pneumococcal immunization. The findings of this study, by helping to delineate the likelihood of receiving the vaccine, identify factors that need to be considered when targeting vaccine to the "low-uptake" elderly. Therefore, the findings from this study could inform future pneumococcal immunization strategies in Canada by identifying those individuals who are least likely to receive the PPV.

Dräger...continued from page 13

to help improve patient outcomes gives us greater insight and inspiration to advance technology beyond today and into the future.

Discuss the educational services you offer for RTs and ancillary specialties.

Dräger's dedicated team of ventilation sales executives and clinical applications staff, many of whom are RRTs, are working closely with customers to realize the current trends in respiratory care. This team provides on-site education as well as regional seminars that are open to all. Dräger has also created a clinical workbook series that focuses on non-invasive ventilation, modes of ventilation, protective lung ventilation, and spontaneous breathing. Additionally, Dräger continues to work cooperatively with Intensive Care On-Line Network (ICON) where customers have access to online education, monthly webinars, and other clinical references 24 hours a day, 7 days a week, 365 days a year. Dräger recently extended the service coverage with ICON to provide state-of-the-art support services to all its ventilation customers. This enhanced clinical support gives clinicians the freedom to access information and continuing education at their convenience and provides the department manager an online tool to view staff's educational progress.

What new technology do you see as having the greatest impact in the near future?

Hospitals are faced with added complexity in patient care, higher demands for staffing, and increased cost pressures. Through innovation and technology, Dräger is helping its customers to achieve more with less. Technologies to improve ICU throughput, increase patient safety, and having clinical data easily accessible will become the standard and expected to continually evolve.

AARC PREVIEW

Aerogen

Booth 510

What new products will you be presenting?

We at Aerogen are very excited to be exhibiting our new **Continuous Nebulization Tube Set** at AARC this year. The continuous nebulization tube set is an accessory to the Aeronex Solo nebulizer system and is intended to ensure safe continuous infusion of liquid medication for aerosolization into the Aeronex Solo nebulizer, while reducing the risk of a potential misconnection of a feed-line from another source.

Why is this product of particular current importance?

The potential for Luer ended tubing mis-connection is very topical and has been identified as a significant patient risk factor by the FDA. As Luer connectors are generic, easy-to-use and compatible between different delivery systems, care-givers can inadvertently connect wrong systems, causing medication or other fluids to be delivered through the wrong route. Aerogen's continuous tube set accessory has been designed to incorporate non-standard, over-sized Luer connectors, ensuring that the risk of misconnection with standard Luer connectors 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. Aerogen is the first company to address the potential of mis-connection to a nebulizer during continuous nebulization. Aerogen is committed to patient safety and is constantly working on product improvement for the benefit of both the respiratory therapist and the patient.

Why should AARC participants visit your display?

RTs should stop by our booth (#510) to receive a demonstration of our unique continuous tube set system. Aerogen provides the most technically advanced nebulizers on the market today with the Aeronex Solo and Aeronex 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.

B&B Medical Technologies

Booth 641

What products will you be featuring, and why?

B&B Medical Technologies will be showcasing our new **Babi.Plus** product line, which includes the Bubble PAP Valve 0-10 cm H₂O for noninvasive ventilatory support of neonates, premature infants and infants weighing ≤10 kg; Silicone Infant Nasal CPAP Cannula (prongs) for delivery of comfortable nCPAP; and a single or dual pole clamp for both the Bubble PAP Valve and humidifier systems; and Danny Ties for a soft, comfortable fit for tracheostomies. B&B Medical Technologies is the first and only company to offer an FDA-cleared, professional Bubble CPAP system specifically designed to deliver precise CPAP pressure for the very small infant population in the NICU through the 10 kg infant in the PICU. Babi.Plus **Bubble Pap**

Valve and Infant Nasal CPAP Cannula eliminates the need for hospital personnel to invest time and money manufacturing and maintaining the "homemade" bubble devices previously used for nasal CPAP application. B&B Medical Technologies will introduce the new Babi.Plus **Pacifier Adaptor** for nebulized medication delivery via the infant's own personal pacifier. The Babi.Plus Pacifier Adaptor is hypoallergenic, latex-free and phthalate-free. The Pacifier Adaptor has been designed to fit and adhere to a wide variety of non-silicone face plate pacifiers. The Pacifier Adaptor holds fast with a specialty adhesive but can be easily removed after treatment, even while the child still is sucking on the pacifier. The Babi.Plus Pacifier Adaptor provides a convenient and cost effective alternative to other methods of nebulized medication delivery for babies and young children. The new **Danny Ties** will be introduced at the booth. Danny Ties are made of a soft, absorbent material that lay smooth at the edges of the collar and significantly minimize skin breakdown beneath the collar. The collar holds its shape, does not fold in half around the neck and does not stretch when it absorbs moisture. The patent pending design of the Danny Ties evenly distributes the padded collar material around the neck to minimize pressure points on the skin. The Danny Ties collar is easy to apply with tapered ends to the collar straps. The ends thread easily through the eyelets of the tracheostomy tube allowing for quick application and changes of the collar on the smallest of infants and the large adult patient. Danny Ties are developed with special care by a Dad wanting to "make a difference" for his son and change the quality of life for tracheostomy patients. His engineering expertise and commitment to finding a better solution is found in the Danny Ties. In addition, B&B will present the new preemie-sized **Sil.Flex Stoma Pad** for advanced tracheostomy stoma care for the very smallest infants.

Discuss educational/training/support materials you'll be promoting.

B&B Medical Technologies will have complete product brochures, clinical application guides to assist the clinician in the introduction and education for the complete line of B&B Medical Technologies specialty airway management products.

Why should AARC participants visit your display?

B&B Medical Technologies' "signature" giveaway, See's Candies Lollypops, will be available at our booth. Please stop by to see how our entire World of Products for Better Breathing will make your life easier in the clinical setting, and enjoy a lollypop from B&B Medical Technologies.

Bunnell Incorporated

Booth 529

What products will you be presenting?

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.

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

The "WhisperJet" patient box with sound reduction technology is the most timely product Bunnell will feature at the 2010 AARC Congress in Las Vegas. The most recent sound reduction upgrade

has lowered the sound output from 56 to 41 dB.

Discuss educational/training/support materials you'll be promoting.

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 Congress. 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, bunl.com.

Why should attendees visit your display?

The number one reason respiratory therapists 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 529; 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.

CareFusion

Booth 417

What new products will you be presenting?

This year CareFusion will be showcasing a number of innovative solutions at AARC, including invasive and noninvasive ventilation products, new ventilator technologies and the latest addition to our comprehensive respiratory diagnostic portfolio. CareFusion's Respiratory Care portfolio spans a wide range of care areas and applications from pulmonary function equipment to mechanical ventilation and consumables. Whether in a clinic, physician office, ambulance, hospital or home, CareFusion is a unique full service respiratory care provider.

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

Three new mechanical ventilator products will be featured:

- **EnVe** ventilator, a powerful 9½ lb ventilator that delivers uninterrupted intensive care, anywhere, any time.
- **ReVel** ventilator, also a 9½ lb transport ventilator to support civilian and military applications.
- **LTV 1100** ventilator, the latest innovation from the trusted leaders in home care ventilation.

Two major new neonatal innovations:

- **Infant Flow LP** and
- **AVEA** ventilator.
- **SentrySuite** (SeS) software: A collection of software applications to assist with clinically intelligent diagnostics to improve the quality of patient data and to help our customers drive productivity and efficiency. SeS is compatible with our existing Vmax and JLab databases.

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

CareFusion will have training materials available at the booth. These will target management of patients on ventilators and utilizing lung protective strategies.

Why should AARC participants visit your display?

CareFusion offers the most complete line of respiratory-related products in the industry, from ventilators to active humidification, from diagnostic tools to advanced circuits, with a full complement of consumables to serve almost any respiratory need. Our focus on lung protection provides the tools to help reduce hospital and ventilator related injury and infections, and our goal is to help you minimize your costs while optimizing respiratory patient care.

Dräger

Booth 817

What new products will you be presenting?

Dräger will demonstrate its newest generation in critical care ventilation and neonatal ventilation. Visitors will get a first-hand preview of the **Evita Infinity V500** as well as the new **Babylog VN500**. Both devices represent one of the most technologically advanced ventilation platforms with a comprehensive array of therapy options. Additionally, congress attendees can see the latest in non-invasive ventilation with Dräger's Carina which is designed for patient comfort and ease of use for the caregiver.

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

The Babylog VN500 was designed with the neonatal respiratory therapist, neonatologist, and tiny patient in mind. After over two decades of experience with the former device, the VN500 brings a wealth of technology in mechanical ventilation to the bedside. The Evita Infinity V500 enters the ventilation marketplace with new tools and options never before available. Features such as APRV with Auto-Release, Variable Pressure Support, Smart Pulmonary View, and configurable SmartCare/PS are some of the examples of new technology that the V500 brings to the respiratory therapist and critical care physician.

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

Every day during exhibit hours, the first 100 visitors to the booth will be given the "Mechanical Ventilation Pocket Guide" by Dana Oakes. Additionally, Mr Oakes will be onsite for a book signing and interview. See the booth receptionist in advance for details.

Why should AARC participants visit your display?

Dräger has been in the forefront of ventilation for 100 years. Our knowledge and experience continues to bring the latest technological advances to caregivers worldwide. Forums such as the AARC allow for sharing of expertise and of course fellowship amongst colleagues, customers, and friends.

Fisher & Paykel Healthcare, Inc

Booth 701

What new products will you be presenting?

Fisher & Paykel Healthcare, Inc understands and appreciates the critical role of respiratory therapists and we are dedicated to providing them with innovative healthcare devices that improve patient care and outcomes. This year Fisher & Paykel Healthcare will be presenting many product lines including the **Evaqua** Infant and Adult breathing circuits, Nasal High Flow using the **Optiflow** nasal cannula, the NIV mask family and the **MR850 Humidification System**. The Evaqua breathing circuit

is a world first in breathing circuit technology that allows water vapor to diffuse through the expiratory tubing wall. We are delighted to announce that for the first time, this technology is now available to all customers. We are also delighted to announce the launch of our enhanced **Neopuff Infant T-Piece Resuscitator** and the new **Ergonomic T-Piece Resuscitation Circuit**. With over 20 years of worldwide use and acceptance involving millions of safe and effective resuscitations, the enhanced Neopuff Infant T-Piece Resuscitator provides further functionality and usability while continuing to raise the standard of care for infant resuscitation. We invite all attendees to experience the many benefits of this new Ergonomic T-Piece Resuscitation Circuit including the new PEEP cap orientation for comfortable and controlled hand positioning; improved PEEP cap adjustment to avoid unintentional changes in PEEP; longer circuit length for better access to your infants and the new duckbill port for suctioning and surfactant delivery.

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

A demonstration of the Evaqua breathing circuit technology used with the MR850 Humidifier is a must see! The high performance inspiratory limb of the Evaqua breathing circuit delivers body temperature pressure saturated gases to ventilated patients with bypassed upper airways while controlling condensation with our unique spiral heater wire technology. This level of heat and humidity mimics the normal physiologic conditions that occur in healthy lungs. The expiratory limb of the Evaqua breathing circuit includes a vapor permeable membrane technology that eliminates expiratory limb condensate. This unique and important feature reduces ventilator circuit maintenance, helps reduce the likelihood of VAPs by eliminating mobile condensate and reduces impact of condensation in ventilator expiratory components. Evaqua breathing circuits are now available for all customers and please visit us in Booth 701 to see this technology in action! Also of importance is our Nasal High Flow System for infants through adults with gas flows from 0.3 to 60 L/min. Our NHF system combines the MR850 Humidifier and Optiflow nasal cannula interface to provide comfortable precise oxygen delivery as well as respiratory support. We will also be exhibiting the first humidified infant resuscitation system using the MR850 Humidifier. The Neopuff Infant T-Piece Resuscitator using a humidified resuscitation circuit provides 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 educational materials will be available at the conference?

We look forward to demonstrating the Fisher & Paykel Respiratory Care Continuum as well as sharing the many AARC CEU and AACN CNE opportunities with all attendees. Each attendee visiting Booth 701 will be provided with small flash drives containing Nasal High Flow, Optimal Humidity and Optimal Resuscitation educational material.

Why should AARC participants visit your display?

Attendees are warmly invited to visit Booth 701 for hands-on demonstrations and practical experience with all of the above-mentioned products, including an invaluable opportunity to try Nasal High Flow for themselves and also to test their resuscitation skills on our resuscitation simulator! Please join

us at the AARC Conference in Las Vegas at Booth 701 for a complete review and demonstration of all Fisher & Paykel Healthcare products.

Hamilton Medical

Booth 817

What new products will you be presenting?

Hamilton Medical will be introducing the first two ventilator system additions to our dedicated ventilation product line that will bring Intelligent Ventilation solutions to expanded patient populations. The **Hamilton T1** is your intelligent solution for the mobile ICU, designed to ventilate pediatric through adult high acuity patients. With its compact and rugged design, built in batteries and turbine, this ICU ventilation can accompany your patient within the hospital or between hospitals, whether on the ground or in the air. The **Hamilton C1** ventilator provides maximum performance in a minimum size. The C1 features a compact design small enough to fit into any ICU environment, a competitive price and a full range of clinical requirements; invasive ventilation, automated ventilation with ASV and Non-Invasive Ventilation. The C1 is the ideal choice for ICU special areas, cardiac surgery recovery rooms, step-down or subacute care units, and long-term care centers.

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

Hamilton Medical has developed all of our ventilation systems with our cornerstone closed loop ventilation technology, Adaptive Support Ventilation (ASV). Not only can ASV be used as a default mode across a wide variety of patients, more importantly, ASV supports evidence based medicine guidelines for weaning and protective lung ventilation, both of which reduce ventilator mortality and length of stay (LOS). To complement the benefits of ASV, Hamilton Medical features PV Tool to optimize PEEP and lung recruitment and our "Dynamic Lung," an innovative object oriented display to more accurately and quickly identify changes in patient status.

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

Hamilton Medical offers product manuals (hard copy and electronic), simulation CD Rom's, reference cards and internet based "Webex" training. AARC approved CRCE credits are available for advanced clinical education/workshops. User registration at Hamilton Medical's website, hamilton-medical.com, provides the clinician with 24/7 access to e-manuals, support documentation and staff access when you need it.

Why should AARC participants visit your display?

Hamilton Medical is the highest ranked ventilator manufacturer for 2010, as rated by the independent company, MD Buyline. Ventilator User's have rated Hamilton Medical the top performer in all categories, including System Performance, System Reliability, Installation/ Implementation, Applications Training, Service Response Time and Service Repair Quality. This rating is inclusive of all Hamilton Medical ventilators on the market today. Hamilton Medical's booth at the 2010 AARC is an ideal place for the clinician to see our ventilator systems and to ask any questions of our sales, clinical or marketing staff. Hamilton Medical is proud of our continued professional relationship with the AARC and we are pleased to once again provide the AARC membership with the first US showing of the new ventilator



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systems in our product line. Stop by for an introduction to the T1 and C1 ventilator systems.

Innovative Respiratory Concepts

Booth 829

What new products will you be presenting?

It is our pleasure this year to highlight another totally new concept to respiratory care, The **Lung Flute**. This innovative technology by Medical Acoustics was awarded the Frost and Sullivan Excellence in Medical Devices Award and selected by Popular Science for the BOWN Award. This Device received FDA approval for both diagnostic and therapeutic use. The technology produces deep lung secretions in place of a hypertonic saline sputum induction. Specimen applications include inflammatory markers, Genotyping of pulmonary tuberculosis, early detection of lung cancer via DNA markers, monitoring of general lung health, and infectious agents. With FDA approval for dual use, this single device creates a whole new dimension for secretion clearance.

Education and training

We will be discussing and providing education, overview, and supportive material for the Lung Flute. Learn how sound is effective for secretion mobilization. Additionally, we will be discussing and educating the RT about the many opportunities and roles for innovation, technology, and research. This year at the AARC, we will be providing opportunities for RTs to evaluate new technology and experience firsthand the value of their experiences. For consideration and additional information, contact us at respiratoryconcepts.com and reference evaluation at AARC.

Why should AARC participants visit your display?

Spirit of Innovation: IRC offers a unique approach to developing technology through clinical perspective. With a network of over 600 RT specialists from the US and Canada, we are able to provide valuable perspective to make the best possible technology for the patient and caregiver.

Instrumentation Laboratory

Booth 1008

What new products will you be presenting?

Instrumentation Laboratory (IL), booth 1008, will showcase innovative products in laboratory and Point-of-Care-Testing (POCT), including: • New Total Bilirubin and Basic Metabolic Panel assays* for the **GEM Premier 4000** critical care analyzer with Intelligent Quality Management (iQM) • New automated operator certification management for **GEMweb Plus** Custom Connectivity; • New **GEMdraw** Arterial Blood Samplers. [*in development; not currently saleable in North America.]

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

The GEM Premier 4000 with iQM offers full automation of the most skill- and labor-intensive processes in critical care testing. Instrument maintenance is automated with the only single-component, multi-use PAK on the market. iQM automates quality management through continuous, active, real-time error detection, correction and documentation, for the most accurate results, every time. Combined with **GEMwebPlus**

Custom Connectivity, operators have system-wide control of all analyzers, fully automating quality control reporting, operator certification management, and more. All of these advanced features address what healthcare providers strive to achieve every day—increased efficiency and enhanced patient care. Additionally, the introduction of Total Bilirubin (tBili) on the GEM Premier 4000 represents a significant breakthrough in quality of care and work-flow efficiencies for the Neonatal Intensive Care Unit (NICU). This new assay allows clinicians to receive lab-quality test results in just 90 seconds from whole blood in the NICU, rather than waiting up to an hour for results from the lab, using traditional chemistry methods. Today, 8-10% of newborns suffer from jaundice, resulting from accumulated Bilirubin in the liver, which can progress to severe hyperbilirubinemia. Left untreated, hyperbilirubinemia can quickly evolve into kernicterus, a devastating, irreversible neonatal brain injury. Total Bilirubin on the GEM Premier 4000 will help clinicians eradicate kernicterus and detect rising tBili early, while still treatable.

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

Throughout the year, IL conducts educational seminars at customer hospitals, online and at national conferences featuring experts in the field of laboratory and point of care testing. These seminars provide Continuing Education Units for attendees and most can be viewed live, or on-demand, through the IL corporate website. More information on seminars scheduled for 2010, and past educational seminars, is available at ilus.com/illuminations.

Why should AARC participants visit your display?

Visitors should visit the IL booth for demonstrations of the breakthrough GEM Premier 4000 with iQM and to review the new exciting features of GEMweb Plus Custom Connectivity, including automated operator certification. The GEM Premier 4000 offers laboratory automation at the point-of-care, with the simple touch of a button, and provides the highest quality patient test results. Learn GEMweb Plus operator certification and see how easy it is to manage the certification of a team of operators. Additionally, IL will offer demonstrations of GEMdraw, IL's high-performance Arterial Blood Samplers, featuring GEM SafetyDraw with the one-handed Sure-Lok safety system, and GEM EasyDraw.

MEDGRAPHICS

Booth 129

What new products will you be presenting?

MEDGRAPHICS will be presenting the new **Ultima CardIO₂** Exercise System. This system combines the leading MEDGRAPHICS gas exchange technology with the premier Mortara ECG into one easy to use metabolic stress testing system.

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 should visit our booth to see the latest innovations in hardware and software, and see how we can provide the best solutions for their diagnostic needs.

Medical Acoustics

Booth 648

What new products will you be presenting?

Medical Acoustics will be featuring the **Lung Flute**. The Lung Flute for Hospitals/Clinics is a safe, non-invasive method to induce sputum samples for diagnostic and pathologic examination as well as providing a clinically proven method for airway clearance and Bronchial Hygiene Therapy.

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

The Lung Flute is of current importance because it is the only FDA and CE cleared respiratory device dual-indicated for diagnostic and therapeutic use. The Lung Flute uses patented low frequency acoustic wave technology to optimize secretion clearance deep in the lungs which has been clinically proven to achieve better results than standard vibration and OPEP therapy.

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

We will be presenting educational material on respiratory disease management, focusing on COPD. A manuscript highlighting three clinical studies indicating efficacy, safety and improvement in Quality of Life scores with the Lung Flute will be available.

Why should AARC participants visit your display?

The Lung Flute's innovative application of low frequency acoustic waves has been lauded by many leading publications and independent research organizations. The Lung Flute was selected by Frost and Sullivan for a Best in Technology Award, *Popular Science* named the device a Best Innovation of 2009 and *MD&DI Magazine* recognized Medical Acoustics as one of the Top 50 Companies to Watch.

Mercury Medical

Booth 428/430

What new products will you be presenting?

Mercury Medical, a leading provider of airway management products for over 45 years, will be unveiling the new **Neo-Tee**, the first disposable infant T-Piece resuscitator with manometer at the AARC Congress meeting in Las Vegas.

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

In addition to the full line of airway management products, Mercury Medical will be featuring the new Neo-Tee disposable infant T-Piece Resuscitator and disposable Flow-Safe CPAP device built-in manometer and choice of CPAP mask styles. The new Neo-Tee is the only disposable infant T-Piece resuscitator that is flow controlled and pressure limited offering the ability to measure more consistent, targeted Peak Inspiratory Pressure (PIP) and PEEP pressure. With the added safety features of a disposable built-in manometer, adjustable PEEP valve and Peak Inspiratory Controller it provides clinicians with an affordable T-Piece resuscitation system that can be placed at every NICU bedside. No capital equipment allows for easy transport and

the manometer offers in-line viewing of delivered pressure to the patient. Mercury Medical is also featuring **Flow-Safe**, the first disposable open CPAP system with built in manometer and pressure relief valve. Flow-Safe is highly portable and is easy to set up. Delivering CPAP pressure is easy since pressure is titratable dependant upon flow—no separate fixed CPAP valves are necessary and it allows up to 100% FiO₂ delivery. Clinicians can easily add a nebulizer with t-adaptor and filter.

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

Mercury Medical offers a fully trained sales force that can fully in-service hospital departments on all of our products. In addition to detailed product brochures with specifications and product advantages, we offer product information wall posters and many of our products included instructional videos.

Why should AARC participants visit your display?

Mercury Medical listens to the needs of respiratory clinicians in developing new products with high quality standards. All Mercury products are designed to fulfill those clinical needs with innovative cost-efficient solutions. For example, we talked to many respiratory therapists who were planning to implement t-piece resuscitation protocols for their NICU departments but could not afford to place expensive capital equipment at every bedside. The Neo-Tee disposable t-piece resuscitator with built-in safety features was designed in response to those clinicians who are looking for an affordable t-piece resuscitator solution. We will be happy to discuss all of our product advantages at the AARC and the Mercury sales force will bring samples of any product of interest to your facility for evaluation. Ideas for new products are always welcomed for discussion.

nSpire Health

Booth 825/827

What products will you be presenting?

HDpft with iFlow.

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

iFlow – new performance standards.

Why should AARC participants visit your display?

To understand why existing performance standards do not meet today's needs.

OPTI Medical

Booth 143

What new products will you be presenting at AARC?

OPTI Medical will present the **OPTI CCA-TS** analyzer for measuring time sensitive diagnostic assays including blood gas, electrolytes, ionized calcium, glucose and measured tHb and SO₂. It features patented optical fluorescence technology which virtually eliminates maintenance costs, test delays, and downtime. The OPTI CCA-TS is portable and easy to use with excellent reliability - making it ideal for the point of care.

Why should AARC participants visit your display?

Stop by the OPTI Medical booth to purchase one of our OPTI Rhythm Pulse Oximeters at a great promotional price. Each

OPTI Rhythm comes with a one year warranty and is backed by OPTI Medical's excellent technical support.

Oridion Capnography

Booth 611

What new products will you be presenting at AARC?

Oridion Capnostream 20 with IPI: The Oridion Capnostream 20 portable capnography bedside monitor enables effective, proven airway management by providing the earliest indication of airway compromise. The Capnostream 20's superior Microstream measurement technology provides an accurate and reliable assessment of a patient's breathing quality, whether intubated or non-intubated. The Capnostream 20 utilizes Oridion's newest Smart Capnography innovation – the Integrated Pulmonary Index (IPI) – to improve clinical utility with a simple, clear and comprehensive indication of a patient's ventilatory status and trends, facilitating easier communication among clinicians. IPI utilizes real time measures and interactions of four parameters (etCO₂, respiration rate, pulse rate, and SpO₂) to provide a single indexed value, enabling clinicians to instantly assess the patient's respiratory status sooner than the value of any of the four parameters individually. The Capnostream 20 also features the SARA (Smart Alarm Respiratory Analysis) alarm management algorithm, which recognizes and reduces respiratory rate nuisance alarms while accurately reflecting the patient's condition and preserving caregiver alarm vigilance.

SSDx (Smart Sleep Breathing Disorder Diagnosis): SSDx (Smart Sleep Breathing Disorder Diagnosis) is part of the Smart Capnography family of innovative algorithms that simplify the use of CO₂ monitoring on Microstream-enabled products to improve patient safety and clinical workflow. SSDx reports apnea and oxygen desaturation events and calculates the associated Apnea Index (AI) and Oxygenation Desaturation Index (ODI) for adult patients. By using Oridion SSDx algorithms – AI and ODI – clinicians are able to identify potential patient sleep apnea while patients are being monitored during their hospital stay. [Pending FDA clearance.]

CapnoLine H O₂ Infant/Neonatal Sampling Line: The CapnoLine H O₂ Infant/Neonatal is a CO₂ sampling line (nasal sampling) providing precise, effective airway management of infants requiring etCO₂ monitoring and supplemental oxygen delivery. It is designed for use with all Microstream capnography-enabled monitors. Microstream's unique measurement technology uses a minimal breath sampling rate of 50 ml per minute, enabling accurate sampling of the small tidal volume of neonates. The CO₂ sampling line and the O₂ delivery line are each 3 meters long, allowing for use in all care environments, including patient transport situations where the oxygen canister and the patient monitor are located at the foot of the bed. Its unique design locates the Nafion below the O₂ and CO₂ junction, keeping the Nafion off the infant's face for optimal infant comfort.

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 breathe from their mouth or nose. 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 reduces 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; • Ideal under masks for accurate CO₂ monitoring during CPAP, bi-level device or NPPV and high flow rate O₂ delivery therapy; • For adult and pediatric 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 don the Oridion FilterLine interface and a pulse oximeter. They are then asked to hold their breath, which simulates apnea. Within 30 seconds, the Capnostream 20 will alarm, detecting inadequate ventilation through etCO₂ measurement, even as pulse oximetry continues to show readings of 97 to 99 percent. 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.

Passy-Muir, Inc

Booth 343/345

What new products will you be presenting?

Passy-Muir, Inc will be debuting at AARC three new exciting and useful products for the clinical professional. The **Pocket T.O.M.** is a more portable pocket-sized version of our popular Tracheostomy Teaching and Observation Model. The new Pocket T.O.M. displays the same cutaway view of the upper aero-digestive track anatomy with tracheostomy, and can be easily taken to the bedside for patient education, and is great for spontaneous staff teaching as well. The Pocket T.O.M. can be easily cleaned between patients. The **Assessment Kit** is our new product to assist clinicians with a complete set of tools to support patient bedside assessment for Passy-Muir Valve use. Documentation forms for recording assessment findings will also be included in the easy to carry kit. Our new **Educational Kit** will enable the clinician to appropriately educate colleagues and patients in Passy-Muir Valve application and care. This easy-to-carry kit will include Pocket T.O.M. along with other graphics and useful tools to help patients and staff understand the function and benefits of the Passy-Muir Valve.

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

Passy-Muir, Inc has long been known for the Passy-Muir Tracheostomy and Ventilator Swallowing and Speaking Valves that have become the standard of care for tracheostomized

patients. 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 shorter ventilator length of stay for the tracheostomized and ventilator dependent patient.

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

Passy-Muir, Inc has always held education and clinical support for professionals and patients to be of primary importance. At this year's AARC new educational opportunities via our web site and through the internet will be featured, along with new, pocket sized quick reference guides.

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 care professional advance as a primary partner in tracheostomized patient outcome management.

Philips Respironics

Booth 617

What new products will you be presenting?

The new Philips Respironics **BiPAP AVAPS** noninvasive ventilator (NIV) for home use has been developed to deliver improved patient care plus simplified patient management. At the heart of the device is our exclusive AVAPS (Average Volume Assured Pressure Support) algorithm that automatically adjusts pressure support to meet changing patient needs while maintaining a target tidal volume. And it all comes together in a new lighter, quieter, and easy-to-use platform. Features include: integrated alarms to help maintain patient safety and System One humidity control that analyzes ambient temperature, relative humidity, and patient flow to deliver optimum humidity and comfort to the patient.

Why should AARC participants visit your display?

In addition to the new BiPAP AVAPS device, Philips Respironics will be showcasing the **Trilogy200** portable life-support ventilator, designed for use in the home and alternative care sites. Trilogy200 provides noninvasive and invasive ventilatory support with added sensitivity for a wide range of adult and pediatric patients (>5 kg).

Respirtech

Booth 1030

What new products will you be presenting?

Respirtech now offers a choice of 3 jacket colors. Respirtech jackets are now the easiest to wash and dry.

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

Respirtech's **inCourage** system is the superior HFCC solution. It has a wide range of clinical applications where secretion clearance assistance is indicated: • Cystic Fibrosis, • Bronchiectasis, • Medically complex children and adults. The inCourage system promotes patient comfort for better clinical compliance. • inCourage jackets are now available in a choice of three colors. • Active Venting makes it easier to breathe during treatments. inCourage jackets are now the easiest to wash and dry, promoting infection control. Respirtech has the widest range of jacket sizes, with custom jackets available to comfortably accommodate all types and sizes – from under 2 years of age on up.

Why should AARC participants visit your display?

Learn about the clinical advantages of high frequency chest compression in treating numerous diseases, and the many benefits Respirtech's inCourage system offers over other HFCC devices: • Active Venting for the most comfortable breathing; • Triangular waveform provides best airflow; • Widest range of jacket sizes for best fit (custom jackets too!) – now in three colors and the easiest to wash and dry; • Durable jacket material for the easiest washing and drying.

Roche

Booth 601

Why should AARC Attendees stop by the Roche booth?

Experience the "Virtually Uninterrupted Performance" of the **cobas b 221** with the latest 7.05 operator software [currently not launched in the US] and **cobas bge** link instrument software. Learn how the new safety engineered Microsampler **PROTECT*** blood gas collection device is ideal for small volume draws and can improve your operational efficiency. Meet with Michael Nibert, Respiratory Therapy Director and Stacy Howard, Lead Therapist at College Station Medical Center, College Station, Texas to discuss solutions for high volume blood gas testing at the point of care and other current and future trends in respiratory therapy.

For all runners and walkers, stop by booth 601 on Monday, December 6, 2010 to register for the Roche sponsored AARC 5K Fun Run which takes place Tuesday, December 7, 2010 at 6:30 am in front of Las Vegas Convention Center. The top three men and women will be recognized and all participants will receive a free T-shirt.

On Tuesday and Wednesday, please stop by and enter the educational giveaway. Each day we will raffle off a fourth edition copy of *The Essentials of Respiratory Care* by Robert M. Kacmarek.

Come and explore the past, present and future of Roche Blood Gas and IT Solutions at the Innovations Tours to be held at the Las Vegas Marriott Hotel 325 Convention Way Drive Monday and Tuesday, December 7-8, 2010, throughout the day.

Contact your Account Manager or Instrument Specialist or stop by the booth as soon as possible to reserve a place at one of four presentation times. Seating at each session is limited.

Salter Labs

Booth 710/712

What new products will you be presenting?

Salter Labs will be presenting several exciting, new products in the areas of sleep diagnostics, oxygen therapy, and skin fixation as well as new clinical data on its **NebuTech HDN** high density nebulizer at Booth 710-712 of the 2010 AARC Conference.

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

With the increased interest in reducing occupational hazards, Salter Labs' unique, optional Disposable Filter Set (for use with the Salter NebuTech HDN high density nebulizer) is well suited for use where occupational exposure to exhaled aerosol particles is a concern. It reduces second-hand aerosol exposure by filtering 99.56% of exhaled aerosol particles. Our expanding line of sleep diagnostic products is particularly useful in assisting sleep professionals in meeting the new AASM guidelines for concurrent nasal pressure and oral/nasal thermal airflow sensing.

Why should AARC participants visit your display?

AARC participants visiting Salter Labs at Booth 710-712 can discuss Salter's exciting new, cost effective products, obtain a Salter roll-up blanket to ward off the December desert chills (while supplies last), and enter a drawing to win a \$50 American Express Gift Card.

Teleflex

Booth 335

What new products will you be presenting at AARC?

Teleflex is excited to present the **ISIS HVT** endotracheal tube and **Gibeck Humid-Flo Passive Humidification Kit**. The Teleflex ISIS HVT is the first convertible endotracheal tube with a design that features an integrated suction port and separate suction line, allowing for subglottic secretion removal on demand. This innovative design increases the candidates for subglottic secretion suctioning, standardizes the tube for both short-term and long-term patients, and reduces endotracheal tube change outs. The Gibeck Humid-Flo Passive Humidification Kit is an integrated system that promotes best practices for VAP risk reduction and contains all the necessary components to initiate passive humidification for a mechanically ventilated patient. The comprehensive kit reduces ventilator circuit breaks by allowing all components, including the heat & moisture exchanger (HME) to remain in-line during the first 72 hours of mechanical ventilation. This allows for adherence to clinical practice guidelines and recommendations from the CDC, AARC and SHEA regarding infection control practices for preventing Ventilator Associated Pneumonia (VAP).

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

Teleflex offers a suite of ventilation management solutions that work together to enhance patient outcomes. With a focus on minimizing risk to maximize outcomes, we have developed products designed to help providers reduce the risk for Ventilator Associated Pneumonia (VAP). VAP is the most common infection acquired by adults and children in intensive care units (ICUs) and is a cause of significant patient morbidity and mortality, increased utilization of healthcare resources

and excess cost.¹ The key products featured at AARC this year are designed to help providers reduce this risk and include Teleflex ISIS HVT, Gibeck Humid-Flo Passive Humidification Kit, ConchaTherm Neptune heated humidifier and ResMed NIV masks. The versatile design of the Teleflex ISIS HVT convertible endotracheal tube eliminates the need to be selective during initial intubation, increasing the number of patients who can be viable candidates for subglottic secretion suctioning, a clinically proven strategy for VAP reduction.¹ An integrated system that promotes best practices for VAP risk reduction,^{1,2,3} the Gibeck Humid Flo passive humidification kit allows all components to remain in-line during the first 72 hours of mechanical ventilation. The ConchaTherm Neptune heated humidifier and ResMed NIV mask work together to promote patient compliance to Non Invasive Positive Pressure Ventilation (NPPV), which has been associated with higher survival rates and reduction of nosocomial infections.⁴ [References: 1. Coffin S MD, MPH, Klompas M MD, Classen D MD, et al. Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals. *Infect Control Hosp Epidemiol* 2008; 29:S31-S40. 2. AARC Evidence Based Guidelines, Care of the Ventilator Circuit and Its Relation to Ventilator Associated Pneumonia. *Respiratory Care* 2003;48:875. 3. Guidelines for Preventing Hospital Associated Pneumonia: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee 2003. 4. Girou E, Schortgen F, Delclaux C, et al. Association of noninvasive ventilation with nosocomial infections and survival in critically ill patients. *JAMA*. 2000;284:2361-7.]

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

Teleflex is proud to offer a variety of educational programs and materials during AARC. On Monday, December 6, Teleflex will be presenting at the RC Solutions Showcase. Jeri E. Eiserman, BS, MBA, RRT, Durham, NC will present "Partnering with Hospitals, Clinicians and Patients to Provide Respiratory Solutions That Support Best Practices for Ventilator Associated Pneumonia (VAP) Risk Reduction." This lecture describes our portfolio of solutions which allows clinicians to better adhere to clinical practice guidelines and recommendations from the CDC, AARC and SHEA regarding infection control practices for VAP. On Tuesday, December 7, Teleflex is sponsoring the breakfast symposium "Navigating the Respiratory Pyramid of Care," presented by David L. Vines, MHS, RRT, FAARC, Rush University College of Health Sciences, Chicago, IL. The respiratory pyramid of care encompasses 5 therapeutic levels that form the basis for effective, informed management of patients who require oxygen therapy and/or ventilator support. This program provides learners with 2 hours of CRCE and the opportunity to become familiar with the devices, signs and symptoms associated with each level of care, as well as the risks and benefits that should be considered when determining a patient's course through the pyramid of care. Also on Tuesday, December 7, Robert M. Kacmarek, PhD, RRT, FAARC, Boston, MA, will be presenting the program "Hospital Acquired Infections: How Are We Doing?" This session is supported by an unrestricted educational grant from Teleflex. Hospital-acquired infections significantly influence health care costs, length of stay, morbidity and mortality. Respiratory Therapists play an influential role in the identification, treatment and prevention of hospital-acquired infections. Strategies from simple to complex can have a direct effect on the outcome of your patient. At our booth, we will provide opportunities for CRCE through Clinical Foundations, a patient-focused education program dedicated to helping

respiratory care professionals stay current on clinical trends. Clinical Foundations offers several modules as an independent study program, focusing on a variety of respiratory diagnostic and treatment topics that are an integral part of clinical practice. Two of the latest editions "Asthma Exacerbations" and "Humidification During Non-Invasive Ventilation" will be offered at AARC. We will also be discussing a Respiratory Peer-to-Peer Clinical Education Program: Advances in Respiratory Therapy. This CRCE program is available for institutions and includes topics such as, Humidification Basics, Passive Humidification, Active Humidification and Navigating the Respiratory Pyramid of Care.

What speakers will your company be working with or featuring?

On Monday, December 6, at 2:45 pm, Jeri E. Eiserman, BS, MBA, RRT, Durham, NC, will be representing Teleflex at the RC Solutions Showcase. She will present "Partnering with Hospitals, Clinicians and Patients to Provide Respiratory Solutions That Support Best Practices for Ventilator Associated Pneumonia (VAP) Risk Reduction." On Tuesday, September 7 at 6 am, Teleflex is sponsoring the AARC Breakfast Symposium "Navigating the Respiratory Pyramid of Care." This program will be presented by David Vines, MHS, RRT, FAARC from Rush University College of Health Sciences in Chicago, IL. At 11:15 am on Tuesday, December 7, Robert Kacmarek, PhD, RRT, FAARC from Harvard Medical School and Massachusetts General Hospital in Boston, MA, will present "Hospital Acquired Infections, How Are We Doing?" This session is supported by an unrestricted educational grant from Teleflex.

Why should AARC participants visit your display?

Patients and caregivers around the world rely on Teleflex Medical and the Hudson RCI brand of respiratory products to make breathing easier. Guided by the voice of the respiratory clinician, Teleflex Medical strives to advance patient care by focusing on caregiver efficiency. Teleflex Medical will highlight new products designed to help with the care and maintenance of the mechanically ventilated patient, including the ISIS HVT endotracheal tube and the Gibeck Humid-Flo Kit, designed to remain in line for the first 72 hours of ventilation. When it comes to infection prevention for mechanically ventilated patients, Every Choice Matters.

VORTRAN Medical Technology1, Inc

Booth 730

What new products will you be presenting?

We plan to present and demonstrate our newest and most cost effective products and packaging. The **VORTRAN Test Lung** kit design features three resistor settings, adjustable lung compliance for single or double breath delivery, and provides the ultimate flexibility and performance at an affordable price. Recently released, the **VAR-Plus Model PTM-5001** ventilates adult and pediatric patients (10 kg and above), provides oxygen (FiO₂) delivery of 100% only, and comes with a special introductory price offer through December 31, 2011. The **VAR-Monitor** works with all current VAR models, easy to set up and use, operates with a standard 9-VDC battery and is financially practical for all new and existing VAR users to stockpile, available for 50% off the published list price until December 31,

2011. The **E-Surge Kit** is ideal for emergency backup ventilation surge, disaster preparedness, MCI (mass casualty incident), or back feed of the main ICU oxygen system. The complete kit organized for rapid deployment, provides a 7-Multi-outlet Manifold with DISS fittings, electronically nonconductive heavy-duty 20' oxygen hose, pressure gauge and regulator providing auto shut off, VAR-Plus devices, high-flow flow meters, VAR-Monitors, and HME filters packed in a water and airtight case preserving contents until deployed. VORTRAN's **supply tubing** is flexible, kink resistant, barbed at each end for maximum flow capability. The **DISS Spin Nut** is suitable for a wide range of applications with maximum operating pressures of 50 PSI.

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

With the health care reform bill in effect, many AARC participants with purchasing authority must be proactive and help their department look for ways to cut cost with the hope of increasing patient care. Our featured products provide a savings measurement in purchasing cost effective, quality medical supplies. Our special introductory price offers and enhanced product improvements offer further cost-savings measurement for respiratory care departments.

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

Product demonstrations with a hands-on training approach, Module Sponsorship program for free online Continuing Education Units (CEU), AARC approved at no charge to the medical professional, an interactive CD ROM featuring the operational characteristics and application use of the products, and the new VORTRAN Test Lung will be promoted at this year's AARC convention. We believe promoting these materials will serve participants with certification tools emphasizing the use of mechanical pressure cycled ventilation assist devices, and provide general ventilatory augmentation in high-impact disaster and MCI medical operations. More importantly, it adds to the element of interactivity connecting them to our future as we strive for total customer satisfaction.

What speakers will your company be working with or featuring?

We are working with pre-eminent experts in developing presentation programs and workshop that supports clinician skill and commitment to respiratory care, as well as foster guidance for the medical community charged with preparing for mass casualty and mechanical ventilation.

Why should AARC participants visit your display?

We recommend AARC participants visit our display to learn about our new and most cost effective products, special introductory price offers, and product demonstrations.

HDpft

iFlow

The next generation in pulmonary function testing



Accuracy Standards

- $\pm 3.0\%$ 1975 Inter-mountain Thoracic Standards
- $\pm 3.0\%$ 1979 Snowbird Spirometry Standards
- $\pm 3.0\%$ 1987 Revised Spirometry Standards
- $\pm 3.5\%$ 1994 Revised Spirometry Standards
- $\pm 3.5\%$ 2005 PFT and Spirometry Standards
- $\pm 3.5\%$ 2009 ISO 26782:2009 Spirometry Standards
- as low as $\pm 0.3\%$ 2010 HDpft with iFlow

The PFT accuracy standards of $\pm 3\%$ haven't changed since 1975, but the patient has. Today's patient can have quality of life with lung volumes significantly below 1 liter. HDpft, powered by iFlow enables today's physicians to manage these most difficult cases.

Isn't it time to rethink your lung function testing equipment?
Isn't it time your lab starts exceeding the obsolete standards?

With up to 10x the accuracy of the published standard, world class connectivity, and the most advance hardware and software architecture the industry has yet to see.

HDpft is revolutionizing spirometry, lung diffusion, lung volumes, and plethysmography. Why settle for 1975 technology?

iFlow and HDpft resets PFT expectations...
Detect Smaller Changes Sooner.*




INSPIRING RESPIRATORY HEALTH

nSpire Health
+1.303.666.5555
www.nspirehealth.com


powered by iFlow

*"If the variability of the results can be diminished and the measurement accuracy can be improved, the range of normal values for populations can be narrowed and abnormalities more easily detected" (from "ATS/ERS Task Force: Standardization of Spirometry", 2005).



TELEFLEX ISIS™ HVT™

The First Convertible Endotracheal Tube

Subglottic secretion removal is a clinically proven strategy for VAP reduction¹. But, the ETT chosen for initial intubation doesn't always allow for easy access to this valuable practice — *until now*. Introducing the new Teleflex ISIS HVT convertible endotracheal tube. Featuring an attachable suction line, this revolutionary design allows for subglottic secretion removal — *when you need it*. The versatile design allows you to use one endotracheal tube to meet the needs of all patients. Visit us at www.teleflexmedical.com to learn more about the Teleflex ISIS HVT — *the right product, every time*.

1 Coffin S MD, MPH, Klompas M MD, Classen D MD, et al. Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals. Infect Control Hosp Epidemiol 2008; 29:S31-S40.

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