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Editorial

H1N1 Flu Ventilatory Requirements

Paul Garbarini, MS, RRT

Paul Garbarini is with Hamilton Medical. This is from the company's newsletter.

The commonly stockpiled ventilators for emergency preparedness are selected based on desired features such as size, simplicity of operation, weight, moderate cost, ability to run on battery power and gas conservation.

These types of ventilators may not have the flow and pressure capabilities of full fledged ICU ventilators. Several recent reports reveal that the ventilatory requirements of H1N1 patients are extremely high. Of 909 H1N1 cases in New York City, 25% of patients required ICU admission and 56% of these patients required ventilatory support. Patients requiring ventilatory support had a 47% mortality rate.

The Michigan Department of Community Health recently reported on characteristics of H1N1 patients requiring ventilatory support. They reported on ten patients who required ventilator support. All ten patients had ARDS, nine of the ten were obese and nine of the ten developed multiorgan dysfunction syndrome. Four of the ten patients had pulmonary emboli upon admission to the ICU. Thirty three percent (33%) of the ten patients died.

All ten patients in the Michigan report required high levels of ventilator support that included high frequency oscillation, airway pressure release ventilation and/or ECMO. (Note, these were the techniques employed in this particular ICU. It's possible that other ventilatory techniques such as ARDSnet or other open lung techniques such as recruitment maneuvers and higher PEEP levels would support these patients).

The on-line journal Critical Care, <http://ccforum.com/content/13/5/R148>, reported characteristics of 32 H1N1 patients admitted to Spanish ICUs

Symptoms prior to admission to ICU:

- Fever: 96%
- Cough: 88%
- Myalgia: 69%
- Headache: 59%
- Sore throat: 58%
- Sudden onset of symptoms: 46%
- Malaise: 30%

Patient Characteristics:

- Mean Age: 40
- 73% male
- 30% obese
- 75% of these patients developed multiorgan dysfunction syndrome.
- 69% required mechanical ventilation; 25% with refractory hypoxemia (prone positioning was needed in 33%)
- 33% of patients expired
- 75% of patients on non-invasive ventilation required intubation.

Based on these initial reports, we may need to anticipate the need to place many of these patients on levels of ventilatory support beyond the capabilities of typical stockpiled emergency ventilators. This might necessitate triaging the ventilator type for non-H1N1 patients.

Additionally, decisions on purchasing disaster preparedness ventilators may need to include high pressure/PEEP capabilities and/or advanced techniques such as PV curves, recruitment maneuvers, APRV etc in addition to aforementioned criteria such as battery life, gas consumption etc.

There are other alternatives to the basic limited feature ventilators commonly thought of for disaster preparedness. When the scope of the disaster you prepare for changes, you need to change how you respond.

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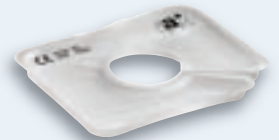
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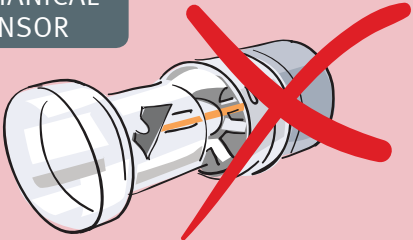
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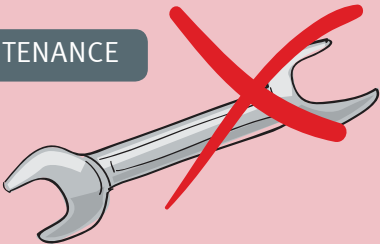
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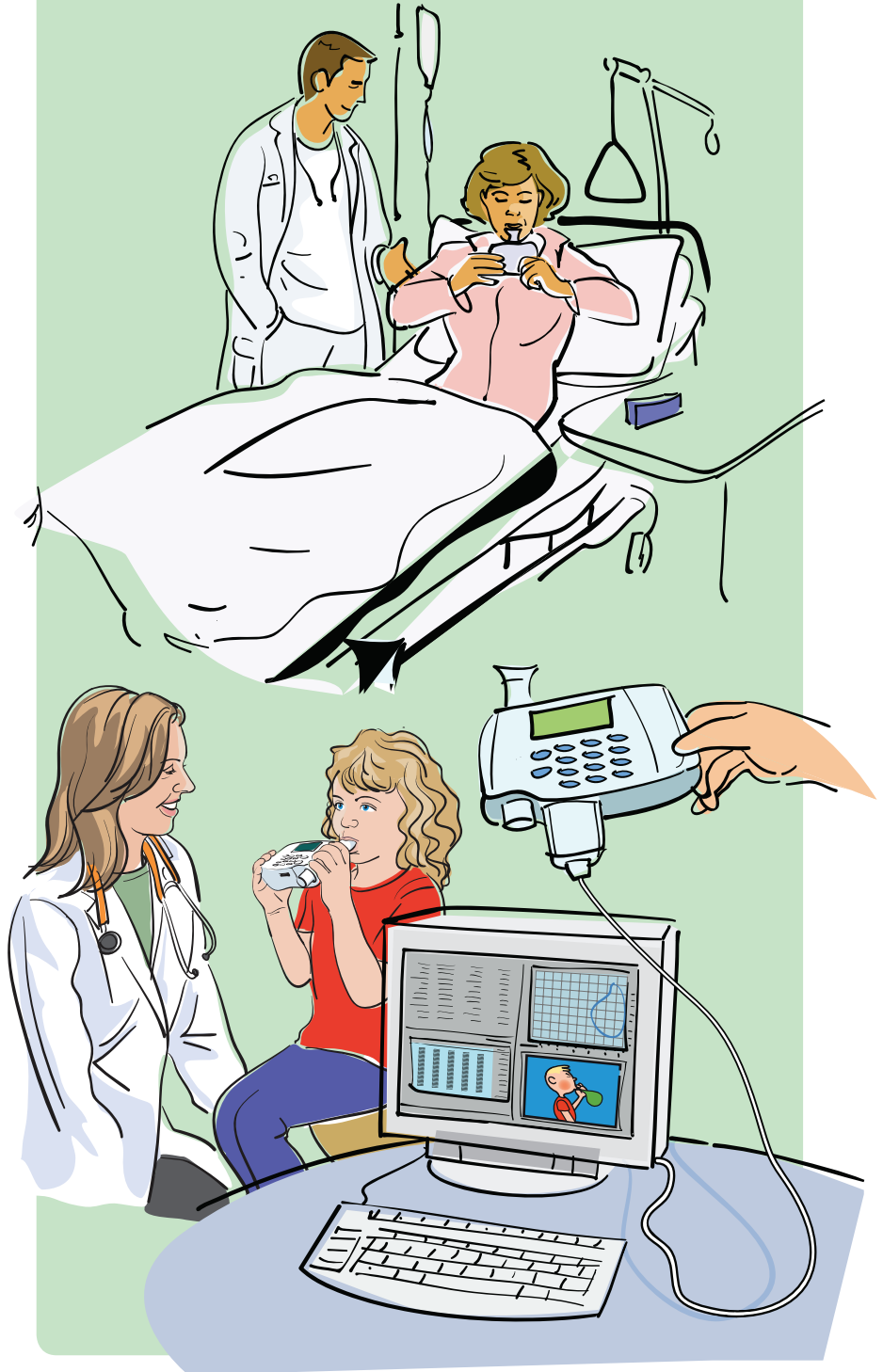
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The patient is a 65 year old male who fell backwards 10-15 feet off of a ladder. He had no underlying health related causes, and a past medical history of hypertension, atrial fibrillation and obstructive sleep apnea. Chest x-ray and CT scan indicated multiple thoracic fractures. 24 hours after admission he became increasingly short of breath, diaphoretic and hypoxic. Impending respiratory failure was evident due to pulmonary contusions, atelectasis, pneumonia while a worsening right sided pneumo/hemothorax was suspected. He had an oxygen saturation of 90% on 4 L/min oxygen via cannula with a respiratory rate of 35-45 per minute.

The solution

Invasive and noninvasive support options were considered. Respiratory Therapists suggested using Nasal High Flow with Optiflow nasal cannula which was applied

at 40% oxygen with a flow of 35 L/min. The humidifier was set to the noninvasive mode. With an epidural and Nasal High Flow, Peter's respiratory rate dropped from 42 to 23 per minute. The patient continued to improve over the next seven days, remaining on Optiflow™ nasal cannula. He was able to ingest fluids and oral medications and was able to speak with staff and family members. Family and staff also noted that he did not snore while sleeping in spite of previously diagnosed OSA. The patient's sole complaint was noticeable drying of the oropharynx, and subsequently we realized invasive mode (37 °C, 44mg/L) would have been the better choice.

Achieving an Optimal outcome

With this patient, Nasal High Flow and pain control led to the best possible outcome. Length of stay and the cost of admission were significantly decreased since intuba-

tion and assisted ventilation were avoided. Overall, the Optiflow system served this trauma patient very well and the eventual outcome could not have been better considering the circumstances surrounding the injury and treatment.



CASE STUDY CONTRIBUTED BY: Andre' Beaumont, RRT (Hon) BSc. MSc. (Cand) York Hospital, Toronto, Ontario, Canada *STORY USED WITH PERMISSION. THE RESULTS REPORTED IN THIS CASE STUDY ARE SPECIFIC TO THE PATIENT IN QUESTION.

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News

□ December-January 2009/2010

CORRECTION

In our last issue, under SLEEP PRODUCTS, the website for Ambulatory Monitoring was incorrect. The correct website address is ambulatory-monitoring.com. We apologize for the error.

GHOST IN THE MEDIA MACHINE

Doctors have been attaching their names and lending their reputations to scientific papers that were drafted by ghostwriters working for drug companies, according to an expose in the New York Times. Senator Charles Grassley, an Iowa Republican, recently known for his spurious claims about so-called “death panels,” is so concerned that he’s putting pressure on the NIH, which underwrites much of the US’s research, to crack down on the practice. But the NIH, while proclaiming its commitment to objectivity, said universities and research institutions should be the enforcers of policies regulating ghostwritten pieces. Recent revelations suggest that the practice is widespread.

Dozens of medical education companies across the country draft scientific papers at the behest of medical companies, and placing such papers in medical journals has become a standard marketing practice. Allegations of industry-sponsored ghostwriting date back to articles about fen-phen, the diet drug taken off the market in 1997. Evidence about the practice was recently revealed in a case dealing with menopause drugs, and its manufacturer’s dealings with a medical writing company hired to prepare about 60 favorable articles. The articles were published in medical journals between 1998 and 2005, even after researchers found evidence about the drug contrary to info published by the company-paid researchers. While some journals have instigated more rigorous rules about author disclosure, others have been slow to react, according to Senator Grassley’s office. A spokesperson for a university used by Grassley as evidence said that authors were responsible for the integrity of their work. But some bioethicists countered that institutions can’t just blow off the subject. In interviews with The Times, some writers explicitly named as contributors to companies providing ghostwritten pieces made various excuses, admitting that, perhaps, mistakes were made in not naming corporate sources, but claimed that more rigorous requirements for disclosure were now in place. However, some writers also noted that they have to rely on research companies for getting vital background information and doing source searches. Information for the above is from the New York Times, August 19, “Senator Moves to Block Medical Ghostwriting,” by Natasha Singer. For the record, Neonatal Intensive Care accepts articles from all sources, as long as the author and all affiliations are clearly named.

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OPEN ACCESS

In a major step forward for the open access movement, Berkeley, Cornell, Dartmouth, Harvard and MIT announced a joint commitment to provide their researchers with central financial assistance to cover open access publication fees, and encouraged other academic institutions to join them. The aim of the Compact for Open Access Publication Equity (COPE) is to create a level playing field between subscription-based journals (which institutions support centrally via library budgets) and open access journals (which often depend on publication fees). The Compact commits each university to “the timely establishment of durable mechanisms for underwriting reasonable publication charges for articles written by its faculty and published in fee-based open-access journals and for which other institutions would not be expected to provide funds.” BioMed Central has long noted the asymmetry between the central support given by institutions to subscription journals via library budgets, in contrast to the relative lack of such central support for open access publishing models at most academic institutions, even where those institutions have strong policies in favor of increasing access to scholarly research. Central institutional open access funds are a natural approach to dealing with this problem, but the practical challenges involved in reshaping the flow of funds that support scholarly communication should not be underestimated, especially given the challenging economic circumstances. This makes the achievement of Harvard and its partners in realizing the Open Access Compact all the more impressive. The two-pronged approach pioneered by Harvard, mandating deposit of faculty publications into the university’s Open Access repository while also providing explicit support for fully open publishing models—looks set to be an extremely influential model and has the potential to dramatically accelerate the already rapid growth of open access journals. BioMed Central also announced that the number of journals in its portfolio has now reached 200. BioMed said, “This major milestone reflects a growing trend as senior academics and learned societies turn to open access to publish their new journals or to improve the reach and visibility of their existing journals.”

AT REST

Severe sleep apnea raises the risk of dying early by 46%, according to a news report by Reuters. Researchers at Johns Hopkins said that people with severe breathing disorders during sleep were more likely to die from a variety of causes than similar people without such sleep disorders. The risks are most obvious in men aged 40 to 70. The researchers studied 6,400 men and women for an average of eight years. Those who started with major sleep apnea were 46% more likely to die from any cause, regardless of age, sex, race, weight or smoking. Men aged 40 to 70 with severe sleep-disordered breathing were twice as likely to die from any cause as healthy men the same age. Among men, 42.9% did not have sleep-disordered breathing, 33.2% had mild disease, 15.7% had moderate disease, and 8.2% had severe disease. About 25% of the women had mild sleep apnea, 8% had moderate disease and 3% had severely disordered breathing. People with milder sleep-breathing disorders were not more likely to die early.

WEST POINT

The 1st Annual West Point Sleep Medicine Conference was held at the Hotel Thayer, West Point, NY on Friday, November 13. This new annual conference, one for sleep technologists, was produced by FOCUS Publications and marketed to all sleep

technologists in the states of NY, NJ, DE, and CT. The conference featured Dr William Dement, known throughout the country and throughout the sleep medicine profession as the father of sleep medicine. Conference subjects included complex apnea, REM behavior disorder, actigraphy, OSA, restless leg syndrome, and central sleep apnea.

SLAYING SEPSIS

Slaying Sepsis: Saving Lives with Faster and Better Treatment, presented by Dr Jeffrey C. Fried, was featured on November 4 as part of Instrumentation Laboratory ILuminations Webinar Series. Dr Fried is Chief Medical Director, Adult Critical Care, Santa Barbara Cottage Hospital, Santa Barbara, CA. Participants received a credit of 1 Professional Education Program hour through ASCLS/AARC. The program offered information about the critical components in achieving early diagnosis of sepsis and septic shock. Dr Fried discussed the relationship between rapid treatment and mortality, including the use of lactate measurements in early diagnosis, and presented a real-life scenario featuring Santa Barbara Cottage Hospital. The session concluded with an open Q&A session. The webinar was free. For info on future seminars, contact ilus.com/illuminations.

EXPANDING

BioMed Central, the world’s largest open access publisher, announced that Bev Ackerman joined the company as Commercial Director. Ackerman comes to BioMed Central from medical publisher Taylor & Francis. BioMed Central reported that it is experiencing rapid growth in manuscript submissions, has many new products in development and sees many opportunities for partnerships and relationships with academic institutions, libraries and societies.

GET THE BUGS OUT

A recent study at Bellevue Hospital Center in South Africa found that patients with cavitary pulmonary tuberculosis receiving anti-TB medications supplemented with nebulized interferon-gamma had fewer bacilli in the lungs and less inflammation, thereby reducing the transmissibility of tuberculosis in the early phase of treatment. The study showed that patients who inhale interferon through a nebulizer can reduce their disease’s transmissibility during the first few weeks of treatment. Researchers recruited 89 eligible patients with active tuberculosis and performed a randomized, controlled clinical trial. One group of the patients took anti-TB medications supplemented with nebulized interferon-gamma over a four-month period, and another took TB medications alone. Patients who inhaled interferon had a significant decrease in the amount of tubercle bacilli from the sputum smear at four weeks and fewer symptoms of cough, night sweats, fever and wheezing. Scientists also found that this group also had fewer inflammatory cytokines in lung cells recovered by bronchoalveolar lavage after four months.

STAY DIRTY

According to a study at the University of Colorado at Boulder, 30% of showerheads harbor significant levels of *Mycobacterium avium* (M avium), a bacterium associated with lung disease that can pose serious health risks for people with weakened immune systems, and can sometimes infect healthy people too. The study analyzed 50 showerheads from nine US cities. Researchers found that some M avium and other pathogens were accumulated in slimy biofilms that stuck to the inside of showerheads at over 100 times the background levels of municipal water. They noted that if you are getting a face full of water when you first turn on

your shower, that means you are probably getting a particularly high load of *Mycobacterium avium*. The increase in pulmonary infections in the USA over the last twenty or so years from nontuberculosis mycobacteria species may be linked to a rise in the number of showers people have been taking in comparison to baths, researchers said. Water spraying out of showerheads can spread pathogen-filled droplets that float around in the air and are inhaled by humans into the deepest parts of the lungs. Symptoms of pulmonary disease caused by *M avium* include fatigue, persistent dry cough, panting and/or shortness of breath, weakness, and a general sense of malaise, symptoms not unlike watching too much cable news. Scientists broke several showerheads into tiny pieces, coated them with gold, coated the surfaces with a fluorescent dye and used a scanning electron microscope to view the surfaces in detail. What to do? Researchers tried cleaning a “hot” showerhead with bleach, but a few months later, the bleach solution had caused a tripling in pathogens. The researchers also found enormous enrichments of *M avium* in soap scum, which is commonly found on vinyl shower curtains and floating on the water surface of warm therapy pools. The researchers said the risk for people with uncompromised immune systems was probably minimal, and added that metal showerheads were “safer” than plastic ones.

STAY STRESSED, TOO

Pantoprazole (Protonix and Prilosec), used to prevent stress ulcers in critically ill patients needing breathing machine support, increases the risk of those patients contracting pneumonia threefold, according to researchers at Wake Forest University School of Medicine. Researchers said that patients who develop hospital-acquired pneumonia or ventilator-acquired pneumonia have about a 20 to 30% chance of dying from that pneumonia. Scientists found, in an analysis of 834 cardiothoracic surgery patients treated with pantoprazole, that they were three times more likely to develop pneumonia. Pantoprazole has become the drug of choice in many hospitals. The study was instigated because doctors were seeing more than the usual number of pneumonias. Acid-reducing drugs can make the stomach a more hospitable place for bacteria to colonize. The researchers said doctors should reconsider the routine use of an acid reducer, noting that stress ulcer bleeding has decreased recently because patients were being fed earlier, and food reduces stomach acid. Researchers also recommended using ranitidine, and that doctors should stop using the drugs as soon as the risk of bleeding passes.

SPIT IT OUT

Scientists at Cincinnati Children’s Hospital Medical Center have identified the main genetic switch that causes excessive mucus in the lungs. The study provides a new understanding of how some cells promote chronic lung infection and excess mucus production. Scientists used to think that mucus cells, ie, goblet cells, divided and proliferated through hyperplasia. But Cincinnati researchers found that “good” Clara cells were instead changing their cell type to become goblet cells through the process of metaplasia. However, they also found that goblet cells can change back to Clara cells if the detrimental genetic influence is blocked. The regulatory gene involved in mucus production is SPDEF. Using ovalbumin to induce an allergic reaction and inflammation in the lungs of mice, researchers saw a dramatic elevation in the expression of SPDEF in the lung tissues. The mice also experienced hyper-production of thick mucus in their lungs. In mice where the SPDEF gene was switched off, inflammation and excessive mucus production did

not occur. Mice lacking SPDEF were unable to increase mucus production or develop goblet cells. Doctors said it would be a while until studies with people were initiated.

DEEPER

Pandemic swine flu can infect cells deeper in the lungs than seasonal flu, according to a study at Imperial College London. Seasonal influenza viruses attach to receptors found on cells in the nose, throat and upper airway. The pandemic influenza virus’s ability to stick to additional receptors may explain why the virus replicates and spreads between cells more quickly: if a flu virus can bind to more than one type of receptor, it can attach itself to a larger area of the respiratory tract, infecting more cells and causing a more serious infection. The virus attaches to receptors mostly found on cells deep in the lungs. Researchers used a carbohydrate microarray with 86 different receptors. Pandemic H1H1 influenza bound strongly to α 2-6 receptors, which are found in the nose, throat and upper airway, and also attached more weakly to α 2-3 receptors, which are found on cells deeper inside the lungs. Seasonal H1N1 influenza could only attach to α 2-6.

PROMISING

A new vaccine against pneumonia may offer better protection from COPD than the currently accepted vaccine, PPSV23. Researchers at the University of Alabama sought to determine the efficacy of a newer type of vaccine, PCV7, a protein conjugate vaccine, which attaches a weak pneumococcal polysaccharide antigen to a stronger diphtheria toxin antigen in the hope that the stronger antigen will provoke a more forceful defense. Conjugated vaccines were originally intended for young children who respond poorly to polysaccharide antigens. Results of a trial of 120 adults with moderate to severe COPD showed that, while both the PPSV23 vaccine and the PCV7 vaccine were well-tolerated, the PCV7 vaccine produced superior immune responses on several measures of immunogenicity. Among patients randomized to take the PCV7 vaccine, the fraction exhibiting a twofold increase in serotype-specific IgG antibodies was higher in five of the seven serotypes tested. Blood drawn from patients who had received the PCV7 vaccine was also more effective at killing pneumococci in six of seven serotypes tested one month after vaccination. Researchers are also working on a capsule of 13 pneumococcal serotypes, PCV13, to expand vaccine coverage.

NOT IMMUNE

There’s no truth to the common belief that kids who go to daycare have lower rates of asthma and allergy later in life than those who stay home. While kids in daycare do get more illnesses and experience more respiratory symptoms, any perceived protection from asthma and allergies is gone by the time they’re eight. Researchers at Erasmus University in the Netherlands found no evidence for a protective or harmful effect of daycare on the development of asthma symptoms, allergic sensitization, or airway hyper-responsiveness at the age of eight years, though early daycare was associated with more airway symptoms until age four, but only in kids without older siblings. The researchers followed a birth cohort of 4,000 Dutch children, whose parents completed questionnaires and reported airway symptoms annually. Children who started daycare early were twice as likely to experience wheezing in the first year compared to those who didn’t go. However, by age five, they were 80% as likely as non-attendees to wheeze, and by eight there was no association between daycare and wheezing. Children with older

siblings and early daycare had more than fourfold higher risk of frequent respiratory infections and more than twofold risk of wheezing in the first year compared to children without older siblings and daycare. Children exposed to both early daycare and older siblings experienced most infections and symptoms in early childhood. The study demonstrated that early exposures caused airway symptoms with no benefit later; that is, early daycare shifted the burden of respiratory morbidity to an earlier age where it is more troublesome than at a later age.

INHALE, ALREADY

Patients with COPD who live in the UK's highest asthma-prone area are under-using their preventive inhalers, according to researchers at Liverpool John Moores University. Sixty-four percent of those queried in the study were holding back on their inhaler-use to make the inhalers last longer. It was suggested that pharmacists take a more active part in monitoring repeat prescriptions and referring patients who are under-using inhalers, as well as advising on inhaler technique. In the study, 2,340 patients with asthma or COPD were studied. Three percent were over-using their inhalers.

WINNERS

Instrumentation Laboratory (IL) announced the three recipients of their Passion & Results Award. The winners were presented with their awards by IL during ceremonies at the Congress for the International Society on Thrombosis and Haemostasis (ISTH) held in Boston and at the Annual Meeting for the American Association for Clinical Chemistry (AACC), in Chicago. The award honors healthcare providers who have demonstrated true passion for their profession, resulting in improved patient care. The company received an overwhelming number of nominations for professionals involved in Critical Care and Hemostasis diagnostics, from all around the world. The winners were Dr Cesare Manotti, president of the Italian Federation of Centers for the Surveillance of Anticoagulant therapies (FCSA) in Milan, Giacinto Gervasi, MS, MT(ASCP), Lead Technologist in the Laboratory Department of Syosset Hospital, NY, and Diane Davis, MT(ASCP)SH, Clinical Laboratory Specialist, Pathology/Laboratory Medicine, All Children's Hospital, St Petersburg, FL. Dr Manotti developed new tools and processes in diagnostics. He pioneered the development of PARMA OAT Software and contributed heavily to quantifiably improving Oral Anticoagulant Therapy (OAT) quality throughout Europe with PARMA and other related software. Giacinto Gervasi was chosen for an exemplary career as a laboratory technologist. His career began in 1966, and ever since, he has been recognized as being "invaluable to the lab" for his intelligence, enthusiasm, good judgment, and for being a resource for the entire staff. Diane Davis developed an entire POC testing program—from scratch and with no set of directions or an existing model. Davis's point-of-care-testing (POCT) program has been heralded as "one of the best in the US." It provides testing for three pediatric ICUs, an 80-bed Neonatal ICU, a Cardiovascular OR, the Cath Lab, and the Emergency Room. Contact ilww.com.

Companies

CHECK PLEASE

With a click of a button, the lives of thousands may have changed for the better. As the winning online bidder for a Siemens Healthcare digital radiography (DR) system, John T. Mather Memorial Hospital in Port Jefferson, NY, presented

a check for \$285,309 to the Children's Health Fund (CHF) (childrenshealthfund.org), a national organization dedicated to providing healthcare for homeless and medically disadvantaged children and advocating on behalf of all children. Mather Hospital's new Siemens DR system, the Ysio, allows the hospital to comfortably image patients of various shapes and sizes, ages and disabilities. In December 2008, Siemens donated a new Ysio to the CHF, which, in turn, posted the digital X-ray system online, enabling hospitals to bid in an online auction over a two-week period. All proceeds from the event benefit CHF to further support the non-profit organization's work with underserved children and their families throughout the country, while the winning hospital can better serve its community with a DR system for virtually all their clinical demands. Online auction bidding took place December 8-18, 2008. The starting bid for the Ysio was \$99,999. (The system's list price is \$450,000.) The newly installed Ysio will enable Mather Hospital to use the DR system as an integrated command center by controlling their workflow from registration to image data management. (Acceptance of the proceeds of the auction did not constitute an endorsement of the Ysio by the Children's Health Fund.) With more than 500 different preset examination positions, Ysio can save preparation time and effort. Simply pressing a button on the wireless remote will automatically move the X-ray tube into position. Ysio's wireless detector (wi-D) handles like a cassette and can be removed from the table and placed directly underneath or next to the patient for exposures that are difficult or impossible to take using a fixed detector. As a digital radiography solution, Ysio delivers pristine image quality with high-resolution images available within seconds of acquisition. Images acquired with the wi-D can be previewed in as little as five seconds without the need to change or process cassettes. Contact usa.siemens.com.

COMFORTABLE

B&B Medical Technologies announced the release of the Sil.Flex Stoma Pad, designed to enhance comfort and care for patients with tracheostomies. Stoma sites require routine care throughout the day and often become sensitive or compromised due to constant pressure or movement of the neck flange against the surrounding tissue. The patent-pending Sil.Flex Stoma Pad is an ergonomically designed device that provides a cushion between the rigid flange of the tracheostomy tube and stoma site. The contoured surface of the Sil.Flex Stoma Pad provides a stable, comfortable interface between the flange and the patient's skin. Use of the Sil.Flex may assist in lowering irritation of the skin at the stoma site. Sil.Flex Stoma Pads are made of a soft, fillerless elastomeric silicone encased in polyurethane. Pliable and flexible, the Sil.Flex Stoma Pad is available in three shapes and sizes to provide a safe and cost effective solution for the smallest infant to the largest adult. Hypoallergenic and latex-free, each sterile Sil.Flex Stoma Pad is individually packaged. The patent pending design allows for easy patient application and is simple to remove for routine cleaning and sanitation. Contact bandb-medical.com.

LIFE SUPPORT

Royal Philips Electronics introduced the Trilogy100 portable at-home life-support ventilator. The highly versatile, lightweight (11 lb / 5 kg) device marks a milestone in home ventilation from a recognized leader in respiratory care. Philips Respironics offers a broad range of clinically proven solutions intended to support breathing in the intensive care, sub-acute, and home care settings. Developed to meet the needs of a wide range of patients, Trilogy100 offers both volume- and pressure-control

ventilation for adult and pediatric use with features intended to help caregivers and clinicians administer patient care in the home and alternative care settings such as skilled nursing facilities. A growth area, the number of home ventilator-dependent patients has risen in the 1980s and 1990s, a result of increased survival rates of critically ill patients and technological advances, such as noninvasive ventilation. Trilogy100 features Respiroics' proven bi-level technology with advanced leak compensation, enabling the patient to receive more types of therapy from a single device. The system streamlines the ventilation process with interchangeable active and passive exhalation ports and the flexibility to choose the best available circuit and patient interface. Trilogy100 can accommodate a mask, mouthpiece or tracheostomy. The portable ventilator also can eliminate cumbersome valves and tubing by utilizing the passive circuit with Whisper Swivel II for invasive ventilation. For patient mobility, the compact design includes detachable, internal, and external power options, with up to 6 hours of battery capacity. Patients can be as active as possible while using the ventilator to support their breathing. The Trilogy100 ventilator's intuitive design allows for quick access to device settings and patient information. The easy-to-read, easy-to-navigate screens and clear, concise directions offer simplified patient views. In addition, optional DirectView patient data management software allows clinicians to more efficiently manage ventilation therapy with access to full patient information, including waveforms, trends, usage patterns, and summary statistics. The Trilogy100 life-support ventilator is backed by Philips Respiroics service and support programs, including a 24/7 call center staffed with clinical and technical specialists, in-depth ventilation workshops, and educational training resources. Contact philips.com. (See other Philips Respiroics products in this issue's AARC Preview Roundtable.)

RADIOMETER UPDATE

Radiometer and Medical Automation Systems (MAS) have begun a limited launch of a RALS-Plus module for Radiometer's ABL series blood gas analyzers. The module will enable users of Radiometer's **ABL800** and **ABL80** analyzers to automatically manage, report and electronically transfer patient blood gas data to the RALS-Plus database and the hospital's laboratory information system. In a recent study comparing Nova StatSensor, i-STAT and laboratory reference methods, the ABL800 with whole-blood creatinine was found to have the best correlation to plasma creatinine and the best clinical concordance when creatinine values are used to calculate GFR. The study findings were presented in a poster session at the 2009 AACC Clinical Lab Expo in Chicago. In other Radiometer news, the Ohio POC Network recently hosted a webinar featuring Dr Jay Jones of Geisinger Health System who presented his study on "Lean POCT and its clinical application." Jones' study examines the use of Radiometer's safePICO syringe and ABL800 analyzer in the process improvement study. Contact radiometer for the full webinar recording... The **ABL80FLEX** offers portability and fast turnaround time in point-of-care testing. Suitable for POC testing in low-, medium- and high-volume testing sites, the ABL80 FLEX measures pH, blood gas, electrolyte, oximetry and metabolite parameters. This portable, cartridge-based analyzer features fast cycle time and automated QC for maintenance-free operation. Contact radiometeramerica.com.

SHHH

Efforts to comply with the American Academy of Pediatrics' recommendation for sound levels in the NICU continues to

drive noise reduction efforts in the ventilator industry. Bunnell Incorporated announced a sound reduction upgrade for the Life Pulse High-Frequency ventilator. The upgrade reduces sound output from an average 56 dB to 41 dB (using an A-weight averaging meter). The upgrade results in a 15 dB decrease that is perceived as a 60% reduction in sound level compared to the current Life Pulse model. The Life Pulse is now 4 dB below the American Academy of Pediatrics' recommended sound level of 45 dB for NICUs. Bunnell Incorporated has been a leading manufacturer of high-frequency ventilators for 20 years. Sound reduction has been a major emphasis for the past ten years. This current effort represents Bunnell's second sound reduction upgrade in the last five years. Contact bunl.com.

SLEEP EASY

ImThera Medical, Inc announced that it has completed development of its Targeted Hypoglossal Neurostimulation (THN) system for Obstructive Sleep Apnea (OSA). More than 800,000 patients in the US are diagnosed annually with OSA. While Continuous Positive Airway Pressure (CPAP) remains as the established therapy, studies show that up to 50% of patients do not comply with CPAP. ImThera Medical's technology and THN Sleep Therapy was developed as a surgical option for patients who cannot or will not comply with CPAP. ImThera Medical's THN Sleep Therapy delivers neurostimulation to the hypoglossal nerve to control certain muscles of the tongue. Using a multi-contact electrode and a programmable implantable pulse generator (IPG), the system delivers muscle tone to key tongue muscles to prevent the tongue from collapsing into the upper airway. This technology includes a small multi-current source IPG, operating in continuous, open loop mode, delivering targeted stimulation. The system is designed to increase airway flow, permitting normal and restful sleep for OSA patients. The company has received Ethics Committee clearance to begin human clinical trials in Belgium. Along with the clinical trial approvals, ImThera has received ISO 13485 certification of its quality system as a prerequisite for the future CE mark application for European commercialization of medical products. ImThera's European clinical trial, a pilot study involving ImThera's THN sleep therapy system, is expected to publish its first results in the first quarter of 2010. The company unveiled its aura6000 neurostimulation system for the treatment of OSA at the American Academy of Otolaryngology-Head and Neck Surgery annual meeting. The system comprises a surgically-placed multi-contact electrode specifically designed for the Hypoglossal nerve, and a wire (lead) that connects the electrode to a programmable implantable pulse generator (IPG) that is placed in the anterior chest wall. Based in San Diego, ImThera Medical is a privately funded, early-stage company developing a patent-pending, neurostimulation medical device for the treatment of Obstructive Sleep Apnea (OSA). ImThera's device is not for sale in the US. Contact imtheramedical.com.

CHAMBER-MADE

Monaghan Medical Corporation (MMC) announced the launch of its newest chamber product, the AeroChamber mini AC. It is a device designed to deliver pMDI aerosols to patients in conjunction with mechanical ventilation, manual resuscitation bags and standard aerosol masks. The AeroChamber mini AC has an anti-static dual chamber design that includes an inhalation and exhalation chamber. The patented exhalation chamber has a one way valve to preserve dose and minimize dead space. The product has an AeroDock canister port that accommodates both standard pMDIs and those with integrated dose counters. The

counters will activate with this feature. The AeroChamber mini AC fits in front of a wye or HME in a ventilator circuit. When in the circuit it is designed to maintain positive end expiratory pressure (PEEP). The unit is effective for use with low tidal volume patients. The AeroChamber gives the clinician the ability to provide aerosol to a wide range of ventilated patients with pMDI formulations with and without dose counters. Contact monaghanmed.com.

INTELLIGENT

Hamilton Medical recently presented the next era of intelligent ventilation at the ESICM Annual Congress in Vienna. The company also launched its first fully closed loop solution AUTOSAFE-ASV for mechanical ventilation. AUTOSAFE-ASV will reduce complexity, giving you more time and safety for your patient. Contact hamilton-medical.com.

STEPPING UP

Royal Philips Electronics announced the appointment of Eoghan O'Lionaird to lead Philips Home Healthcare Solutions' sleep business as Senior Vice President and General Manager. O'Lionaird joins Philips' fast-growing Home Healthcare Solutions group, following his tenure as Senior Vice President and General Manager, Imaging Systems Components. Since joining Philips in 2000, he has served in senior management positions across the organization, including strategy and business development manager and subsequently, business unit manager of Imaging Solutions in Philips Components; General Manager of Philips Lighting in Japan; and General Manager of the Magnetic Resonance business unit in Healthcare.

IT'S A PEPPER

The new Pepper Medical Inc Pedi-Vent-Tie # 401-P is a patented ventilator anti-disconnect device coupled with a trach tube neckband. This unique combination device offers a margin of safety to ventilator dependent patients and clinicians alike. The easy to use Pedi-Vent-Tie features a quick release Velcro strap that is compatible with all trach tubes, elbow connectors, and closed suction devices. The integral anti-disconnect strap eliminates the use of rubber bands, shoelaces and tape to secure the ventilator circuitry to the trach tube. The Pedi-Vent-tie neckband is made of a soft, 100% cotton flannel that offers moisture wicking properties to keep skin dry and cool. This disposable, combination product saves time and money by offering an all-in-one device. The economical Pedi-Vent-Tie is priced at \$3.95 each, individually packaged in boxes of 20. Free samples available upon request. Contact peppermedical.com, (800) 647-0172.

BREATHE EASIER

Nycomed and Forest Laboratories announced the results of four phase III trials of roflumilast (Daxas). Results showed it improved lung function and reduced exacerbations in patients with moderate to severe COPD. Roflumilast, a phosphodiesterase 4 (PDE4) inhibitor and once-a-day oral tablet, is a first-in-class treatment under development targeting inflammation, the underlying cause of chronic obstructive pulmonary disease (COPD). If approved, roflumilast would be the first in an entirely new class of treatments for COPD. The phase III placebo-controlled trials of roflumilast consisted of two 12-month and two six-month studies, and included 4,500 patients in 10 countries. Lung function was the primary or co-primary endpoint in all four studies. Across the studies, roflumilast demonstrated a statistically significant improvement in pre-

bronchodilator FEV₁, in the range of 48 to 80 mL (p<0.001). Nycomed filed a New Drug Application (NDA) with the US Food and Drug Administration and a Marketing Authorization Application with the European Medicines Agency. Roflumilast targets cells and mediators in the body believed to be important in the COPD disease process. Roflumilast is expected to act on the underlying mechanism of COPD and related inflammatory diseases. It could significantly improve the way these conditions are managed, reducing exacerbations requiring medical intervention, including hospitalization. If approved, roflumilast, a once-a-day tablet, will be the first drug in its class. It will also be the first innovative treatment specifically for people with COPD for a generation, according to the manufacturer. Current treatment for COPD patients includes the use of inhaled bronchodilators and inhaled corticosteroids. The two 12-month studies published in *The Lancet* demonstrated that roflumilast produced a statistically significant and clinically relevant reduction in exacerbations, even for patients who were also taking long-acting bronchodilators. The studies showed a reduction in moderate to severe exacerbations by 17% per patient per year (rate of 1.14 events per year with roflumilast vs 1.37 per year with placebo, p<0.001). The reduction in exacerbations was irrespective of concomitant treatment with long-acting beta-2 agonists, a standard bronchodilator therapy. When added to standard bronchodilator therapies in the two six-month studies, a clear trend for the reduction of exacerbations was observed with roflumilast, over and above what was achieved with these therapies alone. There was also a statistically significant difference with roflumilast in other pre-specified endpoints, including median time to first exacerbation (moderate to severe in the salmeterol study, and mild, moderate and severe in the tiotropium study) and in the proportion of patients in both studies experiencing a mild, moderate, or severe exacerbation. Nausea, diarrhea and weight loss were the most common adverse events recorded in patients in the four trials, but they were generally mild to moderate in intensity and generally occurred in the first weeks of treatment. Results showed that in addition to confirming the sustained statistically significant improvements in lung function, roflumilast also showed a trend to reducing exacerbations when given in addition to long acting inhaled bronchodilators. The results of the two six-month trials examining the additive effect of roflumilast on top of salmeterol or tiotropium support and extend the findings of the 12-month trials, by showing a clinically relevant lung function improvement in patients with impaired lung function on top of maximum bronchodilation.

EAR-LY WARNING

Respiratory Technology Corporation (dba Restech) announced that Ear, Nose and Throat Clinic of Fairbanks, Alaska, has adopted the Restech Dx-pH Measurement System to detect acid reflux in the airway. Restech's Dx-pH System provides valuable information about patients' pharyngeal acid exposure and its role in various comorbidities, helping physicians diagnose the cause of each patient's symptoms more accurately, and treat the patient more effectively. The Restech Dx-System can more accurately diagnose patients, enabling more precise treatment. It helps dramatically in titrating diagnoses and ruling out LPR and, in rare cases, sinus problems. The Restech Dx-pH Measurement System is a revolutionary system that comfortably measures pH in the airway. The miniaturized pH sensor at the tip of the Dx-pH Probe is unique in its ability to measure pH in a non-liquid environment, such as the pharynx. By monitoring the pH levels in the pharynx, the Dx-System enables physicians to confirm or

deny the presence of laryngopharyngeal reflux, and evaluate it as a possible contributor to their patients' symptoms. The Dx-pH Probe's miniaturized, patented sensor is housed in the tear-drop shaped tip at the distal end of a thin trans-nasal catheter. An LED blinks during placement, allowing the medical personnel to confirm the proper placement in the oropharynx. The small size and minimally invasive position of the Restech Dx-pH Probe allows patients to carry on normal, everyday activities including eating, talking and sleeping with more comfort than conventional esophageal pH probes. The measurements taken by the pH sensor are sent wirelessly to a recording device which the patient carries throughout the study period. Upon completion of the study (usually 24 hours), the patient returns to the physician's office where the data is downloaded and presented graphically for analysis using Restech's custom Dx-pH DataView software. Contact restech-corp.com.

LET'S FACE IT

SFF, LLC and Wein Products of Los Angeles have introduced the FITSEAL respirator. It is an efficient, comfortable, and the only self-adhesive disposable face mask available today. The FITSEAL respirator is a patented design with NIOSH ratings of N-95, N-99 and P-100. It is a unique self adhesive respirator that insures the least Total Inward Leakage (TIL) of any disposable respirator. It is ideal for quick protection in any environment. It is comfortable for long term wearing, and also puncture, crush, tear and fluid-resistant. It is compact for easy storage and portability. It simplifies fit-testing procedures—one size fits all. Contact superiorfelt.com.

IN MOTION

Ambulatory Monitoring, Inc, Ardsley, NY, is the provider of physiological and environmental monitoring devices. Besides its Inductotrace System—a plethysmograph which has been in existence and in use in sleep and pulmonary laboratories throughout the world for 35+ years—AMI offers its line of Motionlogger Actigraphs, which enable a clinician to monitor the continuous, long-term sleep/wake patterns of patients in their natural environment. Motionloggers provide an ideal modality for obtaining objective data pre in-lab sleep testing as well as a means to determine and document the efficacy of treatment intervention. Unique to its Motionlogger product line, AMI also offers companion environmental sensors. There is one for ambient light, one for temperature, and one for sound; and when any or all of these sensors are used in conjunction with a Motionlogger motor activity recorder, the result is a comprehensive display of the simultaneous effects of environmental factors on one's sleep. AMI, a company which has been in business since 1970, takes pride in the equipment it sells and the service it provides to its world-wide base of customers. Knowledgeable and friendly staff are always on hand to answer customer questions; provide explanations and technical assistance; listen to what our customers have to say and respond to customer needs. With a keen understanding of the importance of sleep as it relates to overall human well-being and life quality and an awareness of the effects of poor sleep on human performance and cognitive ability, AMI will be adding new features to its next generation of Motionloggers such as a user rating scale and on-wrist reaction time test. An additional new feature is a channel called "Life Measures," which dramatically aids the actigraph analyst to discriminate Motionlogger off-wrist times from periods of sleep. Contact ambulatory-monitoring.com.

AARC Product Roundtable

Aerogen

What new products will you be presenting at AARC?

We are very excited to be exhibiting our single patient use disposable nebulizer, the Aeroneb Solo. The Aeroneb Solo is a disposable version of the established Aeroneb Pro nebulizer favored by leading ventilator manufactures and RTs as their high performance nebulizer of choice. The Aeroneb Solo provides effective dose delivery of physician-prescribed inhalation solutions for infants through adults requiring mechanical ventilation. It produces a fine particle, low velocity aerosol optimized for deep lung deposition with the increased flexibility of intermittent and continuous use.

What products will you be presenting of relevance to emergency response and disaster preparedness?

The recent outbreak of H1N1 Influenza-A virus has caused considerable concern in both the healthcare and general community. The ability to use aerosol medication to treat underlying respiratory disorders that may become exacerbated in an infected patient is an essential part of patient care. Our Aeroneb Solo offers a safe option for aerosolizing H1N1 infected patients requiring mechanical ventilation. This is because the Aeroneb Solo is a single patient use nebulizer; it enables the RT to maintain a closed circuit even during refilling of the medication cup and it does not nebulize potentially contaminated circuit condensate. The single patient use nebulizer provides prevention against contamination as the positioning of the nebulizer above the circuit ensures no condensate is nebulized. Also, caregivers do not have to break the circuit to use the Aeroneb Solo. The Aeroneb Solo can be used for up to 28 days.

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

As a leader in the field of aerosol science we promote continued education and research in the field and will continue our policy of supporting relevant research and RT programs and studies which further knowledge of ventilator nebulization. We will be demonstrating our innovative technology and our exciting Aeroneb Micropump Nebulizer product line for pulmonary drug delivery. All our staff are on hand to answer any questions people may have regarding nebulization of the mechanically ventilated patient. Journal articles and case studies on the Aeroneb nebulizers will be available at our booth (#319).

What speakers will your company be working with or featuring?

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

What in booth promotions will you be offering?

Following its huge success last year in Anaheim, we will again be inviting our customers and distributors to join us at our "Irish Party Night" in San Antonio. Please drop by our booth for details (#319).

Why should AARC participants visit your display?

RTs should stop by our booth (#319) if they want a hands on demonstration of the most technical innovation in nebulization for more than 50 years. RTs can learn more about how to

improve the quality of ventilated patients' lives through the use of our highly efficient nebulizers. We will demonstrate how our nebulizer range saves RTs valuable time as our products operate without changing patient ventilator parameters therefore not setting off ventilator alarms and can be refilled without interrupting ventilation. It may change the way you nebulize forever. AARC offers an excellent opportunity to meet with Aeroneb users and hear about their experiences and needs with the technology.

B&B Medical Technologies

What new products will you be presenting at AARC?

Our newest product, the Sil.Flex Stoma Pad, will radically improve comfort and care for patients with tracheostomies. The patented Sil.Flex Stoma Pad is an ergonomically designed soft and flexible cushion that absorbs pressure between the stoma site and the tracheostomy flange. Sil.Flex is made of medical grade silicone encased in polyurethane. Hypoallergenic and latex free, Sil.Flex stoma pads come in three sizes, accommodating small infants to large adults. Each pad is individually packaged, is intended for single patient application and may be used for up to 14 days. Once applied, Sil.Flex is easily removed for cleaning. Sil.Flex Stoma Pads are a cost effective and convenient solution to assist in reducing irritation at the stoma site. The Sil.Flex Stoma Pad can be used in all critical care units, operating rooms, emergency departments and special procedure units as well as alternate care facilities and home care. Sil.Flex Stoma Pads enhance patient comfort with all brands and styles of tracheostomy tubes. B&B's TrachGuard or the TrachStay may be used in combination with the Sil.Flex Stoma Pad.

B&B Medical Technologies also has introduced two new medical grade Heliox regulators with DISS fittings. The compact and versatile Heliox 70/30 DISS and Heliox 80/20 DISS regulators will help medical facilities reduce costs by eliminating the need for two separate regulators for low flow Heliox therapy and high pressure gas delivery devices. Designed for use in critical care, special procedure units and emergency departments, the B&B regulators are easy to set up with either 70/30 or 80/20 Heliox H cylinders. Calibrated for delivery of precise flow and MRI compatible, no conversion or calibration of flow is needed to determine accurate Heliox flow. Easy to set up on H cylinders, the permanent O-ring design eliminates the need for a washer and provides hand tight seal at the yoke connection. The 70/30 DISS regulator and 80/20 DISS regulator are recommended for use with the HOPE nebulizer.

To control the chaos of unruly high pressure cables and power cords found in most departments, B&B Medical Technologies Wrap-Safe is the solution. Attached by a snap-rivet and needing no tools to securely adhere, Wrap-Safe is designed to stay on the cord, cable or high pressure hose permanently and it is easily cleaned with bactericidal cleaner.

Why should AARC participants visit your display?

Most folks who have been around the industry for a while tell us they visit the B&B Medical Technologies display because they know they'll find clinically proven and cost effective products for adult, pediatric and neonatal patients whether the need is for critical care, anesthesia, emergency, transport, home or alternate care environments. But B&B Medical Technologies also is renowned for giving away the most delicious lollipops on the planet, See's Candies Gourmet Lollipops. We think there may be

a few folks who visit the display just to get a See's Lollypop fix. B&B Medical is in booth 813.

Bunnell, Inc

What new products will you be presenting at AARC?

Bunnell Incorporated will be promoting an upgrade to its Life Pulse High-Frequency ventilator that reduces its sound level output by 60%, from 58 dBA to 41 dBA. That makes the Life Pulse the quietest high-frequency ventilator available in the US. The Life Pulse is now 4 dBA below the American Academy of Pediatrics' recommendation for sound level in the NICU.

What products will you be presenting of relevance to emergency response and disaster preparedness?

The Life Pulse High-Frequency ventilator can be rented on an emergency basis to meet peak demands. Ventilators are delivered in 1-4 hours nationwide 24/7, 365.

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

Bunnell has developed a three booklet pocket reference series on the Life Pulse High-Frequency ventilator. The booklets cover "What" high-frequency ventilation is compared to conventional ventilation; "Why" high-frequency jet ventilation is effective and unique compared to other high-frequency ventilators; and "How" to use the Life Pulse to manage patients successfully. A new training DVD is now available from Bunnell that includes a full in-service video, an alarms and troubleshooting video, and a patient management video. The DVD also contains a competency exam and a certificate of completion.

What speakers will your company be working with or featuring?

Bunnell is hoping to participate in the Respiratory Care Solutions Showcase at the 2009 International Congress in San Antonio, Texas. If our proposal is accepted, the presentation will focus on The Life Pulse HFV: How it works & Why it's Effective.

Why should AARC participants visit your display?

AARC participants concerned about noise in the NICU will want to visit the Bunnell exhibit to hear how quiet High-Frequency ventilation can be with new sound reduction technology. At 4 dBA below the American Academy of Pediatrics' recommendation the Life Pulse HFV is just a whisper. Participants will also want to pick up our new educational pockets references and training DVD. Whether they are new to the field of respiratory care or seasoned veterans, these materials will provide new insights into high-frequency ventilation. Bunnell is in booths 731-733.

CareFusion

What new products will you be presenting at AARC?

CareFusion will be highlighting the new EnVe ventilator, a high-end critical care ventilator in a compact 9½ lb package, and the first two items in a series of consumable products designed to eliminate the need to break the ventilator circuit, the AirLife Bypass HME and Closed Suction System. The AirLife Closed Suction System with the Verso adapter is modular and versatile, allowing you to replace the catheter and/or perform a bronchoscopy without changing the adapter or breaking the circuit.

What products will you be presenting of relevance to emergency response and disaster preparedness?

The LTV 1200 Rolling GoPack is the configuration purchased by the CDC for the national stockpile to release for use in Mass Casualty or Pandemic Emergencies.

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

We will be displaying our revised Emergency Set-Up training DVD as well as other respiratory awareness training resources. CareFusion is in booth 135.

Dale Medical Products, Inc

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

Dale Medical Products, Inc, together with Saxe Healthcare Communications, is proud to sponsor the publication, Perspectives Recovery Strategies from the OR to Home. Perspectives strive to provide respiratory therapists and nurses with the most current clinical information on postoperative recovery strategies. Each issue provides the clinician with an opportunity to earn free continuing education credits. To receive a free subscription please call us toll free at (800) 343-3980.

Why should AARC participants visit your display?

Visit for hands on training, to sign up to receive free samples of Dale products and to learn why they are beneficial to RTs. The Dale Tracheostomy Tube Holders build in all the features you demand for maximum security, patient comfort and ease of use. The holder has a moisture repellent lining, which wicks the moisture away from the skin, to reduce the risk of skin breakdown. The exclusive fastener tabs easily attach to the tracheostomy tube and secure it in place. The Dale PediPrints is a printed series of tracheostomy tube holders for your pediatric populations. The holders are not only secure and comfortable, but also comforting, with patterns on the straps. The Dale Stabilock Endotracheal Tube Holder helps prevent accidental extubation by providing a secure method of stabilization. The endotracheal tube is secured in place, you have easy access to the mouth for oral care and the cushioned neckband is soft and comfortable on the face and neck. Dale Medical is in booth 566.

Fisher & Paykel Healthcare

Fisher & Paykel Healthcare has a long history of developing innovative products for respiratory care and will be featuring several of these new products at the 2009 AARC. Some of the items featured for hospital use include Evaqua circuit technology, Optiflow High Flow Humidity Therapy, and the Neopuff T-Piece resuscitation device. Products for the Obstructive Sleep Apnea market include ThermoSmart humidified CPAP for OSA, SensAwake technology and SmartStick Net. As part of the MR850 Humidification System, we are featuring Evaqua circuit technology and Optiflow. The Evaqua technology is an important and unique technology, exclusive to Fisher & Paykel Healthcare. Evaqua circuits have a heated expiratory limb made from a unique material that allows water vapor to exit the circuit rather than collecting as condensate inside the circuit. Optiflow for High Flow Humidity Therapy is a large bore nasal interface capable of handling gas flows to 60 lpm for adults with low system back pressure and superior condensate control performance.

Optiflow has been used successfully in many clinical scenarios with patients in mild to moderate respiratory distress. Optiflow also has applications with neonatal patients with a slightly different setup configuration. The key to success with Optiflow is applying it with body temperature and saturated gases with the MR850 humidifier. The Neopuff T-Piece Resuscitator, mentioned as the device of choice in the new NRP guidelines for infant resuscitation, will be on display. Clinicians at the AARC can try their skill to beat the resuscitation simulator. To complement Neopuff are a unique line of resuscitation masks with the first ever 45 mm mask for very low birth weight patients.

Fisher & Paykel Healthcare provides solutions for the treatment of OSA that include a comprehensive range of CPAP units and humidification technologies in addition to a full range of interfaces. Fisher & Paykel Healthcare's innovative ThermoSmart technology, available on our SleepStyle 600 CPAP Series, offers a unique heated breathing tube that allows for the delivery of higher levels of humidity throughout the night, while preventing condensation in the tubing. ThermoSmart technology clears the way for optimal therapy success and unsurpassed levels of patient comfort.

For users of OSA devices, clinical evidence has shown that patients commonly arouse from sleep (~10/hr) which can sometimes lead to full awakenings. During these awake states, patients can be intolerant of the pressure and patient comfort is critical for the patient to return to sleep. Unique SensAwake technology, available in the SleepStyle 200 Auto Series, detects when a patient is transitioning to a wakeful state and promptly lowers the pressure to aid the transition back to sleep. The result is a more personalized therapy during sleep and awake states.

Finally, Fisher & Paykel Healthcare's new SmartStick Net is our simple, cost-effective, online solution that allows CPAP progress to be monitored remotely. SmartStick Net has no need for card readers or phone lines. The patient simply places their SmartStick Net into their computer and the data will be sent via the internet to the SmartStick Net website. One simple click on the "dashboard" will provide the required insurance documentation. SmartStick Net automatically calculates and identifies compliant and / or non-compliant patients with a color-coded dashboard layout to assist with patient management.

Please join us in San Antonio at booth 503 for a complete review and demonstration of all Fisher & Paykel Healthcare products.

Hill-Rom

Featured Products

From a product standpoint Hill-Rom will be exhibiting its updated full line of disposable vest garments and disposable air hoses for the acute care environment to aid in the minimization of cross contamination.

Educational Opportunities

Hill-Rom will have booth representatives available to demonstrate and instruct participants on home and acute care products. Stop by and see our updated website and new patient stories. We will be giving away "sticky lungs" and disposable tape measures. We will also be offering promotional office supplies with company logo and contact information. Other offerings are being worked on—stop by and check it out.

Why Stop By?

We are excited to discuss Medicare's expanded coverage of High Frequency Chest Wall Oscillation for many neuromuscular conditions and what this means for patients who require our product outside of the acute care setting. Hill-Rom received the 2008 Therapy Times Most Valuable Products award in Respiratory Therapy for the Wrap SPU Vest and The Vest System. The Wrap SPU Vest is a single patient use disposable product designed to minimize the risk of cross contamination and to ease product placement and removal for patients in acute and long-term care settings. The Vest Airway Clearance Model 205 was also the winner of the 2007 Medical Design Excellence Award. Both of these will be displayed at our booth—please stop by to see our full disposable line. We are in booth 217.

Hydrate, Inc

What new products do you plan to exhibit?

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

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

We will be providing demonstrations at our booth at the AARC (#814) and visitors will also have access to copies of posters presented at the AARC and other conferences.

Why should our readers stop by your booth?

If respiratory clinicians want to see tomorrow's humidification technology today then they will want to stop in to see Hydrate at booth #814. Although we are introducing the C-Force T for high flow gas therapy for tracheotomies, we will also feature the mechanical ventilator model, the C-Force V, and the high flow gas model, the C-Force G. This remarkable system will finally enable RTs to fully control and monitor humidification, as they never have been able to before.

Innovative Respiratory Concepts

What new products will you be presenting at AARC?

This year, Innovative Respiratory Concepts (IRC) will be highlighting a new innovation that is 10 years in the making. This technology, which originated from Purdue University, has the potential to change airway safety and prevent unintentional or accidental extubations, saving the caregiver and patients valuable time, expense, and associated risks. IRC and its network of clinical specialists are very excited to be a part of highlighting this device as a sneak peek before its market debut. Look for us at the AARC in San Antonio, Booth # 462. IRC has over 200 respiratory therapists (RTs) and clinical specialists of which some have been involved in ongoing evaluation and feedback into the needs of technology in respiratory care. IRC supports the growth and development of technology, clinical practices, and clinicians.

What will you be offering in terms of emergency response?

This year, we are proud to provide you the opportunity to speak in person with David Swift, RRT who is a highly recognized specialist in disaster preparedness. Swift currently is appointed as the Respiratory Team Lead for Canada's National Office of Care Emergency Response. He has written many articles and provided lectures on preparing your hospital for a real pandemic or disaster. You will be able to check your Preparedness IQ with a real expert to help you as you prepare your hospital.

Discuss educational materials you will be promoting.

We will be offering educational opportunities in accidental extubation and airway safety. Available will be some compelling statistics as well as information collected this year from an independent survey. Also, we will have additional topics in respiratory drug delivery and monitoring.

What speakers will your company be featuring?

We will be highlighting speakers and opportunities for our 2010 conference along with featured and upcoming articles authored by RTs in our Network.

Why should AARC participants visit your display?

RTs and fellow exhibitors should visit us at the AARC to see how truly innovative we are as RTs and as a company. With dual roles, we understand the needs of the caregiver, patient, and manufacturer. As RTs, we are in the frontline of care facing the daily challenges of the clinician. As a company, we work closely with manufacturers and new innovating companies helping to bridge the needs of the caregiver and the demands of producing quality technologies.

Instrumentation Laboratory

What new products will you be presenting at AARC?

Instrumentation Laboratory (IL), booth 331, will feature innovative products in Laboratory and Point-of-Care-Testing (POCT):

- GEM Premier 4000 critical care analyzer with Intelligent Quality Management (iQM)

- New GEM Premier 3500 with iQM
- GEMweb Plus information management system with NEW automated operator certification
- GEM PCL Plus portable coagulation system
- GEM OPL portable CO-Oximeter

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

IL conducts educational seminars throughout the year at customer hospitals, online and at national conferences featuring experts in the field of diagnostics and quality control. These seminars provide Continuing Education Units (CEU) for attendees. More information 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 analyzer with iQM and new GEM Premier 3500 analyzer. The analyzers offer laboratory automation at the point of care, with the simple touch of a button and provide the highest quality patient test results. Additionally, demonstrations of GEM web Plus, IL's state-of-the-art information management system, now featuring automated operator certification will be offered. And, in celebration of our 50th anniversary, the booth will showcase the "50 and Forward" program, including our history of "firsts" in the diagnostic field. Come celebrate with us, enter our Daily Drawing, grab a "celebratory treat" and learn more about our commitment to the future of diagnostics. For more information on the "50 and Forward" program and our "Passion & Results Award" winners, please visit ilus.com/50forward. Visitors of IL's booth will have the chance to enter the daily drawing to win a Flip MinoHD digital camcorder.

Invacare Corporation

What new products will you be presenting at AARC?

Invacare will be featuring the following products:

- Invacare SOLO₂ Transportable Oxygen Concentrator
- Invacare Pneumatic Oxygen Conserver
- Invacare Pediatric Bear Nebulizer
- Invacare Perfecto₂ W Oxygen Concentrator
- Lotus Electronic Oxygen Conserver

What speakers will your company be working with or featuring?

Joe Lewarski, vice president of the Invacare respiratory group.

Why should AARC participants visit your display?

Invacare is the industry leader in home oxygen and respiratory therapy. We are expanding our broad and comprehensive line of oxygen products and will be showcasing a number of those innovations at the show, highlighting how these products enhance patient care and improve quality of life. Invacare is in booth 357.

Masimo

What new products will you be presenting at AARC?

This year, we are presenting several innovative new and enhanced products at the AARC.

- **Continuous and Noninvasive Hemoglobin (SpHb):** SpHb monitoring with Masimo Rainbow SET provides clinicians with an important new way of looking at their patients' hemoglobin levels. Instead of relying on invasive, delayed, and intermittent hemoglobin measurements, SpHb provides clinicians with real-time hemoglobin measurements that may allow earlier and better decisions, improved patient safety, and decreased costs.

- **The Enhanced Masimo Patient SafetyNet System:** The Masimo Patient SafetyNet system combines the gold standard performance of Masimo SET pulse oximetry with respiration rate monitoring and wireless clinician notification via pager, providing an unmatched level of patient safety on general care floors in a system that can either be integrated into your existing IT infrastructure or operate as a stand-alone system. The newly enhanced Masimo Patient SafetyNet remote monitoring and clinician notification system significantly expands the functionality of a system that has already been proven to help clinicians improve patient outcomes and decrease costs. New features such as an intuitive touch-screen interface and the ability to monitor up to 80 patients simultaneously on four separate floors allow hospitals to noninvasively and remotely monitor more patients, more efficiently, and in more clinical detail.

- **The Rainbow ReSposable Sensor System:** The Masimo Rainbow ReSposable Sensor System offers the performance and comfort of a single-use adhesive sensor with the cost-effectiveness and environmentally-green advantages of a reusable sensor. To minimize medical waste and cross contamination risks, the system features a new two-piece design that allows the portion of the sensor that connects to the patient cable to be used on multiple patients, while the portion that attaches directly to the patient is used on only a single patient before disposal. ReSposable Sensors make it possible for hospitals to benefit from continuous and noninvasive measurements of hemoglobin (SpHb), oxygen content (SpOC), PVI for fluid responsiveness, and methemoglobin (SpMet), in addition to oxygen saturation (SpO₂), perfusion index, and pulse rate-at savings of about 50% compared to the existing single patient use adhesive Rainbow sensor.

What products will you be presenting of relevance to emergency response and disaster preparedness?

For emergency response and disaster preparedness operations, the ability to quickly, accurately, and easily detect potentially life-threatening conditions is a critical requirement. Both the Masimo Rad-57 and the Masimo Radical-7 Pulse CO-Oximeters make vital blood constituent measurements and physiological data immediately available to help emergency responders speed patient assessment, diagnosis, and treatment.

- **The Radical-7 is a 3-in-1 (bedside, handheld, transport) Pulse CO-Oximeter** that allows emergency responders to measure a patient's hemoglobin noninvasively and continuously-facilitating earlier detection of internal bleeding and more effective and efficient blood transfusion management. Featuring the breakthrough blood constituent monitoring capabilities of Masimo Rainbow SET Pulse CO-Oximetry-the first and only upgradable technology platform that continuously and noninvasively measures hemoglobin (SpHb), oxygen content (SpOC), carboxyhemoglobin (SpCO), methemoglobin (SpMet), oxyhemoglobin (SpO₂), perfusion index, PVITM and pulse rate-the Radical-7 eliminates the guesswork associated with point-of-

care patient assessments and may facilitate faster, easier, safer, and better clinical decisions.

• The Rad-57 is a lightweight, handheld Pulse CO-Oximeter that allows emergency responders to noninvasively detect elevated levels of carbon monoxide in the bloodstream in just seconds. The ability to quickly, easily and noninvasively detect carbon monoxide poisoning on the scene of an emergency or disaster may help first responders facilitate prompt and possibly life-saving treatment that can also limit the likelihood of long-term cardiac and neurological damage. The Federal Emergency Management Agency (FEMA) recently added the Masimo Rad-57 Pulse CO-Oximeter to its list of required health and safety equipment and authorized funding for its Urban Search & Rescue (US&R) task forces to purchase multiple Rad-57s. Adding the Rad-57 to FEMA's mandatory medical equipment cache enables US&R task forces to quickly, noninvasively evaluate and address the significant health and safety risks associated with CO poisoning for both civilians and rescue personnel in the urban search and rescue environment and on the scene of disaster recovery operations—helping to save and sustain lives, minimize suffering and enhance safety. In addition, the Masimo Rad-57 and Masimo Radical-7 Pulse CO-Oximeters have both received Airworthiness Release (AWR) Certification from the US Army. AWR certification affirms the durability, reliability and superior performance of both devices in a wide range of demanding environments, including those faced by emergency medical services, disaster preparedness teams, military field medical operations, and medevac units.

Discuss educational materials you will be promoting at the convention.

We offer a wide range of educational opportunities and materials designed to support clinicians in advancing their clinical practice. MasimoU (available online at masimo.com/MasimoU/index.htm) provides accredited and non-accredited courses in a convenient, self-paced online learning environment that allows clinicians to learn about noninvasive pulse oximetry and Pulse CO-Oximetry monitoring capabilities and its patient applications. MasimoU modules accredited for Continuing Respiratory Care Education (CRCE) credit include: Monitoring in Critical Care; Use of the Pulse Oximeter Waveform as a Noninvasive Functional Hemodynamic Monitor; Oxygen Transport and Neonatal Pulse Oximetry; Retinopathy of Prematurity; and Carbon Monoxide Poisoning. MasimoU non-accredited learning modules include a variety of sensor application and product training courses that help clinicians to maximize the impact of Masimo technologies, features and products on patient care. In addition, we have a number of printed materials available to help clinicians understand the clinical value and financial benefits associated with integrating Masimo technologies and products into their clinical workflows.

Why should AARC participants visit your display?

We invite AARC attendees to visit Masimo booth #447 to get their hemoglobin measured noninvasively and learn more about the clinical benefits of noninvasively and continuously monitoring of their patients' hemoglobin levels. In addition, they will be able to see a demonstration of the enhanced Masimo Patient SafetyNet System and try the new Masimo Rainbow Resposable Sensor System for themselves.

Medgraphics

What new products will you be presenting at AARC?

• CPX Express simple touch-screen operation and breath-by-breath analysis make it the ideal cardiopulmonary exercise system for patients to athletes, from pediatric to adults.

• CCM Express – The compact, mobile design with simple touch-screen operation and breath-by-breath analysis make the CCM Express an ideal nutritional assessment system for Critical Care to Bariatric medicine.

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

• Online Training and Education: Come check out Medgraphics new online training and education platform.

• Cardiorespiratory Diagnostics Seminar: This course updates participants' knowledge of testing techniques, performance standards, quality assurance procedures, and clinical applications for basic and advanced cardiopulmonary diagnostic testing. Some of the topics to be covered include theory, methodology, clinical indications and performance standards of plethysmography, bronchial provocation, dilutional lung volumes and cardiopulmonary exercise testing. The program format includes lectures, hands-on demonstrations and small group discussions, and is conducted by a faculty of experts from across the country.

Why should AARC participants visit your display?

Visitors will be able to see Medgraphics' new products in action. The company will hold a drawing for tuition for the Cardiorespiratory Diagnostics Seminar. Medgraphics is in booth 725.

Nonin Medical

What new product are you featuring at AARC?

Nonin Medical has designed a new personal fingertip oximeter designed especially for patients. The GO₂ fingertip pulse oximeter, available by prescription, is an accurate and affordable device designed to empower patients to safely go about their daily activities. This oximeter will enable clinicians to partner with their long term oxygen therapy patients. Having an accurate fingertip oximeter helps patients stay within their prescribed oxygen saturation and pulse rate levels—enabling better care management by providing information they need while maintaining their activity levels. Visit www.nonin.com/go2 to learn more about how the GO₂ can benefit your patients.

What educational materials will you be highlighting at AARC?

Nonin will be highlighting Dr Thomas L. Petty's book, *Your Personal Oximeter: A Guide for Patients*. Over one million Americans are on long term oxygen therapy or have been diagnosed with Chronic Obstructive Pulmonary Disease. This booklet explains the body's need for oxygen and differences in oxygen delivery systems, the usefulness of a personal oximeter to monitor SpO₂ saturations during daily activities, and the necessity of communication between the patient and clinician. The book also discusses how to use an oximeter to expand your level of activities, the practice of pursed lip breathing,

participating in pulmonary rehabilitation at home, the limitations of oximetry and warning signs. The book was written by Thomas L. Petty, MD, a pulmonologist who is an international authority on respiratory disease. Petty has published over 800 articles in journals such as the Journal of the American Medical Association, Chest, Annals of Internal Medicine, American Journal of Medicine, Archives of Internal Medicine, and American Journal of Respiratory & Critical Care Medicine. He is the author or editor of 41 books or editions. Dr Petty was also organizer and founding President of the Association of Pulmonary Program Directors (APD) and has served as President of the American College of Chest Physicians. Nonin is in booth 145.

OPTI Medical

What new products will you be presenting at AARC?

OPTI Medical will be presenting an upgraded version of our OPTI R and OPTI CCA-TS, point of care blood gas analyzers. We have made improvements in response to our customers' requests and look forward to sharing them at AARC.

What products will you be presenting of relevance to emergency response and disaster preparedness?

As with any point of care device, our blood gas monitors will give real-time data with a turnaround time of 1-2 minutes that is relevant for emergency response in any situation when respiration may be compromised.

Discuss education materials you'll be promoting at the convention.

We will provide an interactive video to better educate our customers on OPTI Medical, our product, their benefits to respiratory therapists around the world, and supporting white papers.

Why should AARC participants visit your display?

This year, OPTI Medical will have a new, interactive display to educate our customers. We have also made several upgrades to our current instrumentation to include new cassette styles, a scanner, and improved touchscreen. OPTI Medical is in booth 557.

Philips Respironics

The highly versatile, lightweight Trilogy100 (11 lb / 5 kg) device marks a milestone in home ventilation from a recognized leader in respiratory care. Philips Respironics offers a broad range of clinically proven solutions intended to support breathing in the intensive care, sub-acute, and home care settings. Developed to meet the needs of a wide range of patients, Trilogy100 offers both volume- and pressure-control ventilation for adult and pediatric use with features intended to help caregivers and clinicians administer patient care in the home and alternative care settings such as skilled nursing facilities. (For more on the Trilogy100, see "Life Support" in this issue's Companies section.) The Respironics NM3 non-invasively monitors volumetric (VCO) and end-tidal (EtCO₂) capnography. Clinicians can use this information to minimize the duration of mechanical ventilation and optimize the potential for successful extubation when managing critically ill patients. At every stage of care, the NM3 monitors the patient's response to ventilation. Bright,

sharp, and well organized display screens present physiologic information on the patient's readiness for less support and spontaneous breathing trials (VCO₂, MV_{alt}, V_d/V_T). The lightweight, portable design allows inter-departmental use on ventilated patients and non-ventilated patients under deep and conscious sedation. The new Respironics V60 Ventilator takes NIV further by giving you the confidence to treat a wide range of patients. The V60 uses Auto-Trak auto-adaptive technology to help ensure patient synchrony and therapy acceptance. The six-hour internal battery supports emergency back-up and intra-hospital transport for continuity of care. The V60 is cleared for invasive and noninvasive treatment of pediatric and adult patients. Hospital ventilatory care is further supported with exclusive modes and comfort features. The Respironics V60 fulfills the Philips commitment to simplify advanced healthcare. The new Respironics V200 Critical Care Ventilator provides state-of-the-art ventilation modes with synchrony options—Auto-Trak, Flow-Trak, and Baby-Trak—that reduce work of breathing and streamline patient care. The unique speaking mode allows appropriately selected tracheostomy patients to speak without an external valve. The V200 Ventilator has a range of treatment modalities for all patient populations—invasive modes for neonatal through adult patients and noninvasive for pediatric through adult patients. The V200 Ventilator also supports care in any environment by connecting to Philips patient monitors and hospital information systems for a seamless flow of ventilation information. Philips is in booth 413.

RespirTech

What new products do you plan to exhibit?

RespirTech's inCourage System, an advanced high-frequency chest compression (HFCC) device, is preferred by a growing population of physicians and patients seeking the highest quality airway clearance therapy. Features unique to the inCourage System include: 1) Active Venting for comfort when taking deep breaths during treatment; 2) QuickFit Sizing for precise fit and more consistent therapy; 3) QuickStart Programming for a one-touch ramping session; 4) Triangle Waveform shown to increase volume of mucus cleared. Our new wheel-mounted travel bag promotes easy transport and stows easily into aircraft overhead luggage bins.

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

RespirTech is pleased to offer complimentary copies of a monograph devoted to high-frequency chest compression (HFCC) technology and its many applications. Articles include literature reviews and discussions concerning the role of HFCC in managing airway clearance compromise associated with a variety of etiologies. Clinical conditions including cystic fibrosis, bronchiectasis, COPD, primary ciliary dyskinesia and spinal cord injury are represented, as are HFCC applications for acute illness/trauma and post-surgical patients. The potential for HFCC as an adjunct to sputum induction technique is explored from both diagnostic and therapeutic perspectives. All articles were written by Jane Braverman, PhD, an authority on the HFCC literature, and prepared in collaboration with Respiratory Therapy, The Journal of Pulmonary Technique.

What speakers will your company be working with or featuring?

RespirTech's CEO, K. James Ehlen, MD, and clinical programs

director, Jane Braverman, PhD, will be pleased to schedule individual sessions for in-depth technological, clinical and research conversations.

What in-booth promotions will you be offering?

Visitors to the RespirTech booth will be given an opportunity to try on the inCourage System and appreciate for themselves the effect of its active venting system on comfort and ease of breathing during treatments.

Why should our readers stop by your booth?

RespirTech booth visitors will be invited to examine and experience the latest advances in HFCC technology and inCourage System product design. Our clinical and technical experts, including certified respiratory care practitioners, will be happy to discuss product applications and respond to questions and comments. We are excited to discuss the role of the inCourage System as an important tool to advance high-impact clinical practice and healthcare reform goals. Let us share our vision for the future of preventive and therapeutic airway clearance management. RespirTech is in booth 943.

Roche Diagnostics Corp

What new products will you be presenting at AARC?

The new firmware (v7.02) for the cobas b 221 blood gas system will be showcased with live demonstrations. See how it gives healthcare providers more actionable information, with the addition of patient trending of a single analyte. The system now trends any one of eighteen parameters, including glucose, lactic acid, MetHb and COHb. This provides a diagnostic platform for a number of clinical applications. For example, lactic acid trending gives the clinician the ability to monitor the level of lactic acid and track the patient's response to treatment in cases of tissue hypoxia, sepsis and the onset of myocardial infarction. See how the new firmware helps make testing more efficient by enabling user-defined test panels and measurement reports. The QC set-up wizard also helps the user configure new QC lot ranges and run times quickly and easily. See how the new system login function helps healthcare providers comply with security policies for regulatory agencies and their own facility with an Operator ID and password requirement that is administered by the Lab Manager, RT Manager or POC Coordinator.

What educational materials are you promoting?

Roche will showcase a number of educational materials to help healthcare professionals run the system properly and help maintain operator certification, such as the cobas b 221 blood gas system onboard video tutorials to instruct the user in the proper operation of the system, the short Instruction for Use guide, and a customer-based training CD-ROM. As the only blood gas system manufacturer that provides both onsite training and training at its Indianapolis headquarters training facility, Roche will showcase its customer training opportunities. Roche will demonstrate its online CEU courses which are available for all staff members to help maintain their accreditation.

What speakers will your company be working with or feature?

Doug Wilder, RRT, Director of Respiratory Services, Memorial Medical Center, Livingston, TX, Past President of the Texas Society of Respiratory Care will be featured in a booth video providing his insights on the importance of IT solutions in

managing blood gas testing and meets compliance and regulatory standards.

Why should AARC participants visit your display?

For the ninth consecutive year, Roche Blood Gas is proud to sponsor the AARC Fun Run, scheduled for Sunday, December 6 at 7 am. All attendees are encouraged to stop by the booth and register for the 5K run / walk, which will take place on the road around the convention center. All finishers will receive an official Fun Run T-shirt. In addition to the Fun Run, there will be booth drawings for a copy of The Essentials of Respiratory Care by Robert Kacmarek, on Sunday, December 6 and another drawing will occur on December 7. All attendees are encouraged to stop by the booth and register for both drawings.

Healthcare providers will gain a greater understanding of the actionable information the cobas b 221 can provide with the configurable menu that has options for blood gas (pO₂, pCO₂ and pH), electrolytes (Na⁺, K⁺, Cl⁻, Ca²⁺), metabolites (Glucose, Lactate, BUN), tHb/SO₂ and Co-oximetry (O₂Hb, HHb, COHb, MetHb, tHb, Hematocrit, Bilirubin) as well as enhanced applications of patient trended data and automated acid-base mapping trending. Learn how the cobas b 221, with the only FDA 501(k) clearance for testing pleural fluid pH, can help simplify regulatory compliance. And see how the cobas b 221 blood gas system, coupled with cobas bge link Instrument manager software, enables monitoring and control of up to four decentralized systems from one location. cobas bge link enhances operational efficiency of all connected systems through screen sharing to provide immediate real-time performance status, maintenance updates, and remote access for IT technical support 24/7. Roche Diagnostics is in booth 603.

Salter Labs

What new products will you be presenting at AARC?

Salter Labs will be presenting exciting, new clinical data on its NebuTech HDN high density nebulizer at Booth 418-420 of the 2009 AARC Conference as well as several new sleep diagnostic products.

What products will you be presenting of relevance to emergency response and disaster preparedness?

Salter Labs' unique, optional Disposable Filter Set (for use with the Salter NebuTech HDN high density nebulizer) is well suited for use in the event of an H1N1 pandemic or any situation where occupational exposure to exhaled gases is a concern. It reduces second-hand aerosol exposure by filtering 99.56% of exhaled particles.

Why should AARC participants visit your display?

AARC participants visiting Salter Labs at Booth #418-420 can discuss Salter's exciting new, cost effective products, obtain a Salter roll-up blanket to ward off the San Antonio December chills (while supplies last), and enter a drawing to win a \$50.00 American Express Gift Card.

Siemens (Siemens' RapidSystems)

What new product will you be presenting at AARC?
nBilirubin and V3.0 software on RAPIDLab 1265; RAPIDComm v3.0 and RAPIDPoint 350 system.

What product will you be presenting of relevance to emergency response and disaster preparedness?
Our RAPIDSystems product line (RAPIDPoint 400 and 300 series, RAPIDLab 1200 series and RAPIDComm data management solution).

Discuss education materials you'll be promoting at the convention.
Continuing education programs with CEU / PACE credits targeted for management/supervisors and RT professionals.

Why should AARC participants visit your display?
Siemens' comprehensive critical care solutions streamline the monitoring and analysis of critical blood gas results throughout all areas of the hospital—ICU, NICU, Operating Room, Emergency Department, Laboratory, Respiratory—saving vital time when every minute counts. Visit Siemens at booth 244.

Product Review

Acoustic Technology for Airway Monitoring

Catharine Johnson-Tieck, RRT, RCP

The author is President, Innovative Respiratory Concepts, Product Development and Consulting. Information was provided by Innovative Respiratory Concepts.

The SonarMed Airway Monitoring System started its development at Purdue University over 10 years ago. This device is waiting for FDA clearance and has a series of clinical studies planned for 2010, including a large Outcomes Study. It is no surprise that it has had strong interests from the pulmonary and the critical care environment. This is especially exciting and new to respiratory care and airway management and monitoring. Although new in this application, the origin and fundamentals of the technology dates back to the 1970s. Later in the 1990s at Purdue, the application for reflective sound was identified as a means to communicate sound signal from distal airways to provide information that would give precise information as it relates to endotracheal tube and airway monitoring.

The science behind the technology

The device sends sound signals down an artificial airway or endotracheal tube beyond the tip further in the airway, and receives echoes back. As the airways cross sectional area grows rapidly beyond the carina, approximately at the 5th and 6th generation of the bronchus, it acoustically looks like a horn with a bell at the end. When sound travels through a horn with a bell at the end, you get an echo that comes from the bell. Likewise you get an echo that comes from the airways, and you get an

echo from the tube tip. Then the timing of the echo is tracked to determine the relative movements of the endotracheal tube in the airway. Once the system is in place in the airway, the user can set a baseline, and from there the system will tell you how much the tube has moved from its original placement, either higher or lower in the trachea. Another reflection this system uses is an echo from the tip of the tube to communicate the relative size of the passageway or airway that the tube is in relative to the tube itself. This is represented by a number. For example, if the number is greater than 1.0, you have a passage that is larger than the ID of the tube (like the trachea). If the number is less than 1.0, it represents a smaller passage, like the esophagus, or if advanced far enough, a bronchus or smaller bronchi, letting you know you have gone too far. The last set of reflections is used to identify obstructions in the artificial airway or ETT, and can tell where the obstruction is and how big it is.

Here is how it works... You decide where

The small adapter, comparable to a CO₂ adapter, is placed on the proximal end of the ETT tube. This is then calibrated and the baseline is set. Once this baseline is set, a measurement with waveform communicates tube position. This can stay with the patient for the life of the intubation.

So, consider the many circumstances in clinical settings that provide the opportunity for an accidental extubation or unintentional extubation. This can range from movement during transport, turning or placing a patient in a prone position, sedation vacations, and diagnostic procedures, or even the more uncommon risk of airway movement and extubation that occurs with intubation styles and practices that vary in clinical settings. An example of this for an RT could occur in observation of an anesthesiologist's post insertion of the endotracheal tube when the cuff is filled with X volume of air and gently pulled back or withdrawn until the resistance of the vocal cords is felt. This could be a method used for short intubation periods in place of a CXR in the OR with a fully paralyzed and sedated patient but could move in any of the above mentioned settings outside the OR. If it did move in this situation, the cuff pressure increases and the tube sounds like it has a positional leak. What would stand between you and an unintentional extubation at that moment is whether the clinician checks cuff pressure prior to adding air for the leak.

How about airway and tube size? If you're an intubator, you know that difficult airway where nothing is visualized due to girth and swelling. A Grade 3 or 4 airway, or an acute epiglottitis is not easy and may require a smaller ETT. How do you determine? What happens when the swelling subsides? Does your tube move? How do you determine or justify an ETT change to a larger size?

Another example to consider is when the patient is intubated in the ED. Post intubation, the patient is transported to CT, then to ICU. In ICU, the patient is turned and assessed. The patient is restrained and turned every 2 hours. A few hours later, early in the morning the sedation is lessened to assess the patient's spontaneous effort for extubation criteria. During that time, the patient has morning labs and X-rays. How many opportunities in a routine scenario do you see for tube movement? What happens in the routine scenario when the tube is moved or even unintentionally extubated? How does this affect the patient and the hospital? How do current methods compare with evaluation
Continued on page 62...

Risk Assessment: Effects of Unintentional Extubation (UE) During a Pandemic

Dave Swift, RRT

Unintentional extubations (UE) are broken down into two primary categories: accidental extubation, which occurs during the medical care of a patient, and self extubation, which occurs when the patient removes the endotracheal tube. Unintentional extubations are considered to be a healthcare quality indicator and a patient safety indicator. Quality Indicators (QIs) measure healthcare quality by using readily available hospital inpatient administrative data. Patient Safety Indicators (PSIs) are a tool to help health system leaders identify potential adverse events occurring during hospitalization. In addition to the expected adverse outcomes associated with unintentional extubation, such as increased time on the vent and increased length of stay in the ICU and in the hospital, with the outbreak of the H1N1 virus UE now carries increased risks to members of the healthcare team as it is an unanticipated aerosol generating process that is unlikely to allow the timely use of personal protective equipment (PPE).

The incidence of UE varies between 3% and 14%¹ which depends on the following: the reason for intubation, type of medical interventions required, levels of sedation, and time of day (46% of unintentional extubations occur during the night shift).² Another contributing factor to UE is endotracheal tube movement. The repositioning of the patient's head (by healthcare workers or by the patient) can have significant effects on the position/movement of the endotracheal tube. For example, one study showed that with nasotracheal intubation, displacement from the carina was 21 mm by extension of the neck, and 7-8 mm by lateral rotation of the neck to the right and left. With orotracheal intubation, the mean length of displacement from the carina was 12 mm by extension of the neck and almost 28 mm with application of the mouth gag.³ Yet another factor is the use of twill tape which allows for significantly more tube movement than commercially available tube holders⁴ verified by x-ray. Accidental extubation also carries a re-intubation risk of 31% to 74%⁵ with the risk of nosocomial pneumonia of 27% vs 13.8% in self extubation.

As of April 2009, the World Health Organization (WHO) has reported sustained person to person infection of the H1N1 virus.⁶ WHO infection control recommendations/measures (standard plus droplet precautions) should be adhered to at all times:

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“Whenever performing high-risk aerosol-generating procedures use a particulate respiratory (N95, FFP2 or equivalent), eye protection, gowns, gloves, and carry out the procedure in an airborne precaution room that can be naturally or mechanically ventilated.”⁷ CDC recommendations echo the same precautions while providing direct patient care to or collecting clinical specimens from patients with suspected or confirmed novel H1N1 infection.⁸ The H1N1 virus is especially noted for its virulence and its secondary attack rate of 22-33% (compared to seasonal influenza of 5-15%).⁹

Most critical care healthcare workers are very attuned to the risks associated with “aerosol generating procedures” following the severe acute respiratory syndrome outbreak (SARS), and they follow the recommendations and procedures of their healthcare facility when carrying out these procedures. However, unintentional extubations happen with no warning and staff are often faced with responding to the emergency before they have a chance to don their PPE. In order to decrease the exposure risks to the healthcare worker associated with UE, the critical care team needs to review the risk factors associated with UE:

1. Reason for intubation – infectious risks presented by the patient (infected vs noninfected), type of injury or disease process (eg burn patients have a significantly higher risk of UE due to the limitations on how the tube is secured and the types of treatment procedures required).
2. Level of sedation – awake/responsive, agitated/confused, fully sedated, sedation being weaned.
3. Level of mechanical ventilatory support – fully ventilated (chemically sedated/pharmacologically restrained) vs weaning (minimal sedation or chemical restraints)
4. Time of day – decreased vigilance during “quiet” times (eg at night).
5. Hands-on care required/ patient repositioning/ movement.
6. Transfer for diagnostic testing or procedures.

With the team aware of the activities that increase the risk, the incidence of UE has been shown to drop from 3%-14% to around 5%¹⁰ utilizing Q shift monitoring. This drop in the incidence of UE reflects a drop in the risks to the healthcare worker, but a further decrease in UE and its associated risk factors is called for, and can be achieved with improved monitoring throughout the shift.

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A Quality Management System for Blood Gas Testing

Diana Blanco, MT-SC (ASCP), Bruce Toben, RRT-NPS, CPFT

Introduction

Blood gas interpretation and therapy to alter acid-base balance and oxygenation is the foundation of the respiratory care profession. Five decades have now passed since Severinghaus and Bradley built the first three-function (pH, pCO₂, pO₂) blood gas apparatus.¹ By the end of the 1970s, most arterial punctures for blood gas sampling were being performed by Respiratory Therapy departments. In the 1980s many chemistry laboratories began transitioning their bench-top blood gas systems to the pulmonary function laboratories. The early 1990s saw the proliferation of Point-of-Care (POC) blood gas devices, now routinely operated by Respiratory Care Practitioners.

As healthcare facilities continue to use departmental cross-training to streamline operations, the limits of professional boundaries becomes less defined. Specific to blood gas analyzers, regardless of who manages this traditional laboratory diagnostic test, diligent attention to a sound Quality Management System and adherence to regulatory compliance guidelines is essential in providing accurate results yielding quality patient care.

Guidelines that describe implementing a new blood gas system have recently appeared in an earlier issue of this journal.² The article included topics of laboratory licensure, developing normal and reportable ranges, correlation testing, and determination of trueness, precision and linearity. The subject matter of this article concentrates on those aspects of blood gas testing relevant to an ongoing Quality Management System that governs the daily activities designed to provide quality results. The contents of both of these publications follow the standards described by the Clinical Laboratory Improvement Act (CLIA). Other resources used in the guidance of these articles were: College of American Pathologists (CAP), the Joint Commission (JC), COLA (formerly the Commission on Laboratory Accreditation), and international standards for medical laboratories that provide regulatory structure for laboratories outside the United States.³

Quality Management System

A laboratory Quality Management System (QMS) is a sequential integration of policies and processes that transform a physician's order into laboratory information. The objectives of QMS are to provide quality accurate diagnostic test results and reduce the potential for medical error that wastes resources and harms patients.⁴

The core component of QMS is the Policy and Procedures Manual. This combined document describes the facility's guidelines, standards and techniques employed for all aspects of patient testing. Essential adjuncts of patient testing to ensure accurate results are quality control measures and proficiency testing, both of which are addressed in the Manual. Also outlined within the structure of the Manual is the need to conduct system audits. These events ensure continuous quality improvement that have the potential to identify and rectify inadequate procedures or strengthen ambiguous policies. Delegation of personnel responsibilities, operator training and competency certification⁵ are also sections of the Manual that promote the overall objectives of the QMS.⁵ Periodically, a methods assessment of the blood gas device is required to evaluate clinical performance.⁶ The criteria and frequency of these evaluations are highlighted in the Manual. Finally, inventory management,⁶ another key component of the QMS, ensures that all temperature-sensitive disposables are properly stored. The areas illustrated above contribute significantly to the overall quality of patient results, and through adoption into the Policy and Procedures Manual are then integrated into the Quality Management System of blood gas laboratories.

Policy Manual

The Policy Manual is a set of documents that clearly describes the guidelines related to all testing as defined by the institution. An annual review of the Manual and revisions if appropriate, are required by the Medical Director named on the CLIA license. In general, the policies provide a framework that:

- Details patient rights, safety and confidentiality regulations.
- Defines authority and levels of responsibility at each phase of testing.
- Describes the academic and/or professional requirements for operators.
- Outlines training for a new hire orientation period and the ongoing training and frequency throughout employment.
- Describes employee safety guidelines in a biohazardous environment.
- Defines the Quality Control program.
- Records the frequency of review of the Policy and Procedures Manual by operators.
- Describes the activities surrounding documentation of results and correction of errors.

Procedures Manual

The Procedures Manual is a set of documents that describes the

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techniques involved with all phases of blood gas testing.⁵ Written procedures should address the three phases of patient testing: pre-analytic, analytic and the post-analytic process.^{5,6,7}

Pre-analytic phase of testing encompasses all attributes of testing prior to analysis.

- Positive identification of the patient by using a minimum of two (2) unique identifiers.⁷ These could include the patient's full name and date of birth.
- Appropriate sample type for the application being assessed, ie, arterial, mixed venous, capillary, umbilical cord (arterial, venous).
- Supplies necessary to collect the sample including, appropriate needle and syringe or blood collection tube size with appropriate additives, ie, lithium heparin, sodium heparin, fluoride/oxalate, sodium citrate, EDTA, etc.
- Validation and documentation for every instrument has been completed prior to use for diagnostic purposes.
- Correlation study current at time of instrument's use.
- Storage, monitoring and recording of supplies, reagents/ cartridges, and quality control material.
- Sample identification labeling including: laboratory test accession number, specimen documentation requirements, and electronic data entry procedures.
- Acceptable collection method(s) including: site selection, puncture site preparation, Allen's test, heel warming, sampling from an indwelling vascular catheter including waste sample technique.
- Methods to prevent ambient air contamination.⁵
- Storage and handling requirements of specimen.
- Consideration for optimal sampling relative to patient therapy.

Analytic phase of testing comprises the actual sample analysis.

- Instructions as they pertain to the operation of the instrument.
- Procedure and frequency of calibration.
- Procedure, frequency and review of quality control data.
- Procedure that addresses instrument errors during sample analysis.
- Disposal of biohazard waste and supplies.

Post-analytic phase involves all procedures that pertain to the actual reporting of the results.

- Recording the test results.
- Defining criteria for acceptable results.
- Documenting any interfering substances as identified by the manufacturer.
- Normal ranges for each analyte are listed.
- Lists "Critical Values" and the procedure describing the allowable time frame results must be reported to the individual responsible for the patient's care.^{5,6,7}

Critical Results vs Notification Results

A "Critical" value is a patient result that is significantly outside of the normal range for that analyte as specified by the Medical Director of each institution. Critical results are usually of serious consequence if not addressed immediately. Regulations specify that the results must be immediately communicated to the person responsible for the patient's care and documented in the patient's permanent record. The record should include the date and time of notification, and the name of the person receiving the report.

Some facilities have employed a "Notification" results system. These results indicate unfavorable trends or changes in the patient's condition but have not reached the "Critical" results threshold. "Notification" results provide an alert to the medical staff to re-evaluate the patient and optimize therapy.

Quality Control

A robust Quality Control (QC) program will assure that the instruments used for patient testing meet the manufacturer's specifications for optimal device performance. Periodic monitoring of QC^{5,6} provides data regarding the function of the test system. The system incorporates the three primary elements that will ultimately produce a test result; the instrument, the analyte reagent or disposable cartridge, and the operator performing the test.

Internal or Electronic Quality Control—POC devices and some models of bench-top instruments are equipped with a self-contained QC test that checks the integrity of the electronic circuitry of the analyzer. Typically, various levels of current or voltage is passed through the electronic components that analyze the assays. Electronic output of this test determines functionality from a device perspective, but does not qualify the reagents/ cartridges or the operator. Most manufacturers recommend electronic QC to be performed, at a minimum, every 8 hours during a patient testing day combined with periodic external or liquid quality control to assess the complete test system.

External or Liquid Quality Control (LQC)—All blood gas/ electrolyte analyzers are required to qualify the entire test system to ensure optimal instrument performance and accuracy of results reported.^{5,6} This QC test uses a liquid media that simulates a whole blood sample that contains a controlled concentration of pH, carbon dioxide, oxygen, and electrolytes dissolved in solution. Commercially available LQC is assayed, or tested, and the expected results or recovery is documented. These LQC tests are typically manufactured in concentrations that mimic both normal and abnormal physiologic conditions.

Due to inherent reagent or sensor interferences and manufacturing design characteristics, not all commercially produced LQC material is compatible with every instrument. This incompatibility is known as the matrix effect. It is therefore essential to use the LQC recommended by each instrument's manufacturer for their specific model.⁵ This will ensure LQC tests produce results in a predefined range.

The frequency of Electronic Quality Control and LQC is determined by each facility based on the combined manufacturer's recommendations and the regulatory body certifying each laboratory.^{5,6,7} In addition, some institutions may increase their QC testing at the discretion of the Medical Director that oversees blood gas testing. The guidelines that dictate the QC program is documented in the Policy and Procedures Manual, and detailed result of each QC test is reviewed for performance and filed for future reference. The QC log must record:

- Date and time
- Instrument serial number
- Type of QC test
- Test operator
- Quantitative results
- Manufacture type and lot number of LQC material

Analysis of the QC data should indicate if the results are within predefined limits, and/or identify trends or shifts in serial measurements. If the results fall outside of expected ranges, investigation of the root cause followed by corrective action and retesting is required. All records must be retained on-site for inspection for two years.⁵

Proficiency Testing

Proficiency testing (PT)^{5,6,7} is an integral tool in the QMS that evaluates the entire system: instrument, reagent/cartridge, and operator. PT involves the analysis of specimens with unknown values, and statistically compares results with a peer group. A minimum of ten laboratories comprises a peer group. The facilities in the peer group use the same model device and test at a similar altitude. PT samples must be analyzed as patient tests within the environment where testing occurs. PT providers assess the individual site's data and notify the laboratory of how their results compared with the peer group. Results of the PT event are also sent to the regulatory agency designated by the laboratory. PT evaluates the testing system used and provides the assurance that patient diagnosis and management is transparent regardless of the laboratory conducting the analysis.

All analytes defined by CLIA as "regulated" must participate in a PT program.⁶ When evaluating blood gas/electrolytes instruments, PT assessment should be conducted periodically throughout the year as stipulated by their laboratory certification provider. If the facility has more than one device, CLIA recommends that PT events should be rotated among all analyzers used and among all personnel who routinely test patient specimens.

A "Satisfactory" performance is set at 80% for each individual testing event. Typical PT programs supply five samples at various levels or concentrations of analytes. This allows for one unacceptable result or deficiency. If a deficiency is cited by the PT provider, the site must investigate and document their findings. The report should include: possible contributing factors such as improper storage or handling of the PT material, the testing instrument was not in calibration, or the reagents/cartridges had expired. In the event the exact cause cannot be identified, the documentation should contain all supporting studies that confirm the instrument was in calibration for all analytes reported at the time of testing.

The PT event cannot be referred to another laboratory for testing, and there can never be communication prior to site notification with other laboratories to discuss results. This statement is to be included in the Policy and Procedures Manual. If a facility is identified as compromising the intent of the PT program in this manner, the blood gas laboratory will be decertified and the institution may incur further penalties.^{5,6}

System Audits

Integrated into every Quality System is the need for continual improvement. In this regard, system audits are an essential part of every blood gas laboratory. It allows for closer examination of the policies and procedures, and can also identify possible sources of error before they occur. Auditors should be familiar with the test system, but not involved with the development of the policies or procedures.

Auditing the entire process is a necessary step to verify the functionality of QMS. As there are many steps to each part of the

process, each subsection can be divided into component parts and separate auditors can be assigned to review that particular process. Parts of QMS that could be audited are:

- Patient identification
- Sample collection and handling
- Instrument operation
- Instrument maintenance
- QC data analysis
- Results reporting
- Proficiency testing
- Non-compliance management

Auditing QMS is a pro-active process that can enhance the ability to produce a quality patient result and in turn, provide a high level of confidence in the laboratory.

Operator Training and Competency Certification

Annual training is required by all regulatory bodies and should entail a review of the Policy and Procedures Manual.^{5,6} Documentation of training can be accomplished by the operator participating in a written test after review of the Manual, along with the direct observation of specimen testing and certified with a Skills Checklist. The Skills Checklist should include: obtaining the sample, performing the analysis, reporting results, correct management of critical values, and the location of the Policy and Procedures Manual. Final validation of competency can be demonstrated by successful testing of an unknown sample.

Methods Assessment

Calibration, calibration verification/clinical reportable range verification, and a correlation study are bi-annual for events for every instrument.^{5,6}

When an instrument has an operator-controlled calibration feature, calibration is required at a minimum twice per year. Calibration must also be performed when there is a complete change of reagents, significant trends or shifts in QC, and when major maintenance is conducted. Verification that the instrument is properly calibrated is also a requirement in analyzers that have calibration as part of the manufacturer's recommendations. There is a variety of calibration verification kits available for this purpose. These kits include low, midrange, and high concentrations of analytes that are near the clinical reportable range (CRR), and this satisfies the bi-annual requirement for linearity testing. The CRR results verify the lowest and highest values that can be reported.

When multiple instruments that report the same analyte are used in a facility, a method to verify the uniformity of performance is required in the form of a correlation study. This study requires patient samples, not LQC. The acceptable variance between devices is determined by the Medical Director. This procedure validates that results reported from any blood gas device could be interpreted and acted upon in the same fashion.

The methodology of performing a correlation study must avoid issues of preanalytical error. Specific to blood gas correlation testing, introduction of ambient air into the specimen due to sample aspiration needs to be avoided or limited. Best practice dictates that if possible, the instruments should be side-by-side to allow for rapid transfer of the specimen.

A unique aspect of blood gas analysis that must be considered

is the need for barometric pressure measurements.⁵ The barometric pressure reading is integrated into the calibration equation of the instrument. Dalton's Law of Partial Pressure describes the relationship between the barometric pressure and its constituent parts as being directly proportional. Therefore, as the barometric pressure changes, either due to weather patterns or altitude, the pressures exerted by the dissolved calibration gases used for the calibration of the pO₂ and pCO₂ electrodes will be affected. To ensure accurate calibration of the blood gas electrodes, the internal instrument barometer should be verified for accuracy at least annually against a National Institute of Standards and Technology (NIST) traceable barometer and documented.

Inventory Management

The date reagents/cartridges and supplies are received is documented to assist with inventory management.^{5,6} It is also necessary to note when supplies or reagents/cartridges are removed from temperature controlled storage units because this may affect product shelf life. For example, if the reagent shelf life has been determined based on refrigeration conditions, and moving to room temperature shortens that period, then modifying the expiration date on each box or individual reagent package is required.

Daily temperature monitoring and recording of the instrument's environment, reagents or POC disposable cartridges, and LQC material is mandatory. This requirement is necessary to ensure that manufacturer's recommendations for temperature are observed, because temperature cycling events in the storage area or testing site may produce inaccurate results.

Summary

Incorporating the recommendations described in Guide to Validation of a Blood Gas System,² coupled with those in this article, can provide a basis to conduct a compliant blood gas laboratory. Blood gas testing, regardless of the operator's credentials or the department performing the test, is part of an overall system designed to provide quality diagnostic information. Adherence to a comprehensive Quality Management System is paramount in achieving that outcome. Respiratory care practitioners need to be cognizant of all aspects of blood gas testing and especially if they are an integral part of the analytic phase of the procedure.

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NIV: Beyond Conventional Use

Melissa Turner, BS, RRT

Noninvasive ventilation (NIV) has found a definite home in respiratory therapy. Clinicians have witnessed the benefits of using NIV regularly for COPD exacerbations and for chronic respiratory failure in patients with neuromuscular disease. NIV has also been used successfully to thwart re-intubation for recently extubated patients. As the arena for respiratory care continues to grow, so does the realm of useful NIV applications. There are now more ways in which NIV can be utilized as a useful tool.

NIV is being used more and more in the postoperative period. It is very common to see post-op respiratory insufficiency in patients who have undergone major surgery, especially of the chest or upper abdomen. After abdominal surgery, 10% of patients have respiratory complications and, of those, 30% are re-intubated. Some of the contributing factors for the complication and re-intubations are pain, splinting and respiratory muscle dysfunction. Common methods that are used to prevent complications are incentive spirometry, chest physiotherapy, mucolytics and intermittent positive pressure breathing. Recent trials done using NIV and CPAP to reduce post-op complication were found to reduce those complications up to 100%, although a lack of control groups does limit the interpretation of these studies. Squadrone et al² did a study which involved 15 centers in Italy. Patients involved in the study had undergone upper abdominal surgery for at least ninety minutes and had a PaO₂/FiO₂ ratio of ≤ 300 mmHg. Patients were excluded if they had a history of COPD, pH < 7.3, PaCO₂ > 50 mmHg, Hct < 30%, or in a coma. For the study, 104 patients were randomized to control where they were administered a FIO₂ of 0.50 via air-entrainment mask. Another 105 patients were randomized to the treatment arm which consisted of a FIO₂ of 0.50 and CPAP of 7.5 cmH₂O. After six hours, both groups were placed on a FIO₂ of 0.30 via air entrainment mask. If the patient's PaO₂/FIO₂ ratio was ≤ 300 mmHg, the patient was placed back on his/her assigned treatment path. Lower intubation rates as well as lower rates of pneumonia and sepsis were found for the treatment arm of the study.

In another study, Kindgen-Milles et al³ compared controls to a group of patients treated with CPAP for 12-24 hours post surgery. All patients underwent repair of thoracoabdominal aneurysm. The control group received oxygen via a non-occlusive face mask at 25L/m and CPAP therapy at 10 cmH₂O for ten minutes every four hours. The experimental group received CPAP of 10 cmH₂O

for 12-24 hours after the procedure. The experimental group was found to have better oxygenation, decreased pulmonary complication and decreased hospital stay.

In a third study, Auriant et al⁴ did a randomized trial of NIV in Post-op respiratory failure. Patients selected for the study had to meet three out of four criteria for respiratory insufficiency after a lung resection surgery. The four criteria were a respiratory rate > 25, accessory muscle use, PaO₂/FiO₂ ratio < 200 mmHg, and abnormal chest x-ray (atelectasis or consolidation). The included patients were randomly assigned to standard post-op care with oxygen, or standard post-op care with NIV which was adjusted to maintain a tidal volume of 8-10cc/kg, maintain an SpO₂ > 90%, and a respiratory rate of < 25. This study was stopped after the first interim analysis because of the dramatic difference in mortality and re-intubation. In that first interim analysis it was found that 21% of the NIV group was re-intubated versus 50% in the control group. Also, in-hospital mortality for the NIV group was found to be 12.5% versus 37.5% in the control group.

These are small studies, but they certainly show that positive airway pressure used in patients with post-op respiratory insufficiencies does improve outcomes. It is not clear whether NIV or CPAP has an advantage over the other.

Bronchoscopies are a fairly common procedure performed quite frequently on patients. The bronchoscopes themselves occupy approximately 10% of a patient's airway and as a result can cause an increased work of breathing and a decrease in PaO₂ by 10-20 mmHg. Respiratory complication and arrhythmias can also arise due to bronchoscopy.⁵ There have been several studies done to evaluate the use of CPAP and NIV to prevent respiratory complications, especially in at risk patients. Maitre et al⁶ did a randomized controlled trial of bronchoscopy with CPAP versus high flow oxygen in high risk patients. These patients had a PaO₂ < 125 mmHg on a high flow mask. The mask was used to deliver either high flow oxygen or high flow oxygen and CPAP at 7.5 cmH₂O during bronchoscopy. For the study, 15 patients were placed in each arm. Of those, seven patients in the oxygen group required additional ventilatory support (four were intubated) within six hours of the procedure. In the CPAP group, one patient required additional ventilatory support. Statistically speaking, the results were not significant.

Another study by Antonelli et al,⁷ was a randomized controlled trial with high risk patients who had a PaO₂/FIO₂ ratio < 200 mmHg undergoing bronchoscopy. The control group was placed

Melissa Turner is with Hamilton Medical. This article is from the company's newsletter.

on FIO₂ of 0.90 via face mask. The experimental group was placed on NIV at 15-17 cmH₂O inspiratory pressure and 5 cmH₂O expiratory pressure with an FiO₂ of 0.90. FIO₂ was titrated to maintain SpO₂ >92%. During the bronchoscopy the PaO₂/FiO₂ ratio of the experimental group was 261 mmHg versus 139 mmHg in the control group. An hour after the bronchoscopy the PaO₂/FiO₂ ratio of the experimental group was 176 mmHg versus 140 mmHg in the control group.

These studies do show that NIV and CPAP are certainly safe and effective for use in maintaining oxygenation in hypoxemic patients undergoing bronchoscopy, although it is still not known if NIV decreases the incidence of bronchoscopy associated intubation in high risk patients.

NIV has also found a use during percutaneous gastrostomy tube placement. For many neuromuscular disease patients, swallowing and malnutrition can become a problem that can progress to a life threatening situation. Percutaneous endoscopic gastrostomy tube placement prevents large volume aspiration and helps to provide adequate calories. Sedation is required and it is known that intubation in these patients is associated with prolonged and sometimes permanent mechanical ventilation. The American Academy of Neurology recommends that these tubes be placed before FVC is <50% of predicted to decrease the risk of respiratory failure. Some patients fall below this level prior to tube placement. Boitano et al⁸ used NIV with five ALS patients who had FVCs of 21-44% during tube placement. No complications were reported with all five patients. Birnkrant et al⁹ also used NIV with a group of patients with Duchenne muscular dystrophy. FVC was immeasurable in this group although all tube placements were successful without complications.

Uses for NIV now also include patients with obesity hypoventilation syndrome (OHS). Patients with OHS have a body mass index ≥ 30 kg/m², an awake hypercapnea (PaCO₂ ≥ 45 mmHg), and sleep disordered breathing. There are three different types of sleep disordered breathing which are: (1) obstructive sleep apnea (OSA) with hypopneas, (2) obstructive hypoventilation due to upper airway resistance syndrome and (3) central hypoventilation. The treatment algorithm of OHS includes the use of NIV in its protocol. OSA is the most common cause of OHS, so CPAP is tried as first line treatment. If the patient has an SpO₂ on CPAP of $\leq 90\%$, NIV is tried next. During NIV, the inspiratory pressure is titrated to 8-10 cmH₂O above the expiratory pressure which is set at the last CPAP pressure tried with that patient. If the use of NIV is still not effective, then supplemental oxygen is added. Lastly, if the therapy is still not effective after trying all of the above, the patient is then referred to weight loss surgery or tracheostomy with invasive ventilation.

Kessler et al¹⁰ did a prospective trial of CPAP versus NIV in 23 patients with OHS as compared to 23 patients with eucapnic OSA. In this study, 57% of the OHS patients were relieved of their sleep disordered breathing and hypoxemia through the use of CPAP. The remaining 43% needed various levels of NIV with supplemental oxygen. Another study by Perez et al¹¹ was a retrospective study which included 54 patients with OHS who were treated with NIV. At the end of the follow up period whose length was a mean duration of 50 months, the following results were noted: PaO₂ increased by 24 mmHg, PaCO₂ decreased by 17 mmHg, improved subjective daytime sleepiness, and a decrease in dyspnea in all but 4 patients. Death occurred in

three patients, NIV was withdrawn in five patients who achieved significant weight loss and sixteen patients had their conditions maintained without respiratory failure by use of home CPAP.

For most OHS patients, it is evident that CPAP is adequate. For those patients for whom CPAP is not adequate, NIV and supplemental oxygen may be needed and has shown to have success.

The uses and application of NIV will continue to grow in the ever changing arena of respiratory care. As clinicians use NIV more and more, we will begin to see even more novel and creative uses for this application.

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Humidification for Chronic Tracheostomy Patients

Judi Villa

Each year an average of about 75,000 tracheostomies are performed on patients at community hospitals in the United States. This number does not include tracheostomies performed at private and military hospitals. Nebulization, or humidification, is critical for these patients since the natural process of humidification no longer functions. The tracheostomy tube bypasses the natural mechanism by which the nose and mouth filter, moisturize and warm the air you breathe. With the trach tube, the trachea loses the sinus' natural function to humidify the nasopharynx or tracheal mucosa.

Patients are required to spend up to five hours a day (as much as 40% of wake time) nebulizing through a nose/mouth mask and separately through a tracheostomy mask. This laborious process discourages treatment compliance. Non-compliance is widely recognized as leading to multiple complications, including dry nose and mouth, thick mucus, mucus plugs, infection, etc. These complications eventually require inpatient hospitalization for 48 hours of nebulization.

But a new delivery system for humidification addresses the patient compliance issue by reducing the time it takes to nebulize both nose/mouth and the tracheostomy stoma. The Wright Face & Tracheostomy Nebulizing Mask is designed to simultaneously humidify the nose, mouth and tracheostomy stoma. Patients benefit from the Wright Mask's convenience, as do caregivers, respiratory staff, hospitals and insurance providers. The Wright Mask delivery system provides doctors with a solution to the compliance problem, provides hospitals a solution for optimizing nursing time and reduces the cost to insurance companies.

Tracheostomy Facts

A tracheostomy is the procedure in which a tube is surgically inserted through the trachea (wind pipe) to enable a patient's ability to breathe. A tracheostomy is performed when a patient's upper airway is obstructed. Often, the tracheostomy is short-term and can be removed when the problem obstruction is corrected. However, in cases where a patient is suffering from some forms of cancer, ALS, BPD (Bronchopulmonary dysphasia), or TBI (Traumatic Brain Injury), for example, tracheostomies are often long-term or permanent.

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Tracheostomies are expected to increase in coming years. About 79 million baby boomers will reach age 65 by the year 2029, and they are more likely to face pulmonary and respiratory diseases. Other factors that will contribute to increased tracheostomies are the rise in TBI injuries sustained by our servicemen and women engaged in conflicts overseas and multiple births that find newborns requiring immediate, tracheostomies for long-term airway management.

Compliance issues are a concern whether the patient is considered short-term (up to 18 months) or long-term (18 months to 30-plus years). Vivian Wright knows this all too well. Her husband, Dean, had a tracheostomy while he was battling head and neck cancer. Dean had to nebulize 10 times a day—five times for his trach stoma and five times for his nose and mouth. Each time took 30 minutes, with Dean tethered to a nebulizer.

Dean started cutting back. At first, he'd wear only one of the masks for 15 minutes. Then he cut back to once a day. Then he stopped nebulizing his nose and mouth altogether. He said it took too long.

"Later," he would tell Vivian when she urged him to nebulize.

Thick mucus clogged Dean's mouth and his trach. "His breathing was very labored," Vivian said. "It wasn't enough."

While he was flying in from an out-of-town trip, a piece of dry tissue lodged in Dean's trach and clogged the tube. At 10,000 feet on final approach into Miami, Dean began choking to death. "He started gagging for air," Vivian said. "It was horrible. All you could hear throughout the full 737 was Dean gagging for life. He was dying up there, and there was nothing I could do."

Dean survived, but he spent the next 48 hours in the hospital for inpatient nebulizing. When he came home, Vivian realized there was something she could do. In her own living room, she pieced together the nose/mouth mask and the tracheostomy mask to allow Dean to simultaneously nebulize his upper and lower airways. Ten sessions a day were cut to five. Five hours was cut to 2 1/2.

Clinical Trial

After Dean's death in 2002, Vivian patented the Wright Face & Tracheostomy Nebulizing Mask, and it is now available for all trach patients. This summer, the Wright Mask underwent a clinical trial at the University of Miami. The clinical trial showed

Table 1. The following table shows the results of the clinical trial:

	Saturation, mean	Ease of Device Use (1-10, easiest)	Comfort Ratings (1-10, most comfortable)	Difficulty of Breathing (1-10, easiest)
Conventional Facemask	98.93 percent, ± 1.23	8.8, ± 1.4	7.5, ± 1.5	9, ± 2
Trach-collar	98.89 percent, ± 1.23	9.3, ± 0.9	8.6, ± 1.6	9.2, ± 1.4
Wright Mask system	99.07 percent, ± 1.24	8.5, ± 1.6	7, ± 1.7	8.6, ± 1.7

Table 2. In 2007, 12,950 patients were admitted to community hospitals for “other non-operating room therapeutic procedures to nose, mouth and throat,” according to government statistics:

	Other non-operating room therapeutic procedures on nose, mouth and throat
Total number of discharges	12,950
LOS (length of stay), days (mean)	3.5
Charges, \$ (mean)	18,510
Costs, \$ (mean)	6,081

Community hospitals only. Does not include private or military hospital data. <http://hcupnet.ahrq.gov/>

Table 3. The conventional nebulizing process takes 15 steps and two masks. The Wright nebulizing process takes only eight steps and one mask. It’s this simple:

Conventional nebulizing process	Wright Mask nebulizing process
Connect the face mask tube to the nebulizing machine	Place the face mask over your nose and mouth and place the tracheostomy mask over your tracheostomy stoma
Fill the medicant container	Fill the medicant container
Place the face mask over your nose and mouth	Adjust the dents in mask tubes to fit your face
Adjust head straps for comfort	Adjust neck straps for comfort
Turn the machine on	Connect double-face mask tube to the nebulizing machine
After 30 minutes of nebulizing, remove the face mask	Turn the machine on
Turn the machine off	After 30 minutes of simultaneously nebulizing the nose and mouth and the tracheostomy, remove masks
Disconnect the face mask hose from the nebulizing machine	Turn the machine off
Connect the tracheostomy mask hose to the nebulizing machine	
Fill the medicant container	
Place the tracheostomy mask over the tracheostomy stoma	
Adjust the trach mask straps for comfort	
Turn the machine on	
After 30 minutes of nebulizing, remove the tracheostomy mask	
Turn the machine off	
Total steps: 15 Total masks used: 2 Total time: 1 hour	Total steps: 8 Total masks used: 1 Total time: 30 minutes

that the Wright Mask was comparable to the conventional face and trach masks in terms of saturation, ease of use and comfort. But it was superior in terms of saving time.

“The mask appears to have no adverse effects and should cut down the amount of time people humidify,” said Dr Keith Candiotti, who conducted the clinical trial. “It’s a busy world out there. How



many gadgets in your life can cut a necessary task in half? ... If someone had a trach and wanted to humidify, I would tell them to use this mask.” (See Table 1.)

“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,” Dr Candiotti wrote in the abstract. The full abstract from the clinical trial, Evaluation of the Wright Humidification Mask in Chronic Tracheostomy Patients, is posted online at wrighttrachsolutions.com/Abstracts.html

The problem with the conventional humidification procedure is that it takes too long for tracheostomy patients to carry it out day after day. Tracheostomy patients are living with other issues, many life threatening and/or life ending. To add a laborious treatment process that requires up to five hours from their day is the last thing most patients have the emotional discipline and physical endurance to do.

Therefore, most trached patients decrease or end their nebulizing regimen. In doing so, they suffer dry nose, dry mouth and dry sinuses. Their mucus becomes thick, stringy and difficult to expel. With dry tissue, it becomes painful to gag, choke and cough out the mucus. All this increases the probability of life-threatening mucus plugs. The mucus lodges in the trach tube and blocks the tracheostomy airway. In addition, dry
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Impact of Patient Characteristics, Education and Knowledge on Emergency Room Visits in Patients with Asthma and COPD

Margareta Emtner, Anna Hedin, Mikael Andersson, Christer Janson

Abstract

Background: Asthma and COPD are major health problems and an extensive burden for the patient and the health care system. Patient education has been recommended, but the influence on knowledge and health outcomes is not fully examined. Our aims were to compare patient characteristics, education and knowledge in patients who had an emergency room (ER) visit, to explore factors related to disease knowledge, and to investigate patient characteristics, patient education and knowledge in relation to further ER visits over a 12 month period.

Methods: Eighty-four patients with asthma and 52 with COPD, who had had an ER visit, were included. They were interviewed by telephone 4 to 6 weeks after the ER visit and followed for a year.

Results: Patients with COPD were older, more sedentary, had had more ER visits the previous year, and had more co morbidity than patients with asthma. About 80% of the patients had received information from health professionals or participated in education/rehabilitation, but a minority (< 20%) reported that their knowledge about how to handle the disease was good. Patients with "good knowledge" were younger, were more likely to have asthma diagnose, and had a higher educational background ($p < 0.05$). Sixty-seven percent of the patients with COPD had repeated ER visits during the following year versus 42% in asthma ($p < 0.05$) (adjusted HRR: 1.73 (1.03-2.90)). Patients who had had ER visits the year before inclusion had a higher risk of ER visits the following year (adjusted HRR: 3.83 (1.99-7.38)). There were no significant differences regarding patient education and knowledge between the group with and without further ER visits after adjusting for sex, diagnose, age, and educational background.

Conclusions: Patients with asthma had a better self reported knowledge of disease management and were less likely to

have new exacerbations than patients with COPD. Reported level of knowledge was, however, in it self not a predictor of exacerbations. This indicates that information is not sufficient to reduce the burden of disease. Patient education focused on self-management and behavioral change should be emphasized.

Background

Asthma and chronic obstructive pulmonary disease (COPD) are major health problems and an extensive burden on the patient, healthcare system, and the economy. The prevalence of asthma has increased over the last 20 years, and the prevalence of COPD is 9 to 10% in individuals ≥ 40 years. In asthma, patients with a poor asthma control and persistent asthma are associated with higher costs. Hospitalization and emergency room (ER) visits account for about 50% of the total costs. Also in COPD the costs are extensive as over 60% are readmitted to hospital within a year after a hospital admission.

It has previously been shown that exacerbations in asthma are associated with psychological dysfunction, poor symptom and disease control, older age, high doses of inhaled corticosteroids (ICS), oral corticosteroids, concomitant chronic sinusitis, and having a long history of asthma. In COPD, exacerbations are associated with impaired quality of life, increased mortality, limitations of daily activities, disease progression, poor lung function, previous admissions, under prescription of oxygen, increased risk of readmission, and low physical capacity.

A key component of management guidelines in asthma and COPD, is the recommendation for patient education. In asthma, education (information only) improved patient knowledge, but did not have an impact on health outcomes, whereas education programs including self-management strategies, ie aiming at life-style change, could reduce hospitalization and ER visits. In COPD, a Cochrane review found that self-management education had no effect on hospital admissions, ER visits, days lost from work, and lung function, whereas a Canadian study reported that hospitalizations and ER visits could be reduced with self-management strategies.

Although disease severity and psycho-social factors are well known contributors to asthma and COPD morbidity, the influence of education and patient knowledge have received less attention. There is little work in routine practice setting which prospectively examines the relationship of patient education and knowledge, and the serious events of repeated ER visits.

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Table 1. Patient characteristics in the asthma and COPD groups, mean \pm SD and %.

	Asthma n = 84	COPD n = 52	p-value
Age, years	55 \pm 18	69 \pm 9	<0.01
Sex, % female	64	50	0.12
BMI, kg/m ²	26 \pm 5	26 \pm 6	0.47
Respiratory symptoms, years	18 \pm 14	15 \pm 13	0.26
Ever smoked, %	52	94	<0.01
Pack years, years	8 \pm 14	32 \pm 21	<0.01
Current smokers, %	18	19	0.84
ER visits the previous year, %	61	81	0.02
High school or university education (>10 years), %	62	27	<0.01
Physical activity, mainly sitting, %	10	37	<0.01
Physical activity, sitting and walking < 4 days per week, %	93	96	0.45
LABA, %	59	64	0.59
ICS, %	90	76	0.03
LABA + ICS, %	54	60	0.53
Tiotropium, %	3	28	0.01
Co-morbidity, %	34	51	<0.05

ER: Emergency room visits, BMI: Body Mass Index; LABA: Long Acting Beta Agonist; ICS: Inhaled Corticosteroid.

Table 2. Subjective experience on received patient education in the asthma and COPD groups, %.

	Asthma n = 84	COPD n = 52	p-value
Education			
Information about medications	86	79	0.18
Information about medications by physician	68	60	0.37
Information about medications by nurse	20	17	0.68
Information about what can cause an exacerbation	64	46	0.04
Information about what happens in your body during an exacerbation	57	25	<0.01
Information on how to act when getting an exacerbation	68	56	0.16
Participation in group education	17	23	0.25
Participation in rehabilitation	5	17	0.02
Written plan	16	14	0.75
Need for more knowledge			
Wants to learn more in general	77	71	0.23
Wants to learn more about medications	33	27	0.46
Wants to learn more about the disease	38	39	0.92
Wants to learn how to handle exacerbations	41	33	0.36
Wants a written plan	27	21	0.50

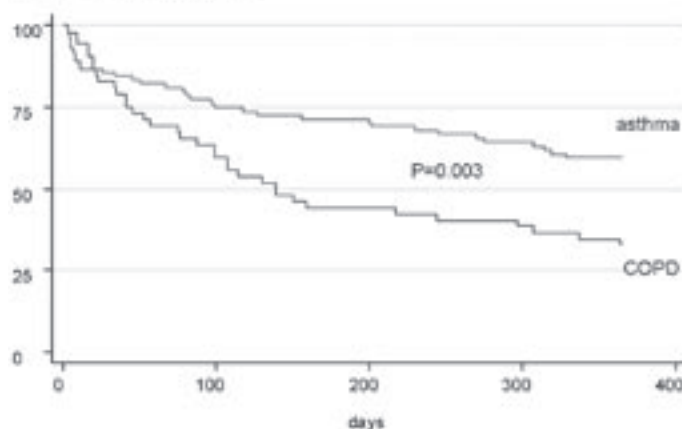
Group education = theoretical education in a group of asthma or COPD patients.

Rehabilitation = education and physical training.

All patients who had participated in rehabilitation are also included in group education.

The first aim was to compare patient characteristics, education and knowledge in patients with asthma and COPD, who had an ER visit because of an exacerbation. The second aim was to explore factors related to disease knowledge, and the third aim was to compare patients with further ER visits for breathing problems over a 12 month period versus patients with no further

% without an exacerbation



ER visits in relation to patient characteristics, patient education and knowledge.

Methods

This was a prospective study of patients with asthma or COPD, who had ER visit because of exacerbation. The University hospital in Uppsala, Sweden, one local hospital, and four general practitioners in the area in and around Uppsala, took part in the study. The study was approved by the ethical committee, Uppsala University. Informed consent was obtained from the patients.

One hundred and sixty-one consecutive patients \geq 18 years with exacerbation of obstructive lung disease, who had ER visits, and had a previous physician diagnosed asthma or COPD, according to the medical record, were during their ER visit invited to participate in the study. Only one patient declined to participate. Four to six weeks later a research nurse called the patients to ask if they still wanted to take part in the study. Two patients had died, three had severe lung cancer diagnosis, and 19 patients were not willing to participate or were impossible to get in contact with. Thus, 136 patients were finally included in the study. All 136 patients were followed up at six and 12 months by a research nurse, who called each patient to ask for ER visits. She also checked the patient-reported ER visits in medical records mainly by calling hospitals. All records were reviewed by the investigator to confirm the diagnosis.

The following data were collected four to six weeks after the ER visit: Structured telephone interview: Demographic characteristics, smoking history, level of formal education, level of physical activity, employment status, housing situation, medication, comorbidity, prior ER visits and hospitalizations, and whether they had received patient education (individual or in a group setting), pulmonary rehabilitation and/or written action plan. Three questions were included to identify personal perceptions of current knowledge; knowledge about what can cause an exacerbation, knowledge about what happens in your body during an exacerbation, and knowledge about how to act when having an exacerbation. Patients scored their knowledge on a four-graded scale (good knowledge, some knowledge, little knowledge, no knowledge).

Enrolled patients were contacted by phone six and 12 months after inclusion in order to obtain information regarding number of ER visits and hospitalizations. Data was confirmed by checking hospital records.

Table 3. Patient education and knowledge.

	No further emergency room visit n = 66	At least one emergency room visit n = 70	HRR
Patient education			
Information about medications	83	85	1.37 (0.67-2.80)
Information about medications by physician	59	70	1.69 (0.97-2.95)
Information about medications by nurse	19	19	1.06 (0.56-2.00)
Information about what can cause an exacerbation	65	50	0.75 (0.46-1.24)
Information about what happens in your body during an exacerbation	47	43	1.28 (0.74-2.21)
Information on how to act when getting an exacerbation	64	63	1.21 (0.73-2.00)
Written plan	12	17	1.47 (0.78-2.76)
Patient knowledge			
Good knowledge about what can cause an exacerbation	21	13	0.87 (0.41-1.83)
Good knowledge about what happens in your body during an exacerbation	15	13	1.34 (0.63-2.78)
Good knowledge about what to do when getting an exacerbation	48	43	1.48 (0.71-3.08)
Need for more knowledge			
Wants to learn more in general	70	80	1.09 (0.68-1.74)
Wants a written plan	26	23	1.27 (0.66-2.44)

Patient education and knowledge in the groups with no further emergency room visits versus at least one emergency room visits during the following year, numbers in percent and HRR.

Adjusted for sex, diagnose, age/10 years, and educational level (>10 years).

The Chi-squared test and an unpaired t-test were used when comparing patients with asthma to patients with COPD, and when comparing patients that had or had not had additional ER visits after inclusion to the study. Mann-Whitney's U-test was used when comparing patients with "good knowledge" versus "some, little or no knowledge." The time until the following ER visit was analysed by the Kaplan-Meier survival analysis and Cox regression. The Cox regression model was used to calculate adjusted hazard ratios. The hazard ratios were adjusted for sex, diagnose, age and educational level but only one knowledge related variable was included in each model in order to avoid collinearity. A p-value of <0.05 was considered statistically significant.

Results

Eighty-four patients with asthma and 52 patients with COPD, who had had an ER visit because of an exacerbation, were included and followed for a year (Table 1). Patients with COPD were significantly older, more sedentary, ex-smokers, had a lower educational background, more co-morbidity, and had had more ER visits the previous year compared to patients with asthma. Both groups of patients were characterized by having had respiratory symptoms for many years, often having had ER visits the year before and being physically inactive. The majority of patients used inhaled corticosteroids (ICS) and/or bronchodilators. Most patients, independent of diagnosis, had received information regarding their disease from a physician or nurse, but few had participated in more formal education (group education) or rehabilitation (education and physical training) (Table 2). While patients with asthma seem to receive better education about the disease than patients with COPD (64% vs. 46%, respectively), the asthma group still wanted to learn more about handling the disease (41%) than those with COPD (33%).

Though many patients had received information, few patients (<20%) reported that their knowledge was "good." Patients with

"good knowledge" were younger, had had respiratory symptoms for more years, were more likely to have asthma diagnosis, and had a higher educational background.

Fifty-two percent had at least one ER visit because of exacerbation of obstructive lung disease within the following year. Patients with further ER visits were more likely to have COPD (67 vs. 42%, $p < 0.05$) (Figure 1). The adjusted hazard ratio, HRR (95% CI) was 1.73 (1.03-2.90). In addition, patients who had had ER visits the year before inclusion had a higher risk of ER visits the following year, adjusted HRR was 3.83 (1.99-7.38). Also, patients with hospital admissions because of exacerbation the year before inclusion had a higher risk of ER visits, adjusted HRR was 2.31 (1.29-4.12).

Regarding patient education and knowledge there were no significant differences between the group with and without further ER visits after adjusting for sex, diagnose, age, and educational background (Table 3). The majority in both groups wanted to learn more and about 20% wanted a written action plan.

Discussion

This study has shown that patients with COPD and an acute ER visit are more sedentary, have more comorbidity, and had had more ER visits the previous year compared to patients with asthma. Most patients had received information, but a minority had good knowledge about the disease. Patients with "good knowledge" were younger, were more likely to have asthma diagnosis, and had a higher educational background. COPD patients were also more likely to have repeated ER visits during the follow-up than patients with asthma. There were no significant differences regarding patient education and knowledge between the group with and without further ER visits after adjusting for sex, diagnose, age, and educational background.

The purpose of this study was to investigate patient characteristics, patient education and knowledge in relation to ER visits in order to identify factors that might help us to get a better understanding of which patients and why patients continued to visit the ER. With a better understanding we might be able to tailor patient education and treatment more specifically and individually. Although many studies have investigated the effects of patient education and rehabilitation in patients with asthma, and COPD, no study has investigated to what extent patients with asthma or COPD are informed/taught about the disease and whether there is an association between patient information/education, patient knowledge and ER visits.

Patient education has been emphasized in guidelines to be included in the treatment of patients with asthma or COPD, and there is a general agreement that patient education improves patient knowledge, but the impact on health outcomes is less well established. In this study, where patient education mainly consisted of information about medications and how to act when getting an exacerbation, patients' subjective experience of their knowledge was poor, and many continued to do ER visits. Though patients in the telephone interview were asked about type of patient education, we were not able (from the interview) to fully identify whether the education consisted of advice, counseling, self-management strategies or behavioral intervention. However, when contacting the included hospitals and general practitioners, we could identify that almost all patients had only received information/advice.

In contrast, self-management programs and sustained patient education in patients with asthma have proven to be successful in improving quality of life and in reducing the economic burden of disease. Patients with acute asthma who took part in a self-management program twice for 30 minutes and were given a written self-management plan were less likely to be readmitted during a 12-month follow-up period than those without a self-management plan. Adult patients with asthma who had taken part in an educational program for one year had significantly fewer ER visits and hospital admissions after 3 years compared to a control group. In COPD, self-management programs resulted in positive effects on the patients' daily life and wellbeing, reduction of exacerbations, reduced ER visits, and hospital admissions. COPD patients who had taken part in a disease-specific self-management multi-component program of skill-oriented teaching reduced ER visits up to two years after the program.

Thus, it seems that the way patient education is performed is associated with the outcome. Patients included in our study had mainly received information about medications which might explain their poor knowledge in handling the disease and the great number of repeated ER visits. Instead patient education should aim at modifying the behaviour of patients by improving self-management skills. Behavioural research suggests that patient education should focus on attitude, social support and self-efficacy in order to modify behavioural patterns and coping style.

Sixty-seven percent of the COPD patients in this study had repeated ER visits during the following year, which is in accordance with other studies. In Spain, 63% were readmitted within the following year, and in the Nordic countries 61%. In asthma, 42% had repeated ER visits, which is higher than have been reported in several previous studies. This may be explained by our study group, which was recruited during an ER visit,

while patients with asthma in other studies were recruited when attending hospital or primary care for a scheduled visit.

In this study, significantly more patients with an increased risk of repeated ER visits had ER visits or hospital admissions the year before inclusion, which is in accordance with other investigators studying patients with asthma or COPD. Compared to results from other investigators, we couldn't find a significant difference between patients who had a written action plan (15% had a written plan) or who used regular corticosteroids in regard to ER visits the following year. Though we didn't measure disease severity, our patients may have had a moderate or severe disease, as all of them had at least one ER visit and 90% of the asthma patients used ICS. As the level of physical activity was extremely low in all our patients, a comparison between physically active versus inactive patients was not possible. However, it has been shown that patients with COPD who had an ER visit because of an exacerbation were extremely physically inactive on weight-bearing activities (walking and standing) during hospitalization. The low physical activity level remained one month after discharge and was lower compared to COPD patients without a recent exacerbation. In addition, patients with hospitalization for an exacerbation within the previous year had an even lower activity level. Also, in patients with asthma the physical activity level is low, and only about 25% of subjects with asthma in the US were considered to be active. Thus, neither patients with COPD nor asthma meet the current recommendations for physical activity. These data are in accordance with ours and are important to highlight as the adverse health effects of inactivity are tremendous.

We had expected a greater proportion of patients to have COPD, as the currently available pharmacotherapy is theoretically more efficient in achieving asthma control than in controlling COPD. However, despite the availability of highly effective drugs research has shown that the control from asthma is far from optimal.

Limitations of the study: Most patients in our study had only received information, thus we could not compare different educational components, and we could not identify if information/advice is sufficient for some patients, i.e. with good educational background. Patients with milder diseases were probably underrepresented since the patients were recruited at an ER setting. Lung function was not measured, which would have been valuable in patients with COPD, but of less importance in patients with asthma in order to identify the risk of ER visits. In our study, the previous ICD-10 diagnosis was used and a lung function test would have been valuable in order to confirm the diagnosis. Unfortunately systemic inflammation was not measured as it has been shown that COPD patients with a heightened systemic inflammation are at increased risk of frequent exacerbations.

Conclusions

Patients with asthma had a better self reported knowledge of disease management and were less likely to have new exacerbations than patients with COPD. Reported level of knowledge was, however, in itself not a predictor of exacerbations. This indicates that information is not sufficient to reduce the burden of disease. Patient education focused on self-management and behavioral change should be emphasized.

Emergency Presentation and Management of Acute Severe Asthma in Children

Knut Øymar, Thomas Halvorsen

Acute severe asthma is one of the most common medical emergency situations in childhood, and physicians caring for acutely ill children are regularly faced with this condition. In this article we present a summary of the pathophysiology as well as guidelines for the treatment of acute severe asthma in children. The cornerstones of the management of acute asthma in children are rapid administration of oxygen, inhalations with bronchodilators and systemic corticosteroids. Inhaled bronchodilators may include selective β_2 -agonists, adrenaline and anticholinergics. Additional treatment in selected cases may involve intravenous administration of theophylline, β_2 -agonists and magnesium sulphate. Both non-invasive and invasive ventilation may be options when medical treatment fails to prevent respiratory failure. It is important that relevant treatment algorithms exist, applicable to all levels of the treatment chain and reflecting local considerations and circumstances.

Introduction

Asthma is the most common chronic disease of childhood in the western countries, and the incidence has continuously been rising during the last decades.¹ In a recently published study from Norway, the accumulated lifetime prevalence of asthma in 10 year old children was as high as 20%.² The majority of children with asthma have stable disease, and only a minority experience exacerbations needing hospitalisation or emergency room visits. In older children, recent advances in treatment seem to have reduced chronic morbidity as well as the number of acute exacerbations.^{3,4} In infants and younger children, this goal may be more difficult to achieve, given the heterogeneity of obstructive lung disease in this age group. Viral wheeze is a very common clinical scenario in young children, and identification and proper treatment of subjects with potential for development of asthma and future exacerbations is still an unresolved challenge.⁵ Furthermore, in all age groups, failure of adherence to regular anti-inflammatory treatment schemes may be an important reason why acute asthma is still a common cause of unscheduled hospitalizations in childhood. Therefore, physicians who care for acutely ill children will regularly be faced with

acute severe asthma. During recent years several guidelines have been published on treatment of stable as well as on exacerbations of asthma. Few of these guidelines have focused particularly on childhood asthma. The aim of this article is to review current knowledge of acute severe asthma in childhood, with special emphasis on the acute management.

Methods: We performed a thorough search in PubMed with the following words in different combinations; asthma, children, severe, attack, exacerbation, epidemiology, pathophysiology, guidelines, treatment, management, oxygen, adrenaline, β_2 -agonist, anticholinergics, theophylline, steroids, magnesium, helium, CPAP, BiPAP, ventilation. Included studies and papers were not systematically evaluated regarding design and quality. However, we have emphasised recent guidelines, Cochrane reviews and other expert reviews.

Clinical definitions: There is no clear definition of an asthma exacerbation.⁶ However, in clinical trials it has often been defined as requirement for hospitalisation, or need for systemic corticosteroids.^{7,8} Status asthmaticus may be defined as wheezing which does not respond to initial treatment with inhaled bronchodilators.^{9,10}

Epidemiology: The majority of asthma exacerbations are mild or moderate and may be treated at home by the parents or by physicians outside hospitals. However, in parallel to the increase of asthma prevalence during the recent decades, the number of children hospitalised for asthma and wheezing disorders has also increased.^{3,4,11} Hospitalisations for asthma and wheezing disorders are most common during the first years of life; in our area ranging from 104/10,000 children in the age group 1-2 years to 7/10,000 in the age group 9-13 years,³ altogether constituting 16% of all emergency admissions in 2003.¹² The hospitalisation rates for asthma in older children as well as re-admissions in all age groups seem to have declined during the last decades.¹¹ Some recent studies from the last few years indicate that also the overall admission rates for asthma and wheezing disorders have begun to level off or even decline in Europe and the USA.^{8,9,12} This development has been paralleled by an increase in the regular use of inhaled corticosteroids, suggesting that acute attacks at least partly may be a preventable complication in asthmatic children.^{8,11} In preschool children, exacerbations of asthma and wheezing disorders are far more common in boys than in girls.^{3,8,12,13} With increasing age, this pattern is reversed, and adult females are twice as likely to be hospitalised for asthma as adult males.^{7,8} In the northern hemisphere there

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Table 1. Symptom score by clinical assessment in children with asthma (modified from K. Aas [25]).

P0.	Normal; no signs of bronchopulmonary obstruction
P1.	No dyspnoea. Slightly faint respiratory sounds.
P2.	No dyspnoea. Moderate rhonchi. Slightly prolonged expiration. The expiration may be audible.
P3.	No dyspnoea at rest. Abundant rhonchi. Slight use of auxiliary respiratory muscles. Low grade jugular recessions may be present.
P4.	Slight dyspnoea at rest. Abundant rhonchi. Obvious use of auxiliary muscles. Jugular and intercostal recessions. No cyanosis
P5.	Severe dyspnoea at rest. Abundant rhonchi. Wheezy expiration audible without stethoscope. Jugular, intercostal and subcostal chest recessions. Slight cyanosis may be present.
P6.	Alarming obstruction, often both inspiratory and expiratory. Faint respiratory sounds. Chest recessions. Use of auxiliary respiratory muscles and high respiratory rate. Cyanosis may be present but not mandatory.

seems to be a seasonal pattern for asthma exacerbations in school children, with a steep rise to a peak during the first part of September from the lowest incidence during the summer months ("the September epidemic").⁸ This is probably due to an increased exposure to viral infections after school recommences. Although not so clear, a similar pattern has been observed also for pre-school children.⁸ Even if severe asthma exacerbations are relatively common, mortality from asthma in children is rare and declining.^{8,14,15} In the UK the mortality rate for children 0-14 years is less than one per 100,000 children per year.¹⁴ In contrast, there has been a vast increase in the economic costs associated with asthma. However, the main economic burden of childhood asthma is linked to indirect costs, long-term follow up and medication, and not to hospitalization.¹

Pathophysiology: Asthma is associated with a chronic inflammation of the airway mucosa, involving a complex interaction between T-lymphocytes, neutrophils, eosinophils, epithelial cells and mast cells.^{9,16,17} Cytokines and other mediators such as histamine, leukotrienes and platelet activating factor are released from these inflammatory cells, and complex interactions between cells and mediators lead to structural and physiological changes and exposed parasympathetic nerve endings.^{9,10,16,17} Airway hyperreactivity is a physiological consequence of these processes, providing the asthmatic child with airways primed for a range of triggers that may lead to further airway obstruction and clinically to asthma exacerbations.^{9,10,16,17} The main trigger in the paediatric age group is viral airway infections, with rhinoviruses being the most common.¹⁸ In addition, allergens, tobacco smoke, environmental irritants, exercise, stress and gastroesophageal reflux may, separately or by concomitant action, initiate a deterioration of the chronic disease and an asthma attack (acute in chronicum).^{8-10,16,18} In some children, food allergy may trigger an acute systemic anaphylactic response, including severe airway obstruction. During an asthma attack, the chronic inflammation is aggravated by degranulation of mast cells and release of histamine, leukotrienes and other mediators, inducing mucosal vasodilatation and oedema, increased mucous secretion and smooth muscle contraction, particularly in the medium sized and small airways.¹⁰ Thereby, the size of the airway lumen decreases resulting in increased resistance to air flow, particularly towards the end of expiration at low lung volumes. The severe airflow limitation will further lead to premature airway closure. To compensate, the patient increases end-expiratory lung volume

by increasing functional residual capacity (FRC), resulting in pulmonary hyperinflation and air trapping.¹⁰ Further, operational lung volume is shifted away from the range with the most severe expiratory airflow limitation. Consequently, airflow resistance is reduced while the work of breathing and the sense of dyspnea are increased since the inspiratory muscles are put in a mechanically disadvantageous position.^{10,19}

Airway obstruction, hyperinflation and air trapping may lead to ventilation/perfusion mismatch and hypoxemia.¹⁰ Hypoxemia and the increased work of breathing may result in anaerobic muscle work and accumulation of lactate. The metabolic acidosis may be further aggravated by dehydration from poor fluid intake. During an asthma attack, metabolic acidosis may initially be compensated for by hyperventilation and a respiratory alkalosis, but as respiratory failure develops, increasing arterial CO₂ will result in a respiratory acidosis and a further decrease in arterial pH.^{9,10}

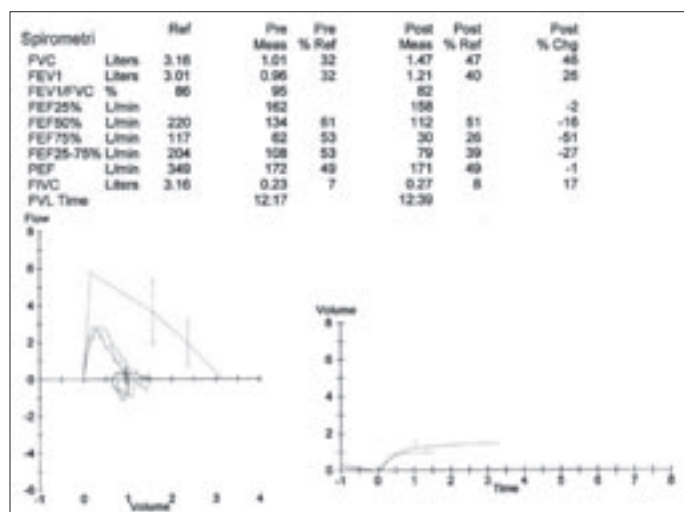


Figure 1: Lung function testing in a girl with severe asthma; Results of lung function testing of a 13 year old girl with a severe asthma exacerbation. Spirometry taken during the first day of hospitalisation measured before (blue line) and 15 minutes after (red line) inhalation with a nebulised β -agonist (Salbutamol 1.0 mg/10 kg). Results demonstrate severely decreased lung function, and further poor reversibility probably due to long standing inflammation and downregulation of β 2-receptors.

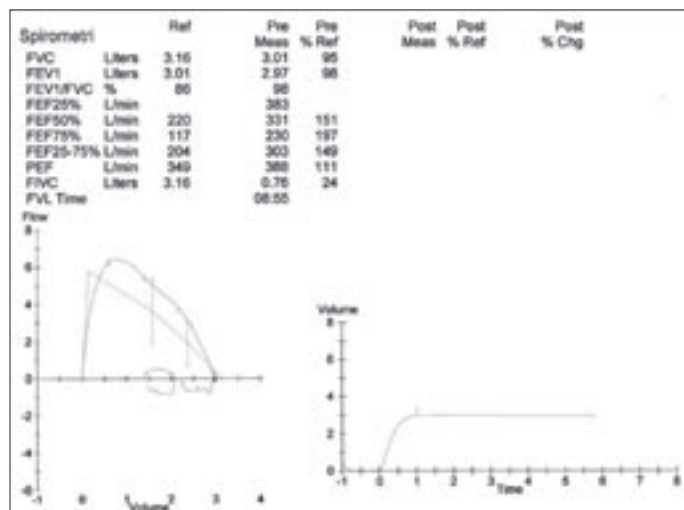


Figure 2: Spirometry taken after a ten days treatment with prednisolone, approximately 1 mg/kg/day. Green lines represent normal values.

Increased airflow resistance and pulmonary hyperinflation combined with increased work of breathing and disturbances in the acid/base balance may impair cardiac function. During a severe asthma attack, the negative intrapleural pressure will rise, increasing left ventricular afterload and the risk of pulmonary oedema.²⁰ Pulmonary vasoconstriction due to hypoxemia, acidosis and increased lung volume will also increase the right ventricular afterload. Altogether, these changes may result in decreased cardiac output and decreased alveolar diffusion, further increasing both hypoxemia and acidosis.¹⁰ Fluid overload caused by overhydration during treatment or fluid retention associated with inappropriate secretion of antidiuretic hormone, will put the patient further at risk of pulmonary edema.^{21,22}

The pathophysiology of an asthma attack is influenced by the age of the patient and the trigger involved. In young children, viral aetiology with mucosal edema predominates, and muscular bronchoconstriction is less important. Conversely, in older children, and particularly during attacks triggered by allergens, acute bronchospasm is the most important factor. These discrepancies also influence the clinical course as well as the response to treatment.²³ Asthma exacerbations mainly involving inflammatory processes may require time to develop and to resolve, and symptoms therefore tend to increase and improve relatively slowly. In these cases, airway narrowing may mainly be due to inflammatory changes, and there may be an associated down-regulation of β -receptors.²⁴ Consequently, the response to β 2-agonists may be limited (figure 1). In contrast, allergen induced attacks may develop very rapidly with bronchoconstriction as the dominating pathophysiology, thereby also responding quickly to bronchodilator treatment.

Assessment

Clinical assessment: The most common symptoms in a child with acute asthma are cough, wheeze, and prolonged expiration. Objective signs include a prolonged expiratory phase, recessions, use of accessory respiratory muscles and cyanosis. On auscultation, varying degrees of high and low frequency expiratory sounds may be heard. In severe and rapid developing attacks the child may even present with respiratory failure or frank cardiopulmonary arrest.

Different grading systems have been proposed to evaluate the severity of acute asthma in children,²⁵⁻²⁷ but no firm consensus exists. A clinical grading system for bronchopulmonary obstruction has been proposed (table 1) and applied in treatment recommendations in a Nordic consensus report.²⁵ It is important to bear in mind that the extent of wheeze does not necessarily reflect the extent of bronchopulmonary obstruction, since some degree of airflow is required to produce a wheeze.²⁸ Therefore, decreasing wheeze and breath sounds and a "quiet chest" in a child with increasing respiratory efforts may signal imminent respiratory failure. Conversely, increasing wheeze in a child with severe asthma may indicate improvement. Development of respiratory failure is clinically best recognised by close observation of the general condition of the child, the ability to speak or cry, the mental status and level of anxiety, the skin colour and the movements of the thoracic cage and abdomen during the respiratory cycle.¹⁰ Inability or unwillingness to lie down may be an ominous sign in a child with acute severe asthma.

Children with a special risk for severe or life-threatening asthma attacks are those with a history of frequent use of β 2-agonists,

frequent or recent treatment with oral corticosteroids, a previous history of severe asthma and chronic severity with impaired lung function.⁸

Laboratory assessment: A chest x-ray may be relevant in the search for underlying complications such as pneumonia or air leakages. However, in moderate asthma attacks a chest x-ray rarely leads to changes of treatment.²⁹

Pulse oximetry is a reliable and noninvasive measure of oxygenation and should be used in all patients to guide oxygen supplementation. However, oxygen saturation is not a good parameter of adequate ventilation in children who receives oxygen treatment. Thorough and repeated clinical assessments are required to discover imminent respiratory failure. Blood gas analyses may support the clinical judgement, as increasing levels of CO_2 is an ominous sign. During a moderate asthma attack, a capillary blood gas analysis may be sufficient, while in patients admitted to an intensive care unit, arterial blood gas analyses should be routine.²⁵ Sequential measurements are important as respiratory alkalosis with hypocarbia is common during the early phases of an asthma attack, while normalisation and a subsequent increase in the pCO_2 may be important indicators of clinical deterioration.¹⁰

Management

The cornerstones of acute asthma management in childhood are oxygen, inhalation of bronchodilators and systemic corticosteroids. Additional treatment should be included

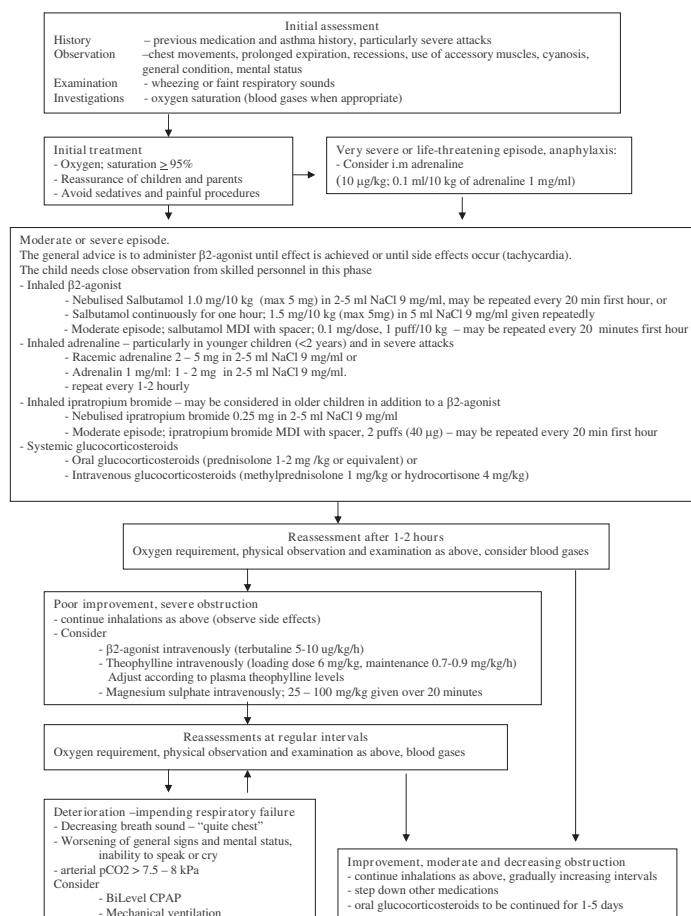


Figure 3

Figure 3: Treatment algorithm for children with moderate or severe asthma exacerbations.

as required. Acute asthma is often associated with anxiety, which may further increase dyspnoea and bronchopulmonary obstruction. Reassurance is therefore important, both directly but also indirectly through the parents. The clinical value of painful procedures must be considered against their possible aggravating effects. Once established, an indwelling arterial line vastly reduces the need for subsequent painful procedures.

Oxygen: Oxygen must be considered as a drug in a situation of acute asthma, reducing hypoxic pulmonary vasoconstriction and interfering with the ventilation-perfusion mismatch characteristic for severe bronchoconstriction.³⁰ Oxygen should be delivered to achieve satisfactory oxygen saturation in obstructive children with suspected or verified hypoxia. No controlled studies have evaluated which level of oxygen saturation that is adequate during an acute asthma attack, but recent guidelines recommend that oxygen saturation in children should be kept above 95%.²⁶ Oxygen may be delivered by a face mask or by nasal cannulae, and the dose should be adjusted by continuous monitoring by pulse oximetry. Oxygen at a rate of 6-8 liters per minute should be used to deliver nebulised drugs.²⁶ In severe cases, oxygen should be administered before other drugs and before assessment is completed.²⁶

Fluid: Acute asthma in children is often preceded by periods of poor fluid intake and vomiting and may therefore be associated with dehydration. Dehydration may increase metabolic acidosis, and treatment should be aimed at restoring normovolemia by oral (preferably) or by intravenous fluid substitution.¹⁰ Overhydration will increase pulmonary oedema and must be avoided. The syndrome of inappropriate antidiuretic hormone (SIADH) has been described in severe asthma attacks, and careful monitoring of electrolyte and fluid balance is therefore important.^{9,10,21,22}

Injection of adrenaline (epinephrine): Intramuscular injection of adrenaline 10 µg/kg (0.1 ml per 10 kg body weight of adrenaline 1 mg/ml) may be given in severe bronchoconstriction during anaphylaxis. This treatment may also be an initial option in very severe exacerbations of asthma and in situations where other treatment options are not available within reasonable time.^{9,26}

Inhalations with β₂-agonists: There is substantial documentation for the effect of inhaled β₂-agonists in acute childhood asthma.^{10,26,31} The drug is traditionally nebulized, and dose recommendations for salbutamol (albuterol) vary between 0.5-1.5 mg/10 kg bodyweight, mixed in 2-5 ml NaCl 9 mg/ml.¹⁰ Inhalations should preferably be given via a face mask, and if necessary delivered with oxygen. During initial therapy, β₂-agonists are often given intermittently, as repeated inhalations every one to three hours.²⁶ There is, however, evidence suggesting that continuous administration of nebulised β₂-agonists may have a better and prolonged bronchodilatory effect compared to intermittent therapy.^{9,10,31} A sustained stimulation of β₂-receptors is accomplished, and a possible rebound bronchoconstriction reported during intermittent therapy is prevented.^{10,31} A recommended dose for children is 0.15 mg/kg in 5 ml NaCl 9 mg/ml given repeatedly by continuous inhalation. This has been reported to be safe and well tolerated.³¹ Recent guidelines suggest a practical approach with continuous inhalation of β₂-agonist during the first hour(s) of treatment and thereafter intermittent inhalations on-demand.²⁶

In cases with a gradually developing inflammation one should remember the possibility of a poor response to β₂-agonists due

to downregulation of β-receptors (figure 1).²⁴ Other types of inhalations such as adrenaline and ipratropium bromid may be beneficial in such cases (see below).³¹

One should also keep in mind that β₂-agonist may have stressful effects on the child, and in some cases high doses may in fact become counter-productive. Therefore, when the dose intervals are shorter than the half life of the drug, or if the strategy of continuous administration is employed, one should carefully consider and monitor the general condition of the child. An often used rule of thumb is that β₂-agonist should be administered until development of significant side effects, a strategy requiring close monitoring by skilled personnel.

There are now several studies demonstrating that pressurized metered dose inhalers (pMDI) in combination with spacers are as good as or even more effective than nebulizers for intermittent administration of β₂-agonist in children with moderate to severe acute asthma.³¹⁻³⁵ This may be the obvious choice for treatment of asthma exacerbations in children at home, and should be included in all written treatment plans. It may, however, also be used initially in emergency outpatient settings as well as in paediatric emergency wards.³¹ In mild attacks, 2-4 puffs of salbutamol 0.1 mg/dose may be sufficient (0.2-0.4 mg), whereas in more severe attacks 10 puffs of salbutamol may be needed.³¹ Oxygen cannot be given with a pMDI and spacer, excluding this method in the most severe attacks. However, in children without initial oxygen requirements, β₂-agonist administered via a pMDI and spacer was less likely to provoke hypoxia and tachycardia compared to the administration via a nebuliser.^{32,35} Therefore, pMDI and spacer has been recommended as the preferred mode of administration for β₂-agonist in pediatric acute asthma.³¹

Nebulized adrenaline: In infants and young children with acute asthma and wheezing, bronchial smooth muscle spasm is not as prominent as in older children, and mucosal oedema and secretion may dominate the pathophysiology.³⁶ Therefore, inhaled β₂-agonists may be less efficient. Nebulised adrenaline has a rapid but short acting effect on mucosal oedema and may be of value as initial treatment also in severely obstructed older children, before administration of inhaled β₂-agonists.

Studies on the effects of nebulised adrenaline in children of different ages with bronchopulmonary obstruction reach various conclusions. Some are positive³⁷⁻⁴⁰ whilst others conclude negatively.^{41,42} In Nordic consensus and national protocols, nebulised adrenaline is recommended in young children (<2 years) with acute asthma, followed by β₂-agonist.^{25,36} The recommended dose is racemic adrenaline 2 mg in children < 6 months of age and 4 mg in older children, inhaled in 3-5 ml NaCl 9mg/ml.²⁵ Alternatively, adrenaline (1 mg/ml) may be inhaled in a dose of 1.5 mg/10 kg bodyweight (maximum 2 mg) in 2-5 ml NaCl 9 mg/ml.⁴³

Inhaled anticholinergics

Current guidelines on acute paediatric asthma recommend inhaled ipratropium bromide as add-on therapy to β₂-agonists. This recommendation is based on several randomised controlled trials demonstrating reduced hospital admission rates and better lung function when β₂-agonists are given in combination with inhaled ipratropium bromide compared to β₂-agonists given alone.⁴⁴⁻⁴⁶ Especially when symptoms are refractory to initial treatment with β₂-agonist anticholinergics should be considered.³¹ The recommended dose of nebulised ipratropium

bromide is (0.125-) 0.25 mg in 2-5 ml NaCl 9 mg/ml or the drug may be mixed with the β_2 -agonist/NaCl solution.^{27,31,44} The dose may be repeated every 20 minute for the first hour and every four hour thereafter.³¹ Ipratropium bromide may also be given as pMDI with a spacer at the dose of 40 μg .²⁷

Steroids: An increased inflammatory response is a major part of the pathophysiology of acute asthma, and prompt treatment with corticosteroids is important. Steroids act on the pathophysiology in acute asthma in several ways, mainly by modifying the action of inflammatory cells, downregulating the release of proinflammatory cytokines and thereby controlling the airway inflammation.^{9,10,16,31} Guidelines recommend that all children with moderate to severe asthma should receive systemic steroids as a part of the initial treatment.^{25,26} This treatment may reduce the need for hospitalization, reduce the risk or relapse after the initial treatment and facilitate earlier discharge from hospital.⁴⁷ There is no evidence to suggest that intravenous steroids are more effective than oral steroids, both having effect after 3-4 hours.^{31,48,49} The usual recommendation for oral treatment is prednisolone 1-2 mg/kg or equivalent.³¹ One study has demonstrated that a lower dose may have similar effect,⁵⁰ but more studies are needed to confirm this. Intravenous hydrocortisone of 4 mg/kg or methylprednisolone 0.5-1.0 mg/kg every 4-6 hour are alternatives to oral steroids, but may be reserved for children unable to receive oral administration due to severity or low age.^{10,31}

Systemic steroids may be given repeatedly, depending on the initial response. Normally a 3-5 days course may be sufficient, but longer treatment periods may be necessary.^{10,26} A prolonged course of treatment may be particularly necessary if the exacerbation is the result of longstanding untreated bronchial inflammation. Prednisolone may be given once daily, and there is no need for tapering down even after longer treatment periods.^{26,51} Figure 1 demonstrates the spirometry at of a 13 year old girl at admission before and after the inhalation of nebulised salbutamol, and figure 2 the spirometry from the same girl after a 10 days course of prednisolone 1 mg/kg.

Inhaled corticosteroids are the cornerstone of regular preventive anti-inflammatory treatment of asthma, aiming at reducing chronic morbidity and preventing exacerbations.²⁶ It has been a widely recommended practise to double or triple the dose of inhaled steroids during exacerbations, but the data to support this is missing.³¹ However, recent studies have suggested that high doses if inhaled steroids during the early phase of an asthma exacerbation may be beneficial,^{52,53} but this approach is not incorporated in current guidelines and more studies are needed to evaluate this issue.²⁶

Additional medication: Theophylline. The positive effect from theophylline infusion on acute asthma is well documented, as are the potential for side effects and severe or even fatal complications.^{10,54-57} In light of the highly efficient inhaled bronchodilators and systemic corticosteroids, a theophylline infusion therefore has no place in the routine treatment of children with asthma exacerbations.²⁶ In our department, theophylline given rectally or as an infusion was used in 85% of admissions for childhood asthma in 1984/1985, and in 3% in 1999/2000.³ However, in one study, theophylline infusion had some additional effect in children with near-fatal asthma, already receiving an aggressive regimen with multiple inhaled bronchodilators and intravenous corticosteroids.⁵⁴ Wheeler et al

concluded that theophylline infusion was superior to terbutaline as add on treatment in children with status asthmaticus.⁵⁶ Theophylline may therefore be considered in children with a poor response to other treatment measures.

Intravenous β_2 -agonists may also be considered in children with severe asthma who do not respond to other treatments.^{31,58,59} Inhaled drugs may have limited effect in children with nearly complete airway obstruction and have practical limitations in ventilated patients. Intravenous terbutaline has been shown to improve pulmonary function and gas exchange in children with status asthmaticus,^{31,59} whereas others have failed to demonstrate efficacy.⁶⁰ A suggested dose may be terbutaline 5-10 $\mu\text{g}/\text{kg}/\text{h}$,²⁵ but the dose may be titrated higher.⁵⁸ However, one should bear in mind cardiac side effects such as dysrhythmias, tachycardia and hypertension. Severe hypokalemia induced by β_2 -agonists may also aggravate possible dysrhythmias.⁶¹ The effect of inhaled β_2 -agonists observed in most cases, limit the need for intravenous administration to very few children.²⁶

Magnesium sulphate. The potential benefit of magnesium sulphate during acute asthma may be via smooth muscle relaxation secondary to inhibition of calcium uptake. Several studies have evaluated inhaled and intravenous administration of magnesium sulphate in severe childhood asthma, but results are diverging.^{62,63} A recent meta-analysis, however, suggested that intravenous magnesium sulphate may be effective in children with severe acute asthma, whereas more studies are needed to evaluate the effect of inhaled magnesium sulphate.⁶³ The recent GINA-guidelines suggest that intravenous magnesium may be considered in acute moderate and severe asthma with incomplete response to initial treatment during the first 1-2 hours.²⁶ It is interesting that this treatment option is listed before intravenous theophylline. The dose of intravenous magnesium sulphate children used in studies is 25-100 mg/kg given over 20 minutes.^{10,63} Intravenous magnesium sulphate is not studied in young children and is not included in recent guidelines for children younger than five years of age.²⁷

At present there is no evidence to support the use of helium oxygen therapy or leukotriene modifiers in the treatment of children with acute asthma.^{9,26,64,65} Furthermore, it is important to avoid the use of sedatives because of the depressant effect on the respiratory efforts.²⁶ In severely agitated children one must consider the possibility of side effects and drug overdoses, particularly from adrenergic inhalation or from theophylline. In children receiving massive treatment with inhaled and/or intravenous adrenergic and/or anticholinergic drugs and maybe also intravenous theophylline, one must observe for cardiac side effects and if suspected, institute adequate measures.

Non-invasive and invasive ventilation: A detailed presentation of the principles of non-invasive and invasive ventilation of children with severe bronchopulmonary obstruction is beyond the scope of this review. However, studies during recent years suggest that bilevel positive airway pressure (BiPAP) in children with severe asthma may improve symptoms and ventilation without significant adverse events and reduce the need for intubation and mechanical ventilation.^{9,65-68} This treatment may therefore be considered in children not responding properly to initial treatment and with threatening respiratory failure. However, in younger children, lack of cooperation, stress and agitation may induce pressure leaks and prevent its use. BiPAP is contraindicated in the patient with altered mental status.⁶⁵

Intubation and positive pressure ventilation of an asthmatic child may increase bronchoconstriction, increase the risk of airway leakage and has disadvantageous effects on circulation and cardiac output.^{10,69} Therefore, intubation should be avoided unless respiratory failure is imminent despite adequate institution of all available treatment measures. Absolute indications for intubation include severe hypoxia, cardiopulmonary arrest, and severe deterioration of the mental status of the child. Relative indications are progress of respiratory failure and/or increasing CO₂ despite adequate utilisation of all available treatment measures. However, children should not be intubated based on blood gas analyses alone.^{9,10} The clinical signs indicating a severe obstruction or a deteriorating clinical situation are described previously under the heading “assessment,” and the importance of close observation of these signs by an experienced staff cannot be overestimated.

Before intubation, the child should be properly preoxygenated. Atropine may be indicated together with a sedative and a rapid muscle relaxant. Ketamine (1-2 mg/kg i.v) is often recommended due to its bronchodilating effect.¹⁰ Shortly after intubation, complications such as hypotension, cardiac arrest, pneumothorax and hypoxia may develop.^{10,70} Hypotension may be caused by hyperinflation with decreased venous return to the heart, aggravated by the vasodilatory effects of medications used during intubation. Hypotension may be prevented by a fluid bolus given prior to intubation, or aggressively treated if occurring.¹⁰

During mechanical ventilation the child should be well sedated. Ventilator setting should aim at avoiding hyperinflation and intrinsic positive end expiratory pressure (PEEP). Normally the settings will involve a low inspiratory to expiratory ratio, a low respiratory rate and low tidal volumes. Pressure control, pressure support and permissive hypercapnia may prevent air-leakage.¹⁰ Positive end-expiratory pressure is debated.^{68,71}

Management plan: Based on the above considerations and recent guidelines, we suggest a treatment algorithm for acute asthma in children, including dose recommendations (Figure 3). The suggested use of nebulised adrenaline has some support from the literature, but has not been included in other guidelines, for instance the GINA. All institutions caring for children with acute asthma should provide to their staff a clear in-house treatment algorithm, taking local considerations and circumstances into account.

Differential diagnostic considerations

Physicians facing a child with a suspected acute asthma attack should consider possible alternative diagnoses.⁷² Respiratory distress resembling an acute attack of asthma can be caused by other pulmonary conditions, such as pneumonia or spontaneous pneumothorax, or by obstruction in central bronchi, such as aspiration of a foreign body, or by obstruction in the trachea or larynx, such as pseudocroup or vocal cord dysfunction. Hyperventilation may mimic as well as complicate an asthma attack, particularly in older children.⁷²

Conclusion

Despite recent progress in the treatment of chronic asthma in childhood, acute exacerbations will continue to occur. Physicians working within the field of paediatric emergency medicine will therefore continue to be exposed to this clinical

scenario. The cornerstones of acute asthma management in childhood are rapid onset of oxygen treatment, inhalation of bronchodilators and systemic corticosteroids. It is important that relevant treatment algorithms exist, applicable to all levels of the treatment chain and reflecting local considerations and circumstances.

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Effect of Traffic Pollution on Respiratory and Allergic Disease in Adults: cross-sectional and longitudinal analyses

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Abstract

Background: Epidemiological research into the role of traffic pollution on chronic respiratory and allergic disease has focused primarily on children. Studies in adults, in particular those based on objective outcomes such as bronchial hyperresponsiveness, skin sensitisation, and lung function, are limited.

Methods: We have used an existing cohort of 2644 adults aged 18-70 living in Nottingham, UK, for whom baseline health and demographic data were collected in 1991 and computed two markers of exposure to traffic: distance between the home and nearest main road and modelled outdoor nitrogen dioxide (NO₂) concentration at the home location. Using multiple regression techniques, we analyzed cross-sectional associations with bronchial hyperresponsiveness, FEV₁, spirometry-defined COPD, skin test positivity, total IgE and questionnaire-reported wheeze, asthma, eczema and hay fever in 2,599 subjects, and longitudinal associations with decline in FEV₁ in 1,329 subjects followed-up nine years later in 2000.

Results: There were no significant cross-sectional associations between home proximity to the roadside or NO₂ level on any of the outcomes studied (adjusted OR of bronchial hyperresponsiveness in relation to living $\leq 150\text{m}$ vs $>150\text{m}$ from a road = 0.92, 95% CI 0.68 to 1.24). Furthermore, neither exposure was associated with a significantly greater decline in FEV₁ over

time (adjusted mean difference in ΔFEV_1 for living $\leq 150\text{m}$ vs $>150\text{m}$ of a road = 10.03ml, 95% CI, -33.98 to 54.04).

Conclusions: This study found no evidence to suggest that living in close proximity to traffic is a major determinant of asthma, allergic disease or COPD in adults.

Background

Many epidemiological studies have examined effects of exposure to road vehicle traffic on chronic respiratory and allergic disease in children, but research of the effects in adults is limited. A handful of studies of adults have reported that living in close proximity to busy or major roads is associated with an increased risk of wheeze, whilst others have shown no effect on wheeze or asthma. Some of this inconsistency may be due to the use of self-reported markers of asthma which are potentially biased, but use of objective markers such as bronchial hyperresponsiveness (BHR) is rare. Lung function measures such as one second forced expiratory volume (FEV₁) have been investigated by a few in relation to traffic indices such as proximity to main roads or modelled traffic-related pollutants, but again findings in adults are inconclusive and evidence of longitudinal effects lacking. Spirometry has also been used to define chronic obstructive pulmonary disease (COPD) in one study of women which reported an adverse effect of close residential proximity to a busy road. Investigations of allergy and atopy in adults have also tended to rely on self-reported outcomes, and use of objective markers such as skin sensitization or elevated immunoglobulin E (IgE) rare.

We have therefore used data from an existing population-based cohort of adults to compute markers of exposure to traffic-related pollution and investigate their relation with objective measures of respiratory and allergic disease, namely bronchial hyperresponsiveness, FEV₁, spirometry-defined COPD, skin test positivity and total IgE, as well as questionnaire reported wheeze, asthma, eczema and hay fever. In addition to these cross-sectional investigations, we have also used longitudinal measurements made on the cohort to examine effects of exposure on change in FEV₁. As the primary traffic related air pollutants are highest at the roadside and decline exponentially, we have chosen to use distance between home residence and the nearest major road as an objective proxy of exposure to traffic pollution, and to look particularly at doseresponse relations across the first 150m from the roadside where most of the decline occurs. We have also used an alternative marker of exposure based on modelled traffic-related NO₂ at the home

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Table 1. Baseline characteristics of Gedling study participants included in cross-sectional and longitudinal traffic pollution analyses and those lost to follow-up.

Baseline characteristics	Cross-sectional analysis (N=2599) Number (%)	Longitudinal analysis (N=1329) Number (%)	Lost to follow-up (N=1267) Number (%)
Age group			
18-29	415 (16.0)	134 (10.1)	281 (22.2)
30-39	553 (21.3)	263 (19.8)	290 (22.9)
40-49	664 (25.6)	369 (27.8)	295 (23.3)
50-59	523 (20.1)	341 (25.7)	341 (26.7)
60-70	444 (17.1)	222 (16.7)	220 (17.4)
Sex			
Men	1299 (50.0)	659 (49.6)	639 (50.4)
Women	1300 (50.0)	670 (50.4)	628 (49.6)
Carstairs deprivation quintiles			
1 st (least deprived)	636 (24.5)	292 (22.0)	282 (22.3)
2 nd	457 (17.6)	255 (19.2)	202 (15.9)
3 rd	523 (20.1)	307 (23.1)	241 (19.0)
4 th	482 (18.6)	220 (16.6)	264 (20.8)
5 th (most deprived)	501 (19.3)	255 (19.2)	278 (21.9)
Smoking status			
Never	1289 (49.6)	705 (53.1)	583 (46.0)
Ex-smoker	722 (27.8)	387 (29.1)	334 (26.4)
Current smoker	588 (22.6)	237 (17.8)	350 (27.6)
Distance to a main road			
<50 m	164 (6.3)	87 (6.6)	77 (6.1)
50 – 100 m	226 (8.7)	112 (8.4)	114 (9.0)
100 – 150 m	190 (7.3)	96 (7.2)	94 (7.4)
> 150 m	2019 (77.7)	1034 (77.8)	982 (77.5)
Modelled quintiles of NO₂ (µg/m³)			
<33.92	520 (20.0)	267 (20.1)	252 (19.9)
33.92 – 34.23	520 (20.0)	279 (21.0)	240 (18.9)
34.23 – 34.73	520 (20.0)	277 (20.8)	242 (19.1)
34.73 – 36.79	520 (20.0)	248 (18.7)	272 (21.5)
>36.79	519 (20.0)	258 (19.4)	261 (20.6)
Outcomes*			
Current wheeze	624 (24.0)	274 (20.6)	347 (27.4)
Diagnosed asthma	231 (8.9)	102 (7.7)	128 (10.1)
COPD**	238 (9.2)	102 (7.7)	135 (10.7)
BHR†	310 (13.0)	147 (11.7)	163 (12.9)
Ever hay fever	662 (25.5)	323 (24.3)	337 (26.6)
Ever eczema	714 (27.5)	365 (27.5)	348 (27.5)
Allergen skin sensitisation	788 (30.3)	406 (30.6)	381 (30.1)
High total IgE‡	549 (22.3)	258 (20.2)	290 (22.9)

NO₂ nitrogen dioxide; COPD chronic obstructive pulmonary disease; BHR bronchial hyper-responsiveness; IgE immunoglobulin E.

* For outcomes, values represent number and % positive where %'s are computed excluding any missing values

**COPD: 7 missing values in cross-sectional study (%=238/2592) and 1 in longitudinal (%=102/1328)

† BHR: 216 missing values in cross-sectional study (%=310/2383) and 74 in longitudinal (%=147/1255)

‡ IgE: 132 missing values in cross-sectional study (%=549/2467) and 53 in longitudinal (%=258/1276)

Table 2. Comparison of Gedling study participants included in data analyses with 1991 Gedling census population

Characteristic	1991 Gedling census pop ^a [20]*	Main cross-sectional analyses N=2599	BHR analysis N=2383	IgE analysis N=2467	Longitudinal analysis of FEV ₁ N=1329
Age group (%)					
18-29	24.9	16.0	16.5	15.2	10.1
30-39	21.2	21.3	21.7	21.2	19.8
40-49	22.0	25.6	27.1	26.1	27.8
50-59	16.7	20.1	20.3	20.2	25.7
60-70	15.2	17.1	14.5	17.2	16.7
Sex (%)					
Men	49.4	50.0	50.4	50.1	49.6
Women	50.6	50.0	49.6	49.9	50.4
Mean (SD) Carstairs deprivation score	-1.29 (2.05)	-1.32 (2.17)	-1.34 (2.16)	-1.32 (2.17)	-1.53 (2.15)

BHR bronchial hyper-responsiveness; IgE immunoglobulin E.

*Age and sex %'s based on Gedling 1991 census population aged 18-69 (n=74899); mean Carstairs based on total Gedling 1991 census population (n=110127)

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location, which may better reflect the level and type of traffic. Data on number of years residence in the current home has also enabled us to look more specifically at long-term effects of exposure by restricting analyses to long-term residents only.

Methods

Study population: Our study population is a cohort of adults aged 18-70 living in the Gedling area of Nottingham City, UK, who were recruited in 1991 as part of a study of the effect of diet

Table 3. Association between residential proximity to a main road and respiratory and allergic outcomes.

Outcomes	Number with outcome (%)	Adjusted OR* (95% CI)	p-value†
Wheezing in last year			
≤150m	129 (22.2)	0.86 (0.68 - 1.08)	0.19
>150m	495 (24.5)	1	
Bands of distance			
<50 m	46 (28.1)	1.60 (0.96 - 2.68)	0.07
50 – 100 m	45 (19.9)	1.00 (0.61 - 1.66)	
100 – 150 m	38 (20.0)	1	
COPD			
≤150m	53 (9.2)	0.97 (0.68 - 1.37)	0.86
>150m	185 (9.2)	1	
Bands of distance			
<50 m	16 (9.8)	1.54 (0.69 - 3.45)	0.29
50 – 100 m	24 (10.7)	1.67 (0.79 - 3.49)	
100 – 150 m	13 (6.8)	1	
BHR			
≤150m	64 (11.9)	0.92 (0.68 - 1.24)	0.57
>150m	246 (13.3)	1	
Bands of distance			
<50 m	13 (8.5)	0.54 (0.27 - 1.11)	0.09
50 – 100 m	25 (12.0)	0.80 (0.44 - 1.45)	
100 – 150 m	26 (14.7)	1	
Allergic sensitisation			
≤150m	163 (28.1)	0.87 (0.70 - 1.07)	0.19
>150m	625 (31.0)	1	
Bands of distance			
<50 m	51 (31.1)	1.72 (1.05 - 2.81)	0.03
50 – 100 m	70 (31.0)	1.53 (0.97 - 2.42)	
100 – 150 m	42 (22.1)	1	
High total IgE			
≤150m	109 (19.7)	0.80 (0.63 - 1.02)	0.07
>150m	440 (23.0)	1	
Bands of distance			
<50 m	31 (20.3)	1.21 (0.69 - 2.12)	0.51
50 – 100 m	43 (19.6)	1.01 (0.61 - 1.69)	
100 – 150 m	35 (19.3)	1	

OR odds ratio; CI confidence interval; COPD chronic obstructive pulmonary disease; BHR bronchial hyper-responsiveness; IgE immunoglobulin E.

* OR adjusted for sex, age group, Carstairs deprivation scores and smoking status

† p-value for trend across bands of distance

on chronic lung disease. Gedling is an area of 46 square miles with an estimated population of 87,000 in 1991 which covers the north east suburbs of Nottingham and surrounding rural villages. Full details of the study have been described elsewhere. Briefly, a representative sample of adults was drawn from the local electoral register and those of eligible age and residing in the study area were invited to take part in the study (figure 1). Information on respiratory and allergic disease symptoms, demographics, smoking, diet, and numerous other lifestyle factors were collected using an interview-led questionnaire. FEV₁ and forced vital capacity (FVC) were measured by a study nurse using a calibrated dry bellows spirometer (Vitalograph, Buckingham, UK) taking the best of three technically satisfactory maneuvers with the subject seated; a methacholine challenge performed to determine BHR using the technique described by Yan et al; allergen skin tests to Dermatophagoides pteronyssinus, mixed grass pollen, cat fur, Aspergillus fumigatus, and Cladosporium herbarum (Bencard solutions, Brentford, UK) carried out; and a blood sample taken. In total, 2,644 individuals participated in the 1991 survey, estimated to be between 48% and 59% of those eligible (figure 1). The exact response rate cannot be computed since it was not known what proportion of the non-responders would have been eligible for inclusion. In 2000 all surviving individuals were invited to participate in a follow-up survey (follow-up rate was 51%) in which these measurements, with the exception of BHR, were repeated. The surveys were approved by the Nottingham City Hospital and Nottingham University ethics committees.

Computation of exposure variables: We took each subjects home address in 1991 and converted it into a grid reference using information from the Local Land & Property Gazetteers database held by Gedling Borough Council. To compute our distance exposure variable, we linked this grid reference to a digitized road map of Great Britain (Meridian database; Ordnance Survey, Southampton, UK), which is a geometrically structured 1:50,000 scale vector database with a coordinate resolution of 1m. We then calculated the shortest distance (in metres) between each address location and the nearest major road, defined as a motorway (freeway), or A or B class road (principal road as classified by UK Department for Transport), using Geographical Information System (GIS) software (ArcGIS 9.0).

To compute our modelled NO₂ variable, we linked each home location grid reference to a high resolution map of modelled traffic-related NO₂ using ArcGIS. This map was generated by the dispersion model ADMS Roads (CERC, Cambridge, UK), which has been widely used to assess the impact of road traffic on local air quality and extensively validated against monitored roadside concentrations of traffic pollutants. Traffic count and composition data supplied by Nottinghamshire County Council and hourly sequential meteorological data (including wind direction and speed) provided by the UK Meteorological Office were inputted into the model. Background concentration data were averaged from pollutant data recorded at automated sites in Nottingham City Centre (urban) and Sutton Bonnington (rural). Modelled annual mean concentrations of NO₂ were verified through comparison with observed concentrations (1998-2003) recorded at 10 diffusion tube survey sites (background, intermediate and roadside) across the study area and overall modelled values correlated well with observed (r=0.63). Closer inspection revealed some underestimation of

observed concentrations at roadside sites close to major road intersections where slow moving or standing traffic is likely during rush hours. In the absence of more detailed information on traffic count, speed and composition the model is unable to reproduce elevated concentrations at such localized hot spots. However given the good level of agreement between modelled and observed concentrations elsewhere (r=0.88 for the other sites), and the fact that only a minority of the study population would live close to such major intersections, the model parameterisation was deemed satisfactory to invoke deployment across the entire study area at a spatial resolution of 10 meters.

Statistical analyses: In cross-sectional analyses we assessed the effect of each exposure variable on each of the following outcome variables using data from the 1991 baseline survey: self-reported wheeze in the past year (Have you had wheezing or whistling in your chest at any time in the last 12 months?), diagnosed asthma (Have you ever had asthma? and Was this confirmed by a doctor?), eczema ever (Have you ever had eczema or any kind of skin rash?) and hay fever ever (Have you ever had hayfever or other nasal allergies?); bronchial hyperresponsiveness (BHR), defined as a methacholine dose provoking a 20% fall in FEV₁ (PD₂₀) of 12.25 mg/ml or less; COPD, defined as stage I or above using the GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria (namely having an FEV₁/FVC less than 70%); allergen skin sensitisation, defined as a response to any of the allergens tested at least 3mm greater than the saline control response in the presence of a positive histamine control; and high total IgE, defined as a concentration above 100kU/l. Multiple logistic regression analyses were carried out to assess the effect of distance, initially treated as a binary variable (<=150m and >150m), on each binary outcome, adjusted for age, sex, smoking

Table 4. Association between modelled NO₂ level and respiratory and allergic outcomes.

Quintiles of modelled NO ₂ (µg/m ³)	Number with outcome (%)	Adjusted OR* (95% CI)	p for trend
Wheezing in last year			
<33.92	124 (23.9)	1	0.18
33.92 – 34.23	134 (25.8)	1.03 (0.76 - 1.39)	
34.23 – 34.73	122 (23.5)	0.86 (0.63 - 1.16)	
34.73 – 36.79	122 (23.5)	0.84 (0.63 - 1.14)	
>36.79	122 (23.5)	0.88 (0.66 - 1.19)	
COPD			
<33.92	46 (8.9)	1	0.95
33.92 – 34.23	50 (9.6)	1.09 (0.68 - 1.73)	
34.23 – 34.73	46 (8.9)	0.95 (0.60 - 1.52)	
34.73 – 36.79	45 (8.7)	0.91 (0.57 - 1.45)	
>36.79	51 (9.8)	1.07 (0.68 - 1.68)	
BHR to methacholine			
<33.92	59 (12.5)	1	0.29
33.92 – 34.23	69 (14.4)	1.08 (0.73 - 1.60)	
34.23 – 34.73	64 (13.3)	0.95 (0.64 - 1.41)	
34.73 – 36.79	65 (13.8)	1.03 (0.70 - 1.54)	
>36.79	53 (11.1)	0.81 (0.54 - 1.21)	
Allergen skin sensitisation			
<33.92	162 (31.2)	1	0.68
33.92 – 34.23	157 (30.2)	0.98 (0.74 - 1.30)	
34.23 – 34.73	160 (30.8)	1.02 (0.77 - 1.35)	
34.73 – 36.79	158 (30.4)	0.97 (0.73 - 1.28)	
>36.79	151 (29.1)	0.94 (0.72 - 1.24)	
High total IgE			
<33.92	114 (23.3)	1	0.22
33.92 – 34.23	117 (23.4)	0.98 (0.72 - 1.33)	
34.23 – 34.73	105 (21.6)	0.90 (0.66 - 1.23)	
34.73 – 36.79	110 (22.4)	0.90 (0.65 - 1.21)	
>36.79	103 (20.7)	0.84 (0.62 - 1.15)	

NO₂ nitrogen dioxide; OR odds ratio; CI confidence interval; COPD chronic obstructive pulmonary disease; BHR bronchial hyper-responsiveness; IgE immunoglobulin E.

* OR adjusted for sex, age group, Carstairs deprivation score and smoking status

Table 5. Effect of proximity and modelled NO₂ on cross-sectional FEV₁ and longitudinal change in FEV₁.

	Mean (unadjusted)	SD	β [†]	95% CI	p-value [‡]
Cross-sectional					
<i>Distance</i> (N=2599)					
≤150m	3202.6	898.7	5.73	-42.80 to 54.27	0.82
>150m	3178.5	924.1	0		
<i>Bands of distance</i> (N=580)					
<50 m	3143.4	925.2	38.30	-63.60 to 140.21	0.47
50 – 100 m	3230.8	886.0	-10.65	-104.77 to 83.48	
100 – 150 m	3220.1	892.9	0		
<i>Quintile of NO₂</i> (N=2599)					
<33.92	3218.0	905.5	0		0.35
33.92 – 34.23	3163.6	940.1	-20.20	-85.00 to 44.59	
34.23 – 34.73	3147.0	927.5	-4.72	-69.41 to 59.96	
34.73 – 36.79	3213.5	937.9	9.79	-54.69 to 74.27	
>36.79	3177.2	880.9	18.12	-45.01 to 81.25	
Longitudinal[§]					
<i>Distance</i> (N=1329)					
≤150m	-30.6	340.0	10.03	-33.98 to 54.04	0.65
>150m	-36.5	334.0	0		
<i>Bands of distance</i> (N=295)					
<50 m	-13.8	334.0	46.08	-53.31 to 145.46	0.35
50 – 100 m	-19.2	361.6	47.25	-47.43 to 141.93	
100 – 150 m	-59.1	320.7	0		
<i>Quintiles of NO₂</i> (N=1329)					
<33.92	-15.3	333.9	0		0.59
33.92 – 34.23	-24.5	334.3	-18.87	-76.85 to 39.11	
34.23 – 34.73	-41.8	329.1	-27.62	-85.68 to 30.45	
34.73 – 36.79	-57.6	327.1	-37.52	-96.16 to 21.12	
>36.79	-39.0	352.4	-21.58	-79.24 to 36.08	

SD standard deviation; β adjusted regression coefficient; CI confidence interval; NO₂ nitrogen dioxide.

* β coefficient for cross-sectional FEV₁ adjusted for sex, age, age squared, height, age-height interaction, smoking status, cigarette pack-years and Carstairs deprivation score, as recorded at baseline

** β coefficient for longitudinal change in FEV₁ residuals adjusted for smoking status and cigarette pack years in 2000 and Carstairs deprivation score as recorded at baseline

† p-value for trend across quintiles of modelled NO₂ and across bands of distance effects

‡ Change in lung function between 1991 and 2000

Table 6: Effect of proximity and modelled NO₂ on Total IgE.

Exposure variable	N	Median Total IgE kU/l (IQR)	Adjusted regression coefficient* (95% CI)	P-value
Distance				
<150 m	553	27 (8-80)	-0.04 (-0.11, 0.03)	0.25
>150	1914	26 (9-87.9)	0	
Bands of distance				
<50 m	153	23 (7-85)	0.05 (-0.11, 0.21)	0.61
50-100 m	219	30 (10-84)	0.07 (-0.07, 0.21)	P _{trend} =0.49
>100 m	181	27 (6-69.4)	0	
Quintiles of NO₂ (µg/m³)				
<33.92	489	26.8 (9-88)	0	0.92
33.92-34.23	501	24 (9-91.5)	-0.04 (-0.13, 0.06)	P _{trend} =0.69
34.23-34.73	487	22 (9.8- 80.8)	-0.01 (0.11-0.08)	
34.73-36.79	492	29.7 (9.7-85.1)	-0.02 (-0.11, 0.08)	
>36.79	498	26 (9-84)	-0.03 (-0.12, 0.06)	

IQR Interquartile range

* β coefficient from linear regression analysis of log transformed IgE

status (current, never or ex-smoker) and quintiles of Carstairs deprivation score (postcode based index of deprivation based on unemployment, overcrowding, car ownership and occupation). To investigate dose response effects, analyses were then carried out in the subset of respondents living within 150m from a road with distance fitted as 50m bands (the smallest categorization possible given the study sample size). Modelled NO₂ was categorised into quintiles and analysed in a similar way to distance.

The cross-sectional association between each exposure and FEV₁, defined as the best of three satisfactory measurements, was analysed using multiple linear regression controlling for sex, age, age squared, smoking status, pack-years of cigarettes smoked, height, Carstairs deprivation score and age-height interaction. Multiple linear regression was also used to analyse total IgE as a continuous variable (transformed to achieve a Normal distribution by adding 1 and taking the logarithm), with adjustment for age, sex, smoking and Carstairs score. In longitudinal analyses, we computed changes in adjusted FEV₁ residuals between 1991 and 2000 using the method described by Carey et al. Briefly, we modeled predicted FEV₁ values for each sex separately in the sub-group of non-smoking, nonasthmatic, non-wheezing individuals, with terms for age, height, age squared, and ageheight interaction, and calculated the difference from predicted as the adjusted FEV₁ residuals in 1991 and 2000. Change in FEV₁ residual from 1991 to 2000 was modeled in relation to the exposure variables using multiple linear regression, controlling for the effect of smoking and number of pack-years of cigarettes in 2000 and for Carstairs deprivation score as recorded at baseline.

For all analyses we tried adjusting for other potential confounders including exposure to passive smoking, older siblings, indoor heating and cooking appliances, pet ownership, vitamin C and E intake, and body mass index. We also tried controlling for social class based on occupation as an alternative marker of socio-economic status to Carstairs score. Since long-term exposure may be most relevant and inclusion of others could weaken any associations, we repeated all cross-sectional analyses restricting to the subgroup of individuals who had lived in the same address for at least 3 years (long-term residents), and longitudinal analysis restricting to individuals who lived in the same address between 1991 and 2000, to assess whether the magnitude of effect estimates were altered.

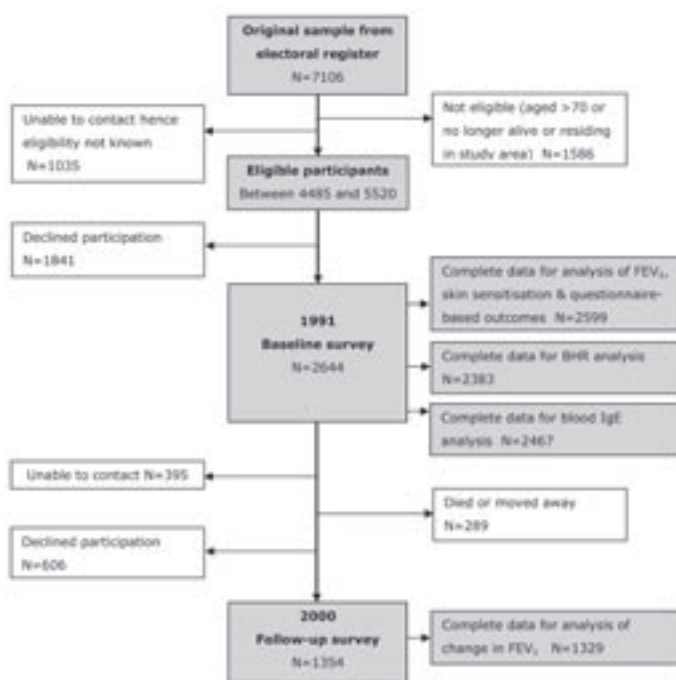
All analyses were performed in STATA 8.2 for Windows (Stata Corporation, College Station, TX). The available sample

provided 80% power to detect an odds ratio (OR) of 1.35 for wheeze (based on an outcome prevalence of 24%) in relation to living within 150m of a road relative to more than 150m (based on an exposure prevalence of 23%).

Results

Population: Of the 2,644 participants in the 1991 baseline survey, we excluded 44 with invalid or incomplete address information and one who had not provided full lung function data. Cross-sectional analyses were therefore carried out on 2,599 subjects (98%), of whom 2,351 (90.5%) were long-term residents (median length of residence 10 years; interquartile range 5 to 20 years). For the longitudinal analyses we excluded 14 without valid address information and 11 without lung function data, leaving 1,329 individuals (98.2% of participants in the follow-up survey) for analysis, of whom 997 (75.0%) had resided at the same address over the period of follow-up. The baseline characteristics of the study subjects and those lost to follow-up are shown in Table 1. Those followed up in 2000 were generally similar to the 1991 baseline group, although slightly less likely to be a smoker or in the youngest age group. Although the characteristics of our original 7106 adults sampled from the electoral role are not known, Table 2 shows how the age, sex and social deprivation (Carstairs) distribution of our participants compares with that of all Gedling residents in 1991, our target population, using census data from that year (Table 2). This shows that those included in our cross-sectional and longitudinal analyses were slightly older than the target population but similar with respect to gender and social deprivation (Table 2). Cross-sectional analyses of BHR and IgE were carried out on slightly smaller datasets due to missing data (figure 1), but demographics were similar to the complete dataset of 2599 subjects (Table 2).

Just under one quarter of individuals (22.3%, n=580) lived within 150m of a main road and the median level of modelled NO₂ exposure was 34.39µg/m³ (IQR 34.01 to 35.94). The concentration of modelled NO₂ was significantly related to

**Figure 1:** Flow diagram showing study participation.

residential proximity to roads (chi square p-value<0.0001) such that those living within 30m of a road had a median level of 39.79µg/m³ (IQR 38.13 to 42.34) decreasing to 34.22µg/m³ (IQR 33.92 to 34.71) for those living more than 150m away.

Effect of proximity to a major road on respiratory and allergic outcomes:

After adjusting for potential risk factors, respondents living within 150m of a major road were not more likely to have BHR, COPD, positive skin test or high total IgE, or self-reported wheeze, than those living further away (Table 3). For wheeze and allergen sensitization there was weak evidence of a positive dose-response relation across the first 150m from the roadside (p for trend=0.07 and 0.03 respectively), but not for the other outcomes. There were no significant associations between proximity and questionnaire-reported asthma, eczema and hay fever (adjusted OR (95% CI) 0.95 (0.68 to 1.33), 0.98 (0.78 to 1.22) and 1.00 (0.81 to 1.25) respectively).

Effect of modelled NO₂ on respiratory and allergic outcomes:

There was no evidence that increasing modelled NO₂ at the home was related to an increase in the risk of wheeze, COPD, BHR, skin sensitization or high IgE (Table 4). Similarly, questionnaire reported asthma, eczema and hayfever were not significantly related to modelled NO₂ (adjusted OR for highest versus lowest quintile 0.96 (0.62 to 1.49), 1.07 (0.81 to 1.41), and 1.02 (0.77 to 1.37), respectively).

Effect of traffic pollution on lung function measurements:

In cross-sectional analyses, those living within 150m of a main road were seen to have a similar FEV₁ to those living further away, and amongst those living within 150m of a road, there was no trend of reduced FEV₁ with increased proximity (Table 5). Similarly, there was no association between measured values of lung function and modeled quintiles of NO₂ at home location.

In longitudinal analyses of lung function over the 9 years of follow-up, decline in FEV₁ was similar for those living within 150m from the roadside and those living further away and showed no trend with proximity amongst those living within 150m (Table 5). Similarly, there was no significant association between modelled NO₂ and change in FEV₁ (Table 5).

Further analyses: Further control for other potential confounders, or occupation-based social class as an alternative to Carstairs deprivation score, did not materially alter any of the results, and restriction of cross-sectional and longitudinal analyses to the sub-group of long-term residents made little difference to the estimates. When total IgE was analysed as a continuous variable rather than a binary variable, no significant associations were seen with distance (adjusted β =-0.04, 95% CI -0.11 to 0.03 for \leq 150 m relative to $>$ 150m, p=0.25) or modelled NO₂ (p for trend =0.69) (Table 6).

Discussion

In this population-based study of Nottingham adults, we found no evidence that living close to a main road or in an area of increased traffic-related pollution was associated with an increased risk of asthma or COPD. This was true for both self-reported markers such as disease symptoms and diagnosis, and objective markers: BHR and lung function. Furthermore, in longitudinal analyses, there was no evidence that increased traffic exposure was associated with decline in lung function. We found some suggestion of an adverse effect of home proximity on allergy with a significant exposure-response across the first

150m from roadside for allergic sensitisation, but not for other markers such as hayfever, eczema or total IgE.

The response rate, both to the original cross-sectional survey and in the 9 year follow-up of these subjects, was only approximately 50%, which raises the possibility of response bias. In the 2000 follow-up study, the characteristics of those who participated were generally similar to the original 1991 sample, and in particular, participation rates did not differ according to proximity to a main road. While the factors associated with participation in the original 1991 survey are not fully known, proximity to a main road is not likely to be one of them since respondents and interviewers were unaware of the current hypothesis of investigation. We did find evidence that our study participants were slightly older than Gedling residents in the 1991 census, but proximity was not associated with age in our dataset (r=-0.03); socio-economic status was comparable to the census population and again was not related to proximity in our dataset (r=0.03). Therefore, whilst we cannot completely rule out the possibility of response bias, it is unlikely to have had a major impact on our study results.

A strength of this study is that our exposure variables were computed using GIS techniques from the participant's exact address rather than postcode used in many previous studies. We estimated that by using the postcode rather than the exact address coordinates in the computation of the binary and the 50m band distance variables, exposure status would have misclassified 5% and 33% of respondents respectively. In addition to the commonly used marker of exposure, residential distance from major roads, we used a more sophisticated marker of exposure based on modelled traffic-related NO₂ concentrations. As this incorporated factors such as traffic patterns on the roads and meteorological influences, it is likely to be a more accurate marker of traffic pollution exposure. While we have endeavored to minimize misclassification by our choice of exposure variables, they still do not allow for exposure away from home and the possibility that they are insufficiently accurate to detect any true adverse effects that exist can not be ruled out. We also addressed the issue of our exposure variables being based on current (1991) home location only, which for those who had moved house may not be the relevant exposure. However our subjects had lived in their home for an average of 10 years and estimates were seen to remain similar when we restricted analyses to the subgroup of long term residents only, suggesting we had not missed any effects because of this issue.

Our findings for asthma fit with a number of previous studies of adults that also found no adverse effect of living in close proximity to a major road on self-reported symptoms. One study that did report an adverse effect looked at US male veterans and showed that those living within 50m of major roads had a increased risk of persistent wheeze, with a significant odds ratio of 1.7 for heavily trafficked roads, but a smaller effect which reached borderline significance when all major roads were considered. Two other recent studies have shown increased risks of wheeze of borderline significance in relation to increased residential proximity to surfaced roads in Ethiopia and living within 20m of a main street in Switzerland. The Ethiopian study differed from most other studies in that it was conducted in a developing country where background pollution was thought to be very low, and it may be that the likelihood of detecting any real effects of home proximity to the roadside are greater in such settings. In our study, the sampling method

and geographical area chosen are likely to have provided a sample broadly representative of the general population, but the fact that the Gedling district is primarily urban means that the majority of the sample live in areas with relatively high background concentrations of pollutants. Insufficient contrast in exposure may therefore explain why we were unable to detect any adverse effects of our localized traffic pollution markers in this study population. Comparison with a recent study in Rome that also modelled NO₂ revealed less variation in our values (IQR 34.01 to 35.94µg/m³) than those that experienced in Rome (IQR 37.3 to 50.3µg/m³), although this study also found no positive associations with asthma either. It is also possible that in some settings, effects of distance on asthma are evident across a wider range of distances than considered here, as suggested by Gauderman et al who reported a dose-response effect across the entire range of distance to the nearest freeway amongst children living in southern California.

A number of cross-sectional studies of lung function have, like ours, found no adverse effect of exposure to traffic on FEV₁. However in a large study of US adults, Kan et al did find a negative association between traffic density at the residential location and FEV₁, although in women only, and a similar finding was reported in a study of German woman in relation to living within 100m of a major road. In our study, no differential effects by gender were observed. As with asthma, adverse effects on lung function have been reported in Californian children in relation to much larger cut-points in distance (500m bands), although again this was for freeways only. Longitudinal studies of decline in FEV₁ are more scarce, but in contrast to our finding of no effect, significant effects have been reported in relation to traffic-related pollution in Japanese women and Swiss adults. The latter used modelled PM₁₀ concentrations, an exposure we were unable to analyse in our study as insufficient data were available for model validation. We also looked at spirometry-defined COPD using the same definition as that used previously by Schikowski et al who unlike us reported a significantly increased odds ratio of 1.79 in relation to living within 100m of a busy roads. Studies that looked at symptoms of COPD such as chronic cough and dyspnea have generally found no significant associations.

Exposure to traffic pollution could plausibly increase the risk of sensitisation to allergens as traffic-related pollutants have been shown to enhance immunological responses to allergens. Our finding of weak evidence of an effect on allergic sensitisation shows some consistency with that of Wyler and colleagues who reported an increased risk of skin sensitisation to pollen in relation to level of traffic at the home location. However, they found no such effect on sensitization to indoor allergens or hay fever. Allergic sensitisation in adults was also investigated by Heinrich et al using specific IgE to common allergens and no relation to living near busy roads was seen. We found no significant effect on hay fever or eczema in adults, which with one exception, is in agreement with others. The lack of consistency of findings across different markers of allergy suggests caution is needed when interpreting one-off findings of adverse effects on allergic outcomes.

Conclusion

In conclusion, we found no evidence to suggest that home proximity to major roads is a major determinant of the risk of asthma, COPD or allergic disease, or progression of obstructive lung disease in adults. However, because of relatively high

levels of background pollution in our study area and possible misclassification of exposure, we cannot completely rule out an adverse effect, and further study is needed which incorporate life-time exposure to pollution in populations with wide variation in exposure.

Product Case Study

Mass Casualty Manifold: Double Duty during a Medical Oxygen Shutdown in an Adult ICU – Saving Manpower and Increasing Safety

Dave Swift, RRT, RRCPC

Background

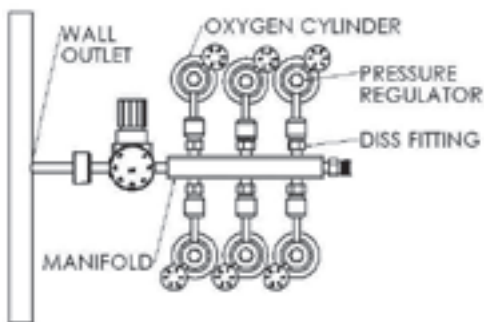
During a routine or urgent oxygen 50 PSIG source shutdown in ICU, each patient must be assured of an uninterrupted source of oxygen both for manual/mechanical ventilation and low flow applications.

This usually requires a “D” or “E” sized cylinder for each patient and a staff person to monitor the cylinder, deliver ventilatory support and respond to emergencies. This places additional manpower requirements on the unit (1:1 patient: staff ratio) and increases the risk to the patient of a medical gas related interruption or inadequate/inconsistent ventilation.

One alternative method that has been used is to back feed a “K” oxygen cylinder through the wall outlet and ensure that the zone valve for the unit is closed. This decreases the manpower requirements and the risk of the gas supply being interrupted, while delivering 50 PSIG of gas. Potentially, a 28 bed ICU using this method could require 4 to 6 additional staff and up to 9 each “K” cylinders equipped with regulators to manage the gas supply (1 cylinder/ 4 beds).

Method

Use a mass casualty manifold E-Vent Case (Figure 1) from VORTRAN Medical Technology 1, Inc (Sacramento, CA) equipped with a 20 foot high pressure oxygen hose, 7 ports DISS oxygen outlets on the distribution block and 6 “K” oxygen cylinders, each equipped with a 50 PSI output regulator and 6 foot hose attached to the 7 DISS outlets (Figure 2). For 3 hours,



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the 20 foot hose is attached to a wall outlet, the unit zone valve is closed, and 3 of the 6 cylinders are turned on.

The cylinder pressures are monitored and once the pressure drops to 300 PSI, the alternate bank of 3 is turned on. The depleted tanks can then be replaced as a routine task. Oxygen is delivered via existing outlets and gas is delivered in the usual manner.

Results

This manifold required only 2 staff RTs to monitor and service the oxygen delivery. The remaining staff was able to continue with patient care in a normal manner, as if there were no interruption in gas delivery. A total of 6 cylinders equipped with 50 PSI output regulators were required. The maximum flow demand was met through the use of 3 ganged cylinders, and line pressure was sustained at 45-50 PSIG. This method allowed for 3 hours of service during a routine service oxygen shutdown.

Conclusion

In a true medical gas failure/emergency, the mass casualty manifold would allow for multiple applications, from the delivery of oxygen to patients in an alternate triage site to sustaining oxygen delivery as a manifold. Utilizing the mass casualty manifold as a mini-manifold allowed for reduced staffing requirements (only 2 RTs instead of 4 to 6), consistent oxygen delivery and no change in the delivery of ventilatory support or therapeutic oxygen delivery.

With consistent replacement of emptied “K” cylinders, this manifold could sustain the ICU indefinitely. This system should be considered as part of the emergency response for every RT department.

Lung-Protective Ventilation: How Often Do We Use It and Is It Cost Effective?

Justin Tse, BS, RRT-NPS

There are many studies that support the use of lung protective strategies in patients with acute lung injury (ALI) or acute respiratory distress syndrome (ARDS). Yet, why do we underuse lung-protective ventilation (LPV)? “Failure to effectively implement evidence into clinical practice is one of the most important challenges in medicine.”¹ In the April 2008 edition of *Respiratory Care*, Mikkelsen et al looked at this very problem. A retrospective cohort study was conducted using physician documentation to identify why LPV was not utilized in patients with ALI. LPV was defined as the use of tidal volume less than or equal to 7.5 ml/kg predicted body weight (PDW). Mikkelsen et al also looked at a sensitivity analysis with LPV defined as tidal volumes less than or equal to 6 ml/kg PDW.

Eighty eight subjects were chosen by using the criteria defined by the American-European Consensus criteria for ALI. Of the 88 patients, only 75 were included in this study due to missing charts, expired, or no longer required mechanical ventilation.

This primary analysis revealed 32% of the subjects were utilizing LPV while only 16% used LPV transiently. Eight (8%) of subjects intended to use LPV but was not implemented. Other reasons why LPV was not used are as follows: metabolic acidosis (2.7%), change in clinical status (6.7%), diagnostic uncertainty (18.7%), and no documented explanation for why LPV was not used (16%).

The sensitivity analysis (VT < or = 6.0 mL/kg PBW) showed different results. Only 9.3% of the 75 patients were sustained on LPV while 16% used LPV transiently. The sensitivity analysis also showed an increase in intended LPV use, but failed implementation of 12%. Mikkelsen et al concluded “... the majority of patients never received LPV at any point during the first 48 hours of ALI, and that LPV, once initiated, is often discontinued.”² They also stated “Our study, the first to directly assess why physicians do not use LPV, suggests that uncertainty in making the diagnosis of ALI may be an important barrier to implementing and continuing LPV, and that physicians may prioritize limiting airway pressure to limiting VT.”²

“Acute lung injury is responsible for up to 75,000 deaths in the United States each year.”³ This number is astounding for the fact that this can be cut if institutions would follow LPV strategies. “Barriers to the delivery of LPV include concern about adverse

effects of low tidal volumes, inadequate knowledge of the LPV protocol, under recognition of ALI, and an unwillingness of the bedside physician to relinquish control of the ventilator.”⁴ If LPV is adopted at an institution, there is still evidence of the lack of adherence to the protocol. “Many of the barriers to LPV adherence could theoretically be overcome by implementing a multidisciplinary approach, including protocolized screening and care, bedside decision support, education of existing staff, and audit and feedback. Yet, these approaches carry costs that must be weighed against the clinical benefits of LPV.”⁴ An article by Cooke et al conducted a study “to determine the cost-effectiveness of LPV and the clinical and economic consequences of an intervention to improve adherence with LPV in ALI patients from the societal perspective.”⁴ Cooke et al found “The lifetime cost of care for a patient with ALI receiving LPV was \$106,821 compared to \$99,588 for non-LPV ALI care, for a difference in cost of \$7,233. The hospital mortality rate in the LPV arm was 31% compared to 40% in the non-LPV arm, resulting in a number of patients-needed-to-treat with LPV to save one life of 11.”

In their discussions, they concluded that “Even a costly intervention to improve adherence with low-tidal volume ventilation in patients with ALI reduces death and is cost-effective by current societal standards.” The US spends more on healthcare than other countries. “Each year, the National Institutes of Health allocates the majority of its research budget to basic science and the development of new treatments, yet < 1% of its budget is directed toward ensuring that patients receive such treatments. As a result, many well-known cost-effective therapies are not delivered to the patients who could directly benefit.”

Closed Loop mechanical ventilation may help improve compliance with LPV in ALI/ARDS patients. A study by Kacmarek et al compared ASV, Adaptive Support Ventilation with the ARDSnet protocol. The group simulated ARDS lung mechanics using an IngMar lung simulator. ASV employs lung-protective rules and adjusts the ventilatory pattern based on the patient's pulmonary mechanics. One hundred eight (108) test scenarios were conducted. The study concluded, “ASV maintains lower plateau pressures and tighter control over plateau pressure than the ARDSnet protocol in low compliance, high PEEP and high target minute volume simulated scenarios. ASV does sacrifice tidal volume in order to maintain plateau pressure target.”⁵

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nose and mouth tissue is susceptible to splitting and bleeding. Corrosive blood threatens the sinus cavity, the esophagus and throat.

The Economic Impact

Proper humidification directly impacts a patient's health, but it also has an economic value. Current statistics on hospital readmissions for non-compliant tracheostomy patients are difficult to come by. However, use of the Wright Mask delivery system should reduce the need for inpatient humidification treatments and save money (see Table 2).

Priced at \$24.95 a unit and assuming each patient would need one Mask per month, the Wright Mask would cost \$299.40 per patient per year. This compares favorably with the cost of even one emergency room stay, amounting to a savings of \$5,781.60 for each hospitalization that is prevented.

For hospitals, nursing homes and rehabilitation center, the Wright Mask delivery system also saves clinician time (see Table 3).

Conclusion

The Wright Face & Tracheostomy Nebulizing Mask is the only delivery system currently available that allows for the simultaneous humidification of the nose, mouth and trach. It cuts humidification time in half, reduces complications, reduces costly hospitalizations, encourages patient compliance and improves quality of life.

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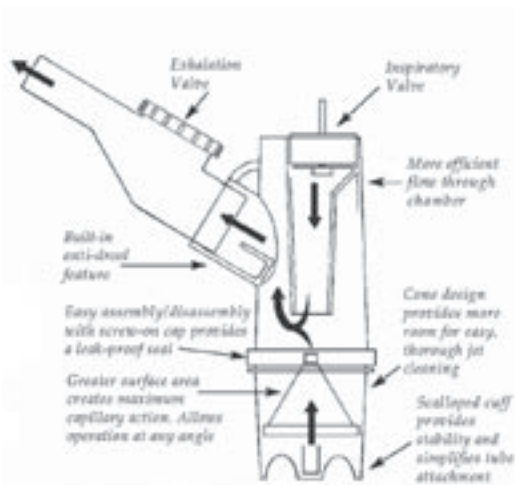
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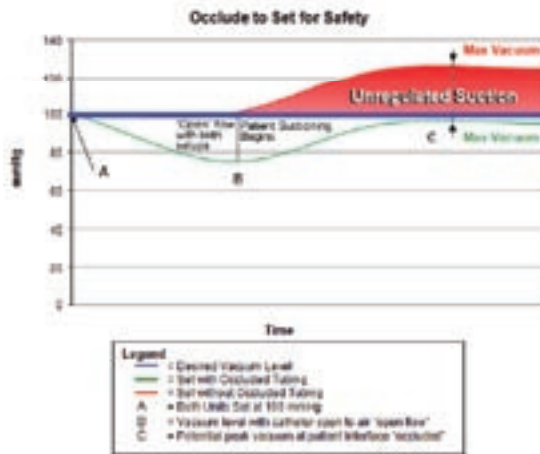
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On June 11, 2009, the World Health Organization (WHO) signaled that a global pandemic of novel influenza A (H1N1) was underway by raising the worldwide pandemic alert level to Phase 6. This action was a reflection of the spread of the new H1N1 virus, not the severity of illness caused by the virus.

<http://www.cdc.gov/h1n1flu/background.htm>

Is Your Facility Adequately Protecting Healthcare Providers from *H1N1*?

H1N1: Protecting Healthcare Workers (NIOSH Science Blog Posted 8/10/09) As of July 31, 2009, there were 162,380 documented cases of human infection with H1N1 throughout the world, including the United States. As of August 6, 2009, there were 6,506 hospitalized cases and 436 deaths in the U.S. From the time of its emergence earlier this year, H1N1 has prompted a concerted response from health agencies here and abroad. Healthcare workers and emergency responders will face increased risk of exposure to H1N1, given their role in caring for sick patients.

http://www.cdc.gov/niosh/blog/nsb081009_h1n1.html

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