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Guest Commentary

Human Error: An inevitable part of healthcare, or a better future?

David Costa
David Costa is Patient Safety Advocate Vice President, Hamilton Medical, Inc, Reno, NV.

If you are admitted to any hospital, you have been placed in the same risk category as bungee-jumping and mountain climbing. Compare that to commercial aviation, an industry that is considered "ultra-safe".[1] Both industries are heavily reliant on human performance to protect lives. Why then is health care's error rate so much higher?

Patients are people and people are being harmed, needlessly. The Institute of Medicine published a landmark report, "To Err is Human,"[2] that is often quoted by the medical industry as a statement of the patient safety crisis in the United States and throughout the world. Medical errors cost the US over $37 billion per year.

The Institute of Medicine suggests that 44,000 to 98,000 Americans die each year from medical errors. Even 44,000 deaths is higher than the annual mortality rates for motor vehicle accidents or breast cancer or AIDS—medical errors are the number eighth leading cause of death in the United States. This number of deaths due to errors is equivalent to a jet airliner crashing every day! Can you imagine the public response to this? Would you fly on a commercial airliner with this safety record? Why has the public not been made aware of the horrible safety results in healthcare?

Are hospital leaders to blame for this sad state of affairs? Perhaps, but let's consider the huge pressures that hospital leaders face every day. The hospital's executive team, headed by the hospital administrator, deals with everything that any medium to large business must deal with—plus all of the challenges inherent in the care and healing of human beings. Hospitals face financial pressures, increased governmental regulation and medical staff shortages. Rick Pollack, Executive Vice President of the American Hospital Association indicates, repeatedly, that bad debt reimbursement, Medicare policy and negative Medicaid margins are creating a very fragile financial situation in the nation's critical access hospitals. Hospitals are risky businesses with unique challenges and horrific consequences for failure. We entrust our family members to these caring professionals and hope for the best, but human error can lead to dire consequences. This is not just a problem in the US. The Canadian Patient Safety Institute calls health care "A service industry that injured 7.5% of its customers through preventable errors (30% of injuries resulting in permanent impairment, 5-10% resulting in death)."

The United States is in the middle of a physician and nurse shortage, and in the next decade, the problem is only going to get worse. By 2020, the US will need an additional 340,000 to 1 million nurses. J. Edward Hill, MD, former president of the AMA, compares the looming physician shortage to a pandemic.

The job of the hospital administrator is about to get even tougher and the medical staff will feel the pressure. Medicare issued rules in August of 2007 that will end payments for the extra care required for certain medical mistakes. The new rules prohibit passing these charges on to patients, so hospitals will bear the costs. Industry experts conclude that private insurers will follow Medicare's lead. This initiative is an aggressive result of the Institute of Medicine's 1999 report estimating that mistakes killed 98,000 patients per year (US News Wire–Consumer Union Supports Proposed Medicare Rules Aimed at Reducing Hospital Infections & Medical Errors–June, 13th 2007).

Finance is important—the hospital must be financially viable to provide healthcare.

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But isn't the mission of the hospital to provide that healthcare put in jeopardy if patient safety isn't as critical as finance? If hospitals are meeting financial goals, but endangering patients in the very process of delivering their services, isn't that the very antithesis of their purpose? Moreover, doesn't patient safety have a huge financial impact on the hospital?

The differences between the attitudes of aviation and health care professionals are dramatic. One study compared the responses of over 31,000 pilots, surgeons, nurses and residents. When asked "Do you make mistakes?" 100% of the pilots answered in the affirmative where only 30% of the health care professionals made that same statement.[3]

There is good news however, and many in the medical industry are devoted to the elimination of patient harm due to errors. Lucien L. Leape, MD, Harvard School of Public Health stated, "Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals". Tim Porter-O'Grady, a healthcare consultant, made a provocative statement while part of an expert panel to reduce hospital errors, "If airline pilots behaved like doctors, there would be planes dropping out of the sky every day." He goes on to say, "The problem isn't so much the people involved—everyone makes mistakes, after all—but the systems or lack of systems to prevent errors from happening in the first place."

Medical professionals are rising to the challenge of improving patient safety. In December of 2004, Dr Donald Berwick, a Harvard professor, organized a campaign to sign up 2,000 hospitals and through improved reporting and patient safety cultures save 100,000 lives. A total of 3,100 hospitals participated and 122,300 lives were saved in 18 months. Mortality and error data was shared throughout the network and they focused on 6 areas of patient safety. This organization, The Institute for Healthcare Improvement (IHI), has now launched the "Protecting 5 Million Lives from Harm" campaign. The safest hospitals all have one key element in common. The hospital administrator is that key to a safe hospital environment. This is the one person who can drive the initiatives that will save lives and reduce the harm that is happening right now to their patients. The first step is to make that decision. Don't all hospital administrators make their avowed number one priority to provide quality healthcare? Then how can there be such a disparity in the Standard of Care between facilities? How can there be such a disparity in attention to patient safety? It happens when priorities get distorted.

Many in healthcare are using "aviation level safety culture" to create a safer health care environment. So what can medicine learn from commercial aviation? What strategies have been proven effective in safeguarding the lives of our loved ones?

What does "aviation level" mean? For the staff (or crew), it means a high level of teamwork, a level of language and communication that lowers the possibility of error, and it indicates clear lines of authority and accountability and decision making. "Aviation level safety culture" also clarifies error procedures and recovery actions.

Medical device companies are taking lessons on safety from commercial aviation as well. In medical technology, an "aviation level safety culture" describes a standard of excellence and a level of automation that lowers human error. Medical devices that maintain the "aviation level safety culture" offer the clinician tools that reduce their workload and improve situational awareness. These tools include "autopilots"; these devices are self-regulating. Medical devices must have strict—redundant accountability and intelligent features that protect the patient at all times. The clinician cannot babysit technology all the time. Medical device companies must also promote education that produces highly trained operators of that technology with the assistance of realistic simulations and scenario-based training designed to reduce human error.

Mechanical ventilators are designed to sustain life and to take over many of the respiratory functions of a person who cannot maintain adequate ventilation on their own. These are some of the most complex and important medical devices in the modern ICU, yet there is a dirty secret that is discussed freely in critical care circles, but not normally discussed with the patient or their loved ones. Ventilator Induced Lung Injury (VILI) is a consequence of mechanical ventilation that is common, but preventable. Hamilton Medical has introduced "aviation level safety culture" to address this problem and has created a whole new standard of care in the field of respiratory care. Intelligent Ventilation takes technologies proven effective in commercial aviation and promises to eliminate patient harm due to mechanical ventilation. This company with US operations in Reno, NV, offers the only ventilators with autopilots and advanced "ventilation cockpits" to make ventilation safer, more efficient and easier to use.

Hamilton Medical, for example, is changing the culture regarding mechanical ventilation. Changing a culture is not a casual commitment or an easy one but it is worthwhile when it eases human suffering. More importantly, there are a great number of clinical leaders that have chosen to become early adopters of this technology with some amazing results.

Commercial aviation uses tools to improve situational awareness, appropriate automation (eg autopilot), reliable equipment platforms and advanced crew training methods in order to make each flight as safe and efficient as possible. These tools improve human performance. It is becoming clear that progress in improving patient safety requires substantial, long-term effort directed at supporting human performance rather than trying to prevent its failure.[4] Hamilton Medical and other medical device companies that focus on patient safety also offer the same types of tools. Current numerical and waveform displays do not support clinicians optimally.[5] Improved situational awareness is enhanced by using simple displays to interpret complex clinical data and present it in such a way that allows the clinician to rapidly assess patient condition and take steps to care for the person being supported by this technology. Errors leading to laparoscopic bile duct injuries stem principally from misperception, not errors of skill, knowledge or judgment.[6] This is why information must be presented in such a way to minimize such misperception. These companies are incorporating appropriate automation and "autopilots" to reduce the workload on the already overworked staff. These autopilots are tireless and can make minute adjustments based upon real-time patient data even when the clinician cannot be at the bedside. Most medical devices are extremely reliable, but have normally been manually controlled. Advanced ICU-team training methods that are similar to the way airline crews train are reinforcing proven, evidence-based actions. The dominant contributing factor to patient death on ventilators was inadequate orientation/training.[7] Medical staff training must now

reinforce procedures, workflows and checklists that lead to error reduction at the system level. Hamilton Medical is one company that is using aviation training methods like realistic simulations and scenario-based training, to improve learning. With proper safety systems and attitudes, one or even two small mistakes are not able to cause patient harm. The "error chain" is broken. Humans will always make errors, but safe systems protect the patients (our loved ones) that we all serve. Dr Arthur Bloomfield, MD said it best. "There are some patients we cannot help, there are none we cannot harm. I am asking each one of us to look at the lives affected by each one of us in the medical industry. I ask each one of us as health care consumers to demand an 'aviation level safety culture.' We will all be judged by our service to those 'loved ones' in our care. It is the responsibility of each of us to do our part."

"Our systems are too complex to expect merely extraordinary people to perform perfectly 100 percent of the time. We as leaders have a responsibility to put in place systems to support safe practice."—James Conway, IHI Senior Fellow; former Executive Vice President and Chief Operating Officer, Dana-Farber Cancer Institute.

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News

☐ June-July 2008

ADDENDUM

Re the article, Biphasic Pressure Release Ventilation: Improving patient comfort when prolonged inspiratory times are clinically necessary, by Cyndy Miller, Dec/Jan 2007/2008: Information and research for the article was also provided by Colin Antenbring, Product Manager, Newport Medical Instruments, Inc.

FACE-OFF

How much of that face mask treatment is getting into your patient? That's what Paul Garbarini, MS, RRT, with Hamilton, is wondering in the latest issue of Hamilton Medical's Newsletter. Garbarini writes: An interesting study in the February issue of Chest looked at a new mask/nebulizer interface for delivery of nebulized Budesonide. What I found interesting, besides the results relevant to the new mask design, was that in this pediatric model (they actually constructed a life size pediatric "face" with simulated spontaneous breathing), when utilizing the standard aerosol type masks with the nebulizer inserted from the bottom of the mask, only about half the solution gets inhaled. Thirty percent of the dose was deposited in the eyes! (a source of concern with steroids), the rest being deposited on the mask and face. More interesting was the revelation that simply front loading the aerosol, eg connecting the nebulizer such that the aerosol flow is directed towards the mouth from the front of the mask instead of from the bottom of the mask, resulted in almost three times as much inhaled mass getting into the patient. Front loading did not reduce ocular or facial deposition unless utilizing the prototype new aerosol mask which incorporates features to reduce eye and facial deposition.

PEEP MEETS VAP?

Melissa Turner, BA, RRT, writes in the latest issue of Hamilton Medical Newsletter: Ventilator-associated pneumonia (VAP) is being scrutinized more closely under the microscope today. Payors are promising to stop reimbursement for mechanically ventilated patients diagnosed with VAP, while clinicians and administrators are seeking ways to prevent VAP. Many facilities have implemented measures such as keeping the head of the bed elevated at 30 degrees, oral care every 2 hours, and keeping endotracheal tube cuffs properly inflated so as to prevent aspiration of upper airway secretions. VAP is known to cause increased ventilator length of stay as well as mortality. It is of critical importance to implement a "best care practice" protocol to prevent VAP. Best care practice protocols should also leave room for the addition of other techniques or practices which prove to be beneficial in the future for preventing VAP. In a recent study by Lucangelo et al, 5cmH_2O positive end expiratory pressure (PEEP) was found to be effective in delaying the passage of fluid around the cuffs of ETTs both in vivo and in vitro. ETTs with high-volume low-pressure (HVLP) cuffs do not prevent upper airway secretions from leaking into the lower airway due to the longitudinal folds within the cuff wall. These folds tend to occur during inflation of the cuff within the trachea even if there is adequate inflation pressure (25-

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30cmH_2O). The study done by Lucangelo et al1 used both a HVLP ETT which incorporated a cuff made of polyvinyl chloride (PVC) and an ETT with a cuff made of polyurethane (SealGuard). Both cuffs were inflated to a cuff pressure of 30cmH_20 in each group of patients. PEEP was applied to both ETT's and no leakage occurred. Once PEEP was removed, leakage was detected in the ETT's with the PVC cuffs. The SealGuard ETT was able to prevent leakage for a longer period of time without PEEP, although there was some leakage that appeared after a longer period of time. Nonetheless, this study was able to show that regardless of what ETT is used, applying 5cmH_2O of PEEP improved sealing around ETT cuffs. Application of 5cmH_2O PEEP may be another means to prevent contamination of the lower airways in intubated patients. Adding a minimal PEEP setting of 5cmH_20 to the current VAP protocols used in facilities could help in the battle to minimize or prevent VAP. Reference: Umberto L, Walter AZ, Vittorio A, et al: Effect of positive expiratory pressure and type of tracheal cuff on the incidence of aspiration in mechanically ventilated patients in an intensive care unit. Crit Care Med 2008; 36(2): 409-413.

PASS THAT ROACH

Cockroaches can trigger asthma attacks, especially in children, and spread 33 different kinds of bacteria, six kinds of parasitic worms and at least seven other kinds of human pathogens, according to the National Pest Management Association. As cockroaches crawl through decaying matter or sewage, they turn into disease-carrying pests by picking up germs on the spines of their legs and bodies. If you see one cockroach, there are sure to be many more, which is why proper control and removal is necessary. Studies have shown that cockroach allergens are responsible for numerous allergic reactions in inner city children.

SMOKE GETS IN YOUR GENES

Genes and smoking together play a significant role in respiratory diseases like chronic bronchitis. Researchers in Sweden studied more than 40,000 twins to determine the extent to which behavior, environment and genes each play a role in the development of chronic bronchitis. Smoking behavior was found to have a known genetic component. The Karolinska Institutet in Stockholm reported that hereditability accounted for 40% of the risk for chronic bronchitis, but 14% of the genetic risk was also linked to a genetic predisposition to smoke, whether or not the individual actually smoked. Chronic bronchitis along with emphysema account for most cases of chronic obstructive pulmonary disease, or COPD. The researchers analyzed data from the Screening Across Lifespan Twin (SALT) study in Sweden, which surveyed all known living twins in Sweden born in 1958 or earlier. The survey included questions on zygosity, smoking history and a checklist of common diseases. The investigators used the survey data and statistical modeling to tease apart the genetic and environmental influences that comprise an individual's risk of developing chronic bronchitis: genetic factors, shared environmental factors experienced by both twins, and non-shared environmental factors. Researchers cautioned that the findings should not be interpreted to mean that smoking has no effect on chronic bronchitis. Although there was some genetic interplay, it is safe to say that smoking itself, and not the genes that predispose one to smoking, is a larger risk factor in developing chronic bronchitis of environmental exposures, rather than genetic predisposition.

AUTOIMMUNITY

Pulmonary specialists at the University of Pittsburgh School of Medicine reported that COPD is an autoimmune disease in many patients. The finding holds relevance regarding possible future treatments, including a clinical trial of inhaled cyclosporine at the University of Pittsburgh. The Pitt researchers tracked immune system antibodies in 55 smokers or former smokers (47 with COPD) compared to 21 healthy people who had never smoked. Abnormal antibodies were found in 68% of smokers and former smokers with COPD but in only 13% of former smokers without COPD and 10% of those who had never smoked. Investigators at the Emphysema Research Center are conducting a clinical trial of an inhaled form of cyclosporine, long used to suppress the immune system in transplant patients.

PANDEMIC

There's still time to prevent drug-resistant tuberculosis from causing the same outcome that's been seen with the HIV/AIDS pandemic, but not much time, according to an editorial in the Los Angeles Times. The World Health Organization reported that drug-resistant TB is no longer affecting just people with HIV and people in poor countries, but is a general population threat. The Times reports that while drugs might be available for drug-resistant TB by 2015, in the meantime, the disease will keep spreading. Meanwhile, TB funding has lagged, with the WHO estimating that it has a $2.5 billion shortfall in TB control resources.

SOUND THE ALARM!

Vitamin E supplements could cause up to 27% increase in lung cancer, according to an alarmist report in the UK's Daily Mail. A study of more that 77,000 people found that moderate to high doses of vitamin E led to a slight but significant increase in lung cancer risk. The study is said to give similar warnings about excessive beta-carotene use. The study, titled VITAL (Vitamins and Lifestyle), by the University of Washington looked at the use of supplemental vitamins (multivitamins, vitamin C, vitamin E and folate) and new cases of lung cancer. Overall, it found no protective effect of supplements on lung cancer. It also found a barely significant increase in risk of lung cancer associated with vitamin E supplementation. However, when looked at closely, the risk is negligible at best. The increased risk was small, a five% increase in risk for every 100mg of vitamin E taken per day over 10 years, and this translated to a small increase in the participants with lung cancer. In the cohort study, the researchers aimed to investigate the links between supplemental multivitamin use, vitamin, C, E and folate, and incidence of lung cancer. The researchers mailed 364,418 questionnaires asking about medical history, cancer risk, supplement use and diet. Responses were obtained from 21.3% of those sent the questionnaire and this provided 77,719 people for analysis. The questionnaire asked the participants about their supplement and vitamin use in the 10 years leading up to the start of the study. From this data, the researchers calculated the amount of multivitamins taken over 10 years, and the quantities of individual vitamins by looking at those contained in multivitamins and from individual supplement tablets. The researchers also examined other factors that could have an effect on lung cancer risk, such as smoking, age, sex, past cancer history, family history, airways disease, ethnicity, education, marital status, BMI and diet. The participants were monitored to see if they developed lung cancer. Of the participants, 521 developed lung cancer, with most occurences in smokers. Few cases developed in people who had never

smoked. There was no link between risk of lung cancer and use of multivitamins, vitamin C, or folate, at any dosage for 10 years. When the researchers looked at vitamin E alone, they found a minimal link to lung cancer, especially non-small cell lung cancer. This amounted to a 28% increased risk of lung cancer at a dose of 400mg/day for 10 years. The researchers found no protective effect of any type of vitamin for lung cancer. The increased risk from vitamin E overall was quite small and thus of borderline statistical significance, and confined mostly to smokers. Although there was an increased risk associated with vitamin E, it cannot be assumed that it was caused by the supplement itself.

SIMPLE TREATMENT

Every year, 10 million new cases of TB are diagnosed and two million people die of the disease. The problem is getting the medicine to the people who need it and, most difficult, making sure they follow the six-month regimen of daily doses. Failure to follow the regimen not only leads to likely death of that patient, but fosters the development of antibiotic-resistant strains of the disease. Now, a team of collaborators may have found the answer in a simple, inexpensive and easy-to-use package. The main component is a "smart" pillbox called the uBox, which has 14 chambers that can each be loaded with several pills, which it dispenses from one chamber per day. To alert the patient that it's time to take the medicine, the box flashes its lights and sounds a buzzer. When the compartment is opened, the uBox records the exact time and prevents double-dosing by refusing to open again until the next treatment is due. After two weeks, a healthcare worker reloads the box and digitally records and transmits the information stored in it. Doctors and public health services can then get complete data on compliance, patient by patient, in almost real time, instead of having to wait until the end of the six-month treatment. The second part of the system is a cell phone, called the uPhone. By using special software, healthcare workers can record a patient's temperature, weight, and answers to a list of questions related to symptoms, which adds to the set of detailed patient data analyzed by doctors monitoring the study. By looking at patterns of effects, the doctors can tell which field workers are achieving the best adherence rates with their patients and find out just what it is that those people are doing right. Researchers have begun their first field test of the product, conducting a training session for 22 workers who will, in turn, train the field workers to distribute the pillboxes.

SKIP SPIROMETRY?

Adults without symptoms of COPD shouldn't be screened for the disease using spirometry, according to a recommendation from the US Preventive Services Task Force. The recommendation and the accompanying summary of evidence were posted online in the Annals of Internal Medicine. The Task Force found that the benefits of screening individuals without symptoms of COPD were very small. Approximately 400 adults between the ages of 60-69 would need to be screened in order to identify a single patient who may later develop COPD symptoms severe enough to require immediate medical care. The Task Force also found that spirometry can substantially overdiagnose COPD in people over the age of 70 who have never smoked and can produce some false positives in younger adults. In those patients experiencing symptoms of COPD, spirometry may be used to confirm a diagnosis of COPD, but the Task Force found evidence that the diagnosis did not have an impact on the number of patients who quit smoking, nor could they find evidence that it increased the number of patients who received the flu vaccine. Researchers said they found that screening for COPD with spirometry in patients who report no symptoms provides very little or no benefit to individuals, even in those who are eventually diagnosed with the disease.

COSTS MORE, WORKS LESS

New, costly controller therapies for asthma are being dispensed more frequently, but it has been difficult to say whether or not they are cost-effective, according to a study reported by the Journal of Allergy and Clinical Immunology. The authors analyzed the 2002 to 2004 records of prescriptions, healthcare utilization and total medical costs of a group of 96,631 asthma patients in a large managed care organization. Within the limits of the retrospective cost analyses they found that total asthma-drug costs were significantly lower for patients who used a single controller inhaled corticosteroid, compared to those who used a single controller leukotriene modifiers, long-acting beta-agonists, theophylline, and most combination controller regimens. Researchers also found that use of a single controller ICS compared to single controller leukotriene modifiers and combination controllers was associated with significantly lower asthma-related utilization of healthcare services. These findings support the national asthma guidelines that recommend single controller ICS as the preferred single asthma controller treatment.

IMPOTENT

Scientists at the University of Leicester say they have isolated the molecular weapons of the TB bacterium and are now assessing ways to make the bacterium impotent. The University's Department of Biochemistry is focusing on two proteins in the TB bacterium which, it is thought, allows it to thrive in white blood cells, paying particular attention to a long arm in a molecule of the bacterium which is thought to be used to bind onto white blood cells. The scientists are also seeking to identify which part of the white blood cell is being targeted. Researchers said one of the most important of the molecular weapons is the ESAT-6/CFP-10 complex, two proteins that bind to become a functional unit, and it is thought that they may be needed to allow the bacteria to thrive inside white blood cells, as happens during the initial infection. Removal of the genes for this complex from the TB genome renders the bacteria unable to cause disease, exposing how important this particular weapon is to the bacteria. Current work is attempting to identify the exact components of the human white blood cells that this complex is targeting. Once found, this should give a greater knowledge of the action of these molecular weapons.

LOOKING BETTER

New research reported by CHEST shows that CPAP provides many benefits for patients suffering from obstructive sleep apnea and heart failure, including an improved prognosis. In the study, Japanese researchers determined the effect of CPAP therapy on the prognosis for 88 patients with heart failure and OSA. The patients were categorized into two groups; CPAP-treated (65) and untreated (23). Those in the CPAP-treated group were further classified according to therapy compliance. The frequency of death and hospitalization was analyzed using multivariate analysis, and after the follow-up period, nearly half of the patients had died or were hospitalized. Researchers concluded that the risk for death and hospitalization was greatly increased in the untreated group, as well as in the patients who used, but were less compliant with, the CPAP therapy.

ROYAL DEAL

Royal Philips Electronics announced it has reached an agreement to acquire all outstanding shares in Shenzhen Goldway Industrial, Inc, in China. Goldway will become part of the Patient Monitoring business within Philips' Healthcare sector. Goldway offers patient monitoring solutions that range from basic standalone to more fully-equipped monitors, including products that have been FDA approved in the United States or carry the CE certification in Europe. Philips spokespersons said acquiring Goldway will secure Philips a broader presence in the Chinese healthcare market, which is estimated to be growing at approximately 10% per year. Goldway is the second largest domestic patient monitoring company in China, employing a staff of 290, with sales growing by 30% in 2007. Philips employs 123,800 employees in more than 60 countries worldwide. Contact philips.com.

PRODUCTS

GOOD STOREY

Vapotherm announced that its President & CEO, Robert Storey earned Maryland's 2008 International Business Leadership Award from the World Trade Center Institute (WTCI). Storey was one of seven winners selected by the WTCI for exceptional business leadership, determination, and creative strategy in international business. Established in 1989, WTCI is the region's premier private sector international business partner. Vapotherm, Inc is a privately held manufacturer of respiratory care devices for hospitals and homecare, based in Stevensville, MD. The company is dedicated to the development of innovative, noninvasive technologies for respiratory therapy, especially for the treatment of chronic lung and acute breathing disorders. For more information, visit vtherm.com.

SEARCH ME

SearchMedica.com, a search engine for medical professionals, unveiled six new searchable disease categories on its site, including respiratory diseases and pediatrics. Medical professionals can search the site for clinical information and register to receive updates, as well as provide feedback to the site. SearchMedica provides free, open access to its contents, including articles from journals and associations, and it can index select clinical info. Its categories are based on the MeSH library and include cardiovascular, diabetes/endocrine, infectious, musculoskeletal, cancer/hemic, pediatric, mental/nervous system and respiratory disorders. The site was recently acknowledged for its outstanding user experience as a recipient of a 2007 Standard of Excellence WebAward. Contact searchmedica.com.

WHY USE TWO

Mercury Medical is pleased to introduce the New Improved $StatCO_2$ and Mini $StatCO_2$, disposable, colorimetric CO_2 Detectors. Verification with Enhanced economy, reliability, and convenience. $StatCO_2$ and Mini $StatCO_2$ provide breath to breath color changes from blue to yellow. The yellow color identifies the presence of CO_2 assisting in verifying proper ET tube placement, initially and throughout transport. The first CO_2 detectors to reliably confirm proper ET tube placement for 24 hours and in 100% humidity are now available with larger viewing windows for improved visibility of vivid color changes. The $StatCO_2$ or Mini $StatCO_2$ is conveniently ready for you when and where you need it. Just pull the activation strip. Significantly more economical to use than some other CO_2 detectors! Contact mercurymed.com.

HALF THE SIZE

Respironics, Inc, announced the introduction of its MicroElite Compressor Nebulizer System for aerosol delivery treatment of respiratory and non-respiratory diseases. Half the size of other common portables, MicroElite is the company's smallest compressor nebulizer system, making it easy to use and easy to carry. This unique, miniature, palm-sized compressor provides treatments in as little as eight minutes and can be powered by three versatile sources, AC, car adapter and battery. MicroElite is suitable for both pediatric and adult use. Paired with the Micro Plus reusable nebulizer, designed specifically for this compressor, it can be used either as a handheld unit or as a tabletop unit by attaching the tubing included with the system.

An optional lithium polymer battery powers the MicroElite Compressor Nebulizer System for up to 60 minutes between charges. Developed from advancing cell phone technology, this small, powerful, gel-filled battery is an evolution from more common lithium ion designs, reducing leakage risks and providing superior stability in over-voltage and high-temperature conditions. The addition of the MicroElite expands Respironics' family of compressors beyond its conventional tabletop Inspiration Elite and portable MiniElite systems, providing asthma and COPD patients with a full range of value options to fit their individual needs. Contact respironics.com.

GET SMART

Draeger Medical, Inc announced its SmartCare/PS option for the EvitaXL ventilator has received market clearance for additional product claims from the FDA.[1] Introduced in November 2005, SmartCare is a knowledge-based ventilation system developed to improve the efficiency and effectiveness of the weaning process for hemodynamically and neurologically stable patients without severe COPD. SmartCare can help reduce patient intensive care days as well as ventilator days by integrating protocolized care into automated ventilation weaning. The newly cleared claims for SmartCare address clinical and efficiency benefits in ventilator therapy, including time reduction: reduced overall ventilation time by 33%; decreases ICU length of stay by up to 20%, reduced weaning duration by up to 40%.[2] By reducing weaning time and potential associated complications and infections, SmartCare may lead to reductions in the cost of care, improved resource utilization, and decreased incidence of ventilator morbidity. This includes potential medical results such as: increased efficiency and improved therapy; reduced ventilator induced injuries and complications; decreased potential for infections; avoiding re-intubation; increasing quality of outcomes; 100% weaning protocol compliance. SmartCare automates the weaning process, based on the user's input, using continuously measured parameters and patient respiratory profiles. As the level of ventilator support is adjusted automatically, the patient's response and ability to adapt to each change in support is evaluated. Traditional methods of weaning vary greatly, do not always progress with the patient's ability to wean, and are labor-intensive for hospital staff. Unlike these intermittent processes, SmartCare continuously monitors the patient, interprets the data, and adjusts the level of ventilator in two- or five-minute intervals. "Literature suggests that a significant amount of clinicians' time is spent in attempts to wean patients off

ventilator support," said Ed Coombs, RRT, Critical Care and Ventilation, Draeger Medical, Inc.[3] "SmartCare is a reengineering of the weaning process through automation of accepted clinical protocols. It is a tool that extends the clinician's ability to make necessary adjustments required to progress care of the weaning patient. By simply observing, adapting and maintaining the patient, SmartCare provides the potential to improve outcome while decreasing cost." References: 1. Lellouche F. et al, A Multicenter Randomized Trial of Computer-driven Protocolized Weaning from Mechanical Ventilation. American Journal of Respiratory Critical Care Med, Vol. 174. pp 894–900, 2006. 2. These results are based on a European Multi-center Randomized Trial with 144 patients demonstrating improved respiratory condition, with stable hemodynamic and neurologic status, and no ARDS prior to initiating weaning. 3. Esteban A, Alia I, Ibanez j, et al. Modes of mechanical ventilation and weaning. Chest 1994; 106:1188-1193. Contact draeger.com.

MONITORING PRODUCTS

CLINICAL CASE STUDIES

Masimo, the inventor of Pulse CO-Oximetry and Measure-Through Motion and Low Perfusion pulse oximetry, reported that multiple clinical studies demonstrating the accuracy and clinical effectiveness of the Masimo Rainbow SET platform were highlighted to over 8,000 anesthesiologists at the 14th World Congress of Anesthesiology (WCA) in Cape Town, South Africa. In addition, WCA attendees were able to preview noninvasive total hemoglobin (SpHb) and oxygen content (SpOC) as part of the Rainbow SET platform (pending FDA clearance). **Continuous Noninvasive Measurement of Hemoglobin via Pulse CO-Oximetry**, a clinical study led by Dr Mark Macknet at Loma Linda University in Loma Linda, California, presented a study that compared an engineering prototype of Masimo Rainbow SET noninvasive total hemoglobin (SpHb) to invasive laboratory hemoglobin measurements in two groups. Group one included 55 patients scheduled to undergo surgery, while group two consisted of 32 healthy volunteers undergoing a hemodilution protocol. After reviewing 1,538 data pairs, researchers found that the Masimo technology accurately delivered total hemoglobin levels, with the study showing accuracy of 1.28 mg/dl and 0.94 mg/dl for group two, respectively, when compared to invasive laboratory CO-Oximetry. Researchers concluded that Masimo's device is the first device developed that can continuously and noninvasively measure hemoglobin concentration, in addition to the other common hemoglobin species, and therefore provides a significant expansion of existing physiologic monitoring technology. **Casual Screening of Hemoglobin Noninvasively Positively Affects a Colleague's Future**, a case report by Dr Martin Allard at Loma Linda University recounted the application of SpHb to assess an anemic hemoglobin level of 10.6 g/dl on a fellow anesthesiologist who otherwise appeared healthy. Invasive hemoglobin testing confirmed the measurement and further diagnostic testing revealed previously undiagnosed and asymptomatic esophageal cancer. Researchers concluded that Masimo SpHb allowed the detection of this potentially devastating tumor before clinical signs or symptoms became apparent, which resulted in early intervention and therapy that may well be curative for this colleague. **New Pulse Oximetry Sensors with Low Saturation Accuracy Claims**, performed by Dr Peter Cox at the Hospital for Sick Children in Toronto, Canada, evaluated 12 patients with congenital cyanotic cardiac lesions (CCCL) to compare noninvasive oxyhemoglobin (SpO_2) measurements from the Masimo Rainbow SET Radical 7 device with Blue Sensor to various other devices. The Masimo Radical with Blue Sensor, the first and only sensor with accuracy claims cleared for cyanotic patients, performed within Masimo specifications and had significantly better accuracy than other devices tested at 3.85%. Study results demonstrate that the Masimo Blue sensor, which was "designed for use specifically in this patient population, is more accurate." Dr Peter Cox, Hospital for Sick Children in Toronto, Canada, said, "accurate monitoring of oxygen saturations in children with cyanotic congenital heart defects is essential for appropriate patient management and, therefore, its impact on their long-term outcome. The Masimo Blue Sensor accurately tracks saturation to levels as low as 60%, which will greatly assist caregivers in the management of this patient population." **Severe Methemoglobinemia Detected by Pulse CO-Oximetry in the Operating Room**, a case report by Dr Steven J. Barker and Dr E. H. Annabi at the University of Arizona in Tucson, Arizona, documented the use of Masimo noninvasive methemoglobin (SpMet) to accurately diagnose a severe case of drug-induced methemoglobinemia and subsequently monitor and guide the patient's treatment and recovery. Researchers concluded that Masimo SpMet can "quickly diagnose" methemoglobinemia in the perioperative setting, where time is of the utmost essence. Masimo also previewed, for the first time, continuous noninvasive total hemoglobin (SpHb) and oxygen content (SpOC) as part of the Rainbow SET platform during WCA's commercial exhibition. Contact masimo.com.

INTO INFINITY

Draeger recently unveiled the newly improved Infinity Omega solution, now with a widescreen. This integrated two-screen patient monitoring solution, consisting of a full-function patient monitor, is also capable of supporting patient transport. Its 20" medical-grade touchscreen bedside computer brings IT applications to the point of care. Infinity Omega displays real-time monitoring and ventilation data together with networked data—such as lab results, DICOM/X-ray images, and patient/anesthesia data management system information—and allows control of monitoring functions from either screen. The Infinity Omega solution integrates an Infinity Delta series patient monitor and docking station with an Infinity C700 for IT workstation and Infinity Explorer software. The Infinity Delta monitor provides continuous monitoring at the bedside and on transport, while the patented Infinity Docking Station provides power, network connectivity and departmental screen configuration data. The Infinity C700 displays integrated patient data at the bedside on a 20" wide touchscreen display. Infinity Explorer software enables two-way communication between the Delta and the Infinity C700, bridging the gap between patient monitors and the IT infrastructure of the hospital. Through the Infinity Network, patient information gathered at the bedside can be viewed simultaneously at the Infinity CentralStation, which gathers and displays information from Infinity bedside and telemetry monitors for up to 32 patients. This data includes alarms, real-time waveforms and parameters, laboratory values, and respiratory and ventilator information. Clinical applications in the Infinity CentralStation—such as Full and Event Disclosure, ST Segment Analysis, and 12-Lead Rest ECG Analysis and Trend Display—enhance patient care management by providing rapid assessment, decision support and clinical reporting. In addition, information from the Infinity

CentralStation can be viewed remotely via the hospital network through Draeger's innovative remote viewing applications. Contact draeger.com.

UPGRADED

Roche Diagnostics today announced the global launch of an enhanced software (Version 7.0) for its flagship bloodgas analyzer; the cobas b 221 system. The new software version is tailored to the demands of critical care clinicians, nurses and POCT coordinators. It provides new features for single parameter trending, and the option to define specific parameters panels. With this new version of software, up to four parameters can be trended not only in percentage of change, but also against absolute values. This means that a graphical plot can be used to monitor disease progression. Upper and lower critical limits can be user defined for each parameter. Onboard patient trending helps healthcare providers to monitor the progress of their patient's condition during the course of treatment. In order to provide the user with the option to perfectly tailor the range of tests to everyday needs in a point of care situation, the new software is equipped with panels that can be modified by authorized users. It is possible to define up to four different panels, increasing not only usability but also allowing control over billable parameters for the hospital. Finally the software means improvement in terms of quality control. Contact roche.com.

BLOOD TEST

Masimo announced the debut of its breakthrough technology for noninvasive and continuous total hemoglobin (SpHb) and oxygen content (SpOC) monitoring at the World Congress of Anesthesiology in Cape Town, South Africa. The advent of noninvasive total hemoglobin within the Masimo Rainbow SET platform will make hemoglobin testing more convenient and broadly available to medical personnel in both the acute and outpatient settings—the measurement is instantaneous and pain-free. Prior to Masimo Rainbow SET, invasive and time-consuming lab tests were the only methods available to determine total hemoglobin levels which provided delayed and intermittent data. Masimo expects to make SpHb and SpOC shipments to select customers for clinical use in the second half of 2008, pending regulatory clearances. There is a 510(k) pending for SpHb and SpOC in the US. The Masimo Rainbow SET technology platform will provide clinicians with access to real-time trending and tracking of a patient's total hemoglobin status enabling quick identifications of anemia, or blood loss. A simple upgrade to most Masimo Radical pulse oximeters is all that will be necessary to transform an existing monitor to Masimo Rainbow SET performance—enabling integration of noninvasive total hemoglobin monitoring into any clinical setting.

A new clinical study, recently published in the Journal of Emergency Medicine, found the Masimo Rainbow SET Rad-57 Pulse CO-Oximeter to be "a safe, easily applied tool at triage that can identify cases of unsuspected elevated levels of carbon monoxide (CO) poisoning" that would otherwise have gone undetected. Researchers at the Rhode Island Hospital, where the study was conducted, also concluded that universal SpCO screening may prevent morbidity through early identification and treatment intervention, stating that: "we can point to several cases during our study period in which patient outcomes were different based upon availability of SpCO, recorded at triage." The study titled "Noninvasive Pulse CO-Oximetry Screening in the Emergency Department Identifies Occult Carbon Monoxide Toxicity" was conducted over a nine-month period on more than 10,850 patients presenting to the Emergency Department at the Rhode Island Hospital in Providence, Rhode Island, by a research team of emergency medicine physicians from the Warren Alpert Medical School at Brown University and the Emergency Department of Rhode Island Hospital. The study tested the ability to screen for CO toxicity in a busy tertiary center ED using the Masimo Rainbow SET Rad-57 Pulse CO-Oximeter and found 28 cases of CO toxicity (SpCO of > 9% for nonsmokers and >13% for smokers), of which 11 were unexpected, and were identified only with the aid of universal SpCO screening using the Masimo Rad-57. In all CO toxicity cases identified, venous or arterial COHb confirmations of elevated SpCO measurements were verified by lab analysis of blood samples taken with data results showing a "good correlation" between SpCO from the Masimo Rad-57 and COHb from the lab analysis. Using data extrapolated from the study at Rhode Island Hospital's level-1 trauma center ED, researchers suggest that potentially "as many as 11,000 occult poisoning cases" go undetected annually—illustrating the significant impact that universal SpCO screening could have on public health and safety. Contact masimo.com.

APPROVED IN JAPAN

Masimo announced Japanese Ministry of Health, Labor and Welfare (MHLW) approval of its PVI measurement. PVI is an index automatically derived from the Masimo plethysmographic waveform, which has been demonstrated to noninvasively assess fluid responsiveness in mechanically ventilated patients and can help clinicians assess if a patient's cardiac function is compromised. PVI may help clinicians and emergency professionals to determine if a patient is dehydrated or over-hydrated—enabling more accurate fluid administration decisions—all by simply referring to the numerical Masimo PVI value that is continuously displayed on Masimo Rainbow SET Pulse CO-Oximeters. With one noninvasive sensor, Masimo Rainbow SET technology delivers multiple physiologic measurements that previously required invasive blood tests, including total hemoglobin ($SpHb^T$) and oxygen content ($SpOC^T$) (both pending FDA and other regulatory clearances), carboxyhemoglobin (SpCO), methemoglobin (SpMet), PVI, oxyhemoglobin (SpO_2), perfusion index and pulse rate. During surgery and post-operatively, the immediate identification and rapid intervention of patients who are most likely to respond to fluid administration (fluid responders) can enable organ preservation, while recognizing patients unlikely to respond to fluid administration (fluid non-responders) can prevent pulmonary edema. Clinical studies have shown that current static methods for assessing fluid responsiveness, including clinical examination, arterial blood pressure, heart rate and central venous and pulmonary artery occlusion pressure, are poor predictors of fluid responsiveness. Also dynamic indices, such as respiratory variations in arterial pulse pressure, inferior vena cava diameter, superior vena cava diameter and stroke volume, present significant limitations, are invasive and often operator-dependent. PVI is a dynamic new indicator of fluid responsiveness that does not require an invasive procedure or manual calculation, yet has been demonstrated to be sensitive to changes in preload and to be an accurate predictor of fluid responsiveness in mechanically ventilated patients. In a current issue of Anesthesia and Analgesia, a clinical study titled, "Does the Pleth Variability Index (PVI) Indicate the Respiratory-Induced Variation in the Plethysmogram and Arterial Pressure

Waveforms?" headed by Dr Maxime Cannesson from the Louis Pradel Hospital and the Claude Bernard Lyon University in Lyon, France, studied 25 patients under general anesthesia and mechanical ventilation and found a strong correlation between Masimo's PVI measurement and the manually measured Delta POP (r=0.92), with a sensitivity of 93% and a specificity of 97%. The researchers had previously shown a high correlation between Delta POP and fluid responsiveness. The recent study findings also confirmed that the relationship between PVI and Delta POP was still significant when performed in the Anti-Trendelenburg (r=0.94) and Trendelenberg (r=0.93) body positions, illustrating the responsiveness of PVI to the dynamic and changing fluid volume status. Dr. Cannesson et al. concluded that PVI has "potential clinical applications for noninvasive fluid responsiveness monitoring."

BRING GOOD LUNGS TO LIFE

GE Healthcare, a unit of General Electric Company announced that it has completed the acquisition of VersaMed Corporation, a provider of portable critical care ventilators for respiratory care. VersaMed's innovative product offering will expand GE Healthcare's capabilities in respiratory care management, offering healthcare professionals a wide choice of unique advanced life support ventilators to meet a variety of patient needs and care settings. Financial terms were not disclosed. VersaMed develops easy-to-use, high performance portable ventilators applicable to a wide range of care settings. VersaMed's flagship product, the iVent 201 ventilator, is an intensive care-grade ventilator designed to be compact and portable, making it ideal for use in hospitals for acute and sub-acute care, in emergency transport and in the home. The iVent201 has already been selected by a number of governmental and healthcare organizations as a key part of their pandemic and other emergency preparedness plans. GE Healthcare's Clinical Systems business is a world class provider of advanced technologies for acute respiratory care. The strong strategic fit between the two businesses will offer substantial customer benefits through complementary product and service offerings. In the US, the iVent 201 is cleared by the FDA for use in hospitals, home, patient transport and emergency/alternate-site care venues. Contact ge-com.

MEET THE ELITE

Medical Graphics Corporation, St Paul, MN, introduces the Platinum Elite Series plethysmograph, providing complete spirometry; diffusion capacity; lung volumes by single breath diffusion, multiple breath diffusion and plethysmography; and airways resistance. Based on the award winning Elite Series design, the Platinum Elite offers many new features to improve diagnostic capability and enhance ease of operation, accuracy, reliability and patient comfort. The system can test pediatric through adult patients and the expanded seating space accommodates larger and tall patients with virtually no weight restriction. The system's advanced sensor technology is self-monitoring, self diagnostic and auto-adjusting to simplify system operation. New digital components offer the maximum in accuracy, reliability and serviceability. The unique "zero clearance" cabinet enables accommodation of tall and larger patients despite its small footprint. Each Platinum Elite comes with the latest release of Windows XP and Vista compatible BREEZESUITE software, upgraded to support the system's enhanced technology. BREEZESUITE provides a common platform for all MedGraphics pulmonary function and gas exchange systems simplifying networking and data management. The Platinum Elite Series is available in three different models, providing combinations of different testing functionality. Contact (800) 950-5597, medgraphics.com.

ROYAL DEAL

Royal Philips Electronics announced it has reached an agreement to acquire all outstanding shares in Shenzhen Goldway Industrial, Inc, in China. Goldway will become part of the Patient Monitoring business within Philips' Healthcare sector. Goldway offers patient monitoring solutions that range from basic standalone to more fully-equipped monitors, including products that have been FDA approved in the United States or carry the CE certification in Europe. Philips spokespersons said acquiring Goldway will secure Philips a broader presence in the Chinese healthcare market, which is estimated to be growing at approximately 10% per year. Goldway is the second largest domestic patient monitoring company in China, employing a staff of 290, with sales growing by 30% in 2007. Philips employs 123,800 employees in more than 60 countries worldwide. Contact philips.com.

BLOOD GAS ROUNDTABLE

Siemens Healthcare Diagnostics

Information provided by Elliot S. Andrews, Marketing Manager.

How does your product help implement quality control in a point of care and/or centralized lab setting?

RapidSystems is comprised of two platform blood gas analyzers-the RapidLab 1200 series and the Rapidpoint 400 series. The Rapidpoint 400 Series analyzer is a sophisticated whole blood analysis system that is designed specifically for point-of-care testing while also satisfying the stringent requirements of the central laboratory. Both systems can be paired with on-board automatic quality control materials which require no operator intervention throughout their 28-day life. This is accomplished through innovative software and our effortless external aqueous based cartridge system.

How does your product provide for accuracy in measurement?

The Rapidpoint 400 Series system automatically analyzes, evaluates and documents three levels of on-board, liquid, quality control materials at a frequency, which equals or exceeds all regulatory agency requirements. These include CAP, JCAHO, COLA and CLIA. When controls are analyzed, the Rapidpoint 400 Series analyzer uses an internal algorithm to assess the acceptability of the results. If the control values are within limits, the system remains ready to analyze patient samples. If the system is not in control, it automatically proceeds with preprogrammed corrective actions, insuring every patient result reported is of the highest accuracy.

What features of your product help reduce error rates?

The Rapidpoint 400 Series System fully automates the entire testing process to provide standardized, laboratory-quality testing at every test site. A single, multiple-use measurement

cartridge contains all of the components of a traditional laboratory analyzer. This long-lasting cartridge includes the sampling unit, all of the sensors and all calibrating reagents. No gas tanks are required. A wash/waste cartridge contains the wash solution and also serves as the collection device for all of the waste, providing a completely closed, bio-safe system. The zero-maintenance, cost-effective multi-use cartridge and auto sampling provides consistent results and reduces the chance of errors.

What educational materials do you provide to help avoid pre-analytical or equipment usage errors?
The Rapidpoint 400 Series analyzer has an intuitive color touch screen user interface with built-in learning audio-videos to simplify training and day-to-day operation. Additionally, the unique bio-safe automatic sampling port is a clot detection and clearance system that maximizes analyzer uptime and operator safety at the point of sample introduction to the system. The sampling port facilitates rapid test time for all sample types- syringe or capillary. Most importantly, we provide ongoing coverage from a dedicated Customer Education Specialist team for on-site training.

What features of your product help clinicians interpret blood gas data?
Designed to meet the various challenges of the critical care setting, Rapidpoint 400 Series analyzers deliver whole blood results in just 60 seconds for one test or a complete panel. It has the most complete point-of-care menu available- pH, blood gas, electrolytes, glucose, CO-oximetry and hematocrit- all with the capability to be monitored remotely by the central laboratory. This allows treatment decisions to be made quickly. Rapid turnaround times help clinicians maximize standards of care, which results in improved outcomes that assist patients to recover quickly.

Does your equipment readily connect with most hospital information systems; if so which ones; are there any problematic issues with connectivity?
Yes—our dedicated Network Systems Specialists and consultants work to ensure that our blood gas systems are readily compatible with current and new hospital programs. All RapidSystem analyzers can connect directly or remotely to central LIS/HIS information systems. Additionally, RAPIDComm Data Management Solution provides connectivity for secure institution-wide communication. It allows you to control multiple functions from a single, automatic interface to streamline administration and management. This enhanced system provides an added level of control through improved documentation and integration with your information system.

Discuss how your product addresses patient safety.
The Rapidpoint 400 Series Point-of-Care analyzer is the first and only cartridge-based blood gas system to seamlessly integrate CO-oximetry from a single sample. It is also the first system to use on-board automatic quality control materials independent from calibrators which insures results are always accurate. The Rapidpoint 400 series analyzer gives you the fastest, most productive system available—with the ability to deliver laboratory-quality results in the POC setting.

What technical support programs do you have in place to maximize equipment uptime?
Siemens is committed to providing the highest quality of service and support to our customers around the world. Dedicated teams of experienced professionals efficiently handle all aspects of customers' needs, from fulfilling orders and handling billing inquires to troubleshooting technical issues by providing 24x7 phone support as well as on-site technical and educational support. These service teams maintain a strong sense of urgency and an unflagging commitment to maximize system uptime and provide technical responses quickly and accurately. We continually strive to exceed customer expectations.

Roche Diagnostics Corporation

Information provided by Larry Healy, Marketing Manager, Point of Care.

How does your product help implement quality control in the point of care setting?
The Roche cobas b 221 blood gas system offers customers the tools necessary to implement quality control and meet compliance standards at the point of care. The cobas b 221 blood gas system's Auto QC has onboard capacity for up to 40 days of QC material. The flexibility of cobas b 221 onboard QC programming provides user-defined programs to meet specific QC protocols. For example, the program manager can program the analyzer to run range studies for the new lot of QC while the current lot of QC is in use. With 20 gigabytes of onboard storage, the cobas b 221 system maintains an average of five years' worth of QC, calibration and patient data for review and reporting. Our real-time peer review QC program, eQAP, helps ensure performance and regulatory compliance. OMNILink Instrument manager software provides real-time screen sharing and allows immediate access to QC, calibration and system status of all connected decentralized systems.

What features of your product help reduce error rates?
To help avoid unnecessary errors, the cobas b 221 blood gas system has a run mode that reduces the number of screens the operator uses. This is called the POC or Point of Care mode. The mode is configured by the RT director, lab manager and POC coordinator and helps provide ease of operation to up to 3,000 qualified users in the decentralized setting. The barcode reader allows for patient IDs to be entered automatically, helping to avoid transcription errors. Barcode entry of all consumables helps document lot numbers, stores ranges and helps prevent use of reagents past their manufacturer or onboard expiration date, assures correct lot number, ranges and expiration date. QC and calibration default settings for all parameters prevent patient samples from being run until QC and calibration are in range. Continuous self-monitoring of consumables tracks expiration dates and automatically helps prevent the use of expired controls, reagents and electrodes. And continuous electronic monitoring provides operational status between calibration intervals, alerting the operator to the problem or re-running a calibration to maximize uptime.

What educational materials do you provide to help avoid equipment usage error?
Roche provides a number of educational materials to help ensure proper use of the system. The cobas b 221 blood gas system comes with onboard video tutorials to instruct the user in the proper operation of the system. A Short Instructions for

Use guide supports the tutorials and a customer-based training CD ROM, along with the Instruction for Use and Reference manuals, provides detailed instructions to help avoid equipment usage error.

How does your product provide for accuracy in measurement?
In addition to the details described above, Roche cobas b 221 customers can be reassured that results are available only from valid calibrations; that errors are detected and, when possible, corrected before alerting the operator; and that QC is automatically run on time to help ensure only accurate measurements are available.

In the critical care setting, spectroscopic analysis of hemoglobin and its derivatives (co-oximetry), in combination with blood gas analysis, provides immediate, actionable information about oxygen transport in human blood. The accuracy of the hemoglobin and bilirubin results depends on the performance of the co-oximetry technology.

The co-oximetry module of the Roche cobas b 221 blood gas system measures both hemoglobin derivatives and bilirubin (spectrophotometrically, in the visible spectrum range (460nm to 660nm)). Absorbance of the sample is measured at a total of 512 discrete wavelengths. The concentrations of hemoglobin, hemoglobin derivates and bilirubin are determined by applying an accepted mathematical algorithm.[1] This enables the cobas b 221 system's co-oximetry technology to detect the presence of light-absorbing substances not covered by the reference spectra and to prevent incorrect values due to interfering substances from being reported.[3] This advanced co-oximetry design helps improve the accuracy of patient test results, which is demonstrated by a high correlation with results from accepted clinical chemistry test methods.[2]

1 cobas b 221 reference manual version 8.0 pp 20, 21.
2 Rolinski, Boris et al. Evaluation of Total Bilirubin Determination in Neonatal Whole-Blood Samples by Multiwavelength Photometry on the Roche OMNI S Point-of-Care Analyzer. Point of Care, The Journal of Near Patient Testing and Technology; Volume4, March 2005.
3 Schweiger, Gerd. Technical Aspects: Determination of Bilirubin on the Roche OMNI S, International Evaluation Workshop, October , 23 2003, Deutschlandsberg, Austria.

What features of your product help clinicians interpret blood gas data?
Blood gas operators that use the cobas b 221 blood gas system facilitate patient diagnosis and expedite treatment decision-making at point of care by delivering up to 18 test results—including blood gases, electrolytes, tHb, O2Hb, HHb, COHb, MetHb, Hct, bilirubin, glucose, lactate and BUN—from one 210 µL sample.* This menu, coupled with automated acid-base mapping trending and patient trending, provides clinicians in the ER, ICU and other critical care environments with immediate actionable information for improved health outcomes. The trending display and result display help answer questions for the healthcare provider: "Is my patient getting better? Has the patient condition changed?" [* Roche cobas b 221 Instruction for Use v. 8.0]

Does your equipment readily connect with most hospital information systems; if so, which ones; are there any problematic issues with connectivity?
The cobas b 221 blood gas system with IT solutions has been designed to provide connectivity for both centralized and decentralized settings. These solutions enable connectivity with most hospital LIS/HIS systems.

- OMNILink – Software that provides the key operator command and control of instruments even if they are remotely placed in decentralized settings.
- DataCare POC – Data management platform recognized for its clinical and report capabilities for all centralized and decentralized customers through HL7.
- MAS RALS Plus – Single IT connectivity and data management solution recognized for its multiple point of care program functionality for decentralized customers.
- Middleware – Direct interface for current Roche chemistry customers in the laboratory to an HIS/LIS.
- Direct Interface – uni-directional output capability from the cobas b 221 blood gas system.
- A dedicated team of agents are available to resolve interface questions.

How does your product address patient safety at the point of care?
Operators of the cobas b 221 blood gas analyzer have access to a broad menu of analytes from one sample. This minimizes the amount of blood or number of blood draws a patient needs to generate accurate results. The ability to provide acid-base map trending and patient result trending can help operators inform healthcare providers, potentially resulting in enhanced patient treatment and outcomes.

Patient safety goals, as announced by the Joint Commission, include accurate patient identification. The use of barcodes for patient ID and the incorporation of an Admission, Discharge, Transfer data stream can help ensure that the right results are run and reported on the right patient.

The cobas b 221 system is designed with a turn-and-dock sample port, without an external needle, to help minimize exposure of the operator to bio-hazardous samples in the critical care setting. This port allows sample aspiration from a syringe and capillary or injection from a syringe. The sample port is automatically rinsed before and after the sample is introduced. All sample waste is pumped to closed waste container housed in the system for proper disposal and helps protect the operator from potential bio-hazards.

What technical support programs do you have in place to maximize equipment uptime?
The cobas b 221 blood gas system with OMNILink Instrument Manager software allows RT directors, Lab managers and POC coordinators to meet compliance requirements with centralized command and control of analyzer operation, documentation and reporting. The system provides remote real-time monitoring of calibration data, QC, maintenance and operator activity of all connected analyzers from one central location—without interrupting analyzer workflow. With this software and available site permissions, the Roche call center can also access and share the analyzer's screen. This helps facilitate faster troubleshooting and resolution, maximizing analyzer uptime for patient result reporting.

Instrumentation Laboratory

Information provided by Bill Manchester, Group Product Manager, WW Critical Care.

How does your product help implement quality control in a point-of-care and/or centralized lab setting?
The GEM Premier 4000 analyzer has patented, on-board Intelligent Quality Management (iQM) to ensure optimal test results in the laboratory and at the point-of-care. iQM is a continuous, quality assurance system that automatically monitors, detects, corrects and documents errors and requires no operator intervention. The completely closed, single-component cartridge technology on the GEM Premier 4000 makes iQM possible. Only a single cartridge is required every 30 days. Once the cartridge is inserted, no external variables can be introduced into the system while the cartridge is in use. iQM has been cleared by the FDA for the GEM Premier 3000 and 4000 instruments to replace the need for traditional quality control materials: "iQM is an active quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls." (FDA-Cleared Intended Use Statement.) iQM reduces time-to-error detection and mitigates the risk of treatment errors to support the ultimate goal-enhanced patient safety and care.

How does your product provide for accuracy in measurement?
The analyzer employs an external product which completes the calibration process, Calibration Valuation Product (CVP). This CVP is tested following cartridge warm-up and confirms cartridge integrity. The analytes must pass the CVP before patient samples can be reported. During the life of the cartridge, the iQM process continuously checks to see if any limits have been exceeded. In addition, all solutions are traceable to an external source, such as NIST.

What features of your product help reduce error rates?
Failure Pattern Recognition (FPR) is a key component of iQM. This feature is the result of the comprehensive analysis of thousands of cartridges used by customers over several years. FPR flags potential errors in real-time based upon the electronic "footprint" of the type of error (eg, clot, interference). In combination with iQM's process control program, errors are detected within minutes compared to the hours it would take using a traditional QC program. Further, when an error is detected, iQM immediately attempts to correct the problem and the respective sensor is disabled. The sensor is re-enabled when the error is corrected, ensuring that erroneous errors are not reported.

What educational materials do you provide to help avoid pre-analytical or equipment usage errors?
A Training Guide and Training Video accompany each installation of the GEM Premier 4000. Onsite, IL representatives perform a regimented training program to ensure that end-users are not only comfortable running the system, but are fully competent in running different types of samples (from capillary tubes to syringes) by addressing both analytical testing and pre-analytical sample handling. IL also holds Quality seminars periodically throughout the year where pre-analytical, analytical, and post-analytical laboratory testing components are discussed in detail by industry experts. These seminars provide Continuing Education Units (CEU) for attendees.

What features of your product help clinicians interpret blood gas data?
The iQM Delta Chart Reports help clinicians easily identify changes or trends with patient results. Furthermore, when GEM Premier 4000 analyzers are connected to the hospital intranet, all results for a patient can be viewed and compared, regardless of which analyzer was used. Clinicians can view a patient history database from any GEM Premier 4000 analyzer or PC in the network.

Does your equipment readily connect with most hospital information systems; if so, which ones; are there any problematic issues with connectivity?
The following major HIS/LIS vendors currently interface with the GEM Premier 4000 system: Cerner, Sunquest, Meditech, Soft, GE, and McKesson. In addition, the analyzer seamlessly interfaces and connects to point-of-care middleware providers, such as MAS and Telcor.

Discuss how your product addresses patient safety.
The quality assurance package included in the GEM Premier 4000 contains iQM and FPR. iQM enhances patient safety, based upon sigma metrics quality, as defined by Dr. James Westgard, by providing quality results on every patient sample. FPR software, a function of the iQM process, identifies interferences that could affect patient results. The instrument software looks for patterns, specific to interfering compounds that affect sensor outputs. Corrective actions, including flagging affected parameters, washing off interferences and temporarily increasing the frequency of sensor drift checks are triggered and documented. Furthermore, when the GEM Premier 4000 analyzer is interfaced to the hospital LIS, medical recording errors are minimized.

What technical support programs do you have in place to maximize equipment uptime?
Since all components for critical care testing are contained in the cartridge itself, a "back up" cartridge, which can be stored at room temperature at any testing site, is simply installed if a failure is detected by iQM. It's simple - after a short warm up period, CVP ampoules are run to validate the cartridge, and the instrument is ready to go.

Nova Biomedical

How does your product help implement quality control in a point of care and/or centralized lab setting?
Nova offers automated on-board quality control as a standard feature on all of our Stat Profile pHOx and Critical Care Xpress (CCX) analyzer models. Auto QC eliminates the steps involved in manually performing quality control, thereby dramatically reducing labor costs and assuring QC compliance. In addition, Nova's Quality Assurance Program provides intra-laboratory and peer group comparisons of quality control data obtained using Nova blood gas and critical care analyzers. Data generated by one laboratory is compared to the data of other laboratories using the same lot number of control material.

NEW GEM PREMIER 4000

So advanced, it's simple.

So simple, it's revolutionary.

Introducing the new GEM Premier 4000. Simply. Revolutionary.

It's the breakthrough whole blood analyzer with integrated CO-Oximetry that quickly provides consistent, accurate, lab-quality results throughout your hospital—in one easy-to-use, comprehensive solution. Minimal set-up. Virtually no maintenance. Remarkable flexibility for every testing need. With GEMweb® Plus you get central control over all testing processes, while iQM®, IL's patented intelligent quality management system, helps assure quality results and QC compliance 24/7, regardless of operator or testing location. The GEM Premier 4000 is revolutionizing blood testing—from the lab to the point of care.

Please contact your IL sales representative, at **1.800.955.9525**, or visit **www.ilus.com**.

Werfen Group | Instrumentation Laboratory

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How does your product provide accuracy in measurement?
Nova analyzers feature state-of-the-art biosensors that have been well characterized and proven to provide excellent accuracy throughout their analytical measurement range. Sophisticated, computerized self-monitoring of the entire analysis and calibration cycles assures error-free and accurate analyzer performance. Extensive automation of Nova analyzers eliminates variability due to operator technique.

What features of your product help reduce error rates?
As above, extensive automation and computerized self-monitoring help reduce error rates.

What educational materials do you provide to help avoid preanalytical or equipment usage errors?
Nova develops CLIA-formatted procedure manuals including topics such as pre-analytical sample handling to help the user follow the appropriate procedures and avoid pre-analytical or equipment usage errors.

What features of your product help clinicians interpret blood gas data?
Stat Profile CCX provides the most comprehensive test menu of any blood gas analyzer. A complete 20 test profile, including blood gases, Chem 8 plus lactate, hemoglobin and hematocrit is provided in one report, at one time, in less than 2 minutes. This consolidated profile allows better interpretation of complex acid base disorders versus separate, partial, or incomplete test results separated by time and changes in patient condition. Test results that are abnormal or critical are prominently flagged to help interpret data. CCX can also display and print out trend reports to monitor the changes in test results over time.

Does your equipment readily connect to most hospital information systems; if so, which ones; are there any problematic issues with connectivity?
Stat Profile CCX is compliant with industry standard POCT1-A interface protocol and is compatible with a wide variety of connectivity platforms and devices that use ASTM or HL7 protocols via serial or TCP/IP connections.

Discuss how your product addresses patient safety.
The comprehensive test menus provided by Nova blood gas/critical care analyzers provide physicians with fast, accurate results to facilitate immediate clinical decisions. Our "right test, right now" philosophy allows physicians to effectively manage the higher acuity of today's critically ill and unstable patients.

What technical support programs do you have in place to maximize equipment uptime?
Nova is committed to providing proactive responsible customer service. Toward that end, we offer 24/7/365 Technical Support Hotline and on-site technical service within 8 working hours to perform corrective maintenance. In addition, Nova Applications Support Specialists can assist with operator training, linearity and correlation studies, regulatory assistance, and onsite education and training.

Radiometer

How does your product help implement quality control in a point of care and/or centralized lab setting?
Both Radiometer's ABL800 FLEX benchtop analyzer and ABL80 FLEX POC analyzer feature fully automated quality control.

How does your product provide for accuracy in measurement?
The ABL800 uses the highest quality technical methods referenced to IDMS using NIST standards. Its quality control routine validates the entire sample path, including the inlet probes. Glucose, lactate and creatinine measurements are interference free, and the instrument incorporates a sealed hemolyzing oximeter.

What features of your product help reduce error rates?
When used with Radiometer's safePICO ABG sampler and FLEXLINK software, the ABL80 and ABL800 analyzers ensure correct sample and patient identification. The safePICO syringe reduces errors related to sample mixing. Errors related to improper mixing and air bubbles are addressed by several features of the safePICO. An integrated mixing ball works with the ABL800's FLEXQ module and the ABL80's safePICO Mixer accessory to ensure a homogenous sample. safePICO's vented tip cap expels air bubbles prior to aspiration.

What educational materials do you provide to help avoid preanalytical or equipment usage errors?
Radiometer offers a free educational pamphlet called "Avoiding preanalytical errors in blood gas testing." It may be requested by visiting our website at www.radiometeramerica.com. Radiometer also sponsors bloodgas.org, a non-commercial knowledge site devoted to blood gas testing and monitoring. Among the topics covered is avoiding preanalytical errors. Radiometer offers advanced customer training programs, including biomed training, in addition to basic instrument training.

What features of your product help clinicians interpret blood gas data?
The ABL800 features an onboard Siggaard-Andersen graph to help in the interpretation of the most important acid-base parameters. The graph illustrates metabolic and respiratory conditions and differentiates between acute and chronic cases.

Does your equipment readily connect with most hospital information systems?
Yes. Radiometer analyzers interface to major HIS/LIS systems (eg, Cerner, Meditech, SunQuest), middleware (eg, MAS-RALS, LDS, Telcor). Used with Radiometer's RADIANCE analyzer management software, our analyzers also link to interface engines, EMRs and bedside monitoring systems.

What technical support programs do you have in place to maximize equipment uptime?
We offer 24-hour call coverage; Techline for expert, real-time phone support; field support covering all 50 states and all Canadian provinces and territories; and remote service via RADIANCE, Radiometer's STAT analyzer management software.

Intubation and Ventilation for Asthma Exacerbation

Melissa Turner, BA, RRT; Paul Garbarini MS, RRT

For most asthma exacerbations that require urgent medical care, treatment options available are usually helpful in deterring endotracheal intubation. A small subset of severe asthma exacerbations becomes life threatening and requires intubation and mechanical ventilation. This group of patients presents too dyspneic to speak and diaphoretic. The peak expiratory flow (PEF) of these patients is less than 25% of predicted or personal best.

Deciding to intubate asthma exacerbation is based on a clinical judgment which must not be delayed once it has been deemed necessary. Some clinical signs to look for are worsening airflow obstruction or worsening muscle fatigue. Signs of impending respiratory failure, such as the inability to speak, altered mental status, intercostals retractions and a PaCO2 greater or equal to 42mm Hg are also indications that intubation is imminent.

Once intubated the patient is placed on mechanical ventilation. The recommended strategy is to use permissive hypercapnia or controlled hypoventilation. Using this strategy provides adequate oxygenation and minimizes high airway pressures and barotrauma. This strategy may require an acceptance of hypercapnia as needed to minimize autopeep. The presence of autopeep due to airway obstruction is the primary cause of elevated pressures. During mechanical ventilation, clinicians must adjust tidal volume, rate and I:E ratio to minimize high airway pressures as well as minimize autopeep. Expiratory time should be adequate so that there can be a complete exhalation before the next breath begins. One option in ventilating this patient population is the use of adaptive support ventilation (ASV), which not only will limit plateau pressures, but will also measure the expiratory time constant and incorporate it into finding the best tidal volume-rate combination for a given minute ventilation so as to mitigate autoPEEP.

I:E ratio is automatically adjusted based on individual patient measurements. Utilizing this closed-loop control system of ventilation will allow the ventilator to make changes in real time, breath by breath according to changes in the patient's pulmonary mechanics.

Alternatively, in conventional modes one should adjust ventilator settings to ensure that expiratory flow returns as close to baseline as possible at end expiration.

Increasing expiratory time by dropping the rate setting is the best way to achieve adequate expiratory time. Consider that halfing the inspiratory time from 1.0sec to 0.5 sec only increases expiratory time 0.5sec whereas dropping the rate from 15 to 10 would yield an additional 2 seconds expiratory time (exponentially more than halfing the inspiratory time). Additional strategies and therapies to consider while treating a ventilated asthma exacerbation are continual utilization of short-acting beta2-agonists, maintaining and /or replacing intravascular volume to prevent hypotension, and the use of other adjunct therapies. Adjunct therapies may include IV administration magnesium sulfate and inhaled heliox. Exclusive of upper airway disease, studies have not provided much support for use of heliox during mechanical ventilation of adults especially if contrasted with simply dropping the rate! Controlled mechanical ventilation for 24 hours will help to rest the respiratory muscles so the patient will recover from fatigue.

The best strategy for asthma exacerbations is early treatment. Clinicians should do all they can to prevent intubation, but intubation is not always avoidable. Once intubated, clinicians should adhere to these strategies known to produce positive outcomes.

Reference

National Heart Lung and Blood Institute, National Asthma Education and Prevention Program; Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. August 28, 2007.

The authors are with Hamilton Medical.

Case Report: Status Asthmaticus Refractory to Conventional Treatment

Patricia Dailey, BS, RRT

A 15 year old known asthmatic was admitted to the Emergency Room for an acute exacerbation. Her mother stated that she had been sick with an upper respiratory infection which triggered her asthma. Over the course of her treatment in the ER she developed status asthmaticus that was refractory to standard treatment requiring intubation. She received several hours of continuous nebulized albuterol at a dose of 15 mg per hour via the Airlife Misty Finity nebulizer, and multiple 2.5 mg doses of albuterol instilled down the ET tube. The patient became increasingly difficult to ventilate and required manual ventilation with a resuscitation bag in conjunction with continuous bronchodilator therapy.

The patient was then transferred to PICU and due to the severity of her exacerbation preparations were made to place the patient on heliox therapy through the ventilator. The nebulizer was changed to an Aeroneb Solo and it was placed in-line on the dry side of the ventilator circuit which previously would not have been feasible with a standard nebulizer. Continuous bronchodilator therapy was resumed at the same dosage of 15 mg of albuterol per hour. After two hours of continuous bronchodilator therapy utilizing the Aeroneb® Solo there was a dramatic improvement in her breath sounds and she subsequently did not require heliox therapy. She continued to steadily improve on Q2 hour bronchodilator therapy and the dose was gradually weaned to 5 mg of albuterol over the next 24 hours. She was extubated the next day and continued using the Aeroneb Solo with a mouthpiece until her discharge twenty four hours later.

Our therapists were quick to recognize the benefits provided by micropump nebulizers such as the Aeroneb Solo and they are excited about our patient's demonstrated clinical response. We have seen numerous positive patient outcomes in a variety of patient populations since its introduction. The Aeroneb Solo has provided us with the superior technology necessary to assure optimal outcomes for our patients.

Patricia Dailey is Clinical Educator, BMC, Springfield, MA. This article was provided by Aerogen.

Scripps Mercy Hospital, San Diego, CA

Providing excellent patient care is a top priority for Scripps Mercy Hospital, the longest-operating hospital in San Diego, CA. To ensure state-of-the-art care in its respiratory services, the hospital recently replaced its entire fleet of ventilators with SERVO-i ventilators equipped with BiVent.

BiVent is an effective mode of mechanical ventilation similar to Airway Pressure Release Ventilation (APRV), but with additional features. BiVent applies Continuous Positive Airway Pressure (CPAP) to maintain adequate lung volume and promote alveolar recruitment. BiVent also adds a time-cycled release phase to lower set pressure (P-low). In addition, spontaneous breathing can be integrated and is independent of the ventilator cycle.

Current research shows that APRV improves respiratory care in critically ill patients, especially patients with low compliance. In a study in Critical Care Medicine in 2005 (Vol. 33. No. 3, S228-240), Nader M. Habashi, MD, FCCP, an assistant professor at the University of Maryland in Baltimore, finds that APRV has distinct clinical advantages for ventilator management of patients with acute lung injury (ALI) or acute respiratory distress syndrome (ARDS). Among them are improvement in cardiac and renal function, decreased use of sedation, and near elimination of neuromuscular blockades. In his study, Habashi notes that some recent research suggests using APRV results in fewer ventilator days and shorter Intensive Care Unit (ICU) stays for many patients. Although randomized controlled trials still are needed, Habashi expects APRV to become the gold standard for patients with ALI or ARDS.

BiVent is an improvement on APRV because it allows pressure support to be set independently. Also, it allows the practitioner to set auto positive-end expiratory pressure (PEEP) when recruiting the lung. “Spontaneous breaths at the P-high improves dependent ventilation through pleural pressure changes, rather than the application of additional applied airways pressure,” explains Jodi Brewer, RCP, RRT, an educator and clinical respiratory specialist in the Respiratory Therapy Department at Scripps. “The advantage is the recruited lung requires less pressure than the recruiting lung.”

BiVent allows Scripps busy trauma unit to offer leadingedge respiratory care: “Since the arrival of these ventilators,” says Stephen Kaminiski, MD, FACS, a leading trauma service physician at Scripps Mercy, “we have been able to advance our ventilator care and our lung management to match state-of-the-art information.”

Scripps Mercy demands state-of-the-art technology because it has one of the busiest emergency departments and trauma centers in San Diego and Chula Vista, the two communities that it has served for 113 years. Last year, the hospital treated more than 50,000 ER patients and 2,200 trauma patients.

Kaminski, who, during his fellowship was trained on APRV, has noticed that his trauma patients are more comfortable on BiVent. Because they are able to breathe on their own, they are not “bucking” the respirator as often happens with conventional ventilation, he explains.

It is widely recognized that the use of sedation makes it more difficult to wean a patient from a ventilator. Because patients on BiVent breathe spontaneously throughout the ventilatory cycle, the mode requires much less sedation and nearly eliminates paralytics.

Thus, Kaminski has found that patients who are on the mode are often easier to wean and may be able to be weaned sooner, lowering the risk of serious complications that are commonly associated with long-term mechanical ventilation.

Jodi Brewer, RCP, RRT, educator and clinical respiratory specialist in the Respiratory Therapy Department, in surgical intensive care unit with Eleanor Vallejos, RCP.

Stephen Kaminski, MD, FACS, leading trauma service physician at Scripps Mercy, has found that patients on BiVent are often easier to wean.

Anecdotally, physicians at Scripps have found that BiVent reduces patient stays in the ICU. The department plans to confirm its anecdotal findings with a retrospective study looking at patients with the same diagnoses before and after it acquired the SERVO-i ventilators.

Kaminski believes so strongly in the benefits of BiVent that he uses it prophylactically on all his trauma patients. The earlier the intervention with BiVent, the better the outcome, he says. The only exception is for those with severe head injuries. "Patients with head injuries might require control of carbon dioxide, and therefore might be better managed by automode," he notes.

BiVent, Kaminski says, works well not only as lung protection strategy but also as a salvage method. "It's good for patients at the risk of ARDS and for patients who are difficult to oxygenate."

When Kaminski introduced BiVent to the five other physicians in his trauma practice, they were eager to incorporate it as well. "They all adapted it with open arms, from our senior docs to our more junior partners," he says.

George Silva, RCP, a lead respiratory therapist, says that as a Level I Trauma Center, Scripps Mercy has always been dedicated to the highest level in trauma care. "So it is the perfect place to use the BiVent mode," he says.

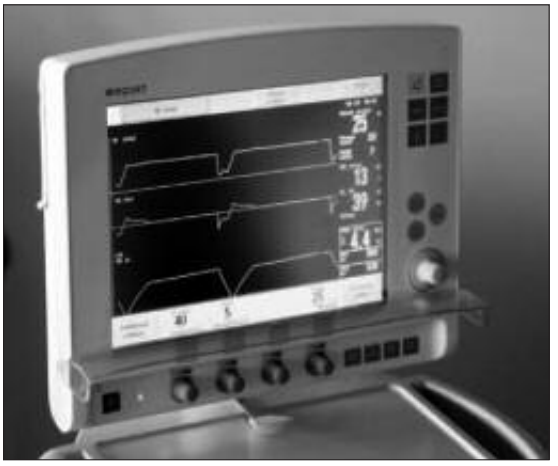
BiVent is proving to be the best mode for acute-care patients at Scripps as well. At Scripps Mercy, BiVent is now not only the mode of choice for trauma patients, but also is becoming so for its critically ill medical/surgical patients.

"It gives us an extra dimension in being able to ventilate our patients, especially the very sick cases," says Julian Lichter, MD, who has been Medical Director of Respiratory Care Services at Scripps Mercy since 2002. The hospital has a total of 32 intensive-care beds, and is among the top hospitals for cancer and cardiac care as well as bariatric surgery. Lichter says that on several occasions, BiVent has proven a lifesaving mode for some patients who are more difficult to ventilate because of their size or other pre-existing health conditions.

"Before we had the BiVent capability, we probably had 20% whom we were not able to oxygenate or who oxygenated very poorly," Lichter says. "Now, we can oxygenate upwards of 95% of patients."

"Thanks to BiVent, we have reduced the need for oscillation." Glenn Tanaka, RRT, RCP, Manager of Respiratory Care Services at Scripps Mercy.

"Now, we can oxygenate upwards of 95 percent of patients." Julian Lichter, MD, Medical Director of Respiratory Care Services at Scripps Mercy.



SERVO-i in BiVent mode.

Members of the Respiratory Therapy Department at Scripps Mercy Hospital.


The nurses station in the medical intensive care unit at Scripps Mercy.

While BiVent requires a change in thinking, it has become standard protocol in difficult cases, Lichter says. "In circumstances where we have patients who are difficult to ventilate, we will always use that mode to see if it helps them."

One advantage to BiVent, Lichter says, is that it can be used in conjunction with proning, which one small study suggests can improve gas exchange and survival rates among critical care patients. BiVent is easier to employ than proning because it is a matter of changing settings, whereas proning is more nurse-and-technician intense because it requires placing the patient on a special bed to be turned. Once the patients are on the bed and prone, it becomes more difficult to examine them, Lichter says. Also, he says, proning requires special care so tubes and other equipment are not displaced when the patient is turned. Still, he says, proning and BiVent can work well together when ventilating difficult patients.

Another positive feature of BiVent is that it can be used in conjunction with pressure support, says Glenn Tanaka, RRT, RCP, Manager of Respiratory Care Services at Scripps Mercy. The SERVO-i allows the judicious addition of pressures support due to its floating exhalation valve, he explains.

"The idea is to use the tools so you don't have change to an oscillatory ventilation strategy," Tanaka says. "Thanks to BiVent, we reduced the need for oscillation."

Some researchers report success with BiVent in neonatal and pediatric populations as well as adults. For that reason, Scripps Mercy is looking at employing BiVent in its Neonatal Intensive Care Unit.

Physicians, staff anxious to incorporate BiVent and help patients: As an educator, Brewer was pleasantly surprised at how well the staff embraced the new mode and other SERVO-i open-lung capabilities. "To be honest," she says, "I didn't expect people to be as enthusiastic as they were because when there is a new theory out there, it is often hard to get everyone thinking it is advantageous." However, Brewer says, the respiratory therapists were eager to learn BiVent and to assist the physicians in using it in appropriate cases. Brewer is helping the hospital to write protocols for BiVent.

With the support of MAQUET's clinical applications specialists, a select group of physicians and RTs were trained first and they, in turn, trained others, including the nurses, on the use of BiVent. MAQUET provides continued support as needed. Scripps Mercy believes in collaborative healthcare and thus crosstrains its staff, which was easy to do in this case because the ventilators and BiVent operate with a touch screen, Tanaka notes. "BiVent is very user-friendly," he says.

The respiratory therapists favored the SEVO-I when the hospital was looking to be able to provide new and more effective ventilation strategies. A committee had narrowed the choices on the recommendations.

"It is very important that the therapists appreciate the ventilator and are comfortable with all its modes because they are very closely involved with the equipment," Lichter says. The hospital has 70 respiratory therapists on staff.

Tanaka says that like anything new, the physicians and staff had to be convinced that BiVent works, but it did not take long once they saw how easily it could be employed, and how beneficial it could be for their trauma and medical patients.

"Going forward," Tanaka says, "we want to be able to provide the best care possible for our patients, and we believe that with BiVent, we can do that."

The views, opinions, and assertions stated by Scripps Mercy staff members in this article are strictly those of the clinicians and administrators, and do not necessarily reflect the views of MAQUET.

The Clinical Utility of Lactic Acid Trending with ABGs in the Critical Care Setting: A Case Study

Doug Wilder, RRT

Introduction

With today's blood gas technology such as the Roche cobas b 221 blood gas system, healthcare providers can trend any four of the eighteen parameters including metabolites such as glucose and lactic acid. This provides a diagnostic platform for a number of clinical applications. For example, trending lactic acid gives the clinician the ability to not only monitor the level of lactic acid but also the ability to intervene early on in cases of tissue hypoxia, sepsis and the onset of myocardial infarction. The following study is a case in point.

Case

A 65 year old female presented to ED with the following clinical findings: shortness of breath, evaluated temperature 101, blood pressure 110/70, swollen ankles. The patient also has a history of COPD and CHF. The patient was given bronchodilator therapy, diuretics, chest x-ray and a blood gas was drawn at 14:39 with the following results:

pH	7.31
$PaCO_2$	50
PO_2	55
HCO_3	28.8
Lac	1.2

The patient was admitted to the hospital and placed on oxygen, bronchodilator therapy, treatment for CHF and antibiotic therapy. A second blood gas was drawn at 20:55 on LPM with the following results:

pH	7.32
$PaCO_2$	48
PO_2	74
HCO_3	14.2
Lac	8.8

After the results were called to the physician the patient was placed on non-invasive ventilation overnight. At 07:59 and another blood gas was drawn with the patient 40% O_2 with the following results:

pH	7.35
$PaCO_2$	45
PO_2	80
HCO_3	16.1
Lac	7.4

At this point the patient seemed to be responding to the therapy. At 12:30 the patient's oxygen saturation started to drop and another blood gas was run with the following results:

pH	7.31
$PaCO_2$	55
PO_2	60
HCO_3	10.1
Lac	13.3

Following this blood gas the patient was moved to the intensive care unit placed on 100% oxygen via mask and another blood gas was drawn to 13:52 with the following results:

pH	7.30
$PaCO_2$	65
PO_2	59
HCO_3	15.3
Lac	13.8

Now the patient was placed on a ventilator and an infectious disease physician was consulted. At 15:15 another blood gas was drawn with the following results:

pH	7.35
$PaCO_2$	50
PO_2	80
HCO_3	10.2
Lac	15.1

At 18:30 a final blood gas was drawn with the following results:

pH	7.35
$PaCO_2$	50
PO_2	84
HCO_3	14
Lac	18.9

The patient was transferred to another facility.

Treatment

At the new facility the patient was placed on the ventilator for several more days and treated for a septic pulmonary infection and finally discharged 2 weeks later.

Conclusion

The respiratory staff had received several in-services on lactic acid prior to the admission of this patient. This knowledge and training was instrumental in providing the physicians with trending data that improved patient care and resulted in a positive patient outcome. Any critically ill patient should have blood gases with electrolytes and a direct measurement of lactic acid. Trending should be considered in cases where sepsis, tissue hypoxia and myocardial infraction are suspected. Hospital should consider blood gas lactic acid testing and trending as a standard of care when dealing with critically ill patients.

Doug Wilder is Manager of Respiratory Services, Memorial Medical Center, Livingston, TX. This article was provided by Roche.

Pulmonary Prophylaxis in Acute Care High-Frequency Chest Compression

Jane Braverman, PhD; Rita Kalema, CRT, RCP

Abstract
Pulmonary complications (PC) are increasingly common in acutely ill, severely injured and/or post-surgical patients admitted to critical care medicine units (CCMU). As advanced medical interventions are offered to higher-risk, increasingly elderly patients, the prevalence of unanticipated respiratory-related morbidity and mortality is escalating. Among PCs, ventilator-associated pneumonias (VAP) - especially those caused by methicillin-resistent Staphylyococcus aureus (MRSA) - impact resource utilization, length of stay, mortality and overall costs profoundly. The CCMU PC crisis is compounded by Medicare's recent policy decision to deny payment for treatment of preventable hospital-acquired illnesses or injuries. If MRSA VAP rates increase at present rates, institutional and financial resources will soon be exhausted. A high proportion of PCs are directly traceable to diminished mobilization of lung secretions. High-frequency chest compression (HFCC) airway clearance therapy with the inCourage system is a practical and effective treatment strategy. Used in conjunction with RespirTech's ClearChest single-patient use products, secretion mobilization in CCMU patients can be improved safely, comfortably and effectively.

News that Medicare expenditure is growing at an unsustainable rate shocks no one. However, the crisis is not limited to Medicare. Rapidly escalating demand for expensive medical services is driving up premiums for private health insurance and employer-based coverage as well. Strategies to anticipate and control costly preventable in-patient complications are urgently needed.

Ominous data

Nearly 5,000,000 Americans are admitted annually to Critical Care Medicine Units (CCMU). That number is expected to double during the next fifteen years as the population ages and median life expectancies increase. Although accounting for only about 10% of total hospital beds, CCMUs are generally the most expensive, high technology and resource intensive area of in-patient care; they consume approximately twenty-five percent of a hospital's operating costs.[1-5] An analysis of two major Medicare databases maintained to identify CCMU use and costs provides the most reliable estimates for the calendar year 2000.[2] Those data show that CCMU patients accounted for 14.4% of inpatient days, consuming about 0.56% of GPD ($55.5 billion) and about 14% of national health care expenditure. CCMU costs are up to sixfold higher than for general population beds, ranging from $2,000 - $3,000 daily.[3] Currently, Medicare beneficiaries account for more than 50% of CCMU days and costs.[4]

The aging of the U.S. population is likely to impact two important areas of medicine disproportionately—critical care and the management of pulmonary disease. In 1997, intensivists provided care to 36.8% of all CCMU patients. As demand grows, projections suggest a shortfall of specialist hours equal to 22% of demand by 2020 and 35% by 2030.[5] Likewise, a reduction in pulmonolgist availability has been noted; the trend is expected to increase to 35% by 2020 and to 46% by 2030.[5]

Chaos in the Lung: Critical Care Pulmonary Complications

Pulmonary complications (PC) are a major cause of morbidity, mortality and high care costs among CCMU patients.[6,7] Advances in anesthetic and perioperative management that reduce the likelihood of PC have been offset by the steady rise in high-risk patients. Major surgery is routinely performed both for the very elderly and individuals with significant co-morbities. The proportion of obese patients, those with a history of smoking, or with conditions including chronic systemic and/or lung disease and acquired immunodeficiencies is also growing.[6-8] Surgical patients—especially those undergoing thoracic and upper abdominal procedures—as well as those experiencing acute illness and severe trauma, are at increased risk for serious, potentially life-threatening PCs.[8] And mechanically ventilated (MV) patients are the most vulnerable of all in terms of susceptibility to PC—most importantly nosocomial pneumonias.[8-11]

Impaired mucociliary clearance

In CCMU patients, airway obstruction and associated symptoms are chiefly consequences of mucus hypersecretion and impaired mucociliary/cough clearance. Several factors may impede mucus mobilization from distal lung regions to central airways:[7, 12-16]

- Increased mucus production
- Abnormal mucus rheology
- Abnormal ciliary activity
- Loss of ciliated cells

Tracheal mucus veleocity (TMV) assessments confirm that most CCMU patients exhibit some degree of one or more of these abnormalities.[13-15] When TMV is significantly slowed, secretion retention follows. Stagnant secretions prolong exposure to entrapped bacteria and viruses and encourage development of pneumonia. Pneumonias are especially serious when they occur in MV patients and potentially catastrophic when the organism involved is methicillin-resistant Staphylococcus aureus (MRSA). Impaired TMV appears to be the common denominator in the development of a broad spectrum of PCs.[16]

Hospital-acquired/ventilator-associated pneumonias: A major threat

CCMU pneumonias are common and frequently antibiotic-resistant. Staphylococcus aureus is most often identified as the cause. MRSA infections occur disproportionately in geriatric patients. Ventilator-associated pneumonia (VAP) is the most common hospital-acquired infection occurring in critically ill patients. VAP—especially MRSA positive VAP- is an increasingly alarming and urgent concern.[9,10,17] Recent methodologically robust studies show grim morbidity and mortality statistics and enormous costs.

- A systematic review of the clinical and economic consequences of VAP found:[10]
  - VAP develops in between 10% and 20% of patients receiving MV > 48 hours
  - VAP patients are twice as likely to die as non-VAP MV patients
  - VAP patients incur > $ 10,000 in additional hospital costs

- When ventilator patients develop PC—especially ventilator-associated pneumonia (VAP)—costs soar. In a retrospective matched cohort study utilizing data from a large US inpatient database for 1998-1999, patients who received MV > 24 hours, 9.3% developed VAP.[11]
  - Ventilator days for patients with VAP were more than double that of unaffected MV users: (14.3 +/-15.5 vs 4.7 +/-7.0 days, $p < 0.001$).
  - VAP significantly increased ICU stay: (11.7 +/-11.0 vs 5.6 +/-6.1 days, $p < 0.001$)
  - VAP significantly increased total hospital days (25.5 +/-22.8 vs 14.0 +/-14.6 days, $p < 0.001$)
  - Mean hospital charges for MV patients with VAP were > $ 40,000 more that those without VAP.

- When VAP is attributed to MRSA, costs significantly exceed those of VAP patients with antibiotic—responsive strains of Staphyloccocus aureus. One small study showed excess costs for MRSA VAP vs non-MRSA VAP of $ 23,856. vs $ 7,731.17

Effective strategies urgently needed

The incentive for hospitals/ICUs to prevent or aggressively manage secretion-related PCs is clear. Retained secretions unequivocally increase susceptibility to PCs ranging from mild to fatal. Among treatment strategies, it is imperative to implement an effective method to rapidly mobilize and evacuate stagnant secretions. For many CCMU patients, high frequency chest compression (HFCC) therapy is an ideal choice.[7] With the support of a growing body of basic research, clinical studies and empirical evidence, CCMUs are rapidly adopting HFCC therapy.[18-28] Because the complex needs of high-tech medicine are evolving rapidly, RespirTech [aka Respiratory Technologies, Inc., St Paul, MN] has created a suite of advanced products. Together with it's inCourage system HFCC unit, Respirtech's new line of sanitary single-patient use ClearChest™Comfort Bands work together to meet the most demanding requirements of busy CCMUs.

RespirTech's ClearChest single patient use wraps and jackets were designed in collaboration with ICU intensivists, other critical care professionals and materials engineers to meet the practical needs of critical care patients. In the hospital setting, ClearChest comfort band is used with the inCourage system. The inCourage system offers state-of-the-art airway clearance therapy incorporating the most recent advances in high frequency chest compression (HFCC) science.

- Triangle waveform: The shape of the waveform delivered by HFCC machines is shown to be important in maximizing mucus clearance.[27]
  - A comparison of triangle versus older sine waveform technology found a mean volume increase of 20% in mucus cleared—with a range up to 41%—with the inCourage System
  - Triangle wave forms may be more effective because peak airflow and maximum lung volumes occur at the same frequencies
  - Triangle waveform therapy may be more comfortable because duration of peak pressure is shorter

- Standard and Custom Programming: The inCourage™ system is pre-programmed for use with an easy-to-understand menu. The machine is equipped with a touch button digital control panel and a choice of treatment sessions to accommodate individual needs.
  - QuickStart: A pre-programmed 30-minute session that begins immediately and ramps up and down through a full range of therapeutic frequencies
  - AutoPause: A pre-programmed 30-minute session that pauses at five minute intervals for users to perform huffing and coughing maneuvers; sessions are resumed with a simple touch of a button
  - MultiStep: A custom programming feature that permits users to enter and save up to 3 individualized sessions containing up to 12 steps

- ClearChest comfort bands have the fastest in-jacket pulse pressure rise with the shortest duration at maximum pressure in the therapeutic frequency range 6-15 Hz.
  - Active venting compensates for chest wall expansion and contraction during the breathing cycle
  - Patients are able to take deeper, more comfortable breaths
  - Greater lung volumes permit larger HFCC-induced expiratory airflow volumes at the mouth—an important measure of treatment efficacy

- Clear Chest products are created using a new proprietary polymer system specifically engineered for use in patient-contact medical supplies. The fabric is a cost-effective PVC-free replacement for currently banned PVC-reinforced membranes and films. Featuring all of the benefits of a PVC-based material, the product is…
  - Stain resistant-easily wiped down
  - Incinerable
  - Compatible with advanced waste disposal
  - Cost effective

- ClearChest products are available in 3 styles to accommodate every CCMU need. All styles and sizes feature:
  - Locking connectors to prevent hose disconnection during therapy
  - QuickFit technology to ensure a precise fit from session to session

- ClearChest comfort bands are easy to apply wrap-style garments that deliver therapy to lung regions from just below the axillae to the lower lobes.
  - Available in four sizes—small, medium, large and extra

large—to fit chest circumferences from 16"-60"

- ClearChestcomfort bands UL (Upper Lobe) are easy to apply wrap-style garments that distribute therapy to the upper lobes as well as to the central and lower segments.
  - Available in four sizes—small, medium, large and extra large—to fit chest circumferences from 16"-60"

- ClearChest comfort jackets are traditional full - coverage garments designed to treat all lung regions. Jackets extend from upper lobes to just above the iliac crest. This model is ideal for patients able to sit upright and has the advantage of maintaining fit from treatment to treatment.
  - Twenty-three (23) sizes (16"-60" in two-inch increments) permit precise fitting for optimal therapy.

A dependable solution for an urgent problem

The importance of preventing or rapidly treating PCs in critical care medicine cannot be overstated.[29] PC/VAP prophylaxis with RespirTech's inCourage system and ClearChest comfort products is safe, effective, convenient and cost-effective. An abundance of studies support the use of HFCC therapy in the CCMU setting. Study subjects include post surgical patients and general medicine patients—as well as those receiving ventilator support.[7,24-26] Effective preventive and interventional airway clearance therapy should substantially reduce the prevalence of preventable PCs and moderate rapidly escalating long-term healthcare costs.

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"Active" Exhalation Valves

Tim France BS, RRT

New ventilators with microprocessor controls are extremely advanced as compared to older first generation ventilators. While the jury is still out on whether mortality has been impacted, most bedside therapists would say the advanced algorithms and control mechanisms can enhance the interface between ventilator and patient. One of these features is the ability for the ventilator to allow unimpeded breathing during inspiration and expiration. This feature is called active exhalation.

The reason active expiratory valves are popular is because it purportedly allows for better synchrony with the ventilator. In ventilation without active exhalation, the valve is closed throughout inspiration. If a patient attempts to breathe spontaneously during this time, they would not be able to exhale, thereby causing dyssynchrony. This is an obvious benefit when using extremely long I-times such as used with APRV (airway pressure release ventilation). However, when using conventional I-times, this is usually not an issue unless the Inspiratory time is inappropriately long. One might question the need to or reason to allow the patient to take a second complete breath cycle during the inspiratory phase vs. simply adjusting the inspiratory time (or flow cycle criteria in pressure support mode) to match the patients desired inspiratory time.

If the patient demands more flow and/or volume during the inspiratory phase, an active valve will allow them to pull more flow. It should be noted that in any pressure mode, the expiratory valve will open during the inspiratory phase to allow more flow as the ventilator will 'regulate' the valve to maintain the target pressure during the inspiratory phase. Indeed, in volume modes with a constant flow, some ventilators will transition to a constant pressure/variable flow breath type so as to allow the patient to obtain more flow and volume. This is often unrecognized by the clinician unless expiratory volumes are carefully compared to the set tidal volume.

Active exhalation valves are said to benefit patients during tracheal gas insufflation (TGI), and during a cough maneuver. During TGI, gas is injected at the trachea in an effort to augment ventilation in order to decrease $PACO_2$.[1] Because of this extra gas peak airway pressures could increase thereby putting the patient at risk for over distention. An active exhalation valve allows the extra gas to be vented, thereby maintaining a lower peak pressure. Active exhalation causes extra gas to be expelled when a patient coughs as well. If a patient coughs against a closed expiratory valve, intrathoracic pressures are increased. This increase in intrathoracic pressures could theoretically cause over distention or cardiopulmonary compromise, not to mention being extremely uncomfortable. (Note: during a normal cough, the glottis is closed so as to allow generation of high pressures for the cough maneuver. This is an isometric maneuver with no change in lung volume. So it's questionable as to whether coughing against a closed expiratory valve would cause overdistension. During Pressure Support ventilation most ventilators will terminate inspiration if the pressure exceeds the pressure support level by 1-3cm. Other ventilators offer pressure limitation algorithms which prevent excess pressures from being generated).

Manufacturers who market the benefits of active exhalation claim better ventilator synchrony because of the exhalation valve opening at any point in the breath phase as well as less sedation because of increased comfort and a decrease in VLOS.

In summary active exhalation valves enable spontaneous breathing at any point during the breath phase. When utilizing TGI, extra gas can be bled off decreasing intrathoracic pressures. During APRV less sedation is utilized enabling patients to breathe spontaneously at any point during the breath phase. Spontaneous breathing has been shown to provide physiologic benefits such as improved V/Q matching and less hemodynamic compromise. However there is no data to support that active exhalation valves in any other mode improves outcomes.

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Asthmatic Children

Julia Pippa RN, BSC, MA

Asthma is the foremost chronic disease affecting children in the United States and is considered by some studies to be in epidemic proportions. We still don't know what causes childhood asthma.

The following is based on a true story:

Jamal is a six year old, a kindergartner, and he has asthma. He is short for his age, but overweight. In spite of the fact that he looks robust, he isn't. A poor diet, too many carbohydrates like bread and macaroni, lots of sweets and fast foods have contributed to his being poorly nourished. Since Jamal was an infant he has been prone to ear infections, colds and bronchitis. Jamal, his mother, and three siblings live in a part of town that is rundown, the buildings old, with remnants of lead paint and factories that spew rancid smoke into the air. The area can be dangerous so his mom never lets him play outside. The only exercise he gets is at school, during recesses. The air in that area isn't good either. In his few short years he has had exacerbations of his asthma and asthma attacks. He visits the emergency room once or twice a month. Because she lost her job, his single mom doesn't have insurance right now and could afford only one inhaler. Although she knows he could keep it at the office at school, she fears it will get lost from sending it back and forth. She didn't tell the school about Jamal's asthma for fear they would think her negligent and report her to Children's Services and perhaps remove him from the home. In her neighborhood, cases like this are all too frequent.

She gave him a couple of puffs every morning before he left for school hoping this would ward off attacks. She had kept him home far too many times this year and the school was preparing to send an attendance counselor to the home. Actually, she wanted Jamal in school as much as he wanted to be there. This morning had been touch and go. His breathing was slightly labored and she could hear wheezing but she felt it might be because there was going to be a Halloween party in his classroom and he was very excited. She gave him two puffs from his inhaler. The party was in progress when Jamal first felt short of breath, but he was just a little boy who didn't know his body well enough to be able to assess that he needed help, and besides, the party was so much fun. The teacher was preoccupied with the chaos in the room and didn't notice Jamal was in trouble until he fell on the floor. She snatched him up and ran with him to the nurse's office. There was no nurse on duty that day. She called out for help and the office staff called 911. It took the ambulance 15 minutes to arrive. He was unconscious by then and was dead by the time they got to the hospital.

Some factors that led to this tragedy:

- Black children are more likely to suffer from asthma than white children and males have a higher incidence than females.
- Poverty makes serving the right foods to growing children difficult and mom didn't really have any idea what constituted "right foods."
- Obesity is now being looked at as part of the asthmatic profile.
- Lack of exercise.
- Environmental triggers at home and throughout the neighborhood.
- Although Jamal's mom doesn't smoke she has a friend and a boyfriend who do. Jamal grew up around second hand smoke, a major trigger.
- Jamal had a history of infections that further compromised his immune system.
- Jamal could have been put on some preventative medication and even have had a pulmonary nebulizer at home, rather than make all the trips to the hospital. There was no money for this.
- Lack of healthcare insurance.
- Mom's fear of agencies she didn't understand and didn't know how to access, such as MediCal. She was afraid to ask for help.
- Mom's fear of being reported for neglect by school personnel.
- Mom's fear of Children's Services removing Jamal from the home.
- No school nurse on duty full time due to district financial cutbacks.
- The problems with school policies on illnesses such as this is complicated and needs to be looked at carefully.
- And finally, preventative help was out there for mom if only someone at school knew that Jamal needed help. That Jamal had asthma.

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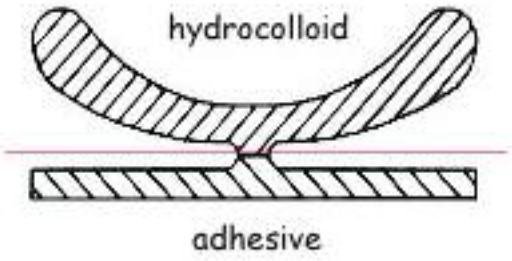

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