Volume 4 Number 4 August-September 2009

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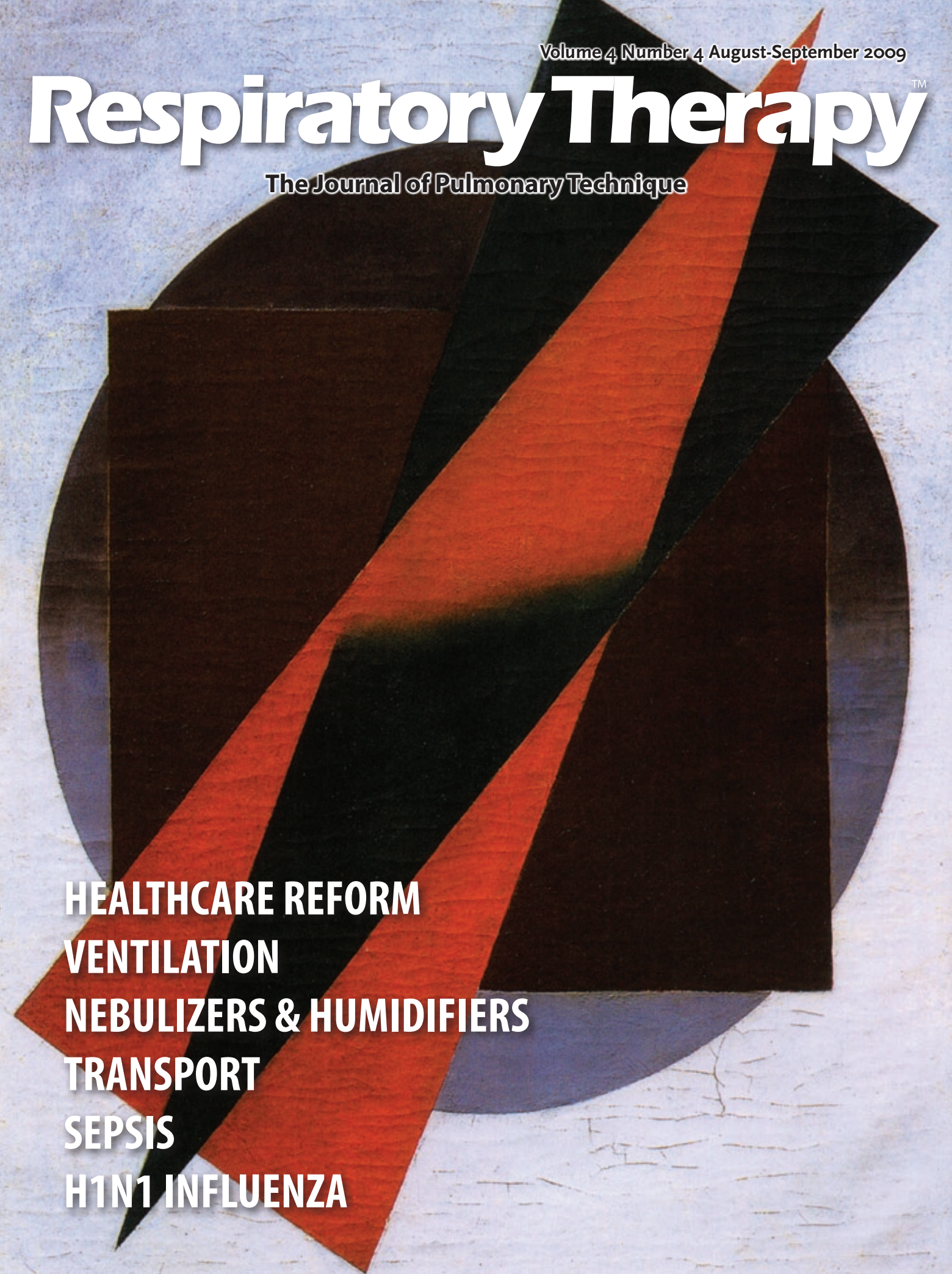
The Journal of Pulmonary Technique



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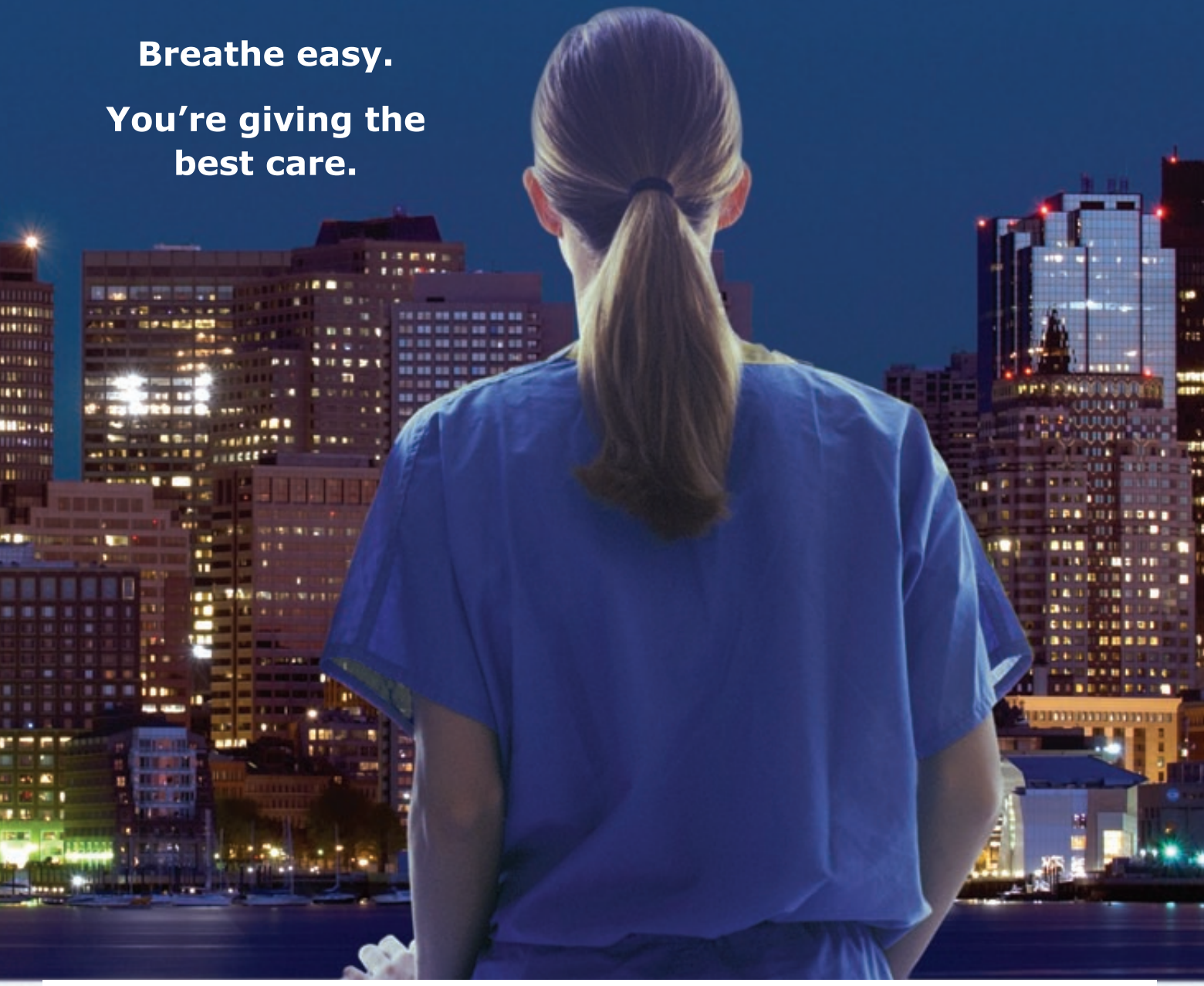

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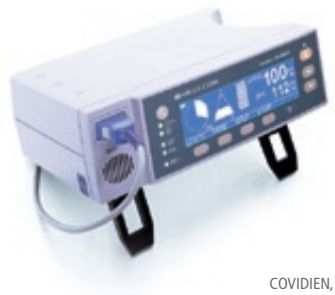

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The Journal of Pulmonary Technique

Vol. 4 No. 4
August-September 2009

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Editorial

The True Cost of Healthcare Reform

Doug Wilder, RRT

During the 2008 Presidential campaign, one of the promises made was healthcare reform. Now the President and the Congress are promising to draft a bill with possible passage by the August recess.

In an effort to bring this issue to the forefront and meet this goal of having a signed bill, the White House has been very vocal. Christina Romer, chair of the President's Council of Economic Advisers has stated, "Healthcare reform is more than a social impetrative—it is an economic necessity." A new study by the Council has concluded that the current American healthcare system is on an unsustainable path. Without reform, American workers and families will continue to experience eroding healthcare benefits and stagnating wages caused by escalating health insurance premiums. And without reform, rising spending on Medicare and Medicaid will lead to massive and unsustainable Federal budget deficits."[1]

From this statement, it is clear that some reform will take place in the next few months. The great debate on healthcare between the White House, Congressional Democrats and Republicans and all special interest groups has begun, with the highest of stakes not only for the healthcare industry but also the economy for years to come.

The following ideas were put forward by a bipartisan Senate Committee to meet this goal: Tax the so called "Cadillac plans" they say promote the overuse of healthcare services and boost the cost of care. Scour Medicare for any and all cost savings. Raise alcohol, tobacco, soda, high fructose corn syrup and sugar taxes to generate revenues to pay for the uninsureds' insurance and alter lifestyle behaviors deemed unhealthy. Extension of the payroll tax for Medicare to include all state and local government employees. Place new limits and/or appeal processes of flexible spending accounts that allow individuals and employers to set aside tax-free income for out of pocket medical expenses, and curb the 25% tax deduction allowed for claims and some other expenses now allowed under Blue Cross Blue Shield plans.

One of the more popular ideas is to reduce payment to home health providers, which has been cited as having the highest profit margin in the Medicare program. The Senators also said the government should seek more appropriate payments for some types of medical equipment including oxygen and power chairs.[2]

All of these will reduce healthcare costs and raise revenues in the short term but will only result in higher costs over the long term, burden the healthcare system at the hospital level and slow economic growth.

In 2009, total healthcare expenditures by the Federal government will be 46% of federal budget and it is projected to increase to 49% by 2017. With Federal debt projected to reach 14.07 trillion dollars by 2010 and the GDP of the United States projected to be 14.3 trillion dollars, the Federal debt is tracking to exceed GDP. Compounding the healthcare crisis, healthcare spending is growing at a rate of between 6 and 7.5% per year.

In 2008, 38% of all hospital discharges were patients 65 years or older. Projections indicate that today's over-65 population of 15.7% will grow to 20.2% by 2050, or 1 in 5 people in the United States will be over 65.

The number of uninsured currently stands at 46 million and is projected to grow to 54 million by 2019. Left unchecked this number will rise to 74 million by 2030.[3]

The combination of the continuous growth in healthcare spending, the aging
continued on page 57…

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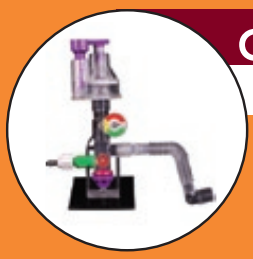

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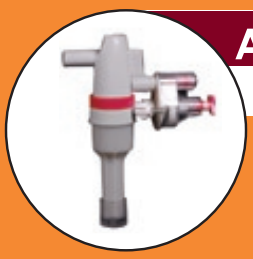

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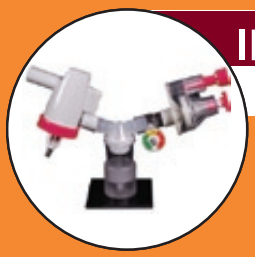

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Tel: 310-443-4109
Fax: 310-443-4110
E-mail: s.gold4@verizon.net
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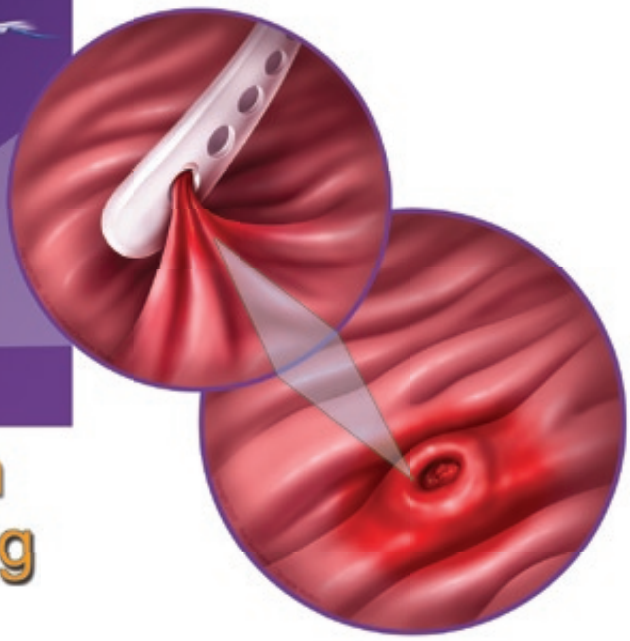

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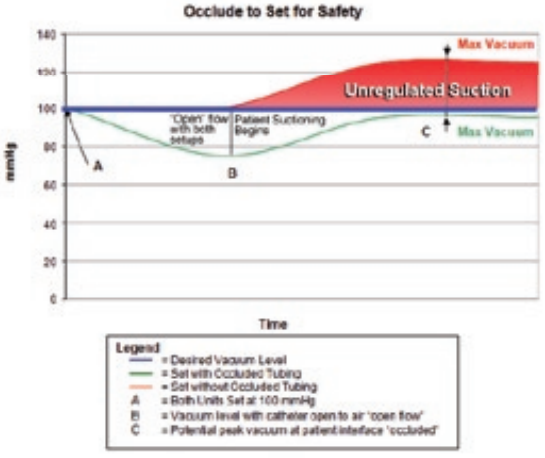

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News

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CORRECTION

The following section was left out of the article, Special Report: Blood Gas Guide to Validation of a Blood Gas System by Diana Blanco, MT-SC (ASCP) and Bruce Toben, RRT-NPS, CPFT, June-July, pages 19-21. It goes between the sections "Trueness and Precision" and "Method Correlation" on page 20. The complete article with the section inserted can be viewed on Respiratory Therapy's website, respiratorytherapy.ca, under "Magazines," June-July. We apologize for the error.

Analytical Measurement Range vs Clinical Reportable Range and Linearity Validation

The Analytical Measurement Range (AMR) is the manufacturer's range of detection for the device. This range can exceed limits of what can be considered compatible with life, eg, pH 6.00-8.00. The Clinical Reportable Range (CRR) is the actual range that can be verified by the facility with either commercially available assayed materials or measuring a blood specimen corroborated by split-sample technique with a calibrated reference instrument. The CRR usually approximates the limits of what is physiologically acceptable in humans, eg, pH 6.80-7.80. Patient results that are lower or higher than the level verified can only be reported as outside the reportable range, exceeding the limits.[9]

Establishing the CRR employs testing both the extreme ends of the assay scale but mid-range points as well. This method permits estimation of the linearity, or the degree of sensitivity to incremental changes in analyte concentration and predicts instrument performance at any point along the measurable range. As described in the CRR development, linearity is commonly performed with assayed calibration verification controls. If no commercially available material is compatible for the device being evaluated, protocols need to be developed using spiked whole blood specimens and verified with a laboratory reference instrument. A minimum of two samples each, of 4-5 incremental concentrations are needed for statistical analysis. The CRR and linearity testing are required for all new devices and each analyte reported, whether replacing an existing instrument or adding multiple devices intended to supplement a current blood gas systems.

PUSH

Business Week reports that GE is launching a $6 billion healthcare initiative. Called "healthymagination," the initiative is aimed at resetting GE's healthcare business, which currently gets most of its revenue from selling diagnostic and imaging equipment to hospital systems, toward rural and emerging markets, as well as toward the priorities set by the Obama

Administration. The $17 billion unit plans to develop far more low-cost equipment, such as the portable ultrasounds already being used in developing regions. At the same time, it will focus on services that help hospitals become more efficient and on healthcare information technology, which is currently just a small part of GE's business. The company's finance arm, GE Capital, is committing $2 billion in financing to external partners, mostly for healthcare IT projects. The company plans to spend $1 billion creating new health-related content at NBC and funding partnerships with outside companies, such as the alliance GE announced in April with Intel to develop home healthcare technology for the elderly or chronically ill. In addition, GE plans to improve the efficiency of the health and wellness programs for its 323,000 employees. The bulk of new spending will be a $3 billion research and development investment over the next six years into affordable healthcare equipment designed for underserved populations. The targets will range from emerging markets to rural or even urban areas where technology is lacking. At least half of the unit's spending, GE says, will be on launching products or services that meet internal goals of expanding healthcare to more people or reducing costs by 15%. GE plans to launch at least 50 basic products tailored to rural or emerging markets, such as the lightweight portable electrocardiograph machines the company has developed for India.

CAPITAL IDEA

The Wall Street Journal reported that General Electric Co's GE Capital division will make 0%-interest loans to hospitals and healthcare providers that purchase GE's healthcare information-technology offerings. GE said it expects to offer $100 million in interim financing to hospitals and health-care providers for projects that are expected to qualify for funds from the U.S. government's economic-stimulus package. GE calls its program Stimulus Simplicity and connects it to the company's Healthymagination marketing initiative. One early borrower is Hazard Clinic in eastern Kentucky, which plans to install an electronic medical-records system. GE said the move offers doctors, community health clinics and hospitals a bridge to qualify for stimulus funds and faster access to electronic medical records. The company said the move also indicates GE will continue certifying its products to government standards. Reported by Paul Glader, copyright the Wall Street Journal.

BAD BREATH

More than 300 million people around the world have asthma, but asthma control often falls short, according to The Global Burden of Asthma Report. In some regions, 25% of children with asthma are unable to attend school regularly because of poor asthma control. The report says that the majority of asthma deaths are preventable. Some people with asthma symptoms may never even receive a diagnosis because of various factors such as poor access to medical care, under-recognition by health professionals, lack of awareness among patients, and overlap of asthma symptoms with those of other diseases. One of the major barriers to asthma control, the report says, is the high cost of medicines, which is often higher than average monthly salary of a nurse in developing countries. Asthma medications are simply not available in some areas with alarming levels of asthma, such as parts of the Middle East, Southern Asia, Central America, and North, West, and East Africa. There are wide variations in clinical management of asthma in different parts of the world, and even when cost is not a barrier under-treatment may still occur. The under-use of inhaled gluco-corticosteroids for long-term management of asthma is a common problem. In many regions of the world, people with asthma may be exposed to conditions such as outdoor or indoor air pollution, cigarette smoke, or chemicals on the job that make their asthma worse. Information for the above was from an article by Bobby Ramakant, for Citizen News Service, via Medical News Today.

GET OFF THE FIELD

Doctors say exercise-induced asthma in kids is fairly common, even if the child has no history of the condition, and few kids or sports teams are prepared to deal with it. The report says just having a rescue inhaler on the sidelines could be a big help, but only 40% of college-level teams have inhalers at hand, and only 17% of the programs that responded to a recent survey said that they used some form of objective testing to document whether an athlete actually has asthma or not.

LA CUCARACHA

For years, scientists have associated growing asthma rates among children with exposure to cockroach allergens, especially among inner-city children. A new study in the Journal of Medical Entomology revealed that using integrated pest management (IPM) to control cockroaches is more effective at reducing cockroaches and their allergens than conventional methods which do not use IPM. Unlike conventional pest-control methods, which often involve periodic spraying of insecticides on a predetermined schedule, IPM involves close monitoring for signs of specific pests, combined with baits and traps to control them. Researchers in North Carolina compared two school districts, and found that the one using IPM had much lower concentrations of cockroach allergens and zero cockroaches caught in pre-set traps. The researchers noted that while the cost of IPM might be higher initially, it pays for itself down the road and provides a healthier school environment.

SEE A PRO

Asthma patients who spend 30 minutes with a healthcare professional to develop a personalized self-management plan show improved adherence to medications and better disease control, according to a new study at the University of California, San Francisco. Researchers noted that many patients struggle to manage symptoms on their own and often end up visiting emergency departments. The study indicates that in a clinical setting, personalized self-management education coupled with self-monitoring may be a cost-effective way to empower patients to better control their disease. UCSF research had previously shown that teaching asthma patients how to self-manage their disease can improve health outcomes and that tailored education is more effective than standardized programs because patients find it more personally relevant. Researchers conducted a 24-week randomized, controlled trial to determine if individualized instruction in asthma self-management adds significantly to the effects of self-monitoring alone on patients' adherence to inhaled corticosteroids. In the study, 84 adults with asthma self-monitored their symptoms and kept a daily log of their peak expiratory air flow. Of that group, 45 patients were randomly selected to also receive a personal 30-minute session that included asthma information, personally relevant allergen exposure reduction, a personal action plan, and instruction in the correct use of their inhalers. Adherence to ICSs was consistently higher in the intervention group and participants in the group experienced fewer nighttime awakenings. They also used rescue inhalers less frequently and had a significant decrease in their levels of tryptase.

BUTCHERING BAKERS

Thousands of British bakers exposed to flour and other bakery dusts could be at risk of developing asthma unless they take sensible precautions, the British Health and Safety Executive (HSE) has warned. Bakers are about 80 times more likely to develop occupational asthma than the average British worker. It is estimated that 27,000 of the 100,000 workers in the British baking industry regularly work with flour. About a hundred new cases of occupational asthma are being diagnosed annually. Bakers are warned to: not drop flour from a height or throw it hard enough to make dust-clouds; to use sprinklers to spread flour instead of throwing it by hand; to not use airlines or brushes to dry-sweep dust; to shovel large amounts gently; and to start mixers at a slow speed until the ingredients are wet.

A LITTLE RSV

Babies who are only mildly premature are at increased risk of respiratory syncytial virus, according to researchers at Kaiser Permanente. Its study included 108,794 babies born at 33 weeks' gestation or later who were discharged from six hospitals between January 1, 1996 and December 11, 2002. The neonatal characteristics assessed included gestational age, race, birth weight, sex, oxygen exposure in the neonatal period, neonatal discharge month, siblings, and being small for gestational age. Results showed that the rate of use of supplemental oxygen during the neonatal period was 6.32% among babies 33 to 36 weeks and 1.63% among babies ≥37 weeks, and the rate of use of assisted ventilation was 9.92% and 0.86% in the two groups, respectively. Overall, the risk of RSV infection was greater in infants who were siblings, had a lower gestational age, were males, and were oxygen-exposed in the neonatal period. Researchers said the results demonstrated that medically attended RSV infection is more common in premature infants, even if they are not very premature. The above information was written by Jill Stein, a Paris-based medical writer, copyright Medical News Today.

WOW FROM WAO

The World Allergy Organization Journal reports on the following studies: **Mepolizumab for prednisone-dependent asthma** with sputum eosinophilia. Researchers treated a group of severe corticosteroid-resistant asthma patients with the IL-5 antibody, mepolizumab (Mep), which blocks the eosinophil-promoting activity of IL-5. The primary outcome was the percentage of patients in the test group vs the placebo group who had exacerbations during the 26-week test period. Secondarily, the reduction in prednisone dose relative to the maximum reduction was determined. Spirometry was performed on the subjects and they were asked to fill out the Juniper Asthma Control Questionnaire. Eosinophils in induced sputum were counted. The placebo group (n = 10) experienced 12 exacerbations while the Mep group (n = 9) had one. Mean prednisone dose was reduced from 11.9 to 3.9 mg in the Mep group compared to the placebo group where the dose went from 10.7 to 6.4 mg. Eosinophilia in sputum and blood was significantly reduced by treatment with Mep and there were no significant alterations in blood chemistry. A second study, Mepolizumab and exacerbations of refractory eosinophilic asthma, examined Mep therapy for severe eosinophilic asthma and demonstrated a significant reduction in the number of exacerbations and improvement in quality of life. WAO noted: Although these are relatively small studies, the results are very promising for helping this group of severe asthmatics. The studies, by Nair et al and Haldar et al, respectively, funded by Glaxo-SmithKline, appeared in New Eng J Med 2009; 360:985-99… **Do childhood respiratory infections continue to influence adult respiratory morbidity?** This meta-analysis examined data from a prior study in which 9,175 individuals, age 20-44, completed questionnaires to provide a family history and previous allergic and respiratory symptoms and underwent lung function testing. The subjects were reinvestigated an average of 8.9 years later. In the initial study, 9.6% reported a serious respiratory infection (SRI) before the age of 5 and in the second study, 2.4% reported being hospitalized for lung disease before the age of 2. SRI was associated with increased risk of wheeze and asthma and reduced lung function. Similar results were found for HLD. An even stronger correlation for risk of adult lung disease was found among children with SRI or HLD from households with maternal smoking. The WAO commented: The implication of this study is that severe respiratory infections during the first 3-4 years of life can cause permanent changes to the airway manifesting in lung disease in adulthood. Reported in Eur Resp J 2009; 33:237-244, by Dharmage, SC, et al. The information above appeared in WAO Medica Journal Reviews, April 2009, Vol 2, Issue 4… **Efficacy of esomeprazole (Eso) for treatment of poorly controlled asthma.** In this multicenter, parallel-group, DBPC trial, 412 patients with poorly-controlled A (moderate-high doses of ICSs, JACQ score of 1.5 or higher, or more than one unscheduled medical care visit in the past year) but with no symptoms of GERD were given either placebo or 40 mg of the proton-pump inhibitor (PPI), Eso 2X/day for 24 weeks. Ambulatory pH measurements were done to identify GERD in asymptomatic subjects [41% in placebo (P), 40% in Eso]. Participants kept daily symptom diaries, completed asthma questionnaires and had spirometry monthly. There was no improvement in A control in the Eso vs P groups, even in those who had GERD documented by pH probe. WAO noted: Eso and possibly other PPIs should not be prescribed for asthmatics who do not have documented GERD or symptoms. Reported in New Engl J Med 2009; 360:1487-1499, Mastronarde, et al… **Effect of formoterol with or without budesonide in repeated low-dose allergen challenge.** This report compared the effects of formoterol (4.5 µg) monotherapy with combination F (4.5 µg) /BUD (160 µg) and placebo on the dose of methacholine necessary to cause a 20% drop in FEV1 (PD20), fraction of exhaled nitric oxide (FeNO), eosinophilia (E) and prostaglandin G2 (PGD2) levels in induced sputum, short-acting beta-agonist use, FEV1 and daily symptom scores. The study was done as a 3-period, double-blind, crossover study on 15 intermittent allergic asthmatics given low levels of the inhaled allergen (8, cat; 4, birch; 2, timothy; 1, dog) to which they were allergic for seven days. F/BUD prevented the allergen-induced increase in AHR, while F treatment alone did not. Allergen-induced sputum E and PGD2 levels increased with F but were unchanged with P or F/BUD. There was no difference between F and F/BUD asthma scores, which were improved, and in use of short-acting beta-agonist relative to P. WAO commented: The observation that sputum E numbers and PGD2 levels increase with F monotherapy but not with F/BUD therapy suggests that treatment with the combination is desirable. Reported by Eur Resp J 2009; 33:747-753, Dahlen et al.

NEWS FROM ATS

Chronic asthma sufferers may find new relief in a simple, minimally invasive outpatient procedure known as **bronchial thermoplasty**, which uses controlled radiofrequency-generated heat to treat the muscles of the airways, preventing them from constricting and narrowing. Researchers at 30 sites in six countries enrolled 297 patients with severe asthma. Patients in

the control group were randomly assigned to receive a placebo, ie, no heat was applied. Researchers used a quality-of-life scale to measure the results at six months, nine months and one year. Overall, 79% of the patients in the experimental group who were treated with bronchial thermoplasty experienced a statistically significant and clinically meaningful improvement in their quality-of-life measurements… **Black Americans are nearly twice as likely to develop ALI**, as white Americans, according to researchers at the Emory University School of Medicine in Atlanta. The study also revealed that black patients did not have a higher risk of in-hospital death when compared to white patients. Researchers collected data from the National Hospital Discharge Survey, dating from 1992 through 2005. The average annual incidence of ALI over the entire study period was 48 cases per 100,000 for black Americans, compared to 25.7 cases per 100,000 for white Americans. Overall, in-hospital mortality among patients with ALI did not vary meaningfully by race… New estimates of the likelihood that **a latent case of tuberculosis** will become active have resulted in a roughly 50% increase over previous estimates of the number of people needed to be screened (NNS) to prevent an active infection, limiting the cost-effectiveness of screening in many Center for Disease Control and Prevention (CDC)-defined risk groups, according to an analysis conducted by experts in the epidemiology of the disease. Among patients with chronic medical conditions, the NNS to prevent an active case of TB ranged from 1,150 for those who are underweight to 2,778 for patients with end-stage renal disease. Previous estimates of the NNS ranged from 806 to 1,923. Screening was not cost-effective for many patients who are currently recommended for screening, including those who are underweight, have had a gastrectomy, or have silicosis, diabetes or end stage renal disease. Screening was a cost-effective strategy under previous estimates of the rate of reactivation TB, but the new, lower estimates of reactivation limited the case finding rate and decreased the cost effectiveness of screening. The NNS was lower in populations with a high prevalence of latent TB infection, including foreign-born residents, recent immigrants, the homeless and injection drug users. It was also lower in patients with a high risk of reactivation TB, including those with HIV infection and those taking immunosuppressive medications. As a result, screening remained cost effective for these groups. To arrive at new estimates of NNS and cost effectiveness, the Boston-based researchers constructed a Markov computer model that simulates the clinical progression of a cohort of patients, can integrate a wide array of parameters and allows the analysts to plug in different estimates to determine which are most important in determining outcomes… A large, well-controlled, multi-national clinical trial program has demonstrated the effectiveness and safety of what may become the first FDA-approved medicine for **idiopathic pulmonary fibrosis**, or IPF. In a Phase III clinical study program called "CAPACITY," investigators discovered that the oral anti-fibrotic and anti-inflammatory agent, pirfenidone, could slow the deterioration of lung capacity in patients suffering from IPF. The CAPACITY trial consisted of two multinational, randomized, double-blind, placebo-controlled Phase III trials (CAPACITY 1 and CAPACITY 2) designed to evaluate the safety and efficacy of pirfenidone in IPF patients with mild to moderate impairment in lung function. The primary endpoint of change in percent predicted forced vital capacity (FVC) at week 72 was met with statistical significance in CAPACITY 2 along with the secondary endpoints of categorical change in FVC and progression-free survival (PFS), defined as time to either death, a 10% decrease in FVC or a 15% decrease in DL_{CO}. The primary endpoint was not met in CAPACITY 1 (p=0.501), but evidence of a pirfenidone treatment effect on the primary endpoint was observed at several periods in that trial. Importantly, greater than 80% of patients in the trials completed treatment and greater than 90% completed the study. An exploratory analysis of pooled data from both trials revealed that treatment with pirfenidone resulted in a 30% relative reduction in the number of patients who experienced an absolute decline in percent predicted FVC of at least 10%. This magnitude of decline is considered clinically meaningful, as a 10% decline in percent predicted FVC has been shown in multiple studies to be an independent predictor of mortality in patients with IPF… Babies born to obese mothers may have an increased risk of asthma. To determine whether the presence of these **pro-inflammatory factors in overweight mothers** did, in fact, put their children at a greater risk of developing asthma, researchers analyzed data from nearly 4,000 children of the Prevention and Incidence of Asthma and Mite Allergy (PIAMA) birth cohort for evidence of asthma. The children were included prenatally and followed up yearly until the age of eight years. More than one in five mothers were overweight. In children who had at least one asthmatic parent, maternal obesity increased their risk of having asthma at age eight by 65% over children of asthmatic parents whose mothers were not overweight. This was true irrespective of confounding factors, such as birth weight and the child's BMI… Research conducted seven years after the terrorist attacks on the World Trade Center (WTC) in New York City (NYC) found that children attending the socioeconomically and ethnically homogeneous elementary school closest to Ground Zero have high rates of self-reported asthma and airway obstruction. Researchers found that one year following the WTC attacks, **asthmatic children living near Ground Zero** at the time of the attacks, showed clinical signs of worsening asthma, including reduced peak expiratory flow rates, increased numbers of asthma medications per child and more asthma clinic visits. Additionally, they found that new cases of asthma among children increased 50% in the wake of the disaster. Researchers collected questionnaire and spirometry data on 202 children who had lived and attended school in the area at the time of and since the attacks, and took air samples to investigate the level of current urban ambient pollution, including 2.5 micron particulate matter ($PM_{2.5}$) as a surrogate for diesel exhaust, and levels of dust mite antigen and other indoor aeroallergens at an elementary school near Ground Zero. The researchers also found high levels of $PM_{2.5}$ measured on the roof of the school, indicating unacceptably high levels of urban ambient air pollution. Surprisingly, indoor aeroallergen exposure to rat, cockroach, dust mite antigen, cat and dog were essentially negligible. Exposure to these indoor aeroallergens, as well as parental smoking, cannot account for acute exposure leading to airway obstruction… **A protein from algae may have what it takes to stop SARS**, according to new research. A recent study has found that mice treated with the protein, Griffithsin (GRFT), had a 100% survival rate after exposure to the SARS coronavirus (SARS-CoV), as compared to a 30% survival for untreated mice. GRFT is thought to exert its anti-viral effects by altering the shape of the sugar molecules that line the virus' envelope, allowing it to attach to and invade human cells, where it takes over the cells' reproductive machinery to replicate itself. Without that crucial ability, the virus is unable to cause disease. Researchers treated experimental mice with GRFT or a sham treatment and then inoculated them with the SARS virus. They analyzed the antiviral activity of GRFT and the extent to which the virus was able to invade and replicate in the mice at two, four and 10 days after infection. They found that mice who had not

been treated with GRFT showed 20 times more plaque-forming units of virus than treated mice. They also noted that the lungs of untreated infected mice showed extensive necrotizing bronchitis and prominent edema, while mice treated with GRFT showed evidence of significantly less severe lung damage. Additionally, mice treated with GRFT did not experience the drastic weight loss of untreated mice, which lost 35% of their body mass. For more information on any of the above studies, contact **thoracic.org**. The above papers were presented at the recent ATS conference in San Diego, CA.

NEWS FEATURE

Ventilator Care Takes 2 Safety Hits

Paul Garbarini, MS, RRT

Paul Garbarini is Clinical Operations Manager, Hamilton Medical. This article is from Hamilton Medical's newsletter.

The ECRI Institute, which independently tests and studies medical devices, published their 2008 Top 10 Health Technology Hazards in a December 2008 news release. (The complete list of 10 is available for a limited time through ECRI at ECRI.org.) Considering the thousands of medical devices in various categories, it's revealing that ventilators are associated with two of the top ten device hazards. The #1 ranked device hazard was related to alarm hazards (ventilators were specifically cited). Some of the hazards were related to issues such as clinicians disabling or dialing out low minute volume or high pressure alarms; using systems with too many nuisance alarms and using alarms that are not easily positioned for viewing. Due to the wide variations in patient's underlying lung disease, breathing pattern, settings and/or modes, policies and let's say, human nature, alarms often are dialed out or simply standardized across all patients.

One of the solutions ventilator manufacturers have started to implement is various levels of alarms such as alerts, cautions, and warning alarms which are differentiated by both color and sound patterns.

I believe the next generation of alarms should include smart alarms such as those recently introduced for pulse oximeters. These systems provide alarms based on the degree of desaturation and the duration of the desaturation. The ventilator analogy might be to not sound a high level warning (eg high pressure alarm) for a patient coughing for only a few breaths whereas a progressive rise in pressure over a longer period of time would warrant a high level warning.

While alarms for obvious hazards like patient disconnects and obstructed exhalation tubings will always be required, the need for alarms such as respiratory rate, high pressure, low minute volume, etc may have already been reduced with the introduction of closed loop ventilation systems. The purpose of traditional respiratory monitoring alarms is to alert the clinician of changes in patient status such as failing a wean trial due to tachypnea.

A high pressure alarm should alert the clinician to assess whether the alarm is a transient event versus, for example, the development of ARDS which would warrant implementing a protective ventilatory pattern. Similarly, a patient that develops severe bronchospasm might develop tachypnea, elevated pressures and/or erratic exhaled volumes due to autopeep/air trapping and set off associated pressure, rate and/or volume alarms. The problem of course is that the alarm is occurring after the adverse event (hazard) has already occurred! Then again, this assumes that the alarm settings have been appropriately set for that particular patient.

Perhaps the best solution would be to prevent the underlying reason for the alarm occurring in the first place. A closed loop ventilation system will prevent some of these deteriorations in patient status from occurring in the first place. For example, a knowledge based closed loop system such as SmartCare follows a set of rules to wean pressure support during a wean trial. So if the tidal volume is too small pressure support will titrate up to prevent tachypnea. Hamilton's Adaptive Support Ventilation (ASV) is a closed loop system that targets the optimal breathing pattern for a given patient's lung mechanics and size. If pressures start increasing due to development of ARDS, ASV automatically decreases tidal volume and increases rate to protect the patient from Ventilator Induced Lung Injury as the clinician would do by manually titrating settings as in ARDS network protocol. ASV creates a safety window such that the system cannot target too high a volume or pressure to prevent volutrauma, too low a tidal volume to avoid deadspace and/or too high a rate to prevent autopeep.

I'd call these systems preemptive and proactive in that they intervene in real time to prevent the hazard from occurring in the first place. (Addressing the issue of alarm visibility, the Hamilton G5 ventilator features a large alarm light bar that is visible from 360 degrees.)

The #7 ranked health device hazard was displays that are misleading, such as infusion pump displays that are misinterpreted and lead the user to program the wrong medication dose. Here again ventilators are culpable. Typical ventilator displays show a gaggle of numeric monitoring data. The problem is that it's difficult for the clinician to easily be aware of what monitored data is out of range or abnormal. For example, how many clinicians know what the normal airway resistance range should be for a 55kg ideal body weight female on a ventilator or what a red flag value should be? Yet this awareness may be critical to know as it may be the cause of weaning failure. Monitored data is not presented in a such a way as to allow the clinician to discern the degree of abnormality or with any point of reference. Certainly the display of waveforms is useful but an even higher skill level is required to interpret pressure, volume and flow waveforms.

EXECUTIVE PROFILE

An interview with Carol Zilm of CareFusion Corporation

CareFusion Corporation is a new company resulting from the "spin-off" of the Clinical Medical Products group from Cardinal Health. The name is new, however the brands should be familiar to most readers. Medical dispensing and infusion brands such as Pyxis and Alaris have been around for several years. Today, we will focus on the Respiratory Care business unit, where some brands have been in the marketplace for over fifty years. Names like Bird, Bear, SensorMedics, Pulmonetic Systems, VIASYS, Jaeger and AirLife. The CareFusion name is new, but the brands and products are very familiar.

Leading the Respiratory Care business is Carol Zilm.

Carol, who is CareFusion?
CareFusion is a global company that is focused on improving the safety and quality of health care. The depth and breadth of our products has made us an industry leader and widely recognized around the world. CareFusion employs about 15,000 people and our products are used in over 120 countries. Two of the biggest issues facing healthcare today are medical errors and infection control. Medical errors cost $6.5 billion dollars in the U.S. and Europe. In the U.S., hospital acquired infections affect more than 1.5 million people and result in a reported 271 fatalities per day! As an industry we must face this challenge, and as a company we are.

What makes CareFusion different?
What makes us unique is how we "fuse" all of our core technologies. We are not just a device, diagnostic or heath information technology company. We combine our innovative core technologies with actionable intelligence to deliver measurable improvements to patient care.

We are also unique in that just about everything we do is driven by our customers. We put extensive effort into building close relationships with our customers and providing them with opportunities to offer feedback and direction to our innovation efforts. We work closely with trade organizations, customer focus groups, advisory boards, key opinion leaders, and our individual customers as we explore new opportunities, develop new products and evaluate new technologies. It is our customers that guide our efforts and this often differentiates us from other companies.

Can you give us an example of CareFusion innovation?
Our new ICU product the EnVe Ventilator, a full featured, critical care ventilator that weighs about 9 ½ pounds. That's one tenth the weight of comparable ventilators. A typical ICU patient on a ventilator makes about two off-unit trips while he is in the hospital. Right now it's very difficult, if not impossible, to move that 90 pound ventilator with the patient. The healthcare team must place the patient on another ventilator for the trip. It makes much more sense to provide the same, high standard of care, by allowing the patient to remain on their current ventilator. This helps reduce the stress on the patient, helps reduce the risk associated with changing ventilators and may reduce the risk of hospital acquired pneumonia. You can essentially provide ICU care anywhere you need to.

What are some of the measureable improvements to patient care you spoke of?
From our infusion and dispensing business, we help prevent a harmful medication error every 2.6 days and protect 1.5 million patients annually from medication errors. Our data/analytics group is projecting an annual savings of 6,800 lives and $1 billon in healthcare costs by helping to reduce hospital acquired infections in member hospitals. We also help improve the bottom line. One hospital doubled its charge capture, while halving its inventory costs with our supply automation technologies.

What products are in your Respiratory Care portfolio?
Our Respiratory offerings are unsurpassed by any other company in the world. We are a market leader in mechanical ventilation with the Avea, Vela, 3100 series HFOV, LTV series, Infant Flow Nasal CPAP and the soon to be released Enve and ReVel ventilators. In sleep diagnostics and therapy, our offerings include the SomnoStar and T-3 brands for sleep diagnostics and PureSom and Orion nasal CPAP devices. We are the market leader in pulmonary diagnostics with the SensorMedics and Jaeger families. Products include the VMax Encore, MasterScreen, MasterScope and FlowScreen devices. We are also a leader in respiratory consumable products. Our AirLife brand of products include a wide variety of disposable devices for use with invasive and non-invasive ventilation, oxygen therapy and medication delivery.

What is on the horizon for CareFusion?
With rising healthcare costs, declining reimbursement, personnel shortages and a global demand for quality, we have clear drivers for growth and innovation. Over the next couple years we estimate that we will have about 40 new products available to further provide safety and value for our customers. We plan to meet our goals by increasing our R&D efforts and further development of our core technologies.

COMPANY PROFILE

Fisher & Paykel Healthcare

Describe your product(s) and its unique features.
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.

How does your product directly affect patient care?
Patient care and adherence to therapy is an area of strength for Fisher & Paykel Healthcare. Patient compliance requires a total solution. This solution must be focused on the three primary areas that create challenges for the patient such as interface, humidification, and pressure relief. Our Interfaces offer 3 primary market differentiators: • Patient ease of use: no dials and no need for complicated adjustments to adjust the T-piece to relieve bridge of the nose pressure and prevent leaks. Instead, by utilizing the FlexiFit auto-contouring technology available in all of our nasal and full face masks, we provide one-step ease of fitting and optimized seal for the patient. • Patient freedom of movement: by offering the unique Glider Strap, patients can

rotate their heads side to side while maintaining the mask seal and minimizing the occurrence of leaks. • Simple: less parts to deal with which simplifies the cleaning and maintenance for patients. Humidification: Patient comfort is improved when adverse effects of therapy are reduced. Evidence suggests that improving patient comfort by providing heated humidification increases patients' CPAP acceptance and compliance. Fisher & Paykel Healthcare's innovative ThermoSmart technology which is 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. We have also developed and manufactured a patented, self-adjusting humidification technology available in our SleepStyle 200 CPAP Series that minimizes condensation and maximizes humidity called Ambient Tracking Plus. Pressure Relief: 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. Outcomes: In today's market measuring compliance has more importance than ever before. Keeping it simple is the hard part. The SmartStick is our compliance measurement solution that is very simple. The SmartStick uses a USB port to download patient data. No need for modems, readers or more expensive solutions that have geographical coverage limitations.

Discuss your R&D process, including end-user input.
Fisher & Paykel Healthcare is a world leader in the design, manufacture and marketing of heated humidification devices used in respiratory care and in the treatment of Obstructive Sleep Apnea. We combine leading-edge technologies with rigorous R&D to provide a line-up of high-performance products for sleeping well and living well. The development team derives its success by a process that generates unique technology solutions from listening to patients, providers and clinicians. This process enables Fisher & Paykel Healthcare to achieve a very valuable objective: Research and Development with targeted markets and customers and designing treatment solutions that are easy to use and have valuable therapeutic benefits such as ThermoSmart, Ambient Tracking Plus, and SensAwake, to name a few.

Discuss the educational services you offer for use of your product.
In addition to an intensive new hire training program, all Fisher & Paykel Healthcare sales and clinical staff are trained periodically throughout the year. Today our customers have access to multiple CEU courses provided at no cost, as well as new and existing product in-services on demand. We also offer our customers and patients a training, education, and support website, vigor8.com, which includes instructional streaming videos on our product line, literature reviews, and clinical pathways. We are also looking to even further improve our employee and customer training utilizing the latest online technologies available.

PRODUCTS

THE NEW STANDARD
Vapotherm, Inc produces the 2000i and the Precision Flow—respiratory therapy devices that allow high flows of breathing gases to be delivered via nasal cannula using patented membrane technology to warm and saturate the gas stream. Vapotherm is defined by its ability to deliver warmed and humidified flows from 1-40 liters per minute via nasal cannula in neonatal, pediatric, and adult applications. This concurrence of attributes—flow, humidity and warmth—permits treatment of a broad range of indications allowing the clinician to deliver safe and effective therapy. Contact vtherm.com.

QUICK!
Darren Braude, MD, a noted airway expert and educator and co-director of the Airway911 program at the University of New Mexico, has recently released the second edition of Rapid Sequence Intubation and Rapid Sequence Airway, An Airway911 Guide. This remains the only book focused exclusively on RSI. All aspects of RSI are covered in an evidence-based fashion including: Basic Principles, Pharmacology, The Difficult and Missed Airway, The Multiple Attempts Algorithm, Pediatric Considerations, The 10 Ps, Legal Issues, Documentation and Quality Assurance. The book is written in a unique, easy-to-read conversational style. The 192 page text is supplemented with over 100 color photos and illustrations, tables and case scenarios, as well as color-coding to highlight key points, pitfalls and evidence-based material. According to Braude, this is a great introduction to RSI for RT students and a great review of the latest thinking and evidence for the experienced practitioner. The book may be purchased on Amazon or through airway911.com.

LITTLE HELPER
Mercury Medical's new Neo-StatCO_2 <Kg is the first CO_2 detector for babies below 1 kg. While Mercury's Mini StatCO_2 detector reliably performs on patients between 1-15 kgs, the new Neo-StatCO_2<Kg is the only CO_2 detector indicated for infants below 1 kg. Neo-StatCO_2<Kg is designed for use on infants between 0.25-2 kgs. The new Neo-StatCO_2<Kg detects CO_2 at 1 ml tidal volume and up to 100 breaths per minute. It offers reliable 24 hour continuous performance in up to 100% humidity. and detects CO_2 with a vivid breath-to-breath color change from blue to yellow. Small and compact, it weighs only 5 grams nominal, readily available for added efficiency. Contact (800) 237-6418, mercurymed.com.

NEBULIZED
The AeroEclipse II Breath Actuated Nebulizer (BAN) means "Fast, Assured Delivery." The BAN sustains aerosol output while continuing to deliver high, effective respirable dose with faster treatment times. The AeroEclipse II BAN creates aerosol in precise response to the patient's inspiratory maneuver—meaning much less medication waste, higher drug delivery efficiency, effective clinical dose and safer working environments for clinicians. The AeroEclipse II BAN is designed to meet all your needs throughout the hospital. Contact monaghanmed.com.

QUALITY CONTROL
The Plethysmograph Simulator from Morgan Scientific, Inc has been designed as a quality control device for body plethysmograph instruments of any manufacture. The simulator is placed inside the cabin and simply connected to the patient

valve. It is a self-contained unit elegantly designed for ease of use. The technician initiates a standard VTG measurement using the manufacturers' software and then controls the simulator via Bluetooth using either a Palm or Windows Mobile PDA. Pumping frequency can be controlled from 25 to 130 cycles/min. The simulator comes with two isothermal chambers (approximately 2L and 4L); the precise container volumes are detailed on test certificates provided. Contact morgansd.com.

COMFORTABLE

Comfort Flo Humidification System: "The Difference is Easy to "C". Comfort Flo and ConchaTherm from Teleflex Medical combine to deliver high flow nasal cannula therapy, without compromise. The Comfort Flo Humidification system allows you to safely and effectively deliver heated, humidified oxygen therapy to a broad range of patients. Featuring an adjustable airway temperature and gradient control, ConchaTherm allows you to customize therapy to enhance patient comfort while minimizing condensation build-up. The disposable delivery system and line of specialty cannula allow flow rates ranging from 1 to 40 LPM. Contact (866) 246-6990, teleflexmedical.com.

BALANCED

The quest for optimal humidification is a balancing act. How do you deliver the right amount of humidity to maximize clinical outcomes without creating additional challenges? Introducing the ConchaTherm Neptune, the heated humidifier that has the flexibility to deliver the perfect balance. Featuring an adjustable airway temperature and gradient control, you can customize the therapy to maximize humidification, while minimizing challenges like circuit or interface condensation. Compatible with a wide range of circuits and accessories, the Neptune can be used across a broad spectrum of patients from neonates to adults and with therapies ranging from Invasive Mechanical Ventilation, to High Flow Nasal Cannula Therapy, to Non-Invasive Ventilation. To find out how the ConchaTherm Neptune can help you achieve the perfect humidification balance call (866) 246-6990 or contact teleflexmedical.com.

DISCOVERIES

Discovery Laboratories, Inc announced that data from a preclinical study using Surfaxin (lucinactant) in a well-established preterm lamb model of RDS demonstrated improved lung surfactant distribution as compared with Curosurf, an animal-derived surfactant. The data were present at the PAS Annual Meeting. Data from the study "Comparison of two pulmonary surfactants administered to premature lambs with respect to cerebral blood flow, oxygenation and pulmonary distribution" were presented by Dr Arlin Blood from the Loma Linda University School of Medicine. It has been hypothesized that a larger dose volume of surfactant could result in more homogenous distribution of surfactant and may result in improved pulmonary and clinical outcomes. The data showed that both surfactants significantly increased pulmonary compliance and tidal volume without adverse effects. However, significantly more homogenous lung distribution of Surfaxin was observed, as measured by pulmonary distribution of a mix of gold-labeled microspheres and surfactant. Contact discoverylabs.com.

LIFELINE

Certified Medical Sales, a national distributor of medical gas pipeline equipment and accessories announced the availability of their new product, the Oxy-Lifeline, a supplemental oxygen delivery system. The Oxy-Lifeline was developed to protect the needs of oxygen-dependent patients in a healthcare facility environment with a remote bulk oxygen tank if the underground main oxygen line suffers damage due to a construction mishap, terrorist act or natural disaster. The Oxy-Lifeline is a rapidly deployable system that can supply your facility with uninterrupted service by taking advantage of gas supplies that you already have on site while repairs are made to your main oxygen line. The Oxy-Lifeline will allow your facility to operate as normal in an emergency without straining available manpower by having to relocate patients, or having to rely on suppliers with portable tanks that may be hours away. The Oxy-Lifeline can be deployed in minutes by 1 to 2 personnel. The Oxy-Lifeline is also being incorporated into Mass Casualty Site planning which allows the healthcare facilities' bulk oxygen tank supply to be routed to the Mass Casualty Site. This eliminates the need for multiple "H" cylinders which are cumbersome and would need to be replaced often. To view a 4 minute product video and for more info contact (800) 537-3090, certifiedmedicalsales.com.

EXHALE

Apieron, Inc highlighted recent clinical panel presentations underscoring the positive impact of measuring exhaled nitric oxide (eNO) for treating asthma in adults and children. The company also cited recognition that design and methodology issues led to mixed results in some randomized trials of eNO-guided therapy. Apieron develops and markets non-invasive monitors that measure exhaled nitric oxide (eNO) for better asthma management. The session was titled "Understanding Exhaled Nitric Oxide Gas Exchange." Panelists concurred with a paper by Prof P.G. Gibson, University of Newcastle in Australia, outlining the limitations present in the design and methodology of ASTRAL studies and suggested design features for future studies. These design features, per Gibson, "should improve study performance and aid in obtaining a better estimate of eNO-guided asthma therapy." Clinical & Experimental Allergy published the paper, "Using fractional exhaled nitric oxide to guide asthma therapy: design and methodological issues for ASthma TReatment ALgorithm studies," in its April 2009 issue. The Insight eNO System uses a proprietary biosensor technology to measure exhaled nitric oxide, a well established indicator of asthma severity and steroid responsive airway inflammation. Measuring eNO and determining the level of airway inflammation can help clinicians more closely manage their patients' inflammatory condition and therefore more precisely titrate medications, which can lead to fewer exacerbations. Contact apieron.com.

EASY ACCESS

CHAD Therapeutics unveiled a new and improved web site, making it easier for its customers to access the company's product information and customer service functions. In addition to a wealth of product information, CHAD's customers now have 24-hour access to a number of Customer Service features online. Customers and prospects alike can download a wide array of information, from product features and benefits to instruction booklets and specifications. They can also begin the account setup process, place an order, request a warranty check or return authorization number and track their shipments… all at the touch of a button. Contact chadtherapeutics.com.

SPOTLIGHT ON VENTILATION

INSPIRATIONAL

eVent Medical's Inspiration ventilators are versatile, high performance ventilators designed with the clinician in mind. The patented Swiss pneumatic design allows high performance PSOL valves to provide outstanding breath delivery. Users find exceptional value in the straightforward interface, ease of transport, comprehensive monitoring and simple preventive maintenance. A unique capability within the Inspiration line is the built-in MiniWeb Server that allows display of all settings, monitoring and alarms on computers, hospital network or on the internet using standard hardware and Windows software. Practical advantages include standard battery, emergency backup compressor, integral nebulizer, Heliox and extreme ease of use. Contact event-medical.com.

ENVE-OUS

Cardinal Health is introducing their latest technology in ventilation in 2009 called The EnVe Ventilator. The EnVe is a comprehensive, full feature Intensive Care Ventilator with unique ActivCore Technology. ActivCore is the basis for an extremely powerful and compact designed ventilator that integrates a full color LCD display and 4 hour, hot-swappable internal battery for complete wall independence. The comprehensive selection of modes, non invasive capabilities and an integrated spontaneous breathing trial makes the EnVe a smart choice for your ventilation needs and represents a major paradigm shift in critical care ventilation. Contact cardinal.com.

SOLUTIONS

You're on the front lines of ventilated patient care every day. And Cardinal Health is there with you, focused on elevating your clinical effectiveness, while enhancing patient safety. We listen carefully to your concerns and respond with solutions that deliver more value to you and your ventilated patients. We are committed to educating front-line clinicians on evolving best practices in ventilated patient care. Cardinal Health is currently introducing several new capital and consumable products including the lightweight and portable Enve critical care ventilator and various consumable products designed to help reduce ventilated patient complications such as Ventilator-Associated Pneumonia. Contact cardinal.com.

TOUT SUITE

The new MR Conditional LTV 1200 System is a critical care mechanical ventilator system designed and tested to function in the MRI suite, incorporating the special needs of the MRI environment while providing superior patient respiratory care. This new ventilator weighs about 50% less than other comparably equipped MRI-compatible ventilators. Because of its small size and full function, the MR Conditional LTV 1200 System allows critical care ventilation for a larger set of patients and patient conditions. It is tested in both 1.5 and 3.0 Tesla environments, and recommended for use behind the 100 Gauss line. Contact cardinal.com.

INTEGRATED

The AVEA is a versatile critical care ventilator for neonatal, pediatric and adult patients featuring both invasive and non-invasive applications, including infant nasal CPAP. Integrated Bicore advanced pulmonary monitoring; Heliox administration and Volumetric Capnography provide clinicians with the tools to improve clinical outcomes. A lightweight internal battery powered compressor facilitates transport within the hospital. AVEA has the combination of features, applications and advanced monitoring capabilities that meet the demanding needs of critical care practitioners. Contact cardinal.com.

DUAL CAPABILITIES

The new Carina ventilator from Dräger offers both invasive and non-invasive capabilities in one device. Its latest technology, known as "Synch Plus," will compensate for leakage and provide effective breath delivery. The Carina is well-suited for the emergency room, general ward, ICU, or subacute facilities as it features an internal battery and can operate independent of a high-pressure gas system. The device offers clinicians a wide array of ventilation therapies in a single device characterized by ease of use and patient comfort. The transportability of the Carina makes patient transfer seamless and expedient, especially when a patient requires non-invasive support. Contact draeger.com.

JET PULSE

The Bunnell Life Pulse High Frequency Ventilator provides improved oxygenation and ventilation of infants at lower mean and peak pressures than other high frequency or conventional ventilators. Jet pulse technology, passive exhalation, and a wide range of I:E ratios are the keys to achieving the lowest therapeutic pressures. The Life Pulse is easy to use with only three control settings: PIP, Rate, and I-Time. All other functions are controlled automatically. Bunnell's LifePort adapter has eliminated the need to reintubate with a special endotracheal tube and the new WhisperJet inspiratory valve has significantly reduced noise levels. Call (800) 800-4358 for a trial evaluation. Contact bunl.com.

VERSATILE

Trilogy100 is a highly versatile, lightweight (11lb) life-support ventilator that has been developed to meet the needs of a wide range of patients in the home and alternative care settings. The Trilogy100 portable ventilator features Respironics' proven BiPAP technology with leak compensation, volume and pressure control ventilation, and the ability to ventilate with either a mask or a tracheal tube. The display screens can be configured to show either detailed clinician information or simplified patient views. Its small size, uncomplicated interface, and power management options make Trilogy100 easy to use, portable, and versatile. Contact respironics.com.

AT YOUR SERVICE

The SERVO-i ventilator is designed to provide a wide range of features for the complex respiratory needs of neonatal to adult patients. SERVO-i includes advanced capabilities such as heliox, easy transportability, an MRI (conditional) package, and invasive or non-invasive ventilation. The unique Open Lung Tool enables users to track and monitor lung mechanics during recruitment. Capnography and Y-Sensor monitoring are designed for "plug-and-play" use as needed. NAVA (Neurally Adjusted Ventilatory Assist) is the first technology to capture the patient's diaphragmatic electrical activity (Edi) with a special Edi catheter to deliver the patient's flow, pressure, and volume requirements for optimized synchrony. Edi monitoring additionally enables decision support in any mode. Contact MAQUET at (888) 627-8383 or maquetusa.com.

OUTCOMES BASED

Hamilton Medical reports: Ventilator development is often driven by a manufacturer introducing new modes. This may be putting

the cart before the horse (eg evidence does not support IMV as a weaning mode). Clinician needs and patient outcomes should drive technology development: minimizing ventilator induced lung injury, performing daily "wean" screens; transitioning to partial ventilatory support/spontaneous breathing trials, preventing errors—alarm settings, confusing interfaces, etc, identifying changes in ventilatory status rapidly. Hamilton's G5 and C2 "Intelligent" ventilators address these needs: ASV closed loop ventilation implements lung protective ventilation, transitions patients from full support though weaning and reduces complexity. "PVTool II" rapidly identifies optimal PEEP and lung recruitment. The "Cockpit" display alerts clinicians to ventilatory support needs, lung function and prescribes a patient driven "safety net." Contact hamilton-medical.com.

SPOTLIGHT ON PULMONARY FUNCTION TESTING

INSPIRED

HDpft from nSpire Health delivers the most accurate results at the lowest cost of operation in the pulmonary function testing industry because it is built on the most advanced technologies. iFlow advanced flow sensor technology delivers the industry's best flow and volume measuring accuracy and reproducibility at 300% better than the industry standard. Autoflow gas delivery system offers ultra-low resistance, improving patient comfort and test compliance. Our plethysmograph eliminates drift and warm-up time to provide lung volume and airways resistance results in less than 60 seconds. Contact nspirehealth.com.

PLATINUM STANDARD

Medgraphics' Platinum Elite Series plethysmograph offers complete spirometry, DLco, lung volumes by nitrogen washout and/or plethysmography, and airway resistance. Incorporating the strengths of the previous award winning Elite Series, the Platinum Elite's enhanced features represent the "Platinum Standard" for ease of operation, accuracy, and patient comfort to meet the most demanding clinician and patient needs. The Platinum Elite offers the largest seating capacity of any available plethysmograph and the new digital components offer maximum accuracy, reliability and serviceability. The Platinum Elite is easy to network and outputs a variety of file formats for EMR connectivity. Contact (800) 960-5597, medgraphics.com.

RELIABLE

Rely on Cardinal Health's complete line of cardio-pulmonary function testing equipment to assess your patient's lung function accurately and efficiently every time. Specializing in patient testing, Cardinal Health's data accessibility, integrity, and reporting tools bring significant improvements to workflow. Connecting to your local area network, hospital information system, or internet are just some of the ways we help improve patient care. Please refer to a recent publication in the European Respiratory Journal (2009; 33: 828-834) "Quality control of DLCO instruments in a global clinical trial" where the performance of many commercially available devices were compared to independent quality controls. Contact cardinal.com.

PRODUCT CASE STUDY

OXY-LIFELINE

In the 1993 NFPA 99 Health Care Facilities Manual a new requirement was placed on hospitals. This requirement was for the hospital to "have a plan to cope with a complete loss of any medical gas system." This language has continued to remain in the NFPA 99 Health Care Facilities Manuals through the 1996, 1999, 2002 and 2005 editions.

Of all the medical gas systems the most important one is the oxygen system and that is the system that we will focus on for this article. Also, the scenario for this article is the disruption of the flow of oxygen into the facility from a remote bulk tank, (typically located a substantial distance from the facility) through an underground mainline. This scenario has played out in Southern California three times in the last four years. Two large 500-plus bed hospitals have damaged their underground medical gas mainlines while digging in their parking lot on construction projects that aren't related to nor have anything to do with the medical gas systems. One of the hospitals has had this happen twice.

Since 1993 hospitals have attempted to meet this requirement in several ways.

One of the more common approaches is to use "H" size cylinders (approx 260 CF) with regulators attached to backfeed the hospital in the case of a disruption with the oxygen system's ability to maintain normal delivery pressure (50-55 psig). A backfeed involves placing multiple cylinders in each affected zone or area and plugging these cylinders into existing wall outlets. The cylinder will send the gas into the outlet and throughout the piping system which will keep the other outlets on this zone or area under normal operating pressure.

This method is a good method and should definitely be part of a comprehensive plan. However there are a lot of challenges with setting up the backfeed and maintaining it for any length of time greater than a few hours. It requires a considerable amount of manpower to place and situate the cylinders in each affected area or zone. Once the cylinders are plugged in to the wall outlets monitoring of the cylinders now becomes the new task. As these cylinders go empty, which could happen very rapidly depending on the demand of the patients, they will need to be replaced with full cylinders. This can also be a problem; if the facility hasn't planned for a lengthy outage they could easily run out of cylinders putting the patients at risk. Furthermore, to store an adequate amount of cylinders, regulators, hoses, adapters, cylinder stands and carts can be a real challenge for hospitals with limited storage capacity.

Another method that should be considered as part of a comprehensive plan is to have a way to bypass the underground mainline which would allow the facility to continue to use the remote bulk oxygen tank. This is where the Oxy-Lifeline comes in. The Oxy-Lifeline is a rapidly deployable system that can supply your facility with uninterrupted service by taking advantage of gas supplies that you already have on site. Utilizing the Oxy-Lifeline the remote bulk oxygen tank can be reconnected to the facility through the "Emergency Low Pressure Inlet." This inlet is typically located on the exterior wall of the facility and is interconnected to the hospitals oxygen mainline. The Oxy-

Lifeline can be deployed within minutes by 1 to 2 personnel and will re-establish normal flow and pressure. This is a major savings on manpower and accessory equipment that would be needed to establish a backfeed. Also by continuing to utilize the remote bulk oxygen tank and its volume of product you won't have the same issue of running out like you would with cylinder gas.

One of the hospitals that damaged their underground mainline continued to leak oxygen to the atmosphere for over eight hours while they scrambled to get cylinders in place in order to turn off the mainline from the remote bulk oxygen tank. If they had a more comprehensive plan that incorporated a way to bypass the underground mainline, they would have been back up and running in less than 30 minutes and would have been able to make the repair in less stressful conditions.

Whatever methodology is incorporated into a comprehensive plan to cope with a complete loss of any medical gas system, it is imperative to take into consideration the speed and ease of implementation as well as the duration of time you can keep the system on line so that repairs can be made.

EMERGENCY PLANNING ROUNDTABLE

We asked participants in this roundtable to answer the following questions: 1. What products do you offer that have emergency applications? 2. Describe your company's experiences with applications of your emergency products; that is, instances where they have been used. 3. Describe the education you provide for users of your emergency products, as well as for your own staff. 4. Discuss your R&D process as it relates to emergency planning products and services, including clinician/user input. 5. What plans does your company have to boost production of your product in case of a disaster or emergency? Respondents were invited to answer any or all of the questions. Some respondents answered questions of their own choosing.

Roche Diagnostics

Information from Larry Healy, Blood Gas Marketing Manager, Roche Diagnostics Corporation.

How will Roche Diagnostics continue to supply products and services to hospitals and clinics should a pandemic escalate?
Roche Diagnostics has identified life-saving products that would be prioritized should the spread of the virus cause us to adjust our production levels at any particular site. We currently are able to deliver orders normally and are well-prepared along the entire supply chain to continue to deliver in an ongoing pandemic crisis situation. Any decisions to reduce service levels would be made locally—in consultation with divisional management—depending upon the local situation.

Should clinics stock up on supply?
There is absolutely no reason to over-stock. We are fully able to fulfill orders currently and are well-prepared along the entire supply chain to continue to deliver in an ongoing pandemic crisis situation.

Will you continue production during a pandemic?
Yes, we will continue production. Depending upon how the spread of the virus develops, we will decide at each location if and when we concentrate our production on predetermined life-saving products.

How do you define life-saving products?
These are products which are indispensable in emergency situations such as blood screening products for blood donations and other emergency parameters.

Does Roche have a diagnostic test for the influenza A (H1N1) virus?
TIB MOLBIOL, a Berlin-based cooperation partner of Roche Applied Science announced on May 5, 2009 the development of a LightMix test to detect the new variant of the Influenza A (H1N1) virus. The test will initially be launched in Europe and Asia and will be available immediately for research use only. The test is an H1N1 specific test and will be able to determine whether a patient has or has not been infected with the virus. It is based on real time PCR (polymerase chain reaction) technology. The DNA of the suspected flu virus is isolated in the patient specimen and its genetic sequence is essentially compared with the known DNA sequence of the A (H1N1) virus. This test has been optimized for use on the Roche LightCycler 480 II, 2.0, and 1.2. Roche Applied Science is in close contact with various research institutions, governments and test centres worldwide to provide assistance in the detection and characterization of the influenza A (H1N1) virus. Roche is currently developing another test with improved characteristics. This test should be available soon. RAS is providing scientists with efficient tools for their research and development work, including Nucleic Acid Purification, Real Time PCR, Microarrays and Sequencing systems.

eVent Medical, Inc.

Information provided by Michael Browning, VP of Sales for North America.

Emergency Products: eVent Medical, with the parent company Kobayashi Pharmaceuticals, produces one of the most comprehensive critical care ventilators for all patient populations including neonatal, pediatric and adult patients. It has a built-in compressor and an internal long-term battery which allows facilities that require transport or do not have access to piped-in gases or power to ventilate their patients seamlessly. An additional external battery pack can be added to extend the standard battery time, as well. The Inspiration LS offers—as standard options—Heliox, volume-targeted modes, APRV and biphasic, auto-weaning and a 5-year warranty (US).

Emergency Product Applications: The Inspiration LS ventilator has been sold throughout the world into areas that have limited resources where they must utilize a simple, yet effective, product to ventilate even the sickest of patients. We utilize a disposable flow sensor to eliminate the chance of the spread of contamination between patients. We also do not allow the expired gases to reenter the expiratory side of the ventilator, therefore reducing cross contamination when moving patients or when sharing equipment. The Inspiration LS can also be used noninvasively to provide mask ventilation before actual intubation can occur—especially in the field.

Education: Our field sales teams are trained Respiratory Therapists and have a history of working in the critical care environment. They have all been trained extensively in the operation of all our products. Our products are developed to be very user friendly with prompts that occur on the screen to move even the most inexperienced clinician to ventilate a patient safely. We have standard settings that can be chosen in emergency situations to allow clinicians to begin ventilation safely and effectively until a physician or advanced practitioner can arrive on the scene. We also offer our MiniWeb wireless or Ethernet access that will allow the clinician to view the ventilator settings, alarms, waveforms and patient monitoring remotely. In a pandemic or emergency situation, remote access can allow a physician to help other clinicians care for patients that would otherwise not receive optimal care. We also have online education through our website to help the clinician review materials that may assist them in the best possible care of the patient. We also provide a comprehensive users guide with every unit that is delivered.

R&D: We have utilized the experience of all clinicians within our company as well as current and future users in roundtable type discussions. Since we are an international company, we must plan all of our products to be used in emergency planning and services. We look to end-users as resources for the direction of the market and the needs of current and future development. We spend a large portion of our revenues to continue the ongoing development of our current products in the market and new ones that are in the process of release in the very near future.

Emergency Production: eVent Medical currently has enough product on the shelf to respond to an immediate surge in demand—for example, we recently shipped 150+ units within a 24 hour period. In addition, we have the resources to double our current build levels at a moment's notice. Because the product utilizes standard state-of-the-art parts, they can be obtained by vendors that don't require special tooling and long lead times. All of our future products will have the development built into them for emergency preparedness in mind. We have added several new functions to the Inspiration based on clinician feedback and they were delivered in a very short period of time due to our complete focus on our specialty—ventilation.

VORTRAN Medical Technology 1, Inc.

Information provided by Jody McCarthy, Vice President, Sales & Marketing.

Emergency Products: VORTRAN Medical Technology manufactures and markets a patented line of fully automatic disposable respiratory devices for patients in the hospital and other market segments (EMS, post acute and home care). Our latest advances in product development and applications have provided for a non-cycling alarm for the VAR (VORTRAN Automatic Resuscitator).

Emergency Product Applications: VORTRAN is able to help an area stricken by disaster or in an emergency situation by marketing our products to emergency service agencies and critical care providers. The VAR and E-vent Case products provide an inexpensive ventilation solution for any Mass Casualty Incident (MCI), whether man-made or natural disasters. The VAR being single patient and disposable eliminates contamination and equipment sterilization issues. The E-vent case is organized for rapid deployment and provides ventilatory support for seven patients simultaneously with the 7-port manifold. Connecting the manifold to a single oxygen source such as wall connection, "H" tank, or medical grade air compressors provides maximum clinical performance during an initial emergency medical response. Our experiences of dealing with man-made or natural disasters have involved communicating with end-users before and after the disasters. We recognized, through our communications with them, what invaluable resources the VAR and E-vent Case have proved to be.

Emergency Production; Our contingency plans for boosting production of our VAR and E-vent Case has remained the same since the 9/11 terrorist disaster situation. We continually monitor our raw materials, finished goods, stocking levels of our dealers and follow up with pending business. With this daily plan, we have been able to meet the demand and be prepared for future production.

Education: Because of the interest and widespread use of our (VAR), for Disaster Preparedness and ventilator shortage due to Pandemic Influenza, we have recognized the need for education and training. The 3 types of education and training we provide relevant to emergency services or disaster planning, are the interactive CDROM which contains a multi-medias presentation for PC platform, includes instructional video, brochure and user guide in PDF for all VORTRAN products. Second, is an online Educational Module Sponsorship for free CEUs. The programs provide online continuing education at no charge to medical professionals at accessce.com/courses.aspx. Third is VORTRAN'S website. We also maintain an informative intranet website at vortran.com with up-to-date information on the clinical research and outcome, product brochure and user guide in PDF format.

The VORTRAN mechanisms in place relevant to our VAR and E-vent Case product to assist hospitals, clinics and users in the event of the emergency use of our products is through annual training, daily utilization in transports, MRI/CT applications, publications and our network of dealers. The hospitals, clinics and users have created and adopted emergency response protocols providing a comfort level for use.

R&D: The role of critical care providers provides key communication links for defining goals in improved product development. VORTRAN'S processing program includes tracking and recording critical care provider comments, suggestions and complaint information that is continually analyzed for identification of corrective action if necessary and product improvement. For example, critical care providers commented that the VAR gas consumption was more than they realized would be needed to drive the pneumatic device and that an FiO_2 delivery option of 100% or 50% would be beneficial as not all patients require 100% FiO_2. VORTRAN launched the VAR RCM Model providing gas conservation utilizing the 50% FiO_2 delivery option. Other comments included addressing the pediatric patient population for disaster preparedness. VORTRAN launched the VAR-Plus PCM Model for patient body mass of 10 kg and above. This model can be used on both pediatric and adult patients as well as provide for the FiO_2 delivery options.

The testing and evaluation process of the VORTRAN products

line for in-house and field use is an integral part of our commitment for continuous process improvement. Clinical trials with established standards and measurements, and the level of quality ensures customer expectations of product performance and features.

The R&D process for our team of mechanical engineers as it relates to disaster preparedness and day-to-day application provides for clinician and user input, patient safety, clinician comfort level and an affordable price tag allows us to assist public health emergencies and natural disasters in addition to meeting the demand for ventilator surge capacity. VORTRAN promotes our VAR and E-vent Case products through various avenues such as tradeshows, on-site visit and training, publication advertising, and our network of specialty dealer representatives.

Certified Medical Sales

Emergency Products: We have our own product called the Oxy-Lifeline. The Oxy-Lifeline is a rapidly deployable Oxygen delivery system that can supply the hospital with uninterrupted service by taking advantage of gas supplies that are already on site. It also is a necessary component to incorporate into a Mass Casualty Preparedness Plan.

Emergency Applications: Our product has not been used as of yet in an actual emergency situation. It has however been field tested and put into use at Southern California hospitals in non-emergency situations and has performed as designed.

Education: Our product is a custom designed product that requires a site survey at each facility in order to provide the appropriate configuration for each customer. Once the system has been built to this custom design it is delivered and the key personnel at the facility are trained on how to implement and use the system should an emergency situation occur. We provide a DVD Training Video for the facility so they can review the instructions for use as well as provide on-going training for their support staff.

R&D: The Oxy-Lifeline was developed over a 3 year period starting with a Northern California hospital that came to our firm with a task to develop a method to re-connect their bulk oxygen tank to the facility should a disruption occur to the existing piping system that feeds the building. Working with their staff we were able to develop our product and ensure that it would perform as required. Following this initial design phase we worked with 2 Southern California hospitals and revised and improved our product to its current design. Staff that was involved at all 3 facilities was from the Respiratory, Engineering and Risk Management departments.

Emergency Production: We currently have a four week build time on our product following our site survey and receipt of a purchase order. This is due to the fact that each hospital is a custom designed product. We suggest hospitals "plan for failure" instead of "fail to plan."

Dräger

Information provided by Edwin Coombs, MA, RRT, Associate Director of Marketing, Respiratory Care Systems.

Emergency Products: Dräger's medical and safety divisions help protect human life in approximately 50 countries around the world with innovative products, services, and system solutions in the areas of emergency/critical care and transport ventilation, anesthesia, and patient monitoring. Gas measuring technology, personal protection, and safety system technologies are also available through Dräger's medical and safety solutions. Dräger's medical division provides an emergency and transport ventilation device that provides high-level, ICU-like mechanical ventilation by including such contemporary features such as pressure support and non-invasive ventilation. Our emergency ventilator known as the Oxylog 3000 is tailor-made for the extreme conditions that transport companies can operate under. It contains the benefits of our intensive care unit ventilators, but with the rugged and simple-to-operate design that you need in extreme emergency situations, including at thousands of feet in the air. Designed and manufactured with the same attention to detail and performance as Dräger's high-end Evita ICU ventilators, the Oxylog 3000 represents a significant advance in emergency and transport ventilation systems. It is light, compact, robust, and is ideal for supporting critical-care patients in transfer situations.

Emergency Product Applications: As a global leader in the medical and safety technology markets, Dräger has a strong global reputation in emergency medical and safety products as well as personal protection. Fighting to save and protect lives while maintaining the highest possible level of safety requires uncompromising performance. Over the years, Dräger has met the challenges of providing products and services that protect, support, and monitor the well-being of caregivers in many emergency situations. Dräger has extensive experience of providing products in an emergent situation to deal with such recent disasters such as the Avian Flu outbreak in Southeast Asia and the SARS outbreak in China. During the SARS crisis in China, Dräger donated over $300,000 in ventilation equipment. Those recent catastrophes, as well as those that have occurred locally in the US, such as Hurricane Katrina in the Gulf, have raised the awareness on the part of hospitals, government, and emergency medical services to be prepared for natural or man-made disasters. As a result, Dräger and other medical equipment providers must be able to provide comprehensive solutions to fulfill the needs of disaster planning and preparedness. In the wake of 9/11, Dräger's safety division dispatched three trucks to New York City to deliver gas detection and protection equipment along with service and technical specialists. Dräger's ability to act was due to the emergency plan that was already in place—a warehouse which is well stocked with long term emergency equipment, ready for immediate use. Without this emergency response plan already in place Dräger's ability to react in an immediate and orderly fashion would have been compromised. We view our customers as partners and will continue to work together to face challenges such as these.

Education: With respect to disaster management, continued education and preparedness planning is essential. Specifically to mechanical ventilation, our clinical applications staff will help make the most of emergency staff and equipment. The comprehensive product training provided enables the clinician to confidently operate the ventilator. Our clinical applications specialists are able to enhance the hospital staff's knowledge base and improve quality by introducing the latest technologies available in respiratory care, and improve their process performance by providing a seamless ventilator solution.

R&D: There is no shortcut to innovation. Every year, we invest around eight percent of our revenues in research and development to turn visions into technology for life. This commitment to our customers has been in place for over 100 years. Our research and development teams are constantly focused on the future as it relates to how patient care is impacted. This leadership paves the way for the best solutions possible. Through actively listening to our customers via focus group meetings, one-on-one discussions, or simply by picking up the phone, Dräger can deliver the products, services and solutions that our customers require. Through our outreach and cooperation with the AARC, industry leaders and customers are involved in the development of new products at an early stage in order to ensure that the clinical demands are understood. This input is essential to the development of Dräger products. The Dräger principle of uncompromising quality results in innovative and relevant products and solutions for our customers. Specifically regarding mechanical ventilation, Dräger sees the future in providing seamless technology from emergency care to intensive care to recovery. The ability to provide high-end technology while addressing portability and disaster management situations will remain on the forefront. "Technology for Life" is our guiding principle and our mission. Wherever they are deployed—in clinical settings, industry, mining or emergency services—Dräger products protect, support and save lives.

Emergency Production: Dräger is always aiming to serve customer needs in the best possible way, including critical situations. Our efforts are focused on continuity of supply lines. In a crisis situation, we proactively manage and prioritize manufacturing and distribution of essential equipment for specific circumstance under guidelines and collaboration of governmental policy. Dräger will fulfill contractual obligations for supply and service of equipment and services in the field. We have procedures in place which allow us to rapidly double our production output. Our production is set up as a breathing factory (play on words is not intended). We not only have trained, full-time staff, but also certified temporary workers who step in at short notice. We have contracts with suppliers which allow a quick ramp-up of deliveries, and in preparation for a crisis we proactively increase the orders for parts which tend to have longer delivery time.

Hamilton Medical

Information provided by Paul Garbarini MS, RRT and Justin Tse BS, RRT , Hamilton Medical Clinical Operations.

Emergency Products: Hamilton Medical ventilators feature "Intelligent Ventilation." This closed loop ventilation system, Adaptive Support Ventilation, (ASV) can ventilate the full spectrum of lung conditions potentially seen in emergency/disaster scenarios. The user simply enters the patient's weight and the patient is automatically ventilated with a minute volume proportional to their size. Only 1 knob need be adjusted to further adjust the level of support. Ventilator management is

simplified for scenarios in which RTs may need to support large numbers of patients. ASV closed loop ventilation reduces the task burden in managing ventilators while protecting patients from ventilator induced lung injury, autopeep and hypoventilation. All Hamilton ventilators also incorporate an Intelligent "Cockpit" modeled graphics displays. The displays continuously integrate monitored parameters, settings and lung mechanics into easily interpreted visual pictures. This patient "assessment" provides a visual graphic that gives even non-experts situational awareness of changes in patient status. In the face of limited resources and personnel during an emergency, recognition of changes in patient status are key to improved outcomes. Hamilton's state of the art graphics displays help clinicians understand and react to changes in patient status rapidly and efficiently; effectively helping the clinician triage such that the sickest patients can be rapidly identified while at the same time patients requiring minimal support may be automatically weaned. Our graphical interface has won several international design awards. Hamilton's G5 ventilator was recently ranked #1 in ease of use among current generation ICU ventilators [Evaluation of the user user-friendliness of new generation ICU ventilators. Intensive Care Med 2008; 34: S140]. Hamilton Medical's newest ventilation system, the C2 ventilator (pending 510k) further meets the needs of the emergency community. Incorporated with ASV and the Cockpit displays, the 20.9 lb C2 brings intensive care capability and portability together. The C2 provides more options for choice of gas supplies as its high flow turbine can be supplemented with a low flow oxygen source if no high pressure gas source is available. A quick release stand and carry handle are provided for enhanced mobility.

Emergency Applications: Our Raphael ventilator with ASV was utilized during the SARS epidemic in China. The Raphael ventilator with ASV helped clinicians take care of a multitude of patients with the limited resources available in China. ASV helped clinicians recognize changes in patient status and make changes to improve patient outcomes.

Education: Our dedicated clinical staff has many years of both intensive care and emergency care experience. They spend many hours in both the development and implementation of our products. Our clinical staff provides on-site education to the end user and provides 24/7 on call clinical support. We utilize both multimedia educational material and hands on training as well as follow up site visits to ensure our users are comfortable with our products.

R&D: Hamilton Medical consulted many experts in the field of emergency preparedness for the development of our ventilation systems. We have also taken many suggestions from our users to help us with product development so Hamilton Medical can continue to provide excellent products that meet the needs of our users. Hamilton Medical continues research in the United States and abroad to bring innovation focusing on increased patient safety to the healthcare community. We have partnered with many leading institutions in order to broaden our understanding of today's healthcare challenges and continue to bring the most innovative and technologically advanced products in order to better serve the healthcare community.

Emergency Production: Hamilton Medical's new green manufacturing facility in Bonaduz, Switzerland, not only increases the manufacturing capabilities to meet a growing market demand, but also allows for quick shift from production of one product to another for enhanced efficiency and to meet product demand in response to worldwide emergencies. Hamilton Medical's new facility was dedicated in June 2009.

Pulmonetic Systems, a CareFusion Company

Information provided by Jim Homuth, Director of Marketing for CareFusion Respiratory Alternate Care and a frequently requested speaker on the topics of Emergency Preparedness and Pan-Flu readiness.

Emergency Products: At Pulmonetic Systems, we offer a complete solution for emergency preparedness, not just a product. The main feature of our solution package is the LTV 1200 Ventilator. The LTV 1200 ventilator is the most comprehensive, yet portable, ventilator on the market today for emergency planning and disaster preparedness. From individual hospital preparedness needs, to national emergency ventilator stockpiles the LTV 1200 meets or exceeds all the criteria set forth in the AARC guidelines for "Positive Pressure Ventilation Equipment for Mass Casualty Respiratory Failure." A relatively lightweight and compact design, the LTV 1200 is capable of ICU level ventilation. The easy user interface allows for minimal training and is therefore operable by emergency responders of many skill levels. The internal turbine of the LTV eliminates the need for compressed air. The "Go Pack" packaging from Pulmonetic Systems incorporates the necessary supplies to make the LTV 1200 ventilator ready to grab and go in an emergency. A hard shell, weatherproof case with wheels, protects and stores this respiratory rescue solution in a ready state for immediate deployment. The ability to recharge the batteries in this storage/deployment container without un-packing is a major advantage in maintaining deployment readiness. In addition, having the circuits and set-up information inside is a favored feature by many preparedness planners for their emergency stockpiles. The complete solution from Pulmonetic Systems, may include warehousing and service solutions, as well as technician training, all customized to meet the needs of individual state or federal agencies.

Emergency Applications: The LTV Ventilator is used widely in emergency transport care both on the ground and in the air. Both the civilian and military emergency transport segments praise the advanced capabilities and compact design of the LTV versus traditional emergency ventilation devices. Used by the military in the field, for air transport, and continuing into the hospital, LTV ventilators perform through the entire continuum of care. The LTV holds airworthiness certificates from the US Air Force and the US Army. It is used onboard both floating and submarine crafts in the US Navy. The Veterans Administration continues to provide acute and long term care for veterans of the armed services that require ventilation on the LTV long term care ventilators. Civilian air and ground transport teams appreciate the high quality of patient care they are able to deliver using the LTV in their work. With pressure support, non-invasive option and sensitive flow triggering, they not only ventilate their patients with the LTV in transit, but are able ventilate patients as small as 5kg. Pulmonetic Systems recognized ease of operation as a primary consideration in a ventilator. Patient presets for infant, pediatric and adult on the LTV 1200 allow healthcare workers not specifically trained in respiratory care to initially

set up the ventilator and therefore leveraging the resources of trained respiratory therapists. To assist these non-respiratory healthcare workers we provide an Emergency Set-Up Card for the LTV 1200. This Set-Up Card is validated for use by healthcare professionals as well as lay-people. This information allows an EMT and other emergency workers to provide ventilation earlier in a crisis and stretch healthcare resources while increasing patient care capabilities. Pulmonetic Systems' experience in disaster relief includes rapidly responding to the international healthcare system's needs for the victims of both Hurricane Katrina and SARS treatment efforts in Canada and Asia. We provided both product and clinical assistance in the 35W bridge collapse in Minnesota and donated ventilators to support earthquake relief efforts in China. A southern US state requested that we stand on alert in the event the hurricanes of 2008 hit their shores, and within 24 hours we were fully prepared to respond. In all cases, LTV ventilators and circuits were shipped immediately to the areas in most need, with additional service provided throughout the periods of need. Being experts in transport ventilation, we supplied large quantities of batteries in addition to ventilators to Katrina and sent clinical consultants to assist with training and troubleshooting. With a combination of shipment re-prioritization and increased production, we are able to meet the demand created by disasters and shortages.

Education: The large installed base of LTV ventilators in hospital, transport and homecare, creates a large trained pool of users who are familiar with the LTV ventilator's operation. The clear and easy front panel operating design is favored by those already trained and adopted easily by new users. Pulmonetic Systems offers many classes to train emergency response workers including the basics of Positive Pressure Ventilation in Mass Casualty Respiratory Failure, Transporting Ventilation Patients, and Troubleshooting. Our clinical consultants and technical staff are available 24/7 for assistance. We train bio-medical technicians to service LTV ventilators and have 6 regional certified technical support centers domestically as well as our central service facility in Minnesota. In addition to the personal training available from Cardinal Health, we offer DVDs for in-service training and an emergency set-up training DVD. We offer an emergency preparedness website to our customers containing this information on-line.

R&D: Through our partnership with emergency planning organizations across the Unites States we have discovered that compressed oxygen will be a critical and scarce resource. Pulmonetic Systems has developed a feature on the LTV 1200 ventilator called O_2 conserve. O_2 conserve will ensure that the available O_2 is delivered to the patient efficiently and stretch limited O_2 resources. Pulmonetic Systems also developed a light weight, and hot-swappable battery solution to provide almost unlimited power with recharging. The SprintPack lithium ion batteries charge while the vent is operational and/or recharged battery units can be swapped without loss of power to the ventilator. The SprintPack recharges from a standard wall outlet or the power point of a vehicle. This power source is integrated into the Go Pack configuration as part of the Pulmonetic Systems Emergency Preparedness ventilator solution.

Emergency Production: Located within the United States, our production facility design is flexible and scalable. CareFusion is one of the world's largest ventilator manufacturers and located in the United States. We maintain full production facilities in both Minnesota and California. Our close relationships with our vendors ensure Pulmonetic Systems production abilities remain scalable as needs change.

GE Healthcare

Information provided by Bill Phelan, Marketing Manager, GE Healthcare—Respiratory and Sleep.

Emergency Products: GE Healthcare has a wide variety of products suitable for emergency, disaster and pandemic situations. In the field of respiratory and ventilatory support, we offer solutions that address the needs of the highly critical to the long term and non-invasive patients. The iVent 201 was developed with specific disaster and emergency response capabilities, offering both invasive and non-invasive ventilatory support in a portable, easy to use form factor. The Engstrom Carestation offers long term invasive support for the most critical of critical care patients and comes equipped with simplified UI option to streamline interactions with the ventilator. The Vivo 40 combines long term non-invasive or short-term invasive ventilatory support with an intuitive, highly portable Swedish design to deliver basic ventilatory support in a variety of care settings.

Emergency Applications: In 2004, the iVent 201 was deployed in the state of Florida in response to Hurricane Wilma. The iVent 201 has also seen extensive use in combat support hospitals in Iraq, where they are able to withstand the heat and dust, which create many problems for traditional critical care ventilators. Furthermore, GE Healthcare's mobile hospital, including the iVent 201, has been chosen for the Canadian Olympics to be the on site medical facility.

Education: GE Healthcare provides extensive training for both clinical and sales staff. We also provide CME accredited courses for Respiratory Care Practitioners. We provide both on-site training throughout the purchase process and ongoing internet-based training. Additionally, we we can supply a variety of training materials to help you educate your own staff.

R&D: The GE Healthcare iVent 201 was designed with disaster scenarios in mind, combining inputs from a variety of caregivers along the spectrum of emergency response. As a direct response to avian flu, the Engstrom Carestation was equipped with a simplified user interface option that allowed easy access to vital patient information and reduces caregiver exposure by reducing caregiver time spent at the user interface. Patient feedback dictated the portability and ease of use of the Vivo 40 which allows it to provide basic ventilatory support in an incredibly easy to use form factor.

Emergency Production: In order to minimize the possibility of regional effects, GE Healthcare ventilators are manufactured across a variety of geographies. Our production facilities are highly scalable, allowing them to quickly and efficiently respond to changing demands in near real time. GE Healthcare is not only adept at production, but we maintain a staff of thousands of technicians and clinical specialists throughout the United States (and more in the rest of the world) who will become a necessary adjunct to the deployment of large amounts of equipment in the event of a disaster. Also GE Healthcare maintains large repair depots throughout the world staffed by trained technicians in the repair of all of the equipment sold by GE Healthcare. In these respects GE stands apart from the rest of the healthcare industry.

NEWS FEATURE

IT MARCHES ON

Business Week recently reported on Kaiser Permanente's paperless medical record-keeping system. The excerpt is from Business Week, April 7, "How Kaiser Permanente Went Paperless," by Rachel King, a San Francisco-based writer for BusinessWeek.com.

President Barack Obama plans to spend $17.2 billion to induce care providers to maintain patient records electronically, scrapping the current paper-based system. The Obama Administration wants electronic health records for every American by 2014.

Kaiser Permanente's medical clinics and two-thirds of its hospitals operate in a paperless environment and the rest are scheduled to be completely digitized by next year. Across the system, about 14,000 physicians access electronic medical records for 8.7 million patients in nine states and the District of Columbia.

Early efforts began more than 40 years ago. Kaiser has spent $4 billion and encountered disgruntled doctors, system outages, and a temporary decrease in productivity as physicians get accustomed to the new system. Industry experts say the upgrade has resulted in a higher quality of care in some cases. A 2002 report indicated that in Northern California, Kaiser Permanente had reduced death from heart disease so significantly among the region's then-3 million members that it no longer was the leading cause of death in that population. The report gave partial credit to Kaiser's databases, reports, and tracking and reminder systems.

As much as 30% of healthcare spending goes to ineffective or redundant care, according to studies that say digital health records can improve care by reducing the incidence of medical errors and eliminating duplicative procedures. For instance, electronically stored results of an MRI or CT scan can be more readily accessible to a wider range of care providers. As records are integrated with a pharmacy, a doctor or nurse can tell whether a patient hasn't filled a prescription. How much those efforts reduce overall costs is another matter. Electronic medical records reduce waste, but patients who live longer may ultimately end up consuming greater health-care resources. "We like what we get for the money but we're not going to save any money," a Kaiser physician has noted. There is no hard evidence that if you invest $20 billion, you'll get back $200 billion.

As a so-called integrated health system, Kaiser Permanente is different from other providers not only because it owns the hospitals, pharmacies, and labs but also because the physicians in the Permanente Medical Groups only see patients insured by Kaiser. Unlike most physicians, who are paid by the office visit or procedure, Kaiser doctors are paid salaries. This is an important distinction because Kaiser Permanente as an organization bore the costs of implementing the system and has the power to mandate that doctors use it.

At NorthShore Unniversity Health System, near Chicago, the situation is more typical of hospitals that work with independent doctors. In 2003 and 2004, NorthShore implemented electronic medical records at three hospitals and 65 medical group offices. Over the past five years, the organization has tried to encourage independent physicians to adopt it, offering 50% discounts on the Epic software. Still, industry experts say it can easily cost $50,000 or more to get a small office up and running. So far, 15 independent offices have installed the software. Today about 60% of the patients who come into the emergency department at NorthShore have a full electronic record, with medications and allergies listed, all of which helps increase patient safety. The first-year cost of installing e-health records for a three-doctor practice is somewhere around $70,000 to $80,000 per doctor. The benefits of digitizing health records are largely realized by entities other than the doctor, including the patient, the hospital, the health plan, and the pharmacy. In fact, if waste does come out of the system, physicians can expect fewer patient visits in the near term. "Explain to me again why the doctor down the street wants to spend $80,000 to put in a system so that Walgreens can save money," one source said.

CIOs at a number of hospitals say that getting doctors to change how they work is one of the biggest hurdles. When this software is first introduced at a location, Kaiser typically cuts doctor patient loads by 50%. Most people bounce back to full volume in about two weeks. Inconveniences aside, most doctors don't want to go back to a paper-based system once the new approach is in place, Kaiser says.

NOT SO FAST

In a related article, Neal Patterson of Business Week reported: The current scramble in health information technology has been likened to the 19th century land rush that opened Oklahoma to homesteaders. The billions in taxpayer funds have energized companies like GE, Intel, IBM, Microsoft and Google to put medical records into the hands of patients. Hospitals can seek millions for tech purchases.

However, some say this is all obscuring the checkered history of computerized medical files and drowning out legitimate questions about their effectiveness. Doctors say industry leaders are pushing expensive systems with serious shortcomings. The high cost and questionable quality of products currently on the market are important reasons why barely 1 in 50 hospitals has a comprehensive electronic records system. Business Week noted, "Hospitals and medical practices that plugged in early have experienced pricey setbacks and serious computer errors. Suddenly dumping more money on hospitals, which will then funnel the cash to tech vendors, won't necessarily improve the situation… So far there's little conclusive evidence that computerizing all of medicine will yield significant savings. And improvements to patient care may be modest. An analysis of four years of Medicare data found only marginal improvement in patient safety due to electronic records—specifically, the avoidance of two infections a year at the average US hospital. Part of the problem stems from a fundamental tension. Info tech companies want to sell mass-produced software. But officials at large hospitals say such systems, once installed, require time-consuming and costly customization. The alterations often make it difficult for different hospitals and medical offices to share data—a key goal. Meantime, the health IT industry has successfully lobbied against government oversight… Britain's experience shows that technology alone doesn't offer an automatic advantage. An $18.6 billion initiative to digitize Britain's government-run health system is four years behind schedule because of software snafus and vendor troubles. Few British

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How Effective is Your HME?

Jeff Borrink, MS, RRT

A Heat Moisture Exchanger (HME), sometimes referred to as an "artificial nose," is a passive humidification device designed to heat and humidify inspired gases. If inspired gases are not adequately humidified, a host of respiratory system compromises can follow, such as thick retained secretions, increased resistance, increased work of breathing, the destruction of cilia and mucus membranes, increased incidence of pneumonia, etc.[1-3]

For mechanically ventilated patients, HMEs can be used to heat and humidify inspired gases rather than an active humidification system. HMEs are placed between the patient Y and the connection to the endotracheal tube, allowing a transfer of moisture from the patient's exhaled air to the HME and then back to the patient on the next inspiration.

HMEs are the most commonly used humidification device in Europe[4] and have become increasingly more popular in North America. Some of the reasons for their popularity may be due to the fact that they have no moving parts, they do not require electricity, and depending upon a number of factors such as how frequently they are changed, they can be a less expensive method for providing an acceptable level of humidity to mechanically ventilated patients.[5] However, HMEs may not be indicated for all patients such as those with a low core temperature, those suffering from dehydration, or those with an increased flow demand or minute ventilation requirement, as the moisture returned to the patient will be diminished or mechanical deadspace increase may be adverse to the patient.

Many basic HMEs consist of a paper medium or sponge filament inside a low compliance case. Some newer versions of HMEs have an interior surface that is treated with a hygroscopic salt (lithium chloride or calcium chloride), which increases its ability to extract moisture. Either type of HME is available with or without a viral/bacterial filter. Numerous HME devices are now available commercially from a wide variety of manufacturers and distributors. Because of the multitude of devices available on the market, it is important for the clinician to be aware that characteristics of the devices such as size, weight, deadspace, amount of moisture return, and resistance to flow can vary greatly from one device to another. Some studies have shown significant differences in the effectiveness of different HME devices in how much humidity is returned to the patient.[6-7] Basic HMEs may return 10mg to 14mg H_2O/L, while others have been shown to return 22mg to 34mg H_2O/L.[7] However, few large scale independent studies have been conducted to assess humidification performance of HMEs.[6-7]

A recent study published by Lellouche et al in Chest online, the official publication of the American College of Chest Physicians, did exactly that, assessing humidification performance of a large number of adult HMEs. According to the researchers, this is the largest evaluation of its type for HMEs and antibacterial filters ever conducted. The researchers assessed 48 devices using a bench test apparatus that reproduced real-life saturated expired gas conditions in order to assess the hygrometric performance of the devices. Thirty-two devices were described by manufacturers as HMEs and 16 were described as antibacterial filters. The bench test apparatus provided expiratory gases with an absolute humidity (AH) of 35mg H_2O/L. A Servo 900C ventilator was used in assist-control mode, a respiratory rate of 20, 500cc tidal volume, positive end expiratory pressure of 5cm H_2O, and a fraction of inspired oxygen of 21%. Room temperature was held constant. The AH of inspired gases was measured after steady state using the psychrometric method. They performed three hygrometric measurements for each device. The devices were classified into different categories: HMEs with an antibacterial filter (HMEF) or without an antibacterial filter (HME) and those described as antibacterial filters. The measurements obtained with the bench test apparatus were then compared to manufacturer data.[8]

Of the 32 HMEs (HME and HMEF) tested, only 37.5% (12) performed well (> 30mg H_2O/L), 12 were intermediate (< 30 to ≥ 25mg H_2O/L), and 8 performed poorly (< 25mg H_2O/L). The average AH of these devices was 17.3 ± 3.6 mg H_2O/L. Humidity efficiency of the devices ranged from 91.1% to 37.8%.[8]

Manufacturer data was available for 29 devices (25 HMEs and 4 antibacterial filters), and the researchers then compared their results to the manufacturer data. Of the 29 devices that could be compared, manufacturer data were higher than the value

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Jeff Borrink is Clinical Application Specialist, Hamilton Medical. This article is from Hamilton Medical's newsletter.

Humidifiers and Nebulizers: Friends or Foes

James B. Fink, PhD, RRT, FAARC

Over the last 20 years, we have learned a great deal about both humidity and aerosol delivery during mechanical ventilation. Many of these lessons have come from in vitro studies, in which specific variables can be isolated and their impact compared. Where results can appear to be quite clear on the bench, some of the lessons learned from research may not always be well applied to the complexities of care for the critically ill patient. This paper explores questions such as the role of heated humidity in aerosol delivery, contamination of nebulizers and best methods to give aerosol with an HME.

Background

Humidity is essential for lung health. Our bodies have been designed to efficiently warm and humidify gas inhaled from a broad range of environments from steamy rainforests and dusty dry deserts, to frigid winter wonderlands. In all of these environments the upper airway regulates both heat and humidity to provide 100% relative humidity at body temperature. When the upper airway is bypassed with an artificial airway, a large component of the heat and moisture recycling system is bypassed as well. We know that cold dry air from a ventilator can paralyze cilia, precipitate bronchospasm and lead to epithelial changes within minutes of exposure, so external systems providing heat and humidity are essential.

Our upper airways are designed to reduce inhalation of a broad range of aerosols that occur in nature, from dust to molds and pollen to smoke from reaching the lung. The filtration system is also bypassed in great measure with the presence of artificial airways. As a surrogate for both functions, heated humidification and filtration of aerosols, the heat moisture exchanger (HME) would appear an attractive option. The HME reclaims and recycles up to 70% of exhaled heat and water, and effectively filters particulate matter from being inhaled. However, in the critical care environment, we apply medical aerosols to the lungs for both local and systemic effect, and it may be argued that bypassing the upper airway may actually increase our ability to deliver medical aerosols to the lungs.

Ventilator Circuit Contamination

In general, as respiratory therapists, there are more opportunities for the ventilator circuit to contaminate us, than for us to contaminate the ventilator circuit. Thirty years ago we used to change ventilator circuits every 8 to 24 hours due to contamination, only to find that the primary source of ventilator circuit contamination is the patient. Within minutes of being connected to a patient's airway the ventilator circuit is contaminated. This occurs whether heated humidity or HMEs are used.

Once we realized that cascade humidifiers generated micro-aerosols, the use of passover and wick humidifiers, which do not generate aerosols, increased. With passover and wick humidifiers, any pathogens that drain into the humidifier reservoir have no way to travel back to the circuit. In addition, hot pot humidifiers heat water up to 70°C, virtually pasteurizing pathogens, and rendering them harmless. Such containment enables the changing of ventilator circuits weekly or on a between patient basis.

With active humidification there is a greater amount of water condensing in an unheated circuit than with the HME. This condensate can act as an active carrier for offending pathogens. As condensate forms in the circuit, pathogens will "go with the flow." This is also true when condensate is removed from the ventilator circuit, where it should be handled as contaminated waste from the patient. Careless handling can rapidly contaminate an ICU.

Use of heated wire circuits to minimize formation of condensate and absorptive materials to wick condensate from the circuit interior, offer opportunity to minimize, if not eliminate contaminated condensate from the circuit. However, the operation of some types of nebulizers may result in additional condensate formation.

Aerosol Generator Contamination

Any secretions or contaminated condensate that enters the inspiratory limb of the ventilator circuit will drain to the lowest level, and collect in either a condensation trap or nebulizer. How many times has a therapist started a nebulizer treatment on a ventilator with 3 ml of medication only to return 30 minutes later to find that there is 6 ml of liquid in the nebulizer. You know what medication you put in the nebulizer, but what about that other liquid?

For standard nebulizers (jet and ultrasonic) aerosol is produced in the same compartment that holds the medication. Consequently, any condensate that drains into the medication reservoir of these nebulizers, contaminates the medication that is then nebulized for deep lung delivery. Even in a well designed heated wire system, the addition of cold dry gas with aerosol into the circuit will precipitate additional condensate between the jet nebulizer and the patient airway.

This is not as big an issue for the pMDI or vibrating mesh nebulizer such as the Aeroneb Solo and Aeroneb Pro as the aerosol pathway is mechanically separated from the medication reservoir, reducing risk of medication contamination. In addition, both types of devices have their reservoirs positioned above the circuit, making it more difficult if not impossible for contaminated liquid to reach the reservoir.

Breaking the Circuit

Breaking the circuit has been associated with increased infection risk and de-recruitment of the lung receiving positive pressure. There is virtually no risk with pathogens entering the ventilator circuit unless they are introduced from the patient's airway, from a contaminated device or contaminated medication added to the circuit. The principle infection risk of opening a pressurized ventilator circuit is primarily related to contaminated condensate being sprayed into the environment surrounding the circuit, like in the therapist's face. The pressure in the circuit pushes fluid like air and condensate out of the "break" in the circuit, and there is no opposing suction drawing fluids back in. The far greater risk of breaking the circuit during mechanical ventilation is interrupting baseline airway pressures such as PEEP or CPAP allowing unstable airways and lung parynchema to collapse. Re-recruitment of these airways may require 30-60 minutes, negatively impacting the stresses within the patient's lungs and oxygenation. Adding and removing a nebulizer from the ventilator circuit serves to break the circuit, and adds to the de-recruitment of the lung. Devices such as valved Tpieces reduce this risk, but the valve acts as a baffle and may reduce nebulizer efficiency.

HME and Aerosol Delivery

As mentioned above, the HME, also called the artificial nose, effectively filters out particles much more efficiently than the tenacious proboscis for which it has been named. Consequently, the HME should never be placed between the aerosol generator and the patient's airway. This leaves the options of either removing the HME from the circuit for each treatment, or placing the nebulizer between the HME and the airway.

Several systems have been devised and marketed to bypass the HME without breaking the circuit, but no studies to date have reported how such systems impact aerosol delivery.

Placement of the aerosol generator between the HME and airway is also an option. However, placement of chamber pMDI adapters and nebulizer can add mass and weight on the airway, increasing the chance that the airway tube might be moved during administration, allowing additional leakage of fluids around the cuff. Leakage around endotracheal tube cuffs has been associated with ventilator associated pneumonia and should best be avoided. In addition, it is known the filters can become loaded with aerosols, with an increased resistance for gas passing through. Nebulizers should not be run continuously between the airway and HME unless it is certain that airway resistance through the HME is not increased.

Should You Turn Off the Humidifier to Improve Aerosol Delivery?

Heated humidity has been associated with decreased aerosol delivery during mechanical ventilation. Whether using a liquid nebulizer (O'Riordan et al) or pMDI, (Fink et al) high absolute humidity is associated with up to 50% reduction in delivered aerosol to the lung. Does it make sense to turn off the humidifier to improve aerosol delivery? Probably not.

We know that cold dry air causes problems for patients with artificial airway, including bronchospasm and inspissated secretions. Why would you risk increasing these problems to administer an inexpensive bronchodilator? In vivo evidence suggests that a dose of albuterol sulfate by standard nebulizer (2.5 mg) or 4 puffs with a pMDI (.36 mg) provide bronchodilator effect for up to 4 hours in stable COPD patients.

Recent evidence suggests that turning off the humidifier for up to 10 minutes did not improve deposition from a pMDI (Lin et al), and that for the first hour after the humidifier is turned on aerosol delivery is similar to a dry circuit. Once condensate has formed in the spacer and circuit, the aerosol delivery was reduced, even after turning off the humidifier.

If you want to give a larger dose, don't turn off the humidifier and put your patient at risk, use an aerosol generator that is more efficient. Both in vitro and animal studies report that the vibrating mesh nebulizers deliver between 10-15% of the nominal dose to adults and infants during ventilation with heated humidity.

Patient Safety Considerations

In the quest to provide safe effective aerosol therapy, clinicians need to temper the desire to deliver large amounts of drug to the lungs with the well being of the patient. Interrupting humidification for as little as 20 minutes may produce damage in the lung that takes days to repair. Contamination of the deep lung with contaminated aerosols can be a causative factor in development of VAP, with up to 50% mortality.

Well beyond the science of aerosol delivery is patient management. Judicious use of available evidence and appropriate technology can help us safe guard our patients while delivering effective aerosol therapy.

High-Frequency Jet Ventilation

High-Frequency Jet Ventilation has been shown to offer improved results when treating respiratory failure. For infants unresponsive to high-frequency oscillatory ventilation, high-frequency jet ventilation has been found to be more efficacious, though not all HFJV devices show the same results in clinical tests.

Summary

In 2003, Friedlich et al reported on the use of HFJV versus high frequency oscillatory ventilation and found that neonates unresponsive to conventional ventilation did respond to high frequency jet ventilation, and showed a marked improvement for a number of critical indices. The researchers noted demonstrable improvements in FiO_2, MAP and oxygenation, which led to a mortality rate of about 10%, much lower than expected when using conventional ventilation.

Backround

Conventional ventilation for hypoxic neonates often leads to barotrauma and volutrauma, and results in air leaks. High frequency ventilation uses higher MAP but not high PIP; therefore, such ventilation, insofar as it mitigates large pressure and volume changes, decreases lung injury. However, ventilated neonates with severe lung conditions often develop gas trapping and are prone to lung over-inflation.

While treatment with this mode of oscillatory ventilation is often efficacious, preemies with increased airway resistance and low compliance don't always respond adequately. There is often a four-fold difference between expiratory and inspiratory airway resistance. While oscillatory ventilation allows for a longer expiratory time by decreasing the I:E ratio, the exhalation phase may cause airway collapse, especially when attempts are made to avoid over-inflation.

Study

Friedlich et al, at Children's Hospital Los Angeles, reported on their study comparing various modes of high frequency ventilation. The researchers selected ten critically ill neonates with hypoxemic respiratory failure who were ventilated with a Sensormedics 3001A high frequency oscillatory ventilator, and who couldn't be adequately ventilated, likely because of gas trapping. Researchers compared the aforementioned ventilator with the Life Pulse High-Frequency Jet Ventilator manufactured by Bunnell Inc. The high-frequency jet ventilator was set at 400 cycles/min, with inspiratory time at 0.02 secs. The FiO_2 was set for saturation between 88% and 95%, and PEEP was set at 5-7 cmH_2O and adjusted as needed. Background intermittent mandatory ventilation was set at 3-5 breaths per minute, with inspiratory time of 0.35. PIP to PEEP volume was controlled by manipulating the jet frequency.

Results

The oxygenation index decreased significantly throughout the study, as did FiO_2 requirements and stayed lower throughout the trial with the use of high-frequency jet ventilation. MAP decreased as well and also stayed lower. The difference in MAP between the two modes of ventilation (oscillatory and high-frequency) remained significant for 72 hours of high-frequency jet ventilation exclusively. No complications due to ventilation were recorded during application of the high-frequency jet ventilator. The survival rate was 90%. (One patient died from circulatory collapse from septic shock at the beginning of the study and another with pneumonia couldn't be ventilated with HFJV.) The neonates all needed oxygen at discharge due to their severe condition at the initiation of the study.

Conclusion

Differences in oscillatory ventilation vs HFJV can be attributed to lower I:E ratio and a longer passive exhalation phase using the high-frequency jet mode. High-frequency jet ventilation can achieve an I:E ratio of 1:3.5 to 1:11.5, resulting in minimized gas trapping and lower lung volumes. The researchers at Children's Hospital, using oscillatory ventilation, could not adequately control gas trapping and over-inflation, and couldn't achieve optimum lung expansion. However, high-frequency jet ventilation showed significant improvement in oxygenation without comprised pH and pCO_2. As such, the researchers concluded that HFJV may have advantages over high-frequency oscillatory ventilation for the management of preemies with chronic lung disease.

Information for this report is from the article, Use of High-Frequency Jet Ventilation in Neonates With Hypoxemia Refractory to High-Frequency Oscillatory Ventilation, P. Freidlich, N. Subramanian, M. Sebald, S. Noori, I. Seri, The Journal of Maternal-Fetal and Neonatal Medicine 2003;13:398-402. The article and information was provided to Neonatal Intensive Care by Bunnell, Inc. For statistical information readers are referred to the above-cited article.

Study Compares Relative Humidity Output for Active Heated Humidifiers

This product feature was provided by Teleflex Medical.

A comparison of humidification output during continuous flow applications for three commercial humidification systems shows the relative humidity output to be greatest with the ConchaTherm Neptune, manufactured by Teleflex Medical.

The benefits of high relative humidity during continuous gas flow are well documented. Optimum humidity is achieved when the inspired gas is at body core temperature with 100% relative humidity. When gases are outside of this level, not only is patient compliance compromised, but further respiratory dysfunction may occur. For this reason, heated humidification is used during delivery of artificial gases, and it is very important that a heated humidification system be able to closely match optimal humidity conditions.

The ability to measure precise relative humidity output from heated humidification systems is difficult as it requires sophisticated equipment to ensure accurate results. The Research and Development Team at Teleflex Medical was able to gather data for this study using Vaisala Humicap Humidity and Temperature Transmitter Series equipment. This equipment is intended for applications where condensation can occur due to high humidity and rapid humidity changes, such as heated humidification for respiratory applications. The warmed probe head is heated continuously so that its temperature is always higher than in the environment. This prevents condensation on the probe and allows more accurate readings at high relative humidity levels.

In the laboratory study, the ConchaTherm Neptune shows higher relative humidity output than the MR850 from Fisher & Paykel/Cardinal and the Vapotherm 2000i heated humidification systems. The ConchaTherm Neptune delivered 97% relative humidity output, the MR850 delivered 79%, while the Vapotherm system delivered 86% relative humidity. This difference is due to a key distinguishing feature of the ConchaTherm Neptune heated humidifier—temperature gradient adjustability.

According to Jeri Eiserman, Director of Clinical Support for Teleflex Medical, "Achieving optimal humidity in clinical practice can be difficult due to fluctuating patient, equipment, and environmental conditions. These challenges often limit the clinician's ability to meet the relative humidity needs of the patient without creating additional issues such as excessive circuit condensation. A key benefit to using the ConchaTherm Neptune heated humidifier is the flexibility to adjust patient airway temperature and temperature gradient settings to adapt to these challenges".

"Adjusting the temperature gradient will change the humidity levels and therefore allow for better control of humidity and condensation in the circuit and patient interface," says Dwyer. "Humidifiers that have this gradient feature allow for various humidification levels for different patient needs and environmental conditions. This feature is unique to the ConchaTherm Neptune heated humidifier. This is why adjusting the temperature gradient resulted in higher relative humidity output for the ConchaTherm Neptune during this study."

The humidity levels presented are measured at the end of the heated circuit and do not take into account the reduction in heat across the unheated patient interface, and the subsequent increase in humidity levels as a result of this cooling. Once the humidified air leaves the circuit, there are numerous variables that could change the temperature and therefore change humidity levels leaving the patient interface. Further studies could determine the impact of the patient interface, higher flow rates and environment on humidity levels.

Table 1

Test	Hudson RCI Neptune	Hudson RCI Neptune	Fisher & Paykel MR850	Vapotherm 2000i
Flow Rate (LPM)	5	5	5	5
Heater Set Temp (degrees C)	37	37	40/37	37
Heater Gradient (degrees C)	0	3	N/A	N/A
Relative Humidity (%)	86	97	79	92

Ventilating Infants in Critical Care Air Transports

Over the past two years, more than 40 critically ill infants have received intensive care quality ventilation in air transports within Sweden and destinations in northern Europe. These transport opportunities have evolved from a close collaboration between the Swedish Air Ambulance company (Svensk Flygambulans AB) and the Astrid Lindgren Children's Hospital at the internationally renowned Karolinska Hospital in Stockholm, as well as new technological solutions that provide support to ventilated infants in fixed wing aircraft.

Critical Care News met with team members of this collaborative effort from both groups; representatives from PETS (Pediatric Emergency Transport Service) at Astrid Lindgren Children's Hospital, as well as representatives from Swedish Air Ambulance, to hear about how this collaborative effort and transport solutions developed within the group. The Pediatric Emergency Transport Service (PETS) at Astrid Lindgren Children's Hospital and the Swedish Air Ambulance company each have a longstanding tradition of transporting critical care and emergency patients.

The PETS service—with origins in the early 90's

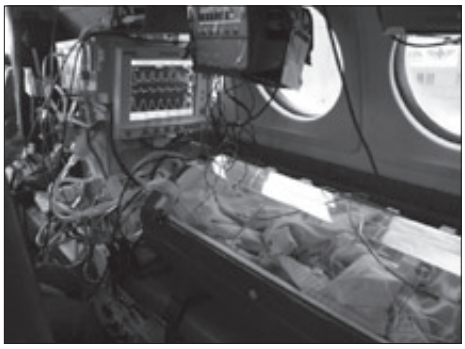
The Astrid Lindgren Children's Hospital within Karolinska Hospital in Stockholm has a long and well-established tradition of transporting children, primarily newborn infants, originating from a decision to centralize cardiac surgery in Sweden to the university hospitals in Lund and Gothenburg in the 1990's. Dr Tova Hannegård Hamrin, anesthesiologist at Karolinska's Astrid Lindgren Children's Hospital, outlines the development process after that point: "We came to believe that there were many critically ill children in general ICUs in hospitals around Sweden, who would perhaps get better care in a dedicated pediatric intensive care unit. That is how the idea for PETS was born, and it started as a project in 2005. We have observed that more and more hospitals have contacted us to transport and treat more and more children." Dr Hamrin has been involved in the PETS program from the very beginning, and is currently responsible for PETS operations, which is a part of the Department of Pediatric Anesthesia and Intensive Care group at Astrid Lindgren Children's Hospital. "Last year we had 27 PETS transports in total, from January to April this year we are already up to 18 PETS transports, an increasing tendency. I think this increase is due to familiarity and confidence, once a hospital has heard about the program and sent one of their children to us and seen that it works, they want to use us again. PETS are not only air transports, but also land based ambulance and helicopter intensive care transports as well. Whatever the transport means, the program can be considered as a mobile ICU for infant and pediatric patients."

The PETS program has twelve physicians as well as twelve nurses, in order to provide staffing around the clock. Dr Hamrin explains: "In the very beginning, staffing was on voluntary basis among our colleagues. A patient transport request came to the doctor on call at the PICU, who then contacted us by mobile text messages that were sent to all of us, and those who had the opportunity to accompany the patient transport could respond. From the beginning of this year, we have chosen to have one physician on rotation for transports for one week at a time. We are also working on a proposal for a rotational schedule among our pediatric intensive care nurses and pediatric anesthesia nurses. It is extremely important that our PETS staff have a good knowledge of how we care for our patients, and that they have worked at least two years at our unit in the hospital."

Swedish Air Ambulance—over 30 years of operations

The Swedish Air Ambulance company started its operations in 1976 with the very first air ambulance in Sweden, and has continually developed ever since. Last year over 1,100 patients in different categories were transported, in a fleet of three Beechcraft 200 aircraft based in Sweden. Managing Director Åsa Englund states, "We fly primarily in Sweden and northern Europe on flights between 2-3 hours. After that, refueling is usually necessary, but is also dependent upon the load that the aircraft is carrying. Each flight has a captain, co-pilot, and aircraft nurse. We have a high requirement for our nurses, who must have flight medical training, emergency training, and maintain clinical competence in order to provide patient care, in case there are situations where no PETS team members are present. Over 90% of the transports are planned, and 10% are acute, according to Åsa Englund, and the company transports in any situation around the clock.

Registered Flight Nurse Carina Ramstedt explains: "It could be a patient that has to be transferred to a specialty center for transplantation, or a patient returning home after specialized care. Sometimes we get patients that have become ill during a business trip or vacation trip. We can provide flight support like an ambulance, ICU or sometimes the patients are capable of sitting upright. We also act as an extended arm. We had a number of patients that arrived in Sweden after the tsunami 2004, who were transported back to their home hospitals."



Infant patient in aircraft, ready for air transport from Sweden to northern Europe, with BabyPod and SERVO-i transport solutions.

Swedish Air Ambulance acting Managing Director Åsa Englund has been employed at the company since 2001, and has been actively involved in the technological developments.

Demonstration of the BabyPod mounting on the transport stretcher with SERVO-i ventilator anchored in place.

Collaboration leads to new infant transport solutions

Karolinska Hospital and Swedish Air Ambulance have collaborated with patient transports for many years, in many different patient categories. The PETS group has used different transport solutions for infants, with different experiences and drawbacks. Dr Hamrin explains about some of the limitations they have encountered and the discovery of the infant pod solution: "When you transport with an incubator, the infant is the component that weighs the least. Transport incubators are large and cumbersome, and not easy to work with. One of our colleagues heard about the infant pod solution in Great Britain, where it has been in use for some time. We purchased one infant pod (BabyPod manufactured by Advanced Healthcare Technology Ltd, UK) and started to use it for transports of our infants with congenital heart disease, and it worked very smoothly. In about the same time frame, the SERVO-i ventilator became available for air transports. The transport incubators today have a rather basic ventilator solution that does not provide high quality ventilation treatment. "The Swedish Air Ambulance became very interested in the infant pod solution that the PETS group had discovered, since it is a much simpler solution to travel with when a transport incubator is not really needed." Dr Hamrin states that the only time when a transport incubator may be needed is when the infant cannot maintain body warmth, which generally is only a problem with premature babies, in her opinion.

Annika Schön, anesthesiology nurse in the PETS group, describes the infant pod solution: "The infant pod is lightweight as it is composed of styrofoam, and has a five point strap system crossing over the child as a harness to keep the infant in place on the mattress. The mattress is a vacuum type, which can be adjusted if the child needs further support within the pod. The pod is affixed to the stretcher at the hospital, and the concept works as one unit from the hospital to the aircraft, during flight and upon arrival at the receiving hospital."

Intensive care ventilation in-flight

The pod solution became very popular for transporting infants, but ventilation was an issue that still needed to be addressed. Swedish Air Ambulance Flight Nurse Carina Ramstedt describes some of the practical problems of the past: "For infants, the greatest concern has always been the risk of extubation when entering or leaving the aircraft. We always worry about tubes or cords fastening somewhere, or movements that might disturb the patient and the equipment, such as one of the staff stumbling, etc."

For the PETS team, the quality of ventilation treatment for infants has been a primary concern. Dr Hamrin explains: "When PETS began, more than 70% of our transported patients were referred because of respiratory insufficiency. In transporting these infants with sick lungs, it can affect the level of treatment quality to transport without a high quality ventilator. We were purchasing the SERVO-i in the hospital to replace our old SERVO 300 fleet in the PICU, and as the SERVO-i can be adapted for transports and was approved for flight, the idea was born to transport with a ventilator that provided ICU-quality ventilation, and to use it on the infant during the entire course of therapy, including bedside. This helps us maintain the same ventilator quality without interruption.

"The Swedish Air Ambulance company was attentive to us when we discussed the fact that the old model of baby transport ventilator was not sufficient for these infants with sick lungs. In the process we took a SERVO-i ventilator and received flight approval for it, and they followed the same process. They also heard about the transport cage to attach and stabilize the SERVO-i to the stretcher, and informed us, as they have always been very attentive to our requirements in regard to ventilation quality during the transport process. The collaboration continues to develop."

The Swedish Air Ambulance company initiated a process to be able to use the SERVO-i ventilator in flight. Åsa Englund clarifies: "We developed the solution to anchor the ventilator and cage to the stretcher on a bottom plate, which is stable from all directions. After that we conducted a series of tests to evaluate stability, electrical disturbance on other instrumentation, and tests to establish that the ventilator was not affected by changes in cabin air pressure or vibrations, and tests of the connecting cables as well." The Swedish Air Ambulance company appreciated the concern about the quality of ventilation in flight. Åsa Englund points out: "It is important that transport of these small ICU infant patients should just be considered as a continuation of the treatment and care they have received at

Carina Ramstedt is Flight Nurse at Swedish Air Ambulance.

The ventilator is securely mounted to the stretcher by means of a special transport cage, which maintains stability throughout the flight.

bedside. They are treated in the pediatric ICU, and during the air transport process the treatment should continue smoothly at the same level as at bedside, the only difference is that we are moving the patient from Point A to Point B."

Single unit concept—infant pod and SERVO-i mounted to the same stretcher

After the different stages of the process, with the discovery of the infant pod solution by the PETS team, and the flight validation of the SERVO-i and transport cage solution by Swedish Air Ambulance, the one unit concept was first utilized during an infant transport flight from Sweden to Dublin, Ireland. Carina Ramstedt recalls the first experience: "The opportunity of mounting the ventilator on the same stretcher where the child is positioned in the pod makes the solution a single unit, which provided a new sense of security. In the past, it has always been a concern with separate lifts of the ventilator and the child, with concern for the tube and risk of extubation. The single unit concept of infant pod and SERVO-i worked very well, and made our work easier."

Annika Schön, who has flown for many years with PETS at Karolinska Hospital in cooperation with Swedish Air Ambulance, agrees that the current single unit solution that so many have contributed to, with the infant pod and SERVO-i ventilator both fixed on the same stretcher has made the process much easier: "Since the children we treat have respiratory problems, we do not like the traditional infant incubator-based transport ventilators. These old traditional infant transport ventilators have a lower level of clinical performance, and sometimes we had to increase sedation for the patient in order to ventilate them on the older transport ventilators. Since we have SERVO-i in the PICU, it delivers ventilation with the clinical performance that is required by these infants with respiratory problems, at bedside in the PICU as well as in the air during transport. This is the most optimal situation for the patient if they receive their treatment on the same ventilator at bedside in the ICU prior to transport, in flight during transport and at bedside at the PICU at the receiving hospital. This also means that treatment parameters, such as settings and sedation levels, can remain the same. For us staff members, it is also optimal from the perspective that we are working with the same equipment in flight that we know and use at bedside in the unit."

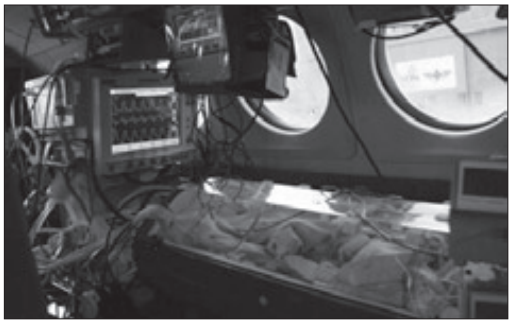
She has also noted increasing trends in acceptance and utilization of the solution: "From November 2006 up to and including the year 2007, we had 27 air transports with the single unit infant pod/SERVO-i ventilator solution. Interestingly, so far [in 2008] in the first four months from January to May 1, we already had 18 transports. There is a growing tendency to request and utilize this solution. I think perhaps it is due to the fact that hospitals throughout the country are becoming familiar with this possibility, contacts have been established and they see that the transport solution has worked well. I think that we have passed an initial level of knowledge and acceptance, and the requests for infant transports with this solution will continue to grow."

Bedside quality ventilation therapy—wherever the infant may be

Dr Hamrin also addressed the benefits of using the same ventilator in the ICU and in the air: "We have many SERVO-i ventilators that are approved for flight, so it is a benefit if the child can continue ventilation on the same ventilator upon arrival without having to switch ventilators. It is what is best for the infant, and reinforces our ambition to provide the same level of quality in ventilation therapy in the air as well as bedside in the PICU." The infants that are critically ill are most often on Pressure Control ventilation, according to Dr Hamrin. "We can change setting parameters during transport, just like we might do bedside in the PICU. We do not usually require muscle relaxants for the infants during transport. Sedation may be used during transport, since the child may be critically ill prior to transport and is sedated at the hospital of origin. We try to use the same trigger settings in transport that have been used at bedside. We try to stabilize before leaving the hospital of origin and want to be satisfied with all treatment parameters, prior to transport, so that the trip goes as smoothly as possible."

The infant clinical situation and need for transport can vary, depending upon each individual patient scenario. Annika Schön

Swedish Air Ambulance Beechcraft 200 aircraft.



The single unit concept, with ventilator and infant pod attached to the same stretcher, has increased ease-of-use and minimized risks, according to staff members.

Annika Schön, RN, has been part of the PETS group at Astrid Lindgren Children's Hospital from the very beginning.

Tova Hannegård Hamrin, MD, is Director Pediatric Anesthesia at Astrid Lindgren Children's Hospital, and has been responsible for the PETS program since 2005.

of the PETS staff has seen different situations throughout the years. "Usually we receive a request for consultancy from another hospital in Sweden, where they might have a case that has a difficult clinical situation, most frequently a child with respiratory insufficiency that is difficult to manage, and they ask for advice. In these situations, we may offer to take this child, with a difficult respiratory insufficiency, to be transported to our center for treatment. Other diagnoses may include sepsis, meningitis, lung disease or perhaps an infant with cardiac difficulties. All of these infants are in need of qualified ventilatory treatment. We also have cases of children receiving Extra Corporeal Membrane Oxygenation or ECMO, which need to be transported, or returned to their home hospital post ECMO treatment. Many of the children with cardiac difficulties have been born with abnormalities and are in need of heart surgery in specialist hospitals in another part of the country. We should also mention here that the infant pod has also been used for children up to 6-8 kilos."

Carina Ramstedt of Swedish Air Ambulance concurs. "We fly everything between short 30 minute jumps to up to 3 hours, with infant transports. Our most frequent route is Stockholm—Malmö, 1 hour and 15 minutes for infants needing heart surgery at Lund University Hospital. But flight length depends upon the destination; to Ireland or other parts of northern Europe it may be 2.5 to 3 hours, and to different regions of Sweden it might be 1-2 hours. Among the longer range flights, we have been to Paris, France where there is a radiologist who is a specialist on birth deformities in infants. When we fly to Dublin, Ireland or to Germany it may be in connection with ECMO cases. Usually these infants are transported post ECMO treatment, and in some cases we have accompanied children to Germany for treatment when the ECMO facility in Sweden has had no available capacity."

The infant transport process—meticulous planning and mobilization

Staff members from PETS and Swedish Air Ambulance are required to follow detailed routines and checklists at each institution, prior to transport. The PETS team members take about one hour to mobilize, from the point of contacting medical staff at home, who initiate the preparation process on the way to the hospital, depending upon the patient situation. According to Dr Hamrin, the same routines and checklists are followed, whether the patient transport is land based, helicopter or fixed wing aircraft. "We have different partners for each alternative, and we always choose the appropriate transport alternative depending upon the patient situation. We receive a call from a referring hospital, often from an intensive care physician, and we find out as much as we can about the clinical situation; which medications the child has received, type of ventilation therapy, drains and which infusion pumps are being used. This gives us a picture of the situation in regard to what we need to bring with us for this particular patient.

"We have a transport inventory where we keep our equipment, and where we have packed and sealed transport bags for different patient age groups; newborn infants, small children and teenagers who are almost fully grown. If the child is receiving a certain type of medication that we normally do not keep in inventory, we make sure that we have it with us. We keep a standard assortment of materials in the bags, which are always filled and on standby, but there can be special needs to customize in special situations. We test all equipment before we leave, see that the batteries are charged for the monitors and infusion pumps, and anything that runs on electrical current. We also double-check if we need oxygen or NO with us.

"These preparations are mainly logistical, but critical for us to ensure that everything works as smoothly as possible when we receive the child. It is an advantage that we have a relatively small size working group, and once you have done a certain number of transports, the logistics become routine fairly quickly. When we return to our hospital, we complete the patient records and equipment log sheets, and see to it that the equipment is in good working condition for the next transport, we refill the bags and inventory to replace anything that has been used. The bags are then sealed so the next staff members on the next transport can feel confident that everything is in order."

Routines and checklists are also carefully followed by the Swedish Air Ambulance group, according to Åsa Englund: "The care team is a combination of PETS staff members and the aircraft staff, or 3 persons in total. One aircraft nurse, who is an anesthesia nurse responsible for the cabin and the

equipment and safety within the aircraft, and one PETS nurse, who can be a pediatric anesthesia nurse or a pediatric intensive care nurse, and one pediatric anesthesiologist from PETS accompanies the patient. Usually there is no room in the aircraft for family members, who have to make the trip on a commercial flight. Each transport situation is unique and requires careful preparation, in terms of the flight and the patient. We follow thorough and detailed checklists."

Prepared for any eventuality

In attending to infant care in flight, the noisy environment can often be a challenge in a fixed wing aircraft and especially on helicopter flights, according to Annika Schön. "It can be problematic to hear equipment alarms during flight, which means that it is especially important that the user interface has a good and clear visual display."

As an anesthesiologist, Dr Hamrin addresses additional challenges in treating ventilated infants in transport. She says that the worst case scenario would be an accidental extubation and losing the airway, requiring re-intubation. "Fortunately this has never happened to us. Another negative case scenario would be cases with diaphragmatic herniation with high airway pressures, where there is a risk of pneumothorax, but fortunately that has never happened to us either. However, we do plan and prepare to be able to handle any type of situation." The new technology and solutions have also contributed to minimizing these risks.

Intensive care transport trends in the future

Representatives from both groups shared the opinion that the trend for air transports of ventilated patients will continue to grow in the future. In regard to the infant transport solution, Annika Schön feels that there is still potential for further development of the concept. "The next step is perhaps a bit larger stretcher for larger children, where the ventilator can also be mounted to serve as a one unit concept. And developments for weight reduction will continue to be important—weight is always a factor for consideration in air transports."

Åsa Englund expressed that the limitations of current land based ambulance models will continue to be a factor for increases in air transports. "I believe that the number of transports will steadily increase, even in the adult patient category. In terms of adults, there is a problem today that conventional ambulances are limited and cannot transport intensive care patients, and there are very few mobile ICU ambulances that are equipped and tested."

Dr Hamrin cited the needs of continuing development and the increasing focus on centralization and quality care in transport as important issues for the future. "There is a need for continued development. Weight and space are always important issues in transport situations and will continue to be so. Alarms can be difficult to hear in the air, especially in helicopters. This means that we continuously need to keep our eyes on the user interface screen, and to be able to see the screen values and alarms clearly.

"There is an increasing tendency to centralize specialized treatments at certain centers, which means an increase in the need for patient transports. There is a movement to more and more quality care during the transport. I think that if you are going to transport intensive care patients, by whatever means, the goal must be to provide the same level of intensive care treatment, and not to accept a lesser level of care during the transport, after receiving the patient. That simply is indefensible."

Biography

Tova Hannegård Hamrin received her medical degree at Karolinska Institute, Stockholm, Sweden in 1990. Her internship and residency in Anaestesiology and Intensive Care took place at Sundsvall Hospital, Sweden 1990-1994. She was certified as a specialist of Anesthesia and Intensive Care by the Swedish National Board in 1998 and worked as a specialist at Stockholm South Hospital, Sweden from 1994-2001. Dr Hamrin was Specialist in Paediatric Anesthesiology and Intensive Care from 2000 to 2007 at Astrid Lindgren Children's Hospital, Karolinska University Hospital, Stockholm, Sweden. She currently holds the position of Director, Paediatric Anaesthesia at Astrid Lindgren Children's Hospital and has been responsible for the PETS (Paediatric Emergency Transport Service) program from 2005 to the present time.

Annika Schön obtained her initial nursing degree in 1986, and worked initially in the adult intensive care unit of St. Göran's Hospital in Stockholm. She received her nursing degree in anesthesiology at the Karolinska Institute University Hospital in 1990-1991, where she also worked within the central anesthesia clinic, as well as within intensive care in the ambulance service at that institution. Annika Schön has held positions within pediatric intensive care at St Göran's Hospital since 1995 and at the Astrid Lindgren Children's Hospital in 1998, where she has been part of the PETS (Paediatric Emergency Transport Service) group from the start. Annika Schön is also currently working to achieve her PhD degree at the Institute for Women's and Children's Health at the Karolinska Institute. Åsa Englund received her initial nursing degree in 1987, and her nursing degree in anesthesiology in 1993. She was employed as an emergency room nurse at the Halmstad Community Hospital in 1988 and as an anesthesia nurse at the Varberg Community Hospital in 1993. During the years of 1999-2000, Åsa Englund was employed as registered nurse on an international cruise ship, with nursing responsibility for guests as well as for fellow staff members from over 50 countries. Åsa Englund started working at SOS Flygambulans (currently named Svensk Flygambulans—Swedish Air Ambulance) in 2001 as head nurse with responsibility for 15 nursing staff members. She became Operations Manager for the company in 2006, in charge of over 30 staff members and responsible for the medical department, marketing and property and operations. Åsa Englund became acting Managing Director of Swedish Air Ambulance in 2007. In this capacity she is currently responsible for corporate accounting, PR, marketing and chief of staff, and is a member of the management group as well as the board of directors. She also retains overall responsibility as Ambulance Chief for the flight planning center and medical departments. Carina Ramstedt obtained her initial nursing degree in 1973 and her nursing degree in anesthesiology at Uppsala University Hospital in 1976. From 1976 to 1986, Carina Ramstedt was employed as a nurse at the Pediatric Intensive Care Unit of Queen Silvia's Children's Hospital in Göteborg. She has also worked as an ambulance nurse as well as nursing positions within coronary care and neurosurgical departments. Carina Ramstedt was also employed by the Swedish Defence Department as a field nurse with assignments in Lebanon in 1990 and in Bosnia- Herzegovina in 2000. She is currently employed as Flight Nurse at Swedish Air Ambulance, where she has been working since 2001.

Towards a Sane and Rational Approach to Management of Influenza H1N1 2009

William R. Gallaher

Abstract

Beginning in March 2009, an outbreak of influenza in North America was found to be caused by a new strain of influenza virus, designated Influenza H1N1 2009, which is a reassortant of swine, avian and human influenza viruses. Over a thousand total cases were identified with the first month, chiefly in the United States and Mexico, but also involving several European countries. Actions concerning Influenza H1N1 2009 need to be based on fact and science, following recommendations of public health officials, and not fueled by political, legal or other interests. Every influenza outbreak or pandemic is unique, so the facts of each one must be studied before an appropriate response can be developed. While reports are preliminary, through the first 4 weeks of the outbreak it does not appear to be severe either in terms of the attack rate in communities or in the virulence of the virus itself. However, there are significant changes in both the hemagglutinin and neuraminidase proteins of the new virus, 27.2% and 18.2% of the amino acid sequence, from prior H1N1 isolates in 2008 and the current vaccine. Such a degree of change qualifies as an "antigenic shift," even while the virus remains in the H1N1 family of influenza viruses, and may give influenza H1N1 2009 significant pandemic potential. Perhaps balancing this shift, the novel virus retains more of the core influenza proteins from animal strains than successful human influenza viruses, and may be inhibited from its maximum potential until further reassortment or mutation better adapts it to multiplication in humans. While contact and respiratory precautions such as frequent handwashing will slow the virus through the human population, it is likely that development of a new influenza vaccine tailored to this novel Influenza H1N1 2009 strain will be essential to blunt its ultimate pandemic impact.

Introduction

On April 9, 2009 it became apparent to public health officials in Mexico City that an outbreak of influenza was in progress late in the influenza season.[1] On April 17, two cases in children were also reported in California near the Mexican border.[2] Virus samples were obtained and the virus determined to be a novel strain of influenza A of the H1N1 serotype. Preliminary tests conducted by the Centers for Disease Control and Prevention (CDC) indicated that the virus was a novel reassortant, containing genetic elements of influenza viruses found in swine, birds and human beings.

Influenza virus, an enveloped virus of the Orthomyxoviridae family, has a unique capacity for genetic variation that is based in two molecular features of the virus family.[3] First of all, the surface proteins of the virus are highly variable, able to mutate up to 50% of their amino acid sequence and still perform their functions in infection. Secondly, the viral genome is segmented, with eight RNA segments that are genetically independent of one another. In a mixed infection of different influenza genotypes, these segments can almost randomly reassort resulting in hybrid genotypes with some segments derived from one virus strain, while the other segments are derived from a second strain.

Less than one month later, hundreds of probable cases of infection by this novel virus, designated Influenza H1N1 2009, had been identified, with 26 deaths, centered about the area of Mexico City. An additional several hundred probable cases had been identified in the United States,[4] most associated with recent travel to Mexico, and concentrated in California, Texas and New York. Sporadic cases, also associated with travel to Mexico in large part, were found in several European countries as well. The World Health Organization (WHO) began to declare ever higher stages on its "pandemic" scale, designating the novel Influenza H1N1 2009 a potential threat to worldwide health.[5] Press coverage and involvement of public officials in the response to the novel virus has reached epic proportions.

This commentary is intended to review and analyze the salient facts of the outbreak and the molecular sequence of the principal external antigens of Influenza H1N1 2009. The discussion will focus on the implications of this analysis for the continued course of the outbreak and the medical response.

Discussion

Actions concerning Flu H1N1 2009 need to be based on fact and

The author is with the Department of Microbiology, Immunology and Parasitology, Louisiana State University Health Sciences Center, New Orleans, LA. The author thanks the Editor-in-Chief, Dr. Robert Garry, for the invitation to write this commentary, and helpful comments on the draft manuscript. Reprinted from BioMed Central, Virology Journal,

science, following recommendations of public health officials, and not fueled by political, legal or media interests and hysteria. This is time for calm, thoughtful action, and not the panic we have seen spread around the globe inspired by media reports. When 10 schools or an entire school district are closed due to one suspected case of influenza, we might well ask if our response has been measured and appropriate. The good faith of the public is a precious commodity. When one day a pandemic is trumpeted, and the next day the outbreak is called no more than normal flu and under control, and then a call goes out for a multibillion dollar vaccine program to defend against a major pandemic, one risks the public feeling whiplash and the credibility of public officials being damaged.

Further, every measure of response has a cost-benefit ratio that needs to be carefully considered, which is best done in collaboration with public health professionals. We have seen unnecessary and useless quarantines, interdictions of trade and excessive closures which cannot be sustained and have little if any benefit. Travel in and out of Mexico has been severely disrupted, but not to New York City which also has many confirmed cases. A cruise ship plies the Pacific, avoiding Mexican ports with little or no influenza activity, but plans to host its passengers an extra night in San Diego, with a higher number of H1N1 cases in the area than most areas of Mexico. At some point in what will probably be a long engagement with this new influenza strain, a more precisely targeted and rational response will be needed.

The Enigma of Response and Responsibility

Every influenza outbreak or pandemic is unique, so the facts of each one must be studied before an appropriate response can be developed.[3] No actual pandemic matches the theoretical influenza pandemic or past history. Each must be judged on its own evolution. The only really accurate assessments have been retrospective, after years or decades of further analysis, so it is important for both the scientific and general public to understand that decisions will need to be made using the best information available at the time and will be fallible. There can be no standard playbook. However, fallible does not mean irrational. Even though elected and corporate officials are charged with the responsibility to make such decisions, and no one wishes to be found negligent in retrospect, the best course is to closely follow the recommendations of recognized experts in the field of influenza virology and public health who have made the study and understanding of this viral disease their life's work. The WHO, CDC, academic virologists and physicians, and state epidemiologists know their business and should be trusted to guide public policy. An elected official cannot and should not try to reproduce and override, with an hour's briefing, their cumulative decades of experience. This is no time to haul out tired agendas concerning immunization or immigration or cultural and ethnic biases, using influenza for cover.

Nature of the Outbreak to Date

This virus constitutes a serious threat not based on the outbreak thus far, which has been, in historical terms, very limited in the total number of probable cases, but rather on the potential of the virus. To date, influenza H1N1 2009 has not made a very successful penetrance into the human population. Even if 22,000 in Mexico City were infected, a high estimate, it would constitute only 0.1% of the population of 22 million—one of the more populous metropolitan areas on earth. In contrast, in a "normal" influenza season, with an "ordinary" strain of influenza, there

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Hemagglutinin (Attachment) HA1

A/California/08/2009(H1N1)
A/USA/WRAMC-1154048/2008(H1N1)

DTLCIGYHANNSTDTVDTVLEKNVTVTHSVNLLEDKHNGKLCKLRGVAPL 50
  X                              XX      X X X
DTICIGYHANNSTDTVDTVLEKNVTVTHSVNLLENSHNGKLCLLKGIAPL

HLGKCNIAGWILGNPECESLSTASSWSYIVETPSSDNGTCYPGDFIDYEE 100
X  X XX           X XXXX       X XXX       X X
QLGNCSVAGWILGNPECELLISKESWSYIVEKPNPENGTCYPGHFADYEE
 Site C         Site E

LREQLSSVSSFERFEIFPKTSSWPNHDSNKGVTAACPHAGAKSFYKNLIW 150
                    X      XXXX  X X X X XX   X  X
LREQLSSVSSFERFEIFPKESSWPNHTVT-GVSASCSHNGESSFYRNLLW
                                  Site A

LVKKGNSYPKLSKSYINDKGKEVLVLWGIHHPSTSADQQSLYQNADAYVF 200
 XX XXX  X     X X X        X   XXXX  XX  XXXX   X
LTGKNGLYPNLSKSYANNKEKEVLVLWGVHHPPNIGDQKALYHTENAYVS
    Site B                          *   Site B

VGSSRYSKKFKPEIAIRPKVRDQEGRMNYYWTLVEPGDKITFEATGNLVV 250
 X  X  X  X    X          X      X    X X   X   XX
VVSSHYSRKFTPEIAKRPKVRDQEGRINYYWTLLEPGDTIIFEANGNLIA
    Site D           ** *

PRYAFAMERNAGSGIIISDTPVHDCNTTCQTPKGAINTSLPFQNIHPITI 300
      XX XX     X XX XXX XXX    X    X      X  X
PRYAFALSRGFGSGIINSNAPMDKCDAKCQTPQGAINSSLPFQNVHPVTI
                     Site C

GKCPKYVKSTKLRLATGLRNIPSIQSR 327
 X     X X   XX
GECPKYVRSAKLRMVTGLRNIPSIQSR
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Figure 1. Amino acid sequence alignment of Influenza. An amino acid sequence alignment of Influenza H1N1 2009 with its predecessor HIN1 virus isolated the previous year, in 2008, at Walter Reed Army Hospital in Washington, DC.

are 200,000 cases and 36,000 deaths in only a few months each winter in the United States alone.[6] Classic pandemic flu attack rates are, unfortunately, far higher. Indeed, influenza is in a class of its own for its potential ability to infect enormous numbers of humans in a very short period of time—thus far with H1N1 2009 we are not even close to that level. This may technically be a "pandemic" in the sense of human-to-human virus transmission of a novel virus in more than one region of the planet, but would not yet be recognizable as an influenza pandemic to anyone who has lived through one.

There are two very separate meanings for "severity" when discussing influenza. One relates to the virulence of the virus in any given host; the other to the attack rate, or numbers of cases of infection per unit of population. Thus, one can have a "severe" pandemic, affecting millions of human beings, with a relatively avirulent—not severe—influenza virus that results in relatively few hospitalizations or deaths. On the other hand, one can have a limited outbreak, such as Southeast Asia has experienced in recent years with bird flu, with a highly virulent, severe virus that produces very high percentages of hospitalization and high mortality.

While it is very early to properly evaluate public health reports and statistics, the Influenza H1N1 2009 outbreak thus far does not appear to be severe in either respect. However, within the viral genetic sequence there is at least the potential for a severe pandemic. Also, an unusually high number of cases appear to be in previously healthy young adults, a feature found more commonly in the more virulent influenza viruses.

Since influenza was first isolated in the 1930s, it has been axiomatic that the severity of an epidemic or pandemic is proportional to the susceptibility of the human population, which is in turn directly related to the degree of change in the surface proteins of the virus, the H and N antigens.[7] The greater the change, the less that preexisting human antibodies to influenza can neutralize the virus, and the lower the "herd immunity" of the entire human population. Minor incremental changes in these antigens, denoted as "antigenic drift," lead to mild outbreaks. Major, sudden changes in these antigens, denoted as "antigenic shift", have led to the major pandemics of influenza in the 20th century. There has not been a major antigenic shift in human influenza since 1968.

Changes in the Hemagglutinin

The major component of influenza virus that determines its epidemiological dynamic is the predominant surface protein on the viral envelope, the H antigen. This protein serves as the hemagglutinin or HA1 attachment protein. It determines whether the virus is able to bind to and infect cells of different species by its ability to attach to carbohydrate receptors on the cells. The protein loops that determine the sites of binding for antibody dominate the immune response to the virus. Thus the H antigen is the principal component of any influenza vaccine and the efficacy of the vaccine is measurable by determining the ability of the elicited antibodies to neutralize viral binding.

Figure 1 shows an amino acid sequence alignment of Influenza H1N1 2009 with its predecessor HIN1 virus isolated the previous year, in 2008, at Walter Reed Army Hospital in Washington, DC. (The 2008 virus is in turn identical in amino acid sequence to the H antigen in the current influenza virus vaccine.) Each change in the sequence of Influenza H1N1 2009 from the 2008 virus is marked with an "X" in the alignment. It is obvious that H1N1 2009 is significantly novel, 27.2% different from the human H1N1 virus circulating in 2008 and the H antigen in the current vaccine. Also noted in the figure are the canonical sites for N-linked glycosylation of the protein, at NxS/T motifs (underlined), as well as the approximate positions of amino acids that determine the antigen specificity at five different protein loop regions on the surface of the protein, designated Site A through Site E.[8] It is obvious that the changes in amino acid sequence are concentrated in these antigenic sites. Additionally, one of the sites, Site C, may be blocked by a novel N-linked glycosylation at N277. All five of the known antigenic sites on the protein are therefore unique, and so no human herd immunity to this virus is to be expected anywhere in the human population of 6.77 billion persons. This constitutes a major antigenic shift which has in the past been the basis of major human pandemics. Additional sequence comparison (not shown) indicates that, as stated by others in the press several times, Influenza H1N1 2009 is not similar to the 1918 pandemic influenza virus (18% different), and not similar to the 1976 swine flu from Ft. Dix, New Jersey (12% different). Also, the amino acids most critical in specifying receptor usage,[9] indicated in the sequence alignment by asterisks, are identical to current human H1N1. Thus the spectrum of human infection in the respiratory tract is not likely to be unusual relative to the 2008 H1N1 or other recent influenza strains. These are positive features of the virus arguing for a lower level of virulence.

Changes in the Neuraminidase

The second external protein of influenza virus, constituting 20-25% of the surface proteins, is the N antigen. This protein is an enzyme named neuraminidase for its ability to cleave neuraminic or sialic acid from complex carbohydrates such as mucins. In infection it serves to allow release of newly produced virus from surface receptors and to digest mucous secretions, allowing the virus better access to the surface of susceptible cells and spread through the respiratory tract. Its value as a spreading factor is underscored by the fact that the currently licensed antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) function as neuraminidase inhibitors. In the absence of herd immunity to the H antigen, partial protection can be provided if the same or similar N antigen is retained. Eickhoff and Meiklejohn showed that the infection rate with the H3N2 virus was reduced up to 50% in Air Force cadets who had received the H2N2 vaccine, due to the shared N2 antigen remaining identical.[10] If the N1 antigen of the 2009 virus proved to be similar to that of 2008, even with an antigenic shift in H, then some cross protection from prior H1N1 infection or the 2008 vaccine might be expected. Unfortunately, in the case of influenza H1N1 2009, the N1 antigen also is significantly novel, differing by 18.2% from the 2008 H1N1 virus. While the antigenic sites within the N antigen are less well defined (reviewed in 11), the pattern of changes in the N antigen of the 2009 virus (not shown) are not encouraging. No cross protection is likely.

Implications from Sequence Changes in H1N1 2009

Overall, it is clear from the sequence alignments of the Influenza H1N1 2009 virus that, even though this virus is still basically in the family of H1N1 viruses, the sequence changes indicate a significant antigenic shift in both surface antigens. The last time such an antigenic shift occurred in both H and N antigens was the 1957 Asian H2N2 pandemic.

A factor present in 1957 was that there was serological evidence that those over 60 years of age retained an anti-H2N2 antibody response from prior exposure to the virus before 1900.[12] This blunted the effect of the 1957 pandemic in the elderly. This factor is not expected in the case of H1N1 2009, since there is no evidence that a virus with a similar antigenic profile has circulated in the human population in over 100 years.

Neither Swine Nor Mexico Are to Blame

The outbreak is due to a rare recombination of influenza gene segments from swine with avian and human influenza. Once this one time event occurred, swine are not a significant immediate source of the human version of influenza H1N1 2009, and the virus cannot be acquired from handling or eating pork. The consensus among virologists is that the actual natural host and ultimate source of influenza variants is migratory waterfowl.[13] The prospective slaughter of pigs in Egypt, and the international interdiction of imported pork, have no rational basis in science or public health.

As for this being a "Mexican" virus, analysis of the H sequence by BLAST[14] reveals that the closest relative to the Influenza H1N1 2009 virus previously isolated is in fact a virus 95% identical to it, from swine in Indiana in 2000 (eg A/Swine/Indiana/P12439/00 (H1N2)). Border interdiction makes no sense when the H gene is All-American, having been in Indiana longer than the Head Coach and most of those playing football for Notre Dame. Similarly, the closest neuramindase sequence, 94% identical, is one isolated in Britain and elsewhere in Europe in the 1990s (eg A/Swine/England/195852/92 (H1N1)). The parts of the virus may well have been imported into Mexico, and accidentally assembled the new influenza 2009 virus there, leading to emergence by

pure happenstance. Such emergence can happen anywhere. Retrospective analysis revealed that the 1918 H1N1 virus, dubbed the "Spanish" flu for decades, is likely to have arisen in the United States.[15] Assigning blame or even a country of origin for an emergent virus is a dubious exercise more likely to reinforce cultural bias and prejudice, and ignite non-cooperation, than to be helpful in controlling influenza.

Factors Predisposing to Control of Influenza H1N1 2009

Two additional facts concerning the virus are positive. First, while the most successful pandemic influenza viruses have changed only the H and N antigens and retained the same human core proteins of the virus, influenza H1N1 2009 has several more components from animal flu strains than the H2N2 and H3N2 viruses of 1957 and 1968, respectively. This may make the 2009 virus less compatible with effective replication in humans, which may in turn be holding it back in its penetrance of the human population. Second, the 2009 virus is sensitive to the two neuraminidase inhibitors licensed as antiviral drugs. A reasonable conclusion from these last two facts is that there is no evidence at all that this is a bioterror event, but rather a novel virus perpetrated by nature alone.

Immediate Prospects for Control

The outbreak appears to be waning or controlled at its origins and certainly not growing logarithmically or of truly pandemic proportions. However, influenza exhibits marked seasonal occurrence even in pandemic years. We have reached the end of the classic flu season in the Northern Hemisphere, and not yet begun that season in the Southern Hemisphere. The outbreak could wane even if we were not doing everything right; indeed it could wane even if we were doing everything wrong, simply because that is what the flu does this time of year. Its true potential may not be revealed until the onset of the flu season in the Northern Hemisphere in October or November of 2009.

The greatest instability of a novel human virus is when it first enters the human population and is under very heavy selective pressure in the environment of the human respiratory tract. As the influenza season in the Northern Hemisphere ends, the virus could simmer for months and co-circulate with the 2008 strains of influenza. While recombination events in the human population have not been documented, the virus could shed more genes from its animal sources, acquire more human influenza genes and become better adapted to human replication and spread. A virus with the new coat of H and N antigens, built onto the core of prior successful human pandemic influenza viruses, could be a threat exceeding anything we have seen since 1918, given the great increase in human populations over the last 50 years. Further reassortment of viral genes in pigs are also possible.[16] Alternately, incremental mutations in other genes of the virus may achieve the same result of enhanced replication in humans without further recombination. There is simply no way to tell where H1N1 2009 will evolve. The only honest answer to the question of how this outbreak will evolve over the next 6 to 18 months is: "I don't know."

General Planning for a Long-Term Response

It is for the continued circulation of an enhanced H1N1 2009 that we should plan, and develop a vaccine based on the novel H and N antigens. Given only a few months, and a worldwide capacity of only about 500 million doses of human vaccine using present methods, use of vaccine and antivirals must be rational and carefully controlled. Already there is evidence that Tamiflu is in high demand disproportional to actual cases, indicating possible attempts to either use the drug for prophylaxis or to horde it for later use. If true pandemic attack rates are reached later this year or next, there is risk that medical professionals would lose control of a valuable resource to treat the ill. Recall that when only a few individuals received letters laced with anthrax, the antibiotic ciprofloxacin became scarce very quickly. Measures need to be taken to assure that a similar scenario is not possible with the limited amount of antivirals available.

Common sense preventive measures, such as frequent handwashing and discretion on close personal human contact, and carefully targeted school and worksite closures, will buy time and slow down the outbreak, until an effective multi-year vaccine program can provide the best prevention. While influenza virus can survive on inanimate surfaces, it is spread most easily by direct human contact. Contact control among human beings, maintaining literally an arm's length from others wherever practicable, and staying home when sick, will achieve more than all the antiseptic wipes and face masks that can be manufactured. The CDC and WHO are actively promulgating behavioral changes that can reduce the circulation of influenza.[17]

Further education and preparation of health care workers and first responders to deal with an influenza pandemic is critical. Only a physician over 60 years of age was even in medical school when the last and mildest influenza pandemic took place in 1968. Only a physician over 70 was in medical school during the last pandemic when both the H and N antigens exhibited significant change, with massive morbidity worldwide in 1957. Few working in virology or the health field today know an influenza pandemic except through the eyes of a child. If and when it happens, it will change our entire frame of reference for epidemic respiratory disease.

Future Strategies

There is also need for enhanced influenza research and development. The priority of influenza waned in the absence of a pandemic, coupled with the availability of drugs and what seemed to be adequate vaccine technology. However, the antivirals will never have been used to the extent that is likely should this H1N1 2009 outbreak continue. If resistance to these antivirals were to develop due to their overuse and misuse, much as in the case of antibiotics for bacteria, then there is currently no backup drug to combat the virus. Antivirals that inhibit infection and fusion have been developed for viruses such as human immunodeficiency virus (HIV)[18] that have very similar entry mechanisms, and should be developed for influenza as well.

As for the influenza vaccine, it is still produced by relatively archaic methods developed in the 1930s to 1950s using mass quantities of embryonated chicken eggs. We are not far beyond the pioneering days of Goodpasture, Woodruff, Buddingh and Francis in this regard.[19] Each dose of flu vaccine requires the use of 1.2 live eggs, or about 600 million embryonated eggs to produce 500 million does of virus for 6.77 billion people. The math is not encouraging. Vaccines targeting viruses such as measles, mumps, rubella and hepatitis B employ cell culture or recombinant technologies and have superior safety characteristics. Programs for greater efficiency in producing effective and safe influenza vaccines have been too long delayed in development and need to be implemented quickly, to assure that this and future threats of pandemic influenza can be met.

Over the long run, immunization provides the best preventive strategy against influenza virus. Critics revel in citing the 1976 swine flu vaccine, which produced 25 vaccine-associated deaths due to Guillain-Barre syndrome while the virus itself only resulted in one death at Fort Dix, NJ. However, such vaccine-bashing ignores the fact that this fatal complication occurred in only 1 in a million vaccinees, and was not seen either before or since that immunization campaign.[3] Many hundreds of millions of doses of trivalent H1, H3 and B influenza vaccine have been administered over the intervening 30 years without significant complications, while saving countless lives.

As a patient with significant cardiopulmonary disability, I have had clinical influenza three times in my life, in 1948, 1965 and 1974, and been hospitalized twice with secondary pneumococcal pneumonia. Since 1977 I have been routinely administered the influenza vaccine, and not only have I been free of influenza since then, but have twice nursed a spouse to health through influenza. To those critics of influenza immunization I can only say that I am certain that I would choose immunization over the disease, even at the risk of complications or the rare possibility of a vaccine associated death. To be frank, when I look at the changes in the H1N1 2009 hemagglutinin from the 2008 virus, I see in them the face of my possible executioner. If they need someone to be first in line to receive the new H1N1 2009 vaccine, I hereby volunteer.

Overall, development of antiviral immunizations have long been recognized as the most cost efficient use of public dollars in the entire health field, both in lives saved and economic impact.

Conclusions

Influenza H1N1 2009 is a novel virus quite unlike even the other H1N1 influenza viruses that have preceded it as agents of human influenza. The fact that its hemagglutinin is 27.2% different and its neuraminidase is 18.2% different in amino acid sequence from the 2008 H1N1 and vaccine virus strains give Influenza H1N1 2009 significant pandemic potential, based on historical pandemics of the 20th century. However, it has yet to prove that potential in what is an outbreak with low community attack rates and modest virulence. Further evolution of the virus toward a more efficient agent of human disease may yet enable it to produce a major pandemic. The future course of the outbreak cannot be predicted, but prudence dictates that a new influenza vaccine, targeted to the novel influenza H1N1 2009 sequence be quickly developed and prepared for worldwide administration. In the absence of existing human "herd" immunity to this virus, only immunization provides a significant hope of suppressing the long-term impact of this newly emergent virus.

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Systematic Review of Worldwide Variations of the Prevalence of Wheezing Symptoms in Children

Swatee P. Patel, Marjo-Riitta Järvelin, Mark P. Little

Abstract

Background: Considerable variation in the prevalence of childhood asthma and its symptoms (wheezing) has been observed in previous studies and there is evidence that the prevalence has been increasing over time.

Methods: We have systematically reviewed the reported prevalence and time trends of wheezing symptoms among children, worldwide and within the same country over time. All studies comprising more than 1,000 persons and meeting certain other quality criteria published over a 16-year period, between January 1990 and December 2005, are reported and a comparison of ISAAC (International Study of Asthma and Allergies in Childhood) and non-ISAAC studies is made, in part as a way of expanding the power to examine time trends (the older studies tend to be non-ISAAC), but also to examine possible methodological differences between ISAAC and non-ISAAC questions.

Results: A wide range of current prevalence of wheeze was observed between and within countries over time. The UK had the highest recorded prevalence of 32.2% in children aged 13-14 in 1994-5 and Ethiopia had the lowest prevalence, 1.7% in children aged 10-19 in 1996. All studies in Australia and the UK were compared using multiple logistic regression. ISAAC phase I and III studies reported significantly higher prevalence of current wheeze (OR=1.638) compared with non-ISAAC studies, after adjusting for various other factors (country, survey year, age of child, parental vs child response to the survey). Australia showed a significantly higher prevalence of current wheezing (OR=1.343) compared with the UK, there was a significant increase in the prevalence odds ratio per survey year (2.5% per year), a significant decrease per age of child (0.7% per year), and a significantly higher response in current wheezing if the response was self-completed by the child (OR=1.290). These factors, when explored separately for ISAAC and non-ISAAC studies, showed very different results. In ISAAC studies, or non-ISAAC studies using ISAAC questions, there was a significant decrease in current wheezing prevalence over time (2.5% per year). In non-ISAAC studies, which tend to cover an earlier period, there was a significant increase (2.6% per year) in current wheezing prevalence over time. This is very likely to be a result of prevalence of wheezing increasing from the 1970s up to the early 1990s, but decreasing since then.

Conclusions: The UK has the highest recorded prevalence of wheezing and Ethiopia the lowest. Prevalence of wheezing in Australia and the UK has increased from the 1970s up to the early 1990s, but decreased since then and ISAAC studies report significantly higher prevalences than non-ISAAC studies.

Background

Considerable variation in the prevalence of childhood asthma and its symptoms (in particular, wheezing) has been observed in previous studies and there is evidence that the prevalence has been increasing over time. These differences may, in part, be due to geographical variations and due to methodological problems in defining asthma symptoms.

There is a multiplicity of endpoints used to define and diagnose asthma in an individual. For example, diagnosis is often based on a detailed medical history, including family health history, combined with examination of the upper and lower respiratory tract. Typically, this information is combined with information from laboratory tests. However, diagnostic criteria often differ between doctors in the same locality as well as between countries, and access to health care in different countries can also have an influence on the reported prevalence of doctor-diagnosed asthma.

Epidemiological studies have used different methods of measuring asthma prevalence and its symptoms in surveys. Questionnaires are administered, and depending on the wording of the questions asked, there has been variation in the symptoms elicited. The symptoms may not be present on a particular day,

Swatee Patel is with the School of Health and Social Care; Authors Järvelin, Little and Patel are with the School of Health and Social Car, The University of Greenwich, London. The authors wish to thank Madeline Kirk for help with journal article retrieval from University libraries and to Vicki Bradshaw for her assistance in part of the literature review. Reprinted from BioMed Central, Environmental Health,

so a one-year period prevalence is often used in epidemiological studies to allow for seasonal variation.

In self-reported asthma, questions are usually asked about wheezing, chest tightness, breathlessness and coughing, but studies have shown that wheezing is the most important symptom for the identification of asthma in epidemiological studies. Some studies have shown that self-reported wheeze has reasonably good specificity and sensitivity for bronchial hyper-responsiveness both in children and adults. Wheeze is rarely a symptom of other diseases, in particular emphysema or chronic bronchitis, which are rare in children, but it is very often indicative of acute viral infection, which is common in this age group.

Doctor diagnosed asthma has been shown to have a lower prevalence than the actual symptoms reported by the individual. Until the early 1990's, there was no standardized method of comparing asthma prevalence between countries. Only a small number of studies had used common protocols. In 1991 the International Study of Asthma and Allergies in Childhood (ISAAC) was set up to achieve uniform diagnostic criteria. Their first worldwide epidemiological study, Phase I, was carried out in 1994-95. It included 56 countries and reported the prevalence of asthma symptoms in 6-7 year old children and in 13-14 year old adolescents. The Phase III study used the same research design as Phase I, but was carried out in 2002-03. The Phase II study comprised a much more detailed investigation of possible correlates of childhood asthma, in particular eczema, and in contrast to ISAAC Phase I and III used 9-11 year old children. The ISAAC questionnaire is now widely used to assess self-diagnosed asthma by asking about the symptoms.

This review has been carried out to assess and summarise the extent of the literature published on wheezing symptoms in children, which includes not only ISAAC but also all non-ISAAC studies that fulfilled specific quality criteria. There are many studies published which are not ISAAC and it is worthwhile to combine the published literature in a review such as this. We report the prevalence and time trends of current symptoms of childhood wheezing in the past 12 months in all studies, worldwide and within the same region over different time periods, and compare the results of ISAAC and non-ISAAC studies. A particular focus of parts of the analysis are studies in the UK and Australia, because of the large number of studies carried out in these two countries—we examine in some detail differences in time trends of wheeze between the two countries. As we shall see, there are distinct, and perhaps surprising, differences between these two developed countries. In what follows one should note the distinction between the underlying medical condition, "asthma" and its principal symptom, "wheezing"; however, as above, we are referring in all cases to studies of wheezing symptoms.

Methods

Studies included in this systematic review had to satisfy the following requirements:

1. listed in Medline or Embase databases; 2. published in the period January 1990 to December 2005; 3. using the keywords: prevalence AND asthma or wheeze or wheezing and child or children or adolescent; 4. full journal articles (rather than abstracts) published in English; 5. epidemiological studies of sample size greater than 1000; 6. prevalence of 'current wheezing' is reported.

In most epidemiological studies of the prevalence of asthma symptoms, two main types of questions are used: (i) Current asthma/wheezing, which is normally a period prevalence, and where the question asked is often of the form Have you had asthma/wheezing in the past 12 months?; (ii) Lifetime asthma/wheezing, in which the question is often, Have you ever had asthma/wheezing at anytime in the past?

Results

From the literature search, 2,839 abstracts were listed in Medline, and 2,844 in Embase, from which 712 full articles were selected for further investigation after reviewing the abstracts. From these, 180 satisfied the above criteria. Some articles had referred to the same data set, thus there were 127 distinct studies reported in this review.

There is a very wide range of current prevalence of wheeze between and within different countries. The UK reported the highest prevalence of current wheeze in the world, 32.2%, in children aged 13-14 in 1994-1995. Ethiopia had the lowest prevalence, 1.7% in children aged 10-19 in 1996.

The USA had the largest number of published studies. A nationwide survey in the USA between 1988-1994 showed that the current prevalence of wheezing among 2-3 year olds was 26.4% and among 9-11 year olds was 13.4%. The highest prevalence rates were recorded in North Carolina, 26.1% in children aged 13-14 in 1999-2000. In the rest of North America, Canada had recorded substantially higher prevalence rates in children aged 13-14 (30.6% in Hamilton and 24.0% in Saskatoon) than in children aged 6-7 (20.1% in Hamilton and 14.1% in Saskatoon). The study in Montreal in 6-12 year olds showed very low prevalence of current wheezing, 5.1%; it has been shown that this is likely to be due to unsatisfactory translation of the term wheezing into French, in another study carried out in Quebec. Mexico had the lowest prevalence of current wheezing (<10%). In Central America, both Costa Rica and Panama showed very high prevalence of wheezing (32.1% and 23.5% respectively) in 6-7 year old children in 1995.

In studies carried out in South America high prevalence rates were observed in Chile (17.2% in 15-yr-olds to 26.2% in 7-yr-olds), as early as 1990. In Brazil, the ISAAC Phase I study carried out in 1994-95 and the same ISAAC questionnaire methodology used in a study among 6-7 and 13-14 year olds carried out in 1999 in one of the same centres as the Phase I study, both showed higher prevalence of current wheezing than in the non-ISAAC study carried out in 1994, using the same ISAAC methodology in two non-ISAAC centres (iron-mining cities in a mountainous region).

Of the five continental groups Europe had the largest number of published studies overall. The UK had the highest prevalence, of 32.2% in 1994-5, in the ISAAC Phase I study of 35,485 adolescents. Low prevalence rates, of less than 10%, were observed in Albania, Austria, Belgium, Cyprus, Estonia, Finland, France, Georgia, Greece, Hungary, Italy, Latvia, Malta, Romania, the Slovak Republic, and Switzerland in children aged 6-10, whereas Bulgaria (14.5%), the Czech Republic (14.7%), Ireland (17.4%), and Norway (13.6%) had markedly higher prevalence rates.

In the UK, national studies of the prevalence of asthma symptoms (wheezing) reported in 1986 that 6.6% of 16-year-olds had wheezing in the past year and by 1995 this had increased to 32.3% among 12-14 year old children, using comparable

questions. In the younger age group (6-10 years) in the UK, the current prevalence of wheezing ranged from 7.6% in 1980 to 20.2% in 1999, using comparable questions.

Apart from the ISAAC studies conducted in 1994-95, very few countries had carried out epidemiological studies of asthma in the Eastern Mediterranean and Africa, reported in English.

In Africa, very low prevalence rates were observed in Ethiopian rural communities (2.0% in 0-9 year olds, 1.7% in 10-19 year olds), intermediate levels of wheeze prevalence (5%-14%) were observed in Algeria, Kenya, Morocco and Nigeria and the highest rates were in South Africa, 26.8% in 7-8 year olds in 1993.

In the Eastern Mediterranean, Iran, Oman and Palestine (West Bank) had the lowest prevalence of wheeze (<11%), while the highest rates were observed in Israel (17.9%), Kuwait (16.1%), and Malta (16.0%), among 13-14 year old adolescents. In Turkey, many of the studies had not used the ISAAC question and the prevalence of wheeze was low.

Among studies conducted in Asia, low prevalence rates (<9%) were observed in China, Hong Kong, India, Indonesia and Malaysia while Japan (17.3%), Korea (13.6%) and Singapore (15.7% in 1994 and 10.2% in 2001) had higher prevalence rates in 6-7 year olds. The majority of the studies reported had used the ISAAC questions relating to current wheeze.

Australia, New Zealand and Fiji had a very high prevalence of current wheezing with the majority of the studies showing the prevalence of current wheezing in the range 18%-30%. The highest prevalence of 30.2% was observed in New Zealand among a very large sample of 13-14 year olds in 1992-93, followed by Australia which observed a prevalence of 29.7% among 12-15 year olds in 1991. Fiji reported a prevalence of 21.0% in 1990 among 9-10 year old children.

Subgroup analysis: Studies in Australia and the UK

Australia and the UK had the largest number of studies carried out and published (14 and 25 publications respectively over the 16-year period), and these are investigated further to assess differences in prevalence and trends in prevalence between the two countries.

Discussion

In this review we have reported the prevalence of current wheezing in children, published in all epidemiological studies comprising more than 1000 persons and meeting certain other quality criteria (see the Methods), over a 16-year-period, between 1990 and 2005, and further investigated the differences in reported symptoms of wheeze between ISAAC and non-ISAAC studies, in the UK and Australia.

Overall, the highest prevalence rates of current wheezing were reported in the UK, Australia and New Zealand, and the lowest prevalence was found in Albania, China, Ethiopia, Indonesia and Turkey, which gives an indication of the difference between developed and developing countries. The pattern in Africa and Asia also supports this. However, this is not supported in America, where Chile, Costa Rica and Peru had equally high wheezing prevalence as the US and Canada. Chile and Costa Rica are relatively developed countries, that may have similar characteristics in relation to development of wheezing in childhood as fully developed countries such as the US and Canada. However, this apparent inconsistency (in relation to Peru) requires further research.

Within the UK there was slightly higher prevalence of wheezing in adolescents in Scotland compared with England but there were no other substantial geographic variations, suggesting no major impact of climate, diet or outdoor environment. Also, prevalence of wheezing was lower in children born outside the UK but currently residing in the UK, suggesting a role of the environment in infancy and possibly heritable genetic factors. However, although genetic factors are important risk factors for individuals with symptoms of asthma, migrant studies indicate that they are unlikely to be responsible for the large variations in asthma symptoms that exist between populations, and cannot be responsible for the increasing prevalence of asthma within populations. Environmental factors are likely to be more important and offer the greatest opportunities for prevention.

The cross-sectional ISAAC phase I study, carried out in 1994-1995, was a major achievement, and repeated in 2002-2003, the phase III study. However, the selected ISAAC centres were most commonly an urban area (a city) and therefore may not be representative of the country. This is illustrated, for example, in Brazil where in the ISAAC phase I centres, which were all major cities, the prevalence of current wheezing in 6-7 year olds was higher than in non-ISAAC centres, which were iron-mining cities and mountainous regions (23% vs 14% respectively). The ISAAC studies also have the disadvantage of reporting wheezing symptoms only among two age groups (6-7 yr and 13-14 yr), and at only 2 time points (phase I and III), whereas this review shows the results of all studies of all age groups.

This review has shown that differing rates of asthma symptoms are observed in developed and developing countries. The validity of the question on wheezing in the questionnaire is likely to have varied across cultures as some languages do not have an equivalent word for "wheezing" as understood by English speakers. However, large variations in the prevalence of wheezing across the countries and over time, found in these studies are unlikely to be explained by methodological factors alone. When making comparisons of the prevalence of wheeze or asthma between different studies, it is necessary to critically assess the content of the question. There is, as yet, no accepted definition of asthma and identification of asthma by questionnaire remains a contentious issue. One question is whether the everyday meaning of the word wheezing has changed over time. Do better educated parents use this word more freely for symptoms in their children? The threshold of observing mild respiratory symptoms could be lower now than previously and health campaigns may have increased parental awareness of symptoms in their children. Another interesting hypothesis is the loss of protective effect of respiratory infection in early childhood, the "hygiene hypothesis." This confirms the importance of the ISAAC phase II data collection, which was completed in 2003, and in which objective measures of pulmonary function and bronchial responsiveness are recorded in conjunction with other factors, so that further study of possible aetiological factors common to different countries can be investigated.

Australia and the UK had the most published studies on wheezing prevalence in children and were investigated in much more detail.

Using all the studies in UK and Australia, we find that there was a significantly higher odds of wheezing in Australia than the UK, but the rate of increase in Australia is significantly lower than the UK, as shown by the highly significant interaction between country and year. The multiple logistic regression analysis we performed for the prevalence of wheezing adjusted for age, time period, type of study (ISAAC vs non-ISAAC) and type of response (parental or self report) and does not appear therefore to result from methodological bias. These differences indicate some significant discrepancy in early life environment between the two countries over the last 20 or so years.

If only ISAAC studies are investigated then there was no difference in prevalence between the two countries, after adjusting for time and age of the child, whereas non-ISAAC studies show significantly higher odds of wheezing in Australia. This is very likely because the ISAAC studies in these countries were carried out at two similar time points and for two age groups. The non-ISAAC studies span a much larger time period, use a wider range of ages and include many more study groups, and in particular are not restricted to large conurbations.

If time trends are explored in all studies in the UK and Australia, then overall there is a significant increase in the odds of wheezing over time, but only ISAAC studies show a significant decrease, which was also reported in the recent results of the phase I in 1995 and phase III in 2002, ISAAC study comparisons. This is almost certainly a result of the different time periods covered by these two sorts of survey. The ISAAC studies cover the period from the early 1990s onwards, whereas other studies tend to cover earlier years, some as early as 1975. This is consistent with the trend of wheezing prevalence increasing since the 1970's but leveling out in the most recent 10-15 years. This is also confirmed in other reports; evidence from many repeat surveys shows that the prevalence has increased over the past 3 decades, but in studies between 1991 to 1998 the increase was confined to minor symptoms of asthma.

A decrease in reported symptoms of wheezing, as the child gets older, was observed in the UK and Australia, which confirms previous reports. In ISAAC studies the age effect is not significant, perhaps because only two age groups were studied. Self-report of wheezing was significantly higher than parental-report, in the UK and Australia, again confirming previous work.

The ISAAC questionnaire has become almost ubiquitous since the early 1990's and we have shown that using an ISAAC question or the results of the ISAAC studies give similar results within Australia and the UK.

Wheeze may indicate undiagnosed asthma in some patients. Some studies have shown that self-reported wheeze has reasonably good specificity and sensitivity for bronchial hyper-responsiveness both in children and adults. Wheeze is rarely a symptom of emphysema or chronic bronchitis in children, but it is very often indicative of acute viral infection, which is common in this age group. Doctor-diagnosed asthma tends to be reported in only a small proportion (about 40%) of persons reporting wheeze, so that the possibility of selection or information bias in studies of asthma or wheeze cannot be discounted in general.

Conclusions

In summary, the strength of this review is the reporting of the prevalence of all studies of more than 1,000 persons, providing a full description of the scale and distribution of asthma symptoms (wheeze in the past year), worldwide and over time within each country. Among the countries surveyed, the UK has the highest recorded prevalence of wheezing and Ethiopia the lowest. We have documented a clear increase in the prevalence over time within Australia and the UK, with a leveling off or even decline in prevalence in more recent years.

Performance Characterization of the New Sidestream Plus Breath-Enhanced Jet Nebulizer

J.P. Young, T.J. Hurren, R.H.M. Hatley, T. Dyche

Introduction

Sidestream Plus (Respironics Ltd, Chichester, UK) is a new breath-enhanced jet nebulizer designed to deliver an aerosol with a high respirable fraction in a short nebulization time. It features an ergonomic design and an efficient flap valve within the nebulizer body, which opens on inhalation to entrain air but seals upon exhalation to prevent wasting drug and leakage to the environment. As in vitro testing is designed to be indicative of in vivo performance, it is of clinical value to compare the in vitro performance in terms of particle size, respirable fraction, respirable dose, exhaled amount of drug, and nebulization time with an available jet nebulizer within the same design category, ie, breath-enhanced jet nebulizers. We used production equivalent prototypes to compare the in vitro performance of Sidestream Plus in terms of particle size and simulated treatment with that of an available breath-enhanced jet nebulizer (LC Plus; Pari GmbH, Starnberg, Germany). Sidestream Plus is CE marked but is not currently commercially available.

Method

One Sidestream Plus and one LC Plus were tested using wall air to determine the aerosol particle size and delivery characteristics using 2 mg/mL salbutamol sulphate (albuterol sulfate) and 250 mg/mL ipratropium bromide.

A Marple 298 cascade impactor was used to determine the aerosol particle size parameters; mass median aerodynamic diameter (MMAD) and respirable fraction (percent particles between 0.5 mm and 5 mm). Each nebulizer was filled with 2.5 mL salbutamol sulphate and run for 120 s or filled with 4 mL ipratropium bromide and run for 240 s. The nebulization time for each drug was selected to ensure that a quantifiable amount of drug was deposited onto each stage of the cascade impactor. The fill volume for each drug was selected to ensure that the sputtering point was not reached during the aerosol particle size tests. Each nebulizer/drug combination was tested in triplicate, and drug analyses were performed with HPLC.

Delivery characteristics comprised respirable dose, exhaled amount of drug, and time to sputter. Delivery characteristics were assessed using the CEN simulated breathing pattern (Vt = 500 mL, f = 15 breaths/min, I:E ratio = 1:1) produced by a Harvard pump (Harvard College, Cambridge, USA). A filter placed between the nebulizer and Harvard pump facilitated the collection of aerosolized drug during the inspiratory cycle, whereas exhaled drug was caught on a filter placed on top of the exhalation valve of the nebulizer. Each nebulizer was filled with 3 mL salbutamol sulphate and 2 mL ipratropium bromide (representing the standard nebule volume used for each drug in the United States), and run until 60 s after the onset of sputter. The respirable dose was calculated from the respirable fraction multiplied by the inhalation filter dose. Each nebulizer/drug combination was tested in triplicate and drug analyses were conducted using HPLC.

Figure 1

Results

The Sidestream Plus nebulizer generated respirable doses of 959 µg salbutamol and 64 µg ipratropium bromide, whereas the Pari LC Plus generated respirable doses of 1121 µg and 81 µg, respectively. The exhaled amounts of salbutamol and ipratropium bromide were for Sidestream Plus 488 µg and 29 µg, respectively, and for Pari LC Plus 864 µg and 58 µg, respectively. The differences in the performance parameters were generally within 10-15%, apart from the amount of exhaled salbutamol, which was approximately 45% less for Sidestream Plus compared with LC Plus.

Discussion

The results of this feasibility study, conducted with one device of each brand, suggest that the performance of the new Sidestream Plus jet nebulizer would compare favorably with the performance of the LC Plus jet nebulizer. The results showed an aerosol MMAD for the Sidestream Plus approximately

The authors are with Respironics Respiratory Drug Delivery (UK) Ltd, Chichester, West Sussex, UK.

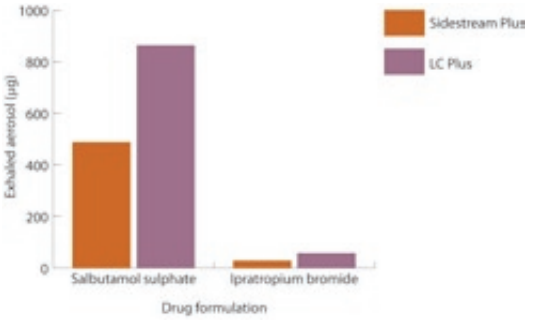
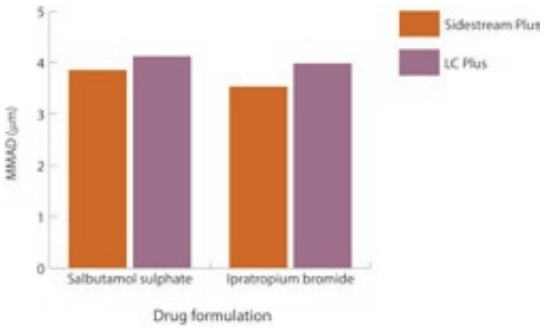


Table 1



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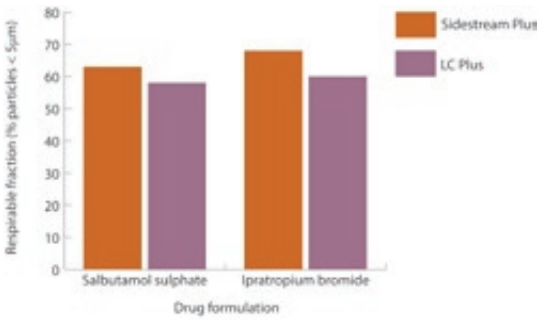

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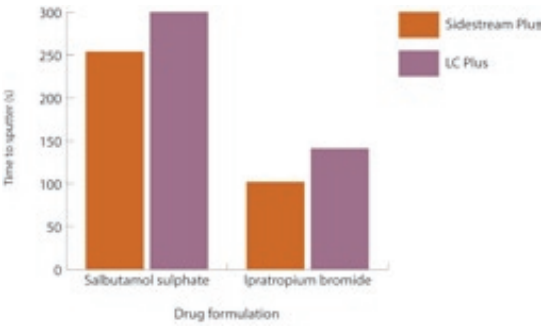


Table 4

10% smaller than that of the LC Plus, and a respirable fraction approximately 10% greater than that of the LC Plus nebulizer. The amount of aerosol wasted to the atmosphere was approximately 45% less from the Sidestream Plus for salbutamol compared to the LC Plus nebulizer. This could be of importance for those in the vicinity of patients nebulizing drugs with unwanted side effects. The time to sputter was also approximately 15% shorter for the Sidestream Plus, which could be advantageous for patients taking multiple daily nebulizer treatments. These in vitro results need to be confirmed in a larger sample of nebulizers.

Conclusions

The two nebulizers created aerosols with similar MMADs and respirable fractions. There were no major differences in time to sputter.

Diaphragmatic Electrical Activity Signaling Unmasks Asynchrony and Improves Patient-Ventilator Interaction

Daniel D. Rowley, BS, RRT-NPS, RPFT, FAARC; Stuart M. Lowson, MD; Frank J. Caruso, BS, RRT

Difficulty in patient-ventilator weaning remains the most frequent reason for prolonged stay on the intensive care unit (ICU). Recent recommendations such as sedation holidays, daily spontaneous breathing trials and increased mobilization have each been shown to contribute to faster ventilator weaning and many intensive care units have now instituted these policies. All of these recommendations, however, are simply refining existing practices and it is clear that despite these practice improvements the problem of patient-ventilator weaning is far from solved. This behooves us to continue to search for new approaches. One such approach is to re-examine the way in which the patient interacts with the ventilator. Recent publications have demonstrated that significant patient-ventilator asynchrony, defined as asynchrony in more than 10% of respiratory efforts, is present in 25% of ventilated patients.[1] These studies analyzed pressure and flow traces to record asynchrony and the authors recognize that better tools such as diaphragmatic EMG studies might reveal even greater degrees of patient-ventilator asynchrony. Neurally adjusted ventilatory assist (NAVA) confirms the authors' hypothesis and lends truth to the old saying that if you don't look for something you're sure not to find it.

In order to use NAVA an esophageal gastric catheter must be inserted in the esophagus to the level of the crural diaphragm. Electrodes embedded in the catheter detect diaphragmatic electrical activity (Edi) and use this signal to trigger pressure assisted breaths. The timing and size of the pressure assist breath is dictated by the onset and termination of the Edi signal and its strength. The exact size of the pressure assist is dictated by a NAVA gain factor that determines the pressure assist (cmH_2O) that is delivered for each microvolt of Edi. The pressure profile of the assisted breath, therefore, almost perfectly matches the Edi signal in both timing, duration and magnitude. Asynchrony is effectively eliminated.

When NAVA preview is selected during conventional ventilation mode, graphic waveforms provide a continuous monitor of the strength and timing of diaphragmatic activity and compares this with the pressure and flow traces generated by the assisted ventilator breath. It effectively provides a real time demonstration of the degree of synchrony between the patient's diaphragmatic activity and the conventionally (flow or pressure) triggered assist breath. Using the NAVA preview option, we have found that various degrees of asynchrony are present in the majority of patients that we have studied and can be present in patients who appear clinically to be comfortably tolerating assisted mechanical ventilation and who are not fighting the ventilator. Other authors have also noted that significant asynchrony can be present in patients who appear to be calm and not exhibiting signs of respiratory distress.[3] NAVA has demonstrated that conventional forms of triggering that we believed efficiently matched patient effort and assisted breath, do not in fact provide efficient patient-ventilator synchrony. Again, if you don't look for something you're sure not to find it. This has probably been the major finding of using NAVA to date.

While NAVA provides an excellent monitor of patient-ventilator asynchrony, the question remains as to how do such findings effect patient outcome. Chao et al[2] reported a higher weaning failure rate in patients with asynchrony. Sixteen percent of patients with asynchrony weaned, compared to 57% of patients in which asynchrony was not detected. Thille et al[1] also found that significant asynchrony was associated with a longer duration of mechanical ventilation and an increased need for tracheostomy. Asynchrony may therefore be an indicator of either greater disease severity, or inappropriate ventilator settings. It has been hypothesized that inefficient diaphragmatic energy expenditure may promote diaphragmatic injury and ventilator induced diaphragmatic dysfunction.[3] Ventilator induced diaphragmatic dysfunction is believed to be a major cause of prolonged ventilator weaning.[4]

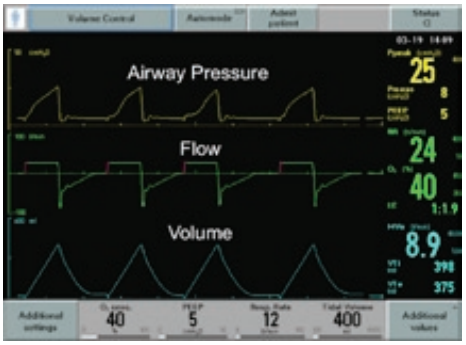
In NAVA mode, the ventilator is triggered directly from the patient's diaphragmatic electrical activity (Edi) and the degree of assist is proportional to the duration and strength of the Edi signal. There is therefore patient-ventilator synchrony both in respect to the timing and the size of the assisted breath. Theoretically, asynchrony is not possible with NAVA if the device is working correctly. It remains to be demonstrated whether eliminating patient-ventilator asynchrony will eliminate

Daniel D. Rowley is Supervisor of Pulmonary Diagnostics and Respiratory Therapy Services; Stuart M. Lowson is Associate Professor of Anesthesiology and Co-Medical Director of Adult Surgical/Trauma/Burn ICU; Frank J. Caruso is Director of Pulmonary Diagnostics and Respiratory Therapy Services, University of Virginia Medical Center, Charlottesville, VA.

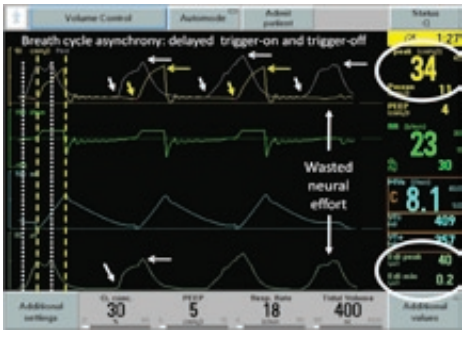
or significantly decrease the degree of ventilator induced diaphragmatic dysfunction and, in turn, decrease the duration of ventilator weaning.

Over the last decade there have been several advances in weaning patients from mechanical ventilation. Standard scalar graphic monitoring during conventional mechanical ventilation displays dynamic airway pressure, flow, and tidal volume delivery waveforms. We have found that current ventilator waveform monitoring technology masks asynchronous breath cycle delivery in many of our patient evaluations. The screen shots are samples that have been obtained from a patient with COPD lung hyperinflation.

Current Technology: Displays airway pressure, flow, and volume delivered waveforms.



New Technology: Two new dynamic scalar graphic waveforms are available with the use of a special gastric tube that has embedded electrodes that measure diaphragmatic electrical activity (Edi).



Unmasking asynchrony: Delayed breath cycle triggering and inspiratory termination is confirmed when comparing Edi and airway pressure waveform morphologies.

White colored broken lines and arrows depict Edi triggered breath cycles during NAVA preview.

Yellow colored lines and arrows represent pneumatically triggered breath cycles during conventional ventilation.

The top scalar graphic waveform displays two simultaneous airway pressure waveforms. The customary airway pressure waveform is yellow colored. The superimposed Edi airway pressure waveform is white colored. A second new waveform is displayed at the bottom of the screen. It represents a new real time physiologic monitoring tool that measures cyclic diaphragm workload. These measurements are referred to as Edi peak and Edi min.

Clinicians may use the new airway pressure and Edi monitoring tools for more sensitive and reliable determination of breath cycle synchrony and diaphragmatic workload.

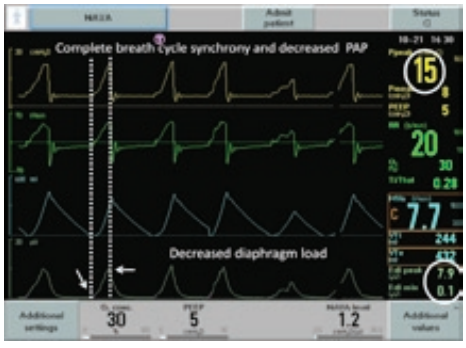
In the NAVA preview screen shot sample, one is able to ascertain total breath cycle asynchrony by comparing morphologies of the Edi and superimposed airway pressure waveforms to that of a conventional airway pressure waveform. Inspiratory and expiratory pneumatic breath cycle asynchrony is clearly present. When the Edi signal increases, the superimposed airway pressure waveform immediately responds to provide the clinician with an estimated airway pressure waveform (Pest) that would be present if the patient were on neurally adjusted ventilation assist (NAVA) mode.

Our preliminary work with 35 adult patients has consistently revealed pneumatic breath cycle asynchrony; especially with lung hyperinflated patients. In the above example, the fourth breath cycle Edi signal indicates that diaphragm contraction occurred but an assisted breath was not delivered by the ventilator because the clinician set pneumatic trigger sensitivity was not reached. The patient's desire for an assisted mechanical breath would have gone undetected if the Edi catheter had not been inserted.

Assessing the diaphragm's ability to cope with changes in pulmonary mechanics may be achieved by trending Edi peak numeric values. Edi peak is typically less than 10 uV during tidal ventilation in healthy individuals but this value is directly proportional to diaphragm workload.

For example, as work of breathing increases the neural signal sent to the diaphragm for muscle contraction often results in increased Edi peak values in order to maintain effective ventilation. As work of breathing decreases, the Edi peak will return to baseline indicating unloading of the diaphragm. The latter response occurs when diaphragm function has improved or when an intervention has relieved the diaphragm with increased assisted ventilation.

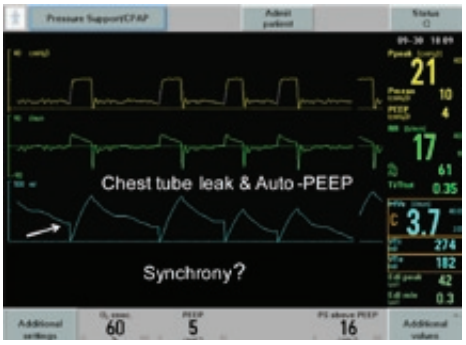
In the previous screen shot, the patient's Edi peak = 40 uV when measured during assist control volume mode of ventilation. When the same patient was changed to NAVA mode, complete breath cycle synchrony is obtained, peak airway pressure is reduced by 50%, and diaphragm load is reduced by greater than 75% . The same responses were recorded when the patient was placed on pressure support ventilation (PSV) mode.

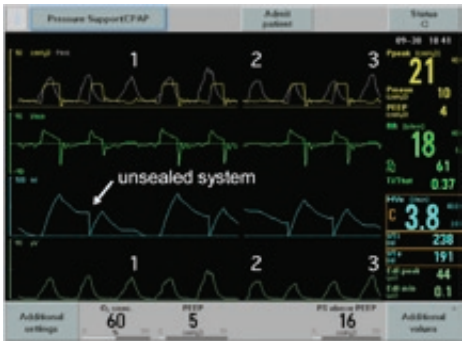


PSV with NAVA preview: In the succeeding screen shots, the same patient was changed from volume target ventilation mode to PSV mode. Breath cycle asynchrony is undetectable when current scalar graphic monitoring is viewed. However, since the Edi catheter was inserted, the bottom Edi waveform captured breathing efforts that did not result in assisted breath delivery upon patient demand. These patient-desired breaths would

have gone unnoticed if standard scalar graphic monitoring had been used. We also unmasked total breath cycle asynchrony by activating NAVA preview during conventional PSV mode of ventilation.

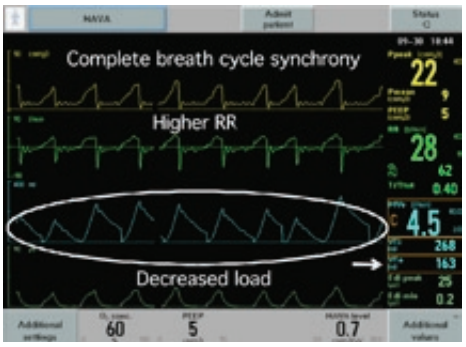
PSV Mode: intrapulmonary leak





Same patient: PSV with NAVA preview

The following NAVA mode screen shot was recorded 3 minutes after the same COPD patient was changed from PSV to NAVA mode.



Same patient on NAVA mode 3 mins later

Recognizing that the patient's inspiratory flow demands improved after changing from volume controlled to PSV mode, total breath cycle asynchrony persisted. Trigger delays continued and the patient's lungs continued to insufflate with pressure well after peak diaphragm contractility occurred. Such breath cycle asynchrony results in unnecessary neuromechanical loading of the diaphragm.

Complete breach cycle synchrony was immediately established when this patient was changed to NAVA mode. Objective evidence of significant diaphragm unloading is preset in this screen shot. The patient's measured respiratory rate increased by 10 breaths when compared to PSV mode. The increased respiratory rate that occurred during NAVA mode is to be expected because patient-demanded Edi triggered breaths are recognized by the ventilator with improved sensitivity when compared to pneumatic pressure or flow triggering. Once breath cycle synchrony was established, diaphragm unloading occurred quickly as demonstrated in the Edi signal histographs.

We recognize that asynchrony during mechanical ventilation increases cost of care, length of days on mechanical ventilation, usage of analgesia, tracheostomy tube placement, and other risks and morbidities associated with increased ICU time. We are interested in determining whether improved synchrony during mechanical ventilation results in improved outcomes; physiologic and reduced ventilator free days. We are also interested in determining if Edi monitoring can be used by clinicians for reliable diagnostic purposes as well as to guide sedative dose titration in the ICU objectively.

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How Effective…continued from page 30
determined using the test apparatus for 23 of the devices (79%).[8]

Resistance measurements were not the primary objective of the study, but they were performed on 34 of the 48 devices tested for humidification properties. The average resistance of these devices was 2.17 ± 0.70 cm H_2O/L/s at 1 Ls. In contrast to hygrometric comparisons, there was no significant difference in resistance measurements compared to manufacturer data.[8] The deadspace of the HMEs ranged from 22 to 95 mL, and deadspace of the antibacterial filters ranged from 24 to 101 mL.[8]

Lellouche et al concluded that several HMEs performed poorly and should not be used as HMEs. The values determined by independent assessments may be lower than what the manufacturer data claim. Describing a device as an HME does not guarantee that it provides adequate humidification. In fact, some should only be used for short term ventilation, such as during anesthesia, as they are mainly antibacterial filters with poor humidification performance.[8]

Standards for HMEs have been developed by organizations such as the American Association for Respiratory Care (AARC), American National Standards Institute (ANSI), and the Internal Organization for Standardization (ISO). The AARC's minimum standard for an HME states that it should deliver no less than 30mg H_2O/L at 30 degrees C 3, however, most HMEs do not meet this minimum standard. In fact, only 12 of the HMEs tested by the researchers met this minimum standard.

This study can be used by clinicians as an important guide to help them make informed decisions about what adult HMEs may be best suited for their clinical environment. It provides the available manufacturer data for the devices by name as well as the data obtained from the bench test apparatus. Further, it provides humidity efficiency data obtained from the bench test apparatus, and ranks the devices from highest efficiency to lowest efficiency. How effective is your HME?

* The Medisize Green and Red product lines came in first and tied for second in a field of 48 products. This study was performed in France. When reviewing the report please note that the products are listed under their European product line names (Hygrovent) and under the Medisize French distributor, Peters. In the US, Medisize products are distributed by Hamilton Medical.

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News Feature…continued from page 29
doctors have been able to use electronic records, and there's little proof that they have saved money or helped patients." Other problems are pharmacy errors, and no way to report problems. For example, "In 2006, doctors [at a major hospital] say they discovered an eightfold increase in dosage errors for high-risk medications. They attributed the trend to a system installed six months earlier. The hospital reverted to a process using paper notes. When health technology fails for one medical provider, there is no central mechanism for reporting problems to others who use it. "The federal government collects and disseminates this kind of information on drugs and medical devices. But tech contracts routinely bar medical providers from disclosing systemic flaws," Business Week reported. At the University of Pittsburgh Medical Center (UPMC), in 2005, researchers there found that patient deaths more than doubled, to 6.6% of intensive-care admissions, in the five months following the installation of a computerized order-entry system. The research on child patient deaths at the University of Pittsburgh found a direct association between [computerized records] and increased mortality.

Respiratory Care and Healthcare Reform

Gene Gantt, RRT

It is obvious that the idea of healthcare reform has taken root and is now a top agenda item in the United States. With a reported 46 million Americans uninsured, it has become apparent that we must find a way to offer coverage to all those in need. Healthcare is also highlighted as a major contributing issue to our overall economic crisis. Millions of Americans are going into bankruptcy as a result of healthcare costs incurred during severe illness. Even those with insurance are at risk because private insurance almost always has monetary limits and thus, in a health crisis, families find themselves without coverage following catastrophic events.

Many are worried about the outcome of the reform process. They constantly point to government operated health systems in Canada and the United Kingdom as a basis for their fears. Long waits for procedures and delays in care, as well as rationing of care, are clearly not what we as patients or providers want to see in our country. If we look at some of the other systems of care across the world, however, we can find that there are many where patients and providers are happy and we should draw from these positives where possible. Regardless of the methods of payment, in the end there are several factors that remain constant in the debate. These considerations include attention to disease prevention, chronic disease management, changing financial incentives from volume of care to incentives for quality outcomes, and finally, the development of alternate care sites.

Respiratory therapy's track record

While we have already made great contributions to the concept of reducing costs thru innovation, there are great opportunities before us. Years ago, we pioneered the concept of therapist driven protocols that dramatically reduced the length of time a patient is required to spend on the ventilator, improved outcomes in patient care, and as a result, reduced costs. These protocols are now the standard of care in most US hospitals.

We have also pioneered advancements in the area of disease management. From smoking cessation programs to asthma education and pulmonary rehabilitation, RTs are in the forefront of efforts to reduce the incidence of chronic disease and to alleviate symptoms and issues for those already suffering from them. We were basically reforming healthcare before it was "in vogue." This is our opportunity to truly make a difference in the reform process. The work we have done is being noticed and the future appears bright for even more innovation from our profession.

Concerning the ventilator population

With reform now on the table, we have an opportunity to dramatically change the paradigm of care for ventilated patients. As Chair of the AARC Long Term Care Section, I am very excited about the possibilities in this particular area. I have seen the innovative efforts of many of our colleagues and section members across the country. From creating access to gaining reimbursement, we have again been on the forefront and pioneered change in the healthcare industry. What we must do now is spread the word about these advancements and seek out policymakers to help us with this quest.

I speak often about the difficult plight of the long term care ventilator population here in the US. (See Prolonged Mechanical Ventilation in the US, April 2009 issue). This population consumes more than one-third of the cost and resources in our ICUs. These patients then go through a virtual maze of care settings and then sometimes home on the ventilator. The paradigm of care varies widely from state to state due to reimbursement mechanisms and access to various levels of care. For example, many state Medicaid programs do not support ventilator care in the skilled nursing facility setting. In these states, patients are discharged directly home on the vent from the acute care or long term acute care hospitals if weaning is not accomplished within a 30-60 day span. Once at home, the patients are destined to spend the rest of their lives on the ventilator as weaning is no longer an option. Conversely, in some states where there has been financial support for extended care, published studies have shown that many of these patients can still be liberated with time and effort. The most recent publication on this subject appeared in the May 2004 issue of the Joint Commission Journal on Quality Improvement. In this study, Dr Mark Lindsay at the Mayo Clinic concluded that 67% of those received at a freestanding skilled nursing facility were liberated. Our personal experience in Tennessee is consistent with Dr Lindsay's study, and other studies have confirmed similar results. Theoretically this leads us to the question: Are patients in some

Gene Gantt is Manager, REMEO Ventilation USA, Linde RSS, Livingston, TN.

states at home on the ventilator when they could have been weaned if access to proper care had been available to them?

If we applied the published results across the US, there would be thousands of instances where liberation could have been achieved with tremendous quality of life improvements and millions of dollars saved in chronic ventilator care.

What are our Europeans colleagues up to?

In April 2009, I had the opportunity to attend the International Conference on Home Mechanical Ventilation in Barcelona, Spain. I was truly in awe of the work our Europeans colleagues do in the area of noninvasive techniques. It was striking to see hundreds of ventilated individuals attending and actually presenting at this conference. They had traveled to Barcelona from around the world and were leading very satisfying lives although dependant on the ventilator. Very few of the individuals I met were tracheostomized, as would have likely been the case in the U.S. These persons were able to eat, speak and function at a high level despite their dependence on a ventilator. In addition to my personal observations that convinced me that we had much work to do in the US, I was given persuasive evidence to substantiate the dramatically decreased cost of care and overwhelmingly increased quality of life of these individuals. Without a tracheostomy and the need for constant suctioning, these individuals were much less likely to have infections and had fewer hospitalizations. There was no need for suction apparatus so they were comfortable in public and quite interesting to talk to.

Interestingly, many of the techniques and theories that are currently employed in Europe were actually pioneered here in the US by our friend Dr John Bach from New Jersey. For years, Dr. Bach has lectured around the world and published volumes of studies and at least two textbooks on the subject. He is a firm proponent of noninvasive ventilation and the concept of quality of life for his patients. I would encourage each of you to look into his writings as we move toward reform. (His web site, developed by one of his patients, is www.doctorbach.com). I am convinced that these techniques will grow in popularity here in our country as they have in the European market.

On the home front in Tennessee

Here in my home state of Tennessee, innovations are coming with regard to access for long term care. We are actively providing ventilator weaning across the state in our REMEO centers (Latin for I return home) with outcomes consistent with the published success rates. Working closely with state government, we have implemented “standards of care” for ventilation in rehabilitation facilities that specify twenty-four hour RT, state of the art monitoring, safety systems, equipment and promote successful outcomes.

Our TennCare program (Medicaid) is taking innovative steps and a bill is currently moving through the legislature that will establish Adult Care Homes. These Adult Care Homes will allow ventilator dependent individuals the opportunity to live more independently outside the walls of a traditional nursing home. Here again, respiratory therapists have had the opportunity to take part in the discussion and development of this new model.

Summary

Regardless of the final outcome of how the face of healthcare reform will look in the future, we know that reform will eventually come. As RTs and providers, we should continue to think outside the box and envision a system where we can contribute even more than we already have to the advancement of patient care. It is our charge to create and improvise new techniques and technology that will not only reduce costs of care but also improve the quality of life for the patients we serve. It is also our charge to design programs that are conducive to the reform process and make sure they are included in the final version of what is to come on the reimbursement front. Now is the time to get involved! I encourage each of you to get engaged in the discussion, and to reach out to your elected officials both at the state and national levels. You can track the health reform process at healthreform.gov.

Think About It

I was going to write an editorial about the swine flu (I know, not from swine, etc—see the article on page 40), but the subject's been done to death, so to speak. Instead, here's something to think about, a different take, from the book, Critique of Cynical Reason, By Peter Sloterdijk:

"What in positive terms is practiced as 'healing therapy' appears from a pragmatic perspective as the fight against disease. Today's doctor proceeds from the naked body in order to uncover the sources of danger in its interior. The body is the bearer of secrets and is to be shadowed. As in espionage, medical apparatuses are 'infiltrated' into bodies. In places, the distinction between diagnostics and intervention becomes blurred. Modern medicine is based on the a priori principle that between the subjects and its sickness, only enmity can exist. To 'help' the subject means to help it to a victory over the aggressor sickness. The idea that sickness—like any hostility—could also be an original and, in a certain sense, 'true' self-expression of the 'subject' is already excluded by modern medicine's approach. In practice, the idea is ridiculed that sickness, at a given time, can be a necessary and authentic relation of an individual to itself and an expression of its existence. Sickness must be thought of as the other and the alien, and this polemically split-off element is treated by medicine in an isolating and objectifying way. The medicine of a latently paranoid society thinks of the body as a subversion risk. In it, the danger of sickness ticks like a time bomb; the body is suspected as the future murderer of the person living in it. My body is my assassin. Today, the body itself is conceived of as a suspected enemy, because it could become sick. This suspicion creates the 'medicinal' body, that is, the body as battlefield of preventive and operative medicine. One can call this procedure methodical pessimism. The secret of its *procedere* lies in painting a bogeyman on the wall with one hand while operating with the other. As with all security systems, such preventive measures exist because of the growth of the readiness to be afraid. If it can be said that societies manifest their feelings toward life in their medicine, then our society reveals that life is too dangerous to live but still also too precious to throw away. Between preciousness and danger, one seeks the safe middle ground. The more life secures itself, the more it becomes virtualized, pushed away, and abandoned. It becomes a mere potential that does not want to engage or realize itself because engagement cannot happen without risk. Medicine holds up a mirror to our society: In it, the existential fears of a civilization appear in which, openly or secretly, everyone has to fear a violent death."

—Les Plesko

The above quote is edited and condensed. It is from pages 343-346, in "Critique of Cynical Reason," by Peter Sloterdijk, Theory and History of Literature, Volume 40, translation by Michael Eldred, © 1987 by the University of Minnesota, published by the University of Minnesota Press.

Editorial…continued from page 4
population and the ever increasing numbers of uninsured will most likely result in doubling the Federal debt by 2050. This will leave the next generation with an insurmountable problem with no solution.

To address the uninsured issue, on June 5th Senator Ted Kennedy proposed a bill requiring all employers to provide health insurance to all employees. While this would reduce the number of uninsured, it is most likely to reduce job creation, as employers' resources are diverted to pay for this required insurance, adding another dimension to an already challenged economy.

The growing involvement of the Federal government as the primary healthcare provider and ballooning Federal deficits requires not just a bill but also a well designed plan. Currently, neither healthcare experts nor the political establishment have a clear vision of this reform bill or its long term repercussions on the citizens of the United States or the economy. The public is told it will require cuts in Medicare spending, some additional taxes along with reallocation of Medicare services, but no real plan or timelines for implementation. Whether this reform bill will lower healthcare costs or merely slow rising costs is to be determined. If its true intent is to lower costs, this will require Congress to make hard choices in deciding the level of healthcare to be provided and how it is to be delivered. It will require a plan.

What is clear is that the cost of this reform for all healthcare providers will require their active participation at all levels of government to assist in the formation of this plan and any subsequent bills required to assure its success. It will also require the creation and adoption of accepted standards of care and oversight to the adherence to these standards. In closing, we as healthcare providers should also be prepared to assist in the creation of these standards of care and their implementation.

Doug Wilder is Director of Respiratory Care, Livingston Memorial Hospital, Livingston, TX. He is the current President of the Texas Society of Respiratory Care and is working with the Texas Department of Health and 12 county governments on a pandemic flu and medical and special needs evacuation policy during hurricanes. Doug has also testified before the Texas State Senate on the shortages of rural healthcare workers and its impact on healthcare delivery.

Sources

1 Christina Romer, chair of the Presidents Council of Economic Advisers
2 Laura Litvan and Nichole Gaouette, Bloomberg.com
3 ModernHealthcare.com

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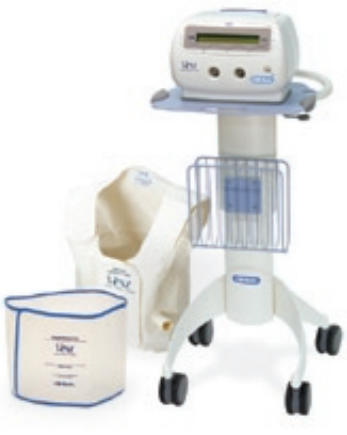

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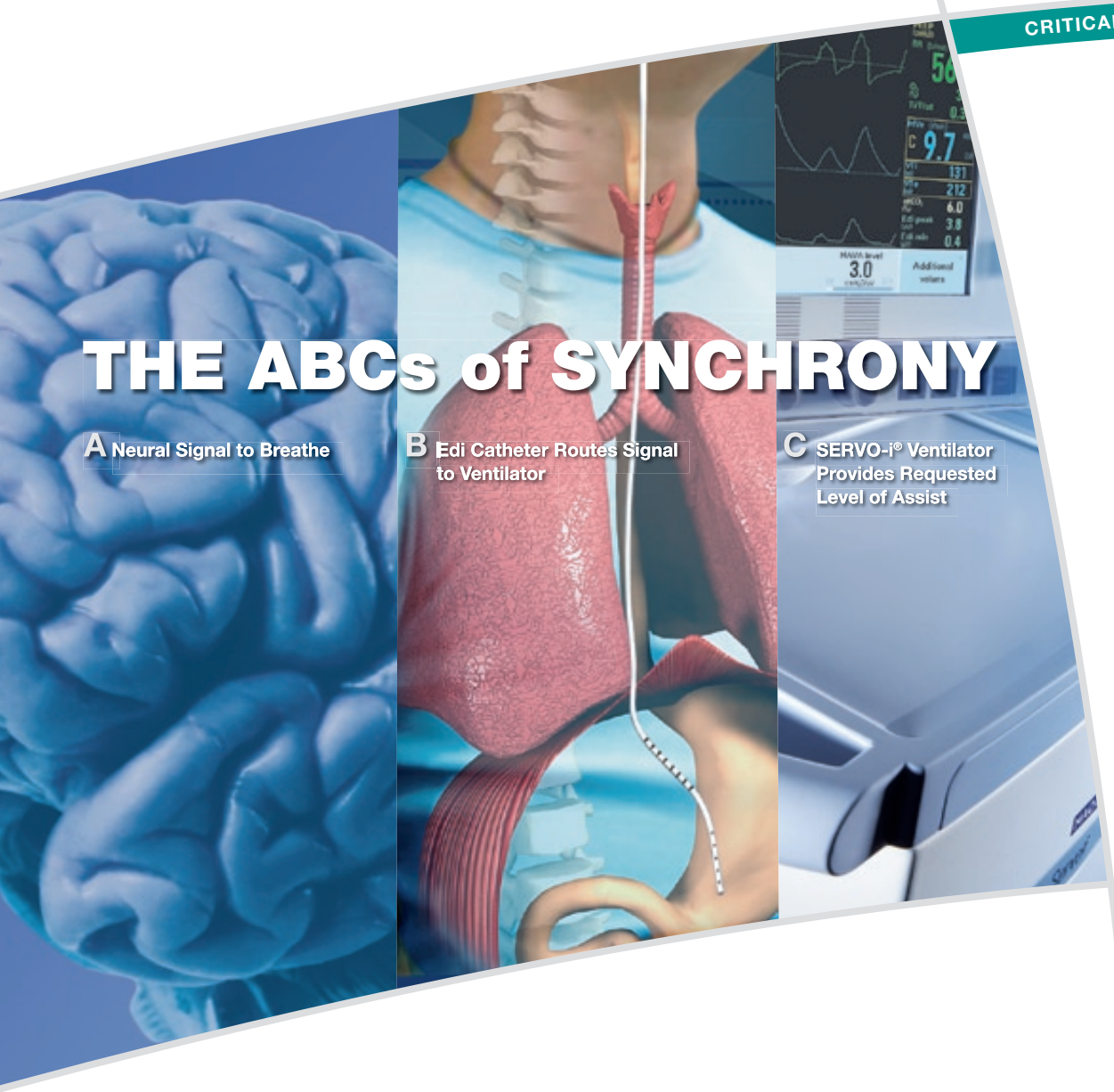

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* See, for example: Thille, A; Rodriguez, P; Cabello, B; Lellouche, F; Brochard, L; "Patient-ventilator asynchrony during assisted mechanical ventilation," Intensive care med., (226), 32:1515-1522, DOI 10. 1007/s00134-006-0301-8

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