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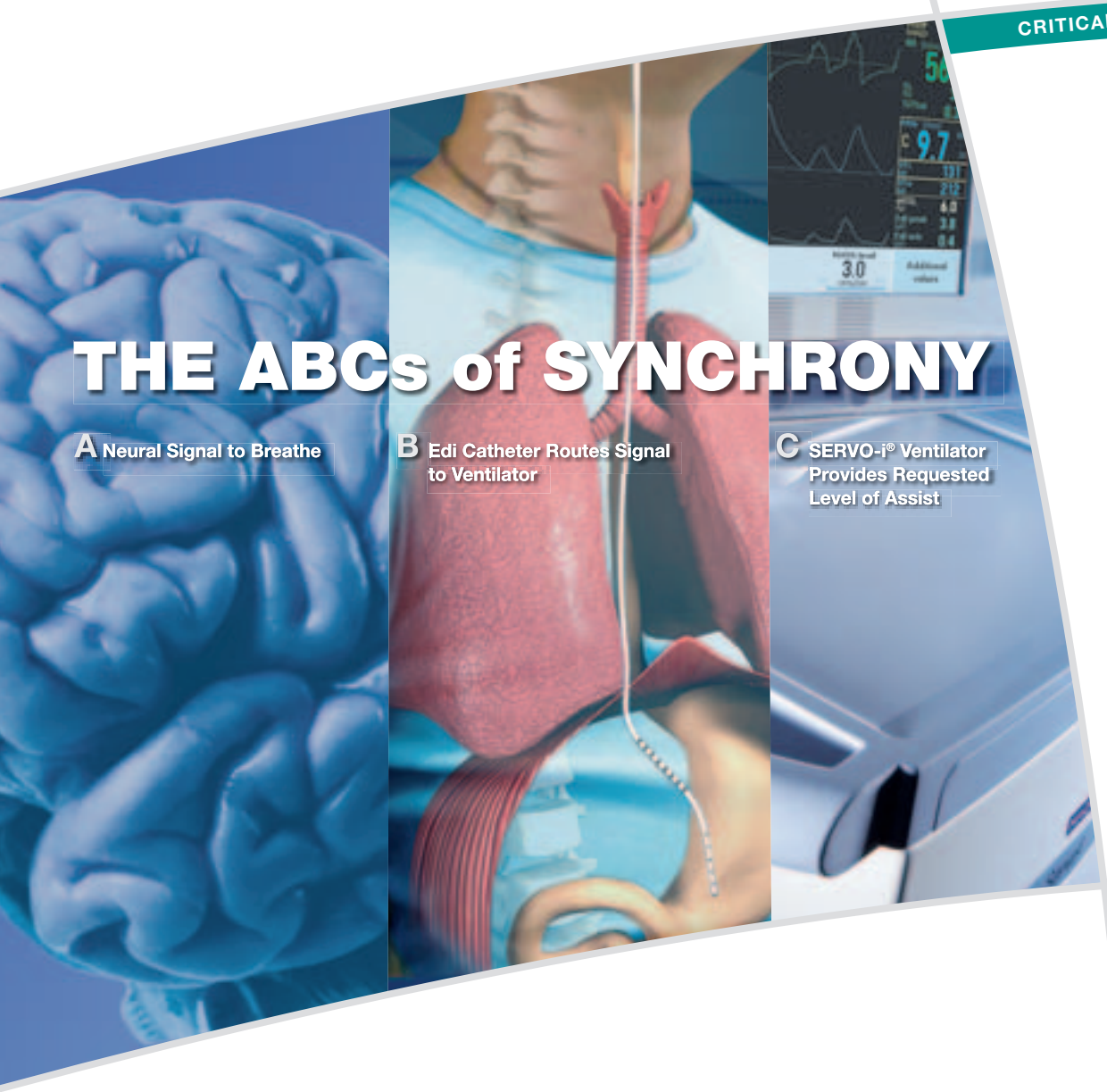

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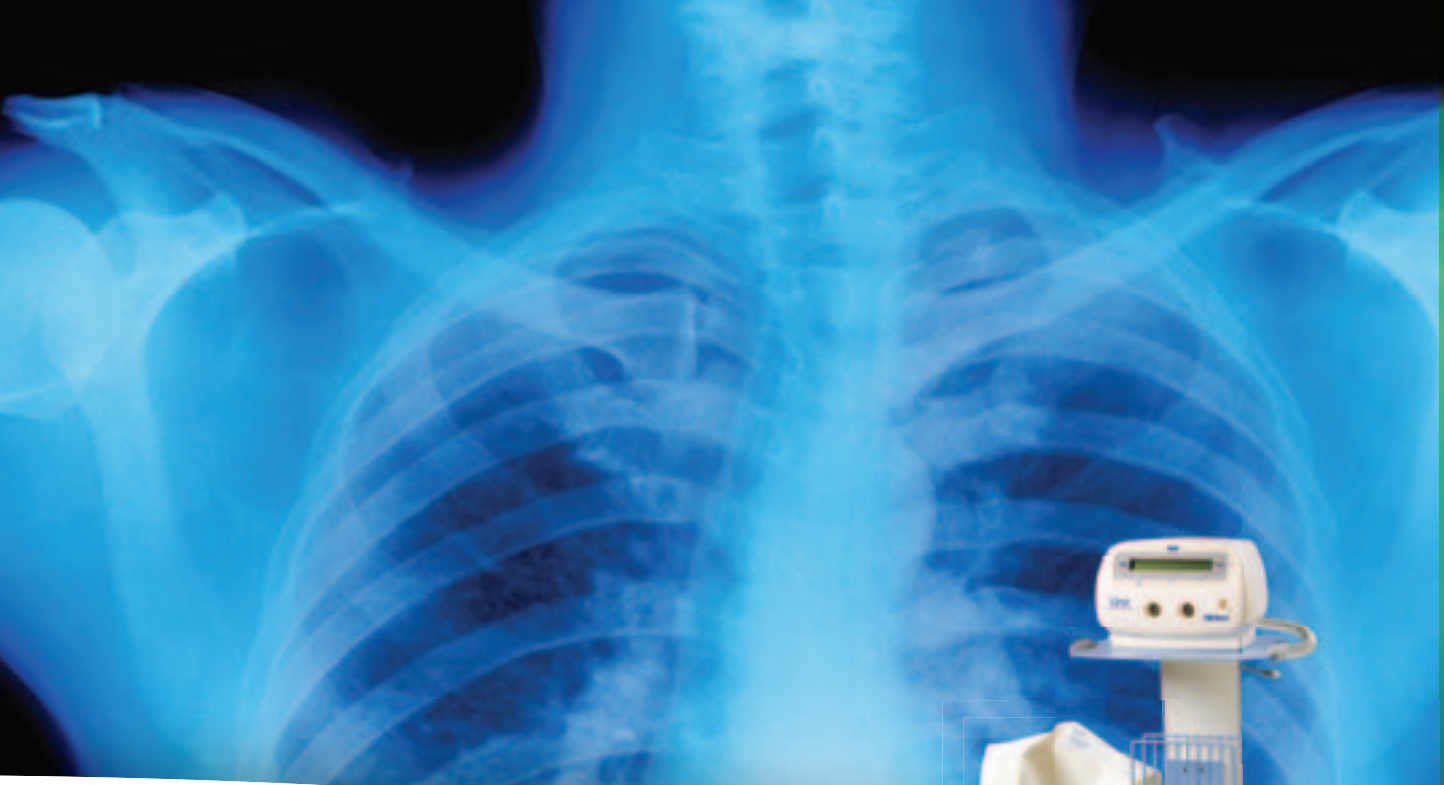

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Editorial

Emergency Preparedness: What is your Plan "B"?

Dave Swift, RRT

Dave Swift, RRT is Ottawa Hospital Campus Coordinator and Charge Therapist, Ottawa Hospital, Ottawa, Ontario, Canada.

Plan "A"

Numerous authors (AARC, Chatburn, Branson, Rubinson, Neyman, Chipman, etc) have stated and reinforced the standards for the "ideal" mass casualty ventilator as being equipped with: tidal volume controls, rate controls, FiO2 control, PEEP, basic alarms, clinically applicable to a wide range of pts (infants to adults) and to be able to operate for 4-6 hours on battery, independent of electrical or gas supplies. The authors have gone a step further advocating that automatic gas powered resuscitators not be considered for Pandemic or mass casualty incidents (P/MCI) as they do not meet the standards for ventilators.

The authors encourage facilities to acquire access to ventilators meeting these criteria. However, the reality is that most facilities do not have the economic resources to acquire these ventilators (and related supplies) in sufficient numbers to meet the suggested 200% patient surge during a P/MC Incident. Most facilities, annually budget to add additional resources, but are limited in the numbers purchased due to costs, storage and other fiscal realities. Buying ventilators "just-in-case" is a hard sell.

The US National Strategic Stockpile has just over 4,000 ventilators, CDC has a few thousand available and coupled with each facilities own limited resources there is a significant shortfall. In a large P/MCI situation these available resources will be quickly used up. The authors fail to address this shortfall. The recommendations, although well researched, only encourage the maintenance of this significant patient care shortfall. Recommendations, establishing a standard of care, infer a responsibility on the author's part to recognize their responsibility and accountability to assist with recommendations to address this gap. The reality is that there will always be a shortfall between on-hand ventilators and expected need during a P/MCI (200% increase in patients). Responsible clinicians recognize this situation and the realities surrounding a P/MCI. Their decisions represent a multi-tiered response in sustained ventilatory options from the recommended standard to achieving basic resuscitation/maintenance ventilation.

Prudent Healthcare administrators and clinicians recognize the existence of this gap in care. Due diligence requires that the effects of this gap be recognized and the risks associated with it minimized. This is the creation of "Plan B".

Plan "B"

After all the "full feature" mechanical ventilators are used, what alternatives are available? Getting additional resources from the government will require at least 72 hours with no guarantee of a positive response, as resources would be allocated on a first-come-first-served basis (depending on when the P/MCI incident starts i.e. nation wide vs. state vs city). Remember, YO-YO 72 (you are on your own for 72 hours), this is the expected minimium response time for higher levels of the government to respond to an event.

Manual resuscitators require trained staff to utilize each unit and the inconsistencies of manual ventilation is well documented. Pneumatic Automatic Resuscitators (PAR) requires trained operators who can supervise multiple units. However, manual (MR) or pneumatic resuscitators (PAR) should never be

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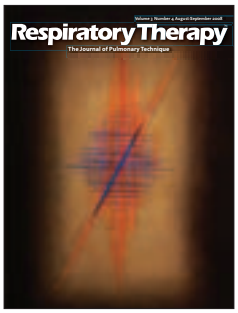

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Table of Contents

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considered as the first choice over “full feature” mechanical ventilators. However, when faced with all available ventilators in use and insufficient trained staff to manually bag patients one-on-one, PAR offers a limited but viable alternative.

As part of your P/MCI plan, it is recommended that facilities should initiate a training program to cross train Allied Healthcare Providers (Physio, Occupational Therapists, etc) to be able to provide the basic respiratory support. Project X-Treme offers solutions to this training requirement (Project X-treme, Cross training Respiratory Extenders for Medical Emergencies, www.ahrq.gov). Cross-training serves to extend your RT resources and allow the RT to act as a supervisor/coordinator in dealing with multiple patients.

A secondary part of the plan is to train staff to be able to appropriately select appropriate patients for use with PAR or conventional “first line” ventilators. As these units are pressure cycled, any disease process that causes dynamic pulmonary changes will result in changing volumes and rates, in turn requiring more RT interventions. Trained staff can insure that your resources are used appropriately.

Responsible clinicians recognize the requirements and realities surrounding a P/MCI. Having “Plan A” as your first response works until all resources are in use. Having a “Plan B”, although not achieving the full standard being put forth, offers a viable alternative to not being able to provide ventilation to the many. The goal of a P/MCI ventilation plan is to ventilate “the many” at a basic level over “a few” at high level ventilatory abilities. You need a plan “B” for when reality meets your plan “A”- 200% surge ventilator capacity will rarely be achieved in today’s fiscally restrictive environment.

Clinicians, acting in a pro-active manner, will review and update their “Plan A” to maximize resources. The prudent clinician will take the next step and develop “Plan B” to deal with situations where the resources of “Plan A” are exhausted before the number of patients are. What is your “plan B”?

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Anesthesia Awareness: There is Room for Skepticism

Jonathan A. Lax, Mark D. Attorri

We recently obtained a defense verdict for our client, an anesthesiologist, in a medical malpractice suit in which the plaintiff alleged an episode of "anesthesia awareness" during sinus surgery. We admit that, upon our initial review of the case, we were skeptical about the plaintiff's claim that she was "awake and aware during her surgery" and that as a result she "suffered severe physical pain, debilitating trauma, emotional upset, [and] recurring and debilitating attacks where she relives the traumatic episode." We questioned how the plaintiff could remember details of conversations she claimed had occurred in the operating room, and whether she could have experienced pain during the surgery if the contemporaneously recorded chart entries of our client, the circulating nurse, and the surgeon suggested adequate doses of local and general anesthetics were given, the surgery was uneventful, and the patient tolerated the procedure well.

After very little initial research, we began to question our preliminary skepticism. We learned that the phenomenon of anesthesia awareness is an infrequent, but well described adverse outcome of surgery performed under general anesthesia.[1] A recent study of nearly 20,000 surgeries at seven different US hospitals revealed an incidence of awareness with recall after general anesthesia of between one to two cases per thousand (0.13%), with a range of 0.09%-0.21% depending on the institution.[1] These findings are consistent with prior studies.[2]

It is documented that episodes of awareness are associated with significant adverse psychological sequelae, including symptoms associated with posttraumatic stress disorder (PTSD).[1] The occurrence of awareness during general anesthesia has been referred to as "a pitfall for the anesthetist, a horror for the patient, [and] an invitation for the prosecutor."[3] Accordingly, any claim of anesthesia awareness needs to be taken seriously. The anesthesiologist is primarily responsible for developing an appropriate anesthesia plan and inducing, maintaining and reversing anesthesia. However, health care providers who interact with patients before and after surgery must be aware of the risk of anesthesia awareness, so they can address a patient's pre-operative concerns and respond appropriately to a patient's claim of awareness following surgery.

Despite our acceptance of the fact that episodes of anesthesia awareness can and do in fact occur, an eight day trial resulting in a jury verdict in favor of our anesthesiologist client has led us to believe that skepticism about awareness claims may still be warranted. As the public's "awareness of awareness" increases as a result of sensational news stories and the depiction of anesthesia awareness in mass media, it is important to know the truth about anesthesia awareness.

What is Anesthesia Awareness?

There is no uniform definition of anesthesia awareness; what it means depends on who you ask. The difficulty with defining the phenomenon is understandable, since the term "anesthesia awareness" is "semantically a contradiction (unawareness is part of the definition of anesthesia)…"[3] According to the founder of the Anesthesia Awareness Campaign, anesthesia awareness is "probably the most helpless and terrifying feeling in the world. It occurs when one is supposed to be completely asleep but the brain is not asleep at all."[4] The American Society of Anesthesiologists (ASA) states "intraoperative awareness occurs when a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall (defined as explicit memory) of the events."[5] The ASA definition specifically excludes from the definition recall of events occurring before general anesthesia is fully induced, or during the emergence from general anesthesia "when arousal and return of consciousness are intended."[5] This differentiation between truly intraoperative awareness, and awareness that may occur when general anesthesia is being either induced or reversed, proved to be critical in our case.

Anesthesiologists have been conscious of the phenomenon of anesthesia awareness for many years, devoting substantial efforts and resources to understanding why it happens and if it can be prevented.[2,6,7] Despite these efforts, intraoperative

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awareness continues to be a daunting problem. The necessary anesthetic dose varies from person to person and, in some cases, awareness may be unavoidable in order to achieve other critically important anesthetic goals.[5]

Recently, a great deal of mass media attention has been focused on the issue. The 2007 suicide of a West Virginia minister after an alleged episode of anesthesia awareness garnered national attention.[9] Just four days before our trial began, CNN's Anderson Cooper anchored a Prime-Time story on the subject in which three survivors tearfully recounted their traumatic experiences.[9] The 2007 national release of the Hollywood thriller "Awake" portrayed the experience of anesthesia awareness from the patient's perspective.[10] Unfortunately, much of the information about anesthesia awareness that can be gleaned from these popular media accounts is sensationalized or incorrect, and perpetuates misunderstandings and possibly causes undue patient concerns about anesthesia awareness.

Is it Painful?

It is regularly assumed that intraoperative awareness is always agonizingly painful. However, studies show that many patients who experience episodes of anesthesia awareness do not experience pain.[11,12] Why? Typically, anesthesiologists use several anesthetic methods during surgery, some of which render the patient unconscious, while others are used to numb pain. In our case, the anesthesiologist administered a combination of inhaled gases (sevoflurane and nitrous oxide) to put the patient to sleep; at the same time, the surgeon injected local anesthetics at the surgical site to deaden the pain of the operation. Evidence that several different anesthetics were used tended to show that even if the plaintiff had been awake during the surgical procedure, it would have been unlikely for her to experience the excruciating pain she described. We argued, and the surgeon involved in the procedure testified, that the patient's recollection of pain could have coincided with his post-operative examination of the patient in the Post Anesthesia Care Unit (PACU), when the local anesthetics he administered were wearing off. Specifically, the surgeon testified that he went to the PACU within a few minutes of the patient's arrival there to investigate a nursing report of post-operative bleeding. The surgeon removed the patient's nasal packing and examined her sinuses with a nasal speculum, and utilized a suction device, all while wearing a halogen head lamp. The PACU nurse and defense's expert anesthesiologist who testified in our case provided anecdotal evidence about how common it is for some patients to be confused about their whereabouts and the timing and sequence of events while emerging from anesthesia. This testimony supported the defense's argument that it is common for patients to sincerely (but erroneously) believe that events and conversations that occurred after surgery in the PACU had occurred during the surgery in the OR.[13]

It is also commonly asserted that intraoperative consciousness is always caused by an anesthesiologist's error. This is not true. In some circumstances intraoperative awareness cannot be avoided because lesser doses of anesthetics are required in order to achieve other critically important medical goals.[5] For example, when a pregnant woman undergoes a cesarean birth, the quantity of anesthesia must be lessened to avoid jeopardizing the wellbeing of the unborn baby. Other patients may require smaller amounts of anesthetics due to certain medical conditions. Even where such medical conditions are not present, however, anesthesia awareness can occur without physician error.[13] Although some cases may be caused by equipment misuse or failure (resulting in interruption of the flow of anesthetic gases) or medication errors (such as providing inadequate amounts of anesthetic agents),[7] it is widely accepted that episodes of anesthesia awareness can occur in the absence of negligence. Patients have reported experiencing intraoperative awareness even when they have received doses of anesthetics greater than those which would put most patients into an adequate state of unconsciousness.[14]

Can it be Predicted?

Although there are certain predisposing patient factors, and particular types of surgeries that may be associated with a heightened risk of awareness, there is no way to accurately predict which patients will not receive the full intended benefits of anesthesia. Studies suggest that certain patients may be at increased risk of anesthesia awareness, including older patients, female patients, patients with ASA physical status scores of IV or V, and patients with a history of drug use or abuse that may increase drug resistance or tolerance.[5] There are also descriptive studies and case reports that suggest certain procedures (e.g., cesarean delivery, cardiac surgery, trauma surgery) and specific types of anesthetic technique (such as rapid sequence induction or the use of reduced anesthetic doses with or without the presence of paralysis) may be associated with an increased risk of intraoperative awareness. The ASA's recent Practice Advisory highlights the importance of performing a detailed pre-anesthesia evaluation to identify factors that may increase a patient's risk of anesthesia awareness.[5]

Can Anesthesiologists Monitor For or Prevent Episodes of Awareness?

There is an increasingly common misperception among patients (fueled in part by recent media accounts) that anesthesia awareness is easily preventable through the use of brain-monitoring devices. In the introduction to his story on anesthesia awareness, Anderson Cooper stated "You can't talk, but you can see and hear and feel the pain of surgery. A device could prevent this. So, why does only one in five operating rooms use it?"[9] The device alluded to is a monitor that measures the Bispectral Index (BIS), a dimensionless number derived from mathematical analysis of a patient's EEG signal. The "BIS Monitor" is a complex, processed electroencephalogram that uses a computer algorithm to assign a numerical value to the probability of consciousness.[14]

Brain-wave monitoring is used at an increasing number of hospitals and out-patient surgical facilities and it may offer a promising avenue for further research. There are case reports and a single randomized prospective clinical study that suggests BIS monitoring may decrease the probability of awareness in high risk patients.[15] There are anesthesiologists who advocate the widespread use of BIS monitoring.[16] However, a study published in the March 18, 2008 New England Journal of Medicine which compared BIS monitoring to more traditional analysis of end-tidal concentrations of anesthetic gases to assess depth of anesthesia during surgeries on high risk patients failed to show any reduction in the incidence of awareness using BIS monitoring. The authors concluded that "Anesthesia awareness cannot predictably be prevented in all patients with the BIS monitoring protocol used in this study… Reliance on BIS technology may provide patients and health care practitioners with a false sense of security about the reduction

in the risk of anesthesia awareness."[17] Thus, BIS monitoring has not been proven to reduce the risk of anesthesia awareness for all patients, and there are documented cases of patients experiencing episodes of anesthesia awareness whose BIS scores did not suggest an inadequate depth of anesthesia.[14] The ASA's 2006 Practice Advisory concluded that the "general applicability of these monitors in the prevention of intraoperative awareness has not been established" and that "brain function monitoring is not routinely indicated for patients undergoing general anesthesia, either to reduce the frequency of intraoperative awareness or to monitor depth of anesthesia."[15] In fact, it has been suggested that the monitoring of brainwaves may even increase the frequency of intraoperative consciousness; if the anesthesiologist gets an increased sense of security from having the monitoring method in place, he or she is more likely to administer only enough anesthetic to keep the patient "just barely" unconscious.[18]

Perhaps most significantly, recent media reports fail to acknowledge how common it is for patients to confuse awareness of events during surgery with their recollection of incidences that happen either before surgery as anesthetics are administered or after surgery as the general anesthesia begins to wear off. Assessing this distinction can be difficult.[12] Since the patient is somewhat groggy during the pre- and post-operative periods, it is easy to understand how he or she can become confused or frightened into believing they were experiencing intraoperative awareness when in fact they were not. In the case we tried, all of the things the patient alleged she heard and felt during surgery could be explained by events that occurred just prior to extubation in the operating room and/or when her anesthetics were initially beginning to wear off in the recovery area.

The Importance of Communication

Unfortunately, in our case, the patient's initial report of awareness was not brought to the anesthesiologist's attention. This is regrettable because an opportunity to diffuse the situation and help the patient may have been missed. Anesthesiologists are experienced in interviewing post-operative patients regarding alleged occurrences of awareness, and they know that individuals with confirmed cases may require prompt counseling in order to lessen feelings of confusion, stress or trauma associated with the experience. In our case, the other providers who were notified of the patient's initial claims were not as familiar with the many circumstances surrounding the phenomenon of intraoperative awareness as our client was. Consequently, their preliminary responses may have unintentionally reaffirmed the patient's fears and misunderstandings, contributing to the severity of her subsequent mental health problems.

Effective communication among the medical professionals who initially dealt with the patient, in addition to a better understanding of the actual facts regarding intraoperative awareness, could have allowed the providers to eliminate much of the confusion and misunderstandings in our case. Additionally, a more complete knowledge of the limited ability of anesthesiologists to prevent or monitor for awareness might have enabled the patient to understand what the jury was able to conclude—that the anesthesiologist was not at fault and that the perceptions and recollections of the plaintiff were not the result of anesthesia awareness, nor did they occur while she was under the general anesthesia administered to her during surgery.

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News

☐ August-September 2008

EDITOR'S NOTE: SLEEP REDUX

In our polling of readers, we found a preponderance of comments relating to reimbursement, the final question for participants in the last issue's Sleep Roundtable. Here's an update.

A recent survey by Wachovia Surveys revealed that sleep revenue would grow, that CPAP pricing was stable, but that national competitive bidding (NCB) may hurt reimbursement rates. According to Wachovia's HME Sleep & Wound Care Survey, "The sleep market is still going strong, and CPAP pricing is currently stable, but reimbursement rates for HME suppliers could be hurt by the NCB program. Wachovia noted that the providers surveyed remain bullish on the sleep market. They estimated 11% growth this year, after growing 10% in 2007. Nearly half of suppliers said they believe unattended home testing for sleep apnea is reliable, and 46% said they would sell home tests if Medicare changed its national coverage determination to include reimbursement for such equipment. Last year, the Centers for Medicare & Medicaid Services announced it was "proposing to expand coverage of CPAP to include those beneficiaries with a diagnosis of CPAP made using a combination of a clinical evaluation and unattended home sleep monitoring using a Type II, III or IV device." More than two-thirds of survey respondents expect to participate in competitive bidding for sleep therapy products when the program reached their region. Asked about CPAP, the respondents said the prices they were paying to purchase the equipment were stable, but under competitive bidding, they expected CPAP reimbursement to fall an average of 15%.

At a recent meeting of the AASM (American Academy of Sleep Medicine), its president, Alex Chediak, discussed his concerns about reimbursement. As reported in Sleep Review Report, Ascend Media, Chediak said what's needed is to level the playing field in the competition for fair reimbursement for sleep medicine services by encouraging government and private insurance payers to work only with facilities accredited by the AASM. While this was clearly pushing his own association's agenda, he noted that it wasn't just about protecting his members' financial interests, but about making sure apples are not compared with oranges when pricing for testing and treatment of sleep disorders is determined. In health care, it can be hard for not only patients, but also experienced health insurance administrators to compare one facility's services to another.

Companies offering sleep healthcare modalities also offer helpful information about reimbursement on their websites. For example: Puritan Bennet offers a "Quick Guide" to Coding, Coverage and Payment of CPAP and Accessories, a guide for respiratory assist devices, general info on dispensing of sleep therapy devices, national coverage determination on CPAP, DMERC regional CPAP policies, HCPCS coding and payment guidelines, coding for auto-titrating CPAP units, coverage guidelines for bilevel devices, and DME payer links. Respironics Reimbursement Services' Reimbursement Service Site guides visitors through hints for filing claims, includes coding and coverage info, includes facts about medical necessity, has info on DME and CPT HCPCS fee schedules and fee schedule amounts, provides general strategies for appealing claims, offers a reimbursement support line for homecare, inpatient and outpatient care, physician office care, long term and subacute care, and home health. The site also includes a government relations update and clinical reference guide. Resmed's CPAP website has info on Medicare coverage of CPAP for OSA, information needed for claims, CMS national coverage determinations and changes, info on policies about polysomnography coverage, proposed regulatory/reimbursement changes, and specific info about modifications and payment parameters.—Les Plesko

CASE DISMISSED

In pretrial motions, the United States District Court for the Northern District of California has granted summary judgment of non-infringement in favor of Nova Biomedical Corporation and against Abbott Diabetes Care in two United States patents on blood glucose technology that were being asserted in a case brought against Nova by Abbott Diabetes Care and Abbott Laboratories. The Court ruled that Nova's blood glucose meters and strips, which allow diabetic patients to monitor their glucose levels throughout the day, do not infringe current US Patents. The Court finessed related rulings on other patents with some addenda. For details contact Nova Biomedical, novabio.com.

DO INHALE

Dr Harold Palevsky, professor of medicine and chief of the Pulmonary, Allergy and Critical Care Division at the University of Pennsylvania presented data from the TRIUMPH I study at the recent ATS meeting. The data demonstrated the safety and efficacy of inhaled treprostinil in pulmonary arterial hypertension (PAH) patients currently receiving Tracleer (bosentan) or Revatio (sildenafil). The study highlights the importance of Tracleer as the cornerstone of PAH therapy, and validates the importance and efficacy of inhaled prostacyclin therapy as an improvement over IV prostacyclin therapies and their direct risks for blood stream infections and catheter/pump related complications. Actelion's Ventavis is an inhaled prostacyclin approved by the FDA for the treatment of Functional Class III or IV PAH. When used in combination with Tracleer, Ventavis is the only inhaled prostacyclin therapy that has shown functional class improvement, slowed progression of clinical worsening, and improved hemodynamics. The abstract presented was: TRIUMPH I: Efficacy and Safety of Inhaled Treprostinil Sodium in Patients with Pulmonary Arterial Hypertension (PAH), V. McLaughlin, MD, et al. Aim: To determine the effects of chronically administered inhaled treprostinil (TRE), a prostacyclin analogue, on exercise capacity and safety in patients with severe PAH. Methods: Double-blind, randomized placebo-controlled, parallel-group study comparing inhaled TRE (up to 45 g four times daily via ultrasonic nebulizer) to placebo (PBO) over 12 weeks in patients with NYHA functional class III-IV after at least 3 months of bosentan 125 mg twice daily or sildenafil. Baseline entry criteria included six-minute walk distance (6MWD) of 200-450 meters. The primary endpoint was change in 6MWD (compared to PBO)

from baseline to Week 12. Secondary efficacy included changes in NYHA functional class, Borg Dyspnea Score, signs and symptoms of PAH, and clinical worsening. Results:235 patients were enrolled at 31 centers. Baseline characteristics included mean age of 53.7 years with 56% idiopathic PAH, and 98% and 2% NYHA class III and IV, respectively. Baseline 6MWD was 34866 meters with 165 receiving bosentan and 70 receiving sildenafil. 212 patients completed 12-weeks of dosing. Median 6MWD (peak) at week 12 improved 20 m ($p<0.0006$) compared to PBO, while 6MWD (trough) improved 14 meters ($p<0.01$). Clinical worsening, change in NYHA class and Borg Dyspnea Score were not significantly changed. TRE was well tolerated with the most frequent AEs reported as cough, headache and nausea. Conclusion: Inhaled TRE provides incremental benefit to patients currently receiving oral medications for PAH, and offers several advantages including patient convenience, targeted drug delivery, peak and trough benefit, and an improved systemic safety profile.

IT'S IN YOUR GENES

Researchers from the University of Pittsburgh School of Medicine have identified genetic components of the dendritic cells that are key to asthma and allergy-related immune response malfunction. Targeting these elements could result in more effective drugs to treat allergic disorders and asthma. The researchers' study illuminated a pathway that allergens use to act directly on dendritic cells to propel differentiation into the T lymphocytes. The molecule, c-Kit, was found to be central to the process of allergic response. Genes encoding for c-Kit and the cytokine IL-6 were significantly activated when allergens were present, but c-Kit was the very first molecule that got triggered. Using cells cultured from c-Kit mutant mice, the researchers studied molecular reactions to assaults by cholera toxin and house dust mites. In addition to c-Kit and IL-6, they found effects on stem cell factor and Jagged-2-immune system molecules that are parts of the activation process. Dendritic cells were incubated with cholera toxin and house dust mite allergens, and both substances induced significant secretion of c-Kit and IL-6, initial steps in a cascade resulting in the activation of T helper cells. Dual upregulation of c-Kit and stem cell factor has been noted in some cancers, such as small cell lung cancer. IL-6 has been associated with cancers such as multiple myeloma.

FILTERED

Researchers have begun investigating the effectiveness of new operating room filtration systems that can protect staff and patients from TB. According to a study at Saint Joseph Mercy Hospital in Ann Arbor, a supplemental portable anteroom high-efficiency particulate air (PAS-HEPA) filter unit placed outside operating room suites may prevent secondary transmission of airborne microorganisms like Mycobacterium tuberculosis. The study compared the efficiency of freestanding HEPA filtration units to a new portable anteroom system combination unit in removing harmful airborne infectious pathogens. Freestanding HEPA units were evaluated in the operating room, while the PAS-HEPA unit was placed outside over the main operating room door. Both smoke plume and non-infectious particles similar in size to M. tuberculosis were used to mimic movement of airborne pathogens within highly pressured environments. Deployment of the PAS-HEPA combination unit pulled the smoke downward, away from the operating room table and toward the floor and main door. The second phase of the study (which involved simulated microscopic particles) mirrored these observations; within 20 minutes, over 94% of submicron particles were cleared from the operating room. The portable system also offers the option of deployment at any point in a daily schedule of surgeries and can be moved with the patient to a private recovery room to avoid postoperative transmission. Researchers noted, however, that they were using tuberculosis surrogates, and that pathogen behavior was unpredictable.

IT'S RELATIVE

A study at Columbia University revealed that children with older brothers or sisters were more likely to experience respiratory symptoms than only children, or oldest children. Children with at least two older siblings were also 50% more likely to have gone to an ED or been hospitalized overnight for breathing problems. Having older siblings increases a child's risk of exposure to infectious agents before age two years, and in turn increases the child's risk for wheezing, researchers said, adding that some studies have found that having older siblings increases the risk of wheeze in babies and toddlers. The children in the study were picked from Head Start programs in New York because their neighborhoods had the highest rates of childhood asthma hospitalization in the city. Previously, it was believed that exposure to infectious agents at a young age reduced the likelihood of later asthma. The study found a prevalence of recent wheezing to be higher among boys than girls (32 vs 21%) and higher among children with an asthmatic parent (53 vs 22%). Having younger siblings, unlike having older siblings, was not associated with respiratory symptoms. The associations of birth order with respiratory symptoms were statistically significant only among those children who were not atopic and among those without an asthmatic parent.

INTERFERENCE

University of Texas Medical Branch at Galveston researchers tested two types of complex, custom-designed molecules to interfere with the genetic machinery that RSV uses to replicate itself within cells. "Morpholino oligomers," created by AVI BioPharma, penetrated cultured human airway cells easily and produced only minimal toxicity. One of the two, AUG-2, significantly reduced RSV replication in both cell culture and mouse experiments. Because a dangerous inflammatory response occurs so soon after RSV begins replicating in the lungs, researchers said, antiviral therapy by itself was unlikely to be sufficient to treat severe RSV infection in infants, but it could be a critical part of a combination therapy that also included drugs to reduce RSV-induced lung inflammation and boost T-cell response.

YOU READ IT THERE FIRST

A recent issue of the journal CHEST reports that a recent study of COPD, compared with placebo, LABAs reduced severe exacerbations by 21%, and patients given LABAs did not differ in all-cause or respiratory-related mortality. The review also found that LABA treatment was associated with significantly more severe COPD exacerbations compared with tiotropium. The journal also reported that, over the last decade, mortality rates for patients with ARDS or ALI have declined. Belgian researchers reviewed 72 studies published over a 12-year period, which showed mortality rates for patients with ARDS or ALI in the15 to 72% range, with the overall pooled mortality rate at 43%. Further analysis showed a significant decrease in overall mortality rates of approximately 1.1% per year over the time period analyzed. The decrease in mortality was more pronounced for hospital mortality than for mortality in the ICU.

The journal also reported that acute eosinophilic pneumonia may be associated with recent changes in smoking patterns. Japanese researchers reviewed the smoking history and habits of 33 patients with AEP. Alterations in smoking habits, such as initiating the smoking habit or increasing the number of cigarettes smoked, were seen in 87.9% of patients. A cigarette smoke provocation test was performed in nine patients, and all tested positive. Data suggest that cigarette smoking, particularly changes in smoking habits, is a possible AEP etiologic factor. These studies were published in the May issue of the journal CHEST.

BAD BREATH

Canadian researchers have found that uncontrolled asthma during the first trimester of pregnancy greatly increases the risk of birth defects in babies, and concluded that women who had an active asthmatic episode in the first three months of pregnancy were 48% more likely to have a baby with at least one congenital defect than asthmatic mothers who did not have a flare-up in the first trimester. The rate of birth defects among these moms was 12.8%, vs 8.9% for mothers with controlled asthma. Researchers analyzed more than 4,300 pregnancies. The likely reason for the defects is that when a pregnant woman has trouble breathing, both mother and fetus experience a drop in the level of oxygen in the blood.

RESUSCITATED RABBITS

Researchers at MIT have healed airway injuries in rabbits using a new technique that could work on humans, that heals airway injuries by placing new tracheal cells around the injury site, in which two types of embedded tracheal cells take over the functions of the damaged tissue. The researchers found that it's not necessary to recapture the ordered layering of the trachea to heal injuries, but concentrated on restoring cellular health. When cells are intact and have regained their biological function, they need only reside near the injured tissue to enhance overall repair. The MIT engineers delivered a mixture of new healthy cells derived from the epithelial lining and the nourishing blood vessels and the combination of epithelial and endothelial cells took over the biochemical role lost with cell damage. The healthy cells released growth factors and other molecules necessary for healing tissue, and modulated their delivery in response to physiological feedback control signals. Because of the similarities between the trachea and other tubes in the body, such as those of the vascular, genitourinary and gastrointestinal systems, the researchers believe their approach could translate to other organs.

ANTIBODIES

The second-generation humanized monoclonal antibody motavizumab significantly decreases hospitalizations due to respiratory syncytial virus (RSV) and outpatient acute lower respiratory tract infections (ALRIs) in term American Indian infants at high risk of RSV disease, according to interim results of an ongoing phase III study by Johns Hopkins. Researchers randomized 1,410 term, healthy American Indian infants in a 2:1 design to receive five monthly intramuscular doses of motavizumab, 15 mg/kg, or placebo during their first RSV season. In an interim intent-to-treat analysis, motavizumab-treated patients had an 83% reduction in the incidence of RSV hospitalizations compared to placebo-treated patients (8.3% for placebo vs 1.4% for motavizumab). Researchers also documented a 71% reduction in outpatient RSV-specific medically-attended ALRIs. The above information is from a story on Medical News Today, copyright Medical News Today, written by Jill Stein.

VETS

Many soldiers returning from Iraq have been diagnosed with bronchiolitis, according to a Vanderbilt University Medical Center study. Fifty-six soldiers from Fort Campbell, KY were evaluated for unexplained shortness of breath and lung biopsies were performed on 31 of them; 29 had bronchiolitis. Most of these had a prolonged exposure to sulfur dioxide from a sulfur mine fire near Mosul, Iraq in 2003, but some had no known exposure. The soldiers were initially evaluated with chest x-rays and computerized tomography, which typically turned up normal, as did pulmonary function tests. All the soldiers were physically fit at deployment. After their return, none of the soldiers with bronchiolitis met training standards and were declared unfit for duty. The Mosul sulfur fire was the largest man-made release of sulfur dioxide on record, a hundred times greater than Mount Saint Helen's volcanic eruption. Sulfur dioxide levels in the area were at toxic levels. Five of the soldiers had toxic lung injury, however, without exposure to the Mosul sulfur fire.

COUGH & CUT

Scientists believe they may have identified a biological explanation for the link between cesarean-section delivery and risk of allergy and asthma in childhood. They presented their findings at the American Thoracic Society's 2008 International Conference in Toronto. Studies have shown immunological differences between children with and without allergy at the time of birth. For example, increased cord blood levels of cytokine have been positively associated with allergy among children with a family history of allergy. A previous study demonstrated an association between cesarean section and increased neonatal secretion of IL-13. This time, researchers measured the expression and function of specific regulatory T-cells in the cord blood of 50 newborns born by cesarean section, and 68 delivered vaginally, all of whom have at least one parent with allergies and/or asthma. They found that babies born by c-section showed a reduction in the suppressive function of their regulatory T-cells. The study suggested that the mode of delivery may be an important factor influencing immune system development in the neonate. The researchers postulated that the stress of labor or exposure to specific microbes through the birth canal in vaginal as compared to c-section delivery may influence neonatal immune responses.

COPD DATA

Researchers at the University René Descartes in Paris studied 5,008 subjects visiting health prevention centers in France. Prevalence of airflow obstruction was 7.5%. A diagnosis of respiratory disease was reported for only 6.1% of these subjects. Severity was mild to moderate in 95%. Despite this, quality of life was significantly impaired in these subjects, who also reported more dyspnea and more missed working days than those without COPD.

EBV & COPD

Researchers at Mater Hospital in Belfast examined the role of the Epstein-Barr virus in chronic obstructive pulmonary disease. They tested subjects with and without this disease for the presence of EBV and found that EBV was much more commonly found in those patients who had developed COPD. EBV is thought to be a possible factor in the development of

COPD. To see the original article, go to the European Respiratory Society webite, European Respiratory Journal, and see the title "High levels of Epstein-Barr Virus in COPD."

POLLUTION AND BREATHING

Global increases in traffic, industrialization, and the growth of cities have all contributed to a rise in emissions and increasing levels of air pollution, according to research at University Hospital, Umea, Sweden. They note mounting epidemiological and laboratory evidence regarding the negative short-term, as well as long-term, health effects of air pollutants on the respiratory and cardiovascular systems. Ozone and diesel exhaust are two major contributors to traffic-related air pollution and have both been shown to trigger inflammation in the airways, with concentrations peaking at rush hours and in the afternoons, respectively. In order to investigate the consequences of this sequential exposure, healthy subjects underwent two separate exposure series within controlled walk-in chambers. These comprised a one-hour morning exposure to DE or filtered air followed five hours later by a two-hour exposure to O3. Bronchial rinse samples were obtained via bronchoscopy 24 hours after the start of each morning exposure, with inflammatory cells and immune cell factors assessed. Healthy subjects exposed in sequence to environmentally relevant levels of DE and O3 demonstrated significantly increased pro- inflammatory cells, revealing a potentially adverse amplification in airway inflammation. See the original article, Diesel exhaust exposure enhances the ozone-induced airway inflammation in healthy humans, in The European Respiratory Journal.

TB DEATH

A recent study at the Institut de Veille Sanitaire, St-Maurice, France, reported an 8% death rate in a TB population of 40,000. Old age and multidrug-resistant TB were the strongest predictors of death, while being a male, being of European origin, having lung disease and having been treated in the past for TB presented a weaker risk.

STINKY SKIES

The Global Cabin Air Quality Executive (GCAQE), an organization representing airline air crews, complained that a recent study about the quality of air in airplane cabins was flawed. The organization said that the study wasn't properly bid, that the companies providing research info may have received money from aerospace firms, that sampling methods were flawed or not available for review and sampling methods weren't comprehensive, that the government was stalling in releasing the data, and so forth. The GCAQE said the UK government must no longer delay taking action to prevent contaminated air events occurring, and stated that "air passengers and airline crews remain at serious risk from exposure to aircraft contaminated air, even though solutions are currently available to greatly reduce this problem."

FIREFIGHTERS

The Montana Center for Work Physiology and Exercise Metabolism (Montana WPEM) presented a study at the American College of Sports Medicine meeting that showed that wildland firefighters who consumed the yeast based (beta glucan) antioxidant supplement, Wellmune WGP, had 23% less upper respiratory tract infections than firefighters who took a placebo. The results were consistent with previous clinical research involving marathoners, individuals with high stress lifestyles and the general population. Fifty-four firefighters were given Wellmune WGP or placebo for 14 days, followed by a three-day washout period and another 14-day treatment period. Subjects kept daily health logs recording cold and flu symptoms and overall feelings of well-being. Forty-eight percent of the firefighters experienced an upper respiratory tract infection while taking the placebo, but only 37% had an upper respiratory tract infection while taking Wellmune WGP. Additionally, there was strong statistical significance in the wildland firefighter's perceived health.

HOW TO BREATHE

A presentation that demonstrates breathing exercises designed to help reduce the use of asthma inhalers is available from the Cooperative Research Centre (CRC) for Asthma and Airways website. The 40 minute production is in response to a research paper on the management of asthma through the use of breathing exercises, was conducted by doctors at Sydney's Woolcock Institute of Medical Research and Melbourne's Alfred Hospital, and was published in the August edition of Thorax. The study showed that asthmatics who undertook regular breathing exercises reduced their medication levels by up to half and inhaler use by up to 86%. Two groups of breathing techniques are demonstrated, one for daily practice, and the other for specific relief of asthma symptoms.

PRODUCTS

INNOVATIVE

Draeger Medical, Inc announced the release of Innovian Anesthesia Version 2.2. Enhancements have been made based on extensive physician feedback and include expanded capabilities for IT performance in the perioperative suite. Innovian 2.2 is the latest result of Draeger's ongoing commitment to developing and supporting IT solutions at the acute point of care. Innovian Anesthesia is the information backbone that integrates near real-time, life-critical information from patient monitoring, medical therapy devices, and other ancillary information systems. It gives clinicians fast access to patient data, which can minimize the duplication of effort that often occurs with paper record systems. Web API provides programmatic read/write access to Innovian Anesthesia data that is stored within the centralized system database. Version 2.2 enables access to Holding and PACU data in addition to supporting customized stored procedure calls that may be used for data mining or other cross-case data analysis. These new additions are also provided for use by the PreOp eForms product, which supports the creation of web-based documents similar in presentation to existing hospital paper forms. The ReportViewer has been expanded to enable users to browse Innovian Anesthesia Clinical Reports through a third-party application. This Service Oriented Architecture (SOA) approach enhances data sharing in a secure, flexible and maintainable manner. Sharing data via network access enables expanded workflow flexibility for viewing patient data from any location, including remotely. This offers the user a variety of ways to access the data as well as a number of manners in which the data can be viewed. Together, the API and ReportViewer expand Innovian Anesthesia's interoperability and permit increased site customization to meet unique hospital workflow. Innovian Anesthesia continues to provide advanced IT tools and solutions to integrate within the larger hospital IT infrastructure. Contact draeger.com.

SIEMENS SAYS

Siemens Healthcare announced the expansion of clinical education offerings with the opening of the Siemens Healthcare Training Center at the University of Utah in Salt Lake City. Through an educational partnership with the University of Utah's Department of Radiology, under the direction of Dr Steve Stevens, Siemens can now offer even more opportunities to expand clinical experience and develop technical skills with Siemens latest imaging technologies. The learning environment at the University blends traditional and alternative learning methods to serve various learning styles and preferences. Imaging professionals can choose from virtual education, onsite and classroom training, workshops, fellowships, and printed self-study programs. In addition to the University of Utah training facility, classroom training is also offered at Siemens training sites. Siemens current portfolio of educational services and offerings can be viewed at medical.siemens.com/education. Donald Quinn has been appointed new head of the Diagnostics division of the Siemens Healthcare Sector. He succeeds Jim Reid-Anderson, who became the new CEO. Prior to his new job, Quinn served as executive vice president and chief customer officer of the Diagnostics division. He has worked for Abbott and Mallinckrodt. In other Siemens news, the company has been selected as the winner of the 2008 VHA Service Excellence Award for Supplier of the Year. VHA Inc is a national healthcare provider alliance of more than 1,400 not-for-profit hospitals and 21,000 non-acute healthcare organizations. Candidates for the award are recommended and selected based upon their sales interactions with VHA members, overall customer satisfaction, and responsiveness to VHA staff and members, as well as contract administration compliance criteria. Contact siemens.com.

CARING CARINA

Draeger Medical Systems, Inc announced that it has received 510(k) clearance from the FDA to market the Carina, Draeger's latest product in its ventilator product line to the US market. The Carina ventilator offers both invasive and noninvasive capabilities in one device. Its latest technology known as "Synch Plus" will compensate for leakage and provide effective breath delivery. The Carina is well suited for the emergency room, general ward, ICU, or sub-acute facilities as it features an internal battery and can operate independent of a high pressure gas system. For patients who are mechanically ventilated long term, the Carina-home facilitates similar style ventilation technology for chronic patients outside of the hospital. The Carina-home has been in the US marketplace for over a year. For more see draeger.com.

NEW DISCOVERIES

Discovery Laboratories, Inc announced that new data supporting potential unique properties of its novel KL-4 Surfactant Replacement Technology (SRT) were presented at the Pediatric Academic Societies Annual Meeting. Preclinical studies were presented demonstrating that KL-4 does not induce an immune response known as anaphylaxis and that Surfaxin (lucinactant) displays antimicrobial properties. The Pediatric Academic Societies (PAS) Annual Meeting is internationally recognized as the largest, most relevant medical meeting dedicated to pediatric research. One study assessed the potential for KL-4, a 21 amino acid peptide that is structurally similar to pulmonary surfactant protein B (SP-B), to induce anaphylaxis. In this study, a well-established animal model was used to test whether KL-4 would trigger anaphylaxis. The data showed that KL-4 did not induce active or passive anaphylaxis, even when the immune system was potentiated and sensitized. Another study presented at PAS investigated the antimicrobial properties of Surfaxin. In that study, gram-positive and gram-negative bacterial broth was mixed with Surfaxin and Survanta (beractant), as well as with saline, a negative control, and ciprofloxacin. While both Surfaxin and Survanta suppressed gram-positive bacterial growth, only Surfaxin suppressed gram-negative bacterial growth.

WATCH OUT

A new MSA white paper, Bioterrorism; Understanding Threats and Technology is now available. This overview discusses the biological warfare from ancient times to the present and the various technologies developed to detect biological agents. Mine Safety Appliances makes products for respiratory emergencies. The Safesite Wireless System monitors, detects and communicates the presence of up to six potential threats, including chemical warfare agents (CWA), gamma radiation, volatile organic compounds (VOC), toxic industrial chemicals (TIC), combustible gas and oxygen deficiency and enrichment. The Biosensor 2200R Biological Agent Detector from MSA has been selected as a product offering through the 2008 CEDAP Program. CEDAP assists law enforcement and first responders in smaller communities, providing equipment grants to help them prevent, deter, and respond to terrorist attacks. HAZMATCAD and HAZMATCAD Plus Detectors provide highly reliable chemical warfare agent (CWA) detection, including nerve and blister agents, with superior selectivity in easy-to-use portable handheld devices. Both units use advanced Surface Acoustic Wave (SAW) technology, while the HAZMATCAD Plus includes electrochemical sensors to detect selected Toxic Industrial Chemicals (TICs), for simultaneous detection of nerve and blister agents, hydrogen cyanide, phosgene, hydride and halogen gases. MSA's new Responder CBRN PAPR is the first CBRN Powered Air-Purifying Respirator with a tight-fitting facepiece. Contact msanorthamerica.com.

BE COMPLIANT

Respiratory Inductance Plethysmography is required under the new AASM Scoring Recommendations, are you compliant? The Compumedics Summit IP continues a long Compumedics history of providing inductive plethysmography for our customers. Compumedics has offered this technology to our customers since 1988 with our innovative and ground breaking P-Series and S-Series amplifiers as used in the Sleep Heart Health Study. The Summit IP provides this same trusted technology to all PSG users regardless of amplifier manufacturer. Standard features include automatically calibrated SUM channel output, compact interface box with replaceable batteries for long life and high sensitivity belts with washable and replaceable covers. Contact compumedicsusa.com.

APPROVED

Masimo, the inventor of Pulse CO-Oximetry and Measure-Through Motion-and-Low-Perfusion pulse oximetry, today announced it has received FDA clearance for its breakthrough noninvasive and continuous total hemoglobin monitoring technology (SpHb). The availability of Masimo SpHb technology should make hemoglobin measurement more convenient and broadly available to clinicians in both hospital and outpatient settings—helping them make earlier and better clinical decisions, improve patient safety and decrease costs. Noninvasive total

hemoglobin will be offered as part of the upgradable Masimo Rainbow SET technology platform. The need for better hemoglobin monitoring to manage blood levels is reinforced by recently published controlled studies that show the safety of blood transfusions can be improved by the use of transfusion thresholds. In a 2008 study by the Cochrane Collaboration titled Transfusion Thresholds and Other Strategies for Guiding Allogeneic Red Blood Cell Transfusion, reviewers examined evidence from ten trials—reporting outcomes on a total of 1,780 patients—and found that "restrictive transfusion strategies reduced red blood cell transfusions by 42%." Additionally, while noting that not all of these results were statistically significant and that additional studies are required to confirm the findings, the Cochrane reviewers also reported that, "on average, mortality was 20% lower with the restrictive compared with the liberal transfusion triggers." Similarly, five of the ten studies examined showed a reduction in hospital length of stay, while three showed a reduction in ICU length of stay. Continuous, noninvasive hemoglobin monitoring with Masimo Rainbow SET SpHb may enable more restrictive transfusion triggers and help maintain optimal hemoglobin levels for critically-ill patients. In addition to facilitating better blood level management, Masimo Rainbow SET's noninvasive hemoglobin monitoring capability should also help clinicians better manage chronic anemia, a blood disorder affecting two billion people worldwide that is one of today's most prevalent public health problems. Masimo Rainbow SET SpHb should provide hospitals, emergency medical professionals, dialysis centers, family physicians, cardiologists, pediatricians and other care providers with a more convenient and accessible way to manage this pervasive condition. Contact masimo.com.

BURY THE OLD

Hill-Rom Holdings, Inc, formerly known as Hillenbrand Industries, Inc, announced completion of the spin-off of Hillenbrand, Inc, formerly Batesville Holdings, Inc, the parent of its funeral services operating company Batesville Casket Company. Hill-Rom is a leading worldwide manufacturer and innovator of medical technologies and related services, for the health care industry. The company will now focus exclusively on its medical technology business. Hill-Rom is a leading worldwide manufacturer and provider of medical technologies and related services for the health care industry, including patient support systems, non-invasive therapeutic products for a variety of acute and chronic medical conditions, medical equipment rentals, and information technology solutions. Hill-Rom's comprehensive product and service offerings are used by healthcare providers across the health care continuum in hospitals, extended care facilities and homecare settings to enhance the safety and quality of patient care.

CHOKE HOLD

Restech Corporation announced that the Central California Ear, Nose & Throat Medical Group (CCENT) of Fresno, California, has adopted the Restech Dx-pH Measurement System to detect acid reflux in the throat. The Restech Dx-pH Measurement System allows easy measurement of stomach acid levels. If an initial examination indicates voice pathology, the Restech Dx-pH Measurement System can be used to determine whether stomach acid is refluxing into the larynx through a miniaturized pH sensor at the tip of the Dx-pH Probe, which sends measurements wirelessly to a miniature recording device carried by the patients during the test period, which takes 24 hours. The probe is 1.5mm in diameter and rests at a comfortable position in the back of the throat behind the soft palate and does not disrupt normal activity or eating. Contact restech-corp.com.

EMERGENCY ROUNDTABLE

Cardinal Health Respiratory Care

Information provided by Jim Homuth, Senior Director of Marketing, and a frequent speaker on emergency preparedness and pan-flu readiness.

By way of background, describe your product(s) and its unique features, including the latest advances in product development and applications.

The LTV 1200 ventilator is the most comprehensively suitable ventilator on the market today for Emergency Planning and Disaster Preparedness from individual hospital needs to National Emergency ventilator stockpiles. The LTV 1200 meets or exceeds all the criteria set forth in the AARC guidelines for Positive Pressure Ventilation Equipment for Mass Casualty Respiratory Failure. A relatively lightweight and compact design, with the capability for ICU level ventilation, the easy user interface allows for minimal training and is therefore operable by emergency responders of many skill levels. The internal turbine of the LTV eliminates the need for compressed air, a resource that has proven to be scarce in a natural disaster, and will likely be in the event of a Pan-Influenza pandemic.

How can your company help an area stricken by a disaster or in an emergency situation?

Cardinal Health brings extensive distribution network expertise to manage all aspects of disaster management. Ventilators and respiratory care capitol equipment leads to accessories and disposable products, pharmaceuticals, all available within the Cardinal Health family as a single source provider for disaster management medical needs.

What products does your company offer to assist in this type of effort?

Cardinal Health Respiratory Care offers portable ventilators with ICU capability for patients 5kg through Adult. In addition we supply circuits, ventilation accessories and portable power sources.

Has your company had any experiences with dealing with made-made or natural disaster situations?

Cardinal Health Respiratory Care's experience in disaster relief includes assisting the victims of both Hurricane Katrina and SARS treatment efforts in Canada and Asia. We provided both product and clinical assistance in the 35W Bridge Collapse in Minnesota and most recently donated ventilators to support Earthquake relief efforts in China. In all cases, LTV ventilators and circuits were shipped immediately to the areas in most need, with additional service throughout the periods of need. Through a combination of shipment re-prioritization and increased production, we have been able to meet the spikes in demand created by disasters and shortages. Being experts in transport ventilation, we supplied large quantities of batteries in addition to ventilators to Katrina victims to compensate for the

lack of electrical power, and sent Clinical Consultants to assist with training and troubleshooting.

What contingency plans does your company have to boost production of your product in case of a disaster or emergency?
Cardinal Health Respiratory Care is one of the world's largest ventilator manufacturers, and located in the United States. We maintain full production facilities in Minnesota and Canada. Our flexible relationships with our vendors ensure Cardinal Health's production abilities are responsive as needs change. In addition we maintain a fleet of ventilators to meet emergent needs.

What types of education do you provide, relevant to emergency services or disaster planning, for both your own personnel and for those using your products?
Cardinal Health Respiratory Care offers many classes to train emergency response workers including the basics of Positive Pressure Ventilation in Mass Casualty Respiratory Failure, Transporting Ventilation Patients and Troubleshooting. Our Clinical Consultants and Technical staff are available 24/7 for assistance. We train biomedical technicians to service LTV ventilators and have 6 regional certified technical support centers domestically as well as our central service facility in Minnesota. In addition to the personal training available from Cardinal Health, we offer DVDs for in-service training and an emergency set-up training DVD.

What mechanisms relevant to your product are in place to assist hospitals, clinics, and users in the event of emergency use of your products?
Cardinal Health also recognized ease of operation as a primary consideration in a ventilator. The patient presets for infant, pediatric and adult on the LTV 1200 allows healthcare workers not specifically trained in respiratory care to instigate the initial set up of the ventilator to expand the resources of respiratory therapists. To assist these non-respiratory health care workers we provide an Emergency Set-Up Card for the LTV 1200. This Set-up card has been validated as extremely effective in clinical trials among healthcare non-professionals.

The Go-Pack configuration is a "grab and go" assembly of all items necessary for mass emergency ventilation deployment. The ability to recharge the batteries in this storage/deployment container without un-packing is a major advantage to maintain deployment readiness. In addition, having all the circuits and set-up information inside has been a favored feature by many states for their emergency stockpiles.

Discuss the role of critical care providers in research, development, and improvements and/or new applications of your products in emergencies and for disaster-preparedness.
Through our partnership with emergency planning organizations across the Unites States we have discovered that in the event of an emergency, compressed oxygen will likely need to be rationed. In response to this prediction, Cardinal Health has developed a feature on the LTV 1200 ventilator called O2 conserve. O2 conserve will reduce any wasted oxygen to ensure that the available O2 is delivered to the patient, and not leaked away. This will assist in expanding the limited compressed oxygen resources in a time of emergency.

Power availability is restricted in times of emergency, and Cardinal health developed a light weight, and hot-swappable battery solution to provide almost unlimited power with recharging. The SprintPack Lithium Ion batteries charge while the vent is operational and/or recharged battery units can be swapped without loss of power to the ventilator.

Talk about how you test and/or evaluate your product in-house and in the field.
All LTV ventilators are subjected to rigorous user preference studies before release for sale. The evolution of the LTV 1200 in the current configuration is a response to the input we received from users, clinicians and emergency planners combined. The LTV Series Ventilators have a proven track record and are the preferred ventilator by thousands of Emergency Transport Teams civilian and military, air or ground ambulance.

Discuss your R&D process, including clinician and user input, both in terms of emergency and day-to-day applications.
Our clinicians, engineers and vendor partners have created many solutions for individual users that have gone on to be integrated into our overall offerings. Solutions for non-invasive ventilation, portability and power, mounting and carrying, modes of ventilation, are some of the contributions incorporated at the request of clinicians, users and emergency planners.

Tell us about how you're promoting your product as it relates to emergency usage and applications.
Cardinal Health participates in Emergency Management and Disaster Preparedness planning meetings on county, state, national and international levels. We partner with the decision making bodies to prepare plans, create storage and maintenance programs and provide training. Our service model allows us to develop solutions to respond to the unique needs of the customer. As of June 1, 2008 we have partnered with 26 states and Washington DC by providing more than 7000 ventilators ready to deploy for use in disaster management respiratory care.

Draeger

Information provided by Ed Coombs, MA, RRT, Director of Marketing—Ventilation.

What products does your company offer for emergency planning and/or implementation?
Draeger's medical and safety divisions help protect human life in approximately 50 countries around the world with innovative products, services, and system solutions in the areas of emergency/critical care and transport ventilation, anesthesia, and patient monitoring. Gas measuring technology, personal protection, and safety system technologies are also available through Draeger's medical and safety solutions. Draeger's medical division provides emergency and transport ventilation devices that provide high-level, ICU-like mechanical ventilation by including such contemporary features such as pressure support and non-invasive ventilation. Our transport ventilators known as the Oxylog 1000, 2000, and 3000 are designed to be light, compact, robust, and support a wide range of critically ill or injured patients.

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

What type of educational materials and opportunities do you offer for users and/or potential users of your product?
With respect to disaster management, continued education and preparedness planning is essential. Specifically to mechanical ventilation, our clinical applications staff will help make the most of emergency staff and equipment. The comprehensive product training provided enables the clinician to confidently operate the ventilator. Our clinical applications specialists are able to enhance the hospital staff's knowledge base and improve quality by introducing the latest technologies available in respiratory care, and improve their process performance by providing a seamless ventilator solution.

Discuss the role of the critical care product providers in researching, developing, and implementing strategies for emergency planning and execution.
Through actively listening to our customers via focus group meetings, one-on-one discussions, or simply by picking up the phone, Draeger can deliver the products, services and solutions that our customers require. Through our outreach and cooperation with the AARC, industry leaders and customers are involved in the development of new products at an early stage in order to ensure that the clinical demands are understood. This input is essential to the development of Draeger products. The Draeger principle of uncompromising quality results in innovative and relevant products and solutions for our customers.

What trends do you see in new products and product applications for emergency planning and preparedness?
There is no shortcut to innovation. Draeger historically invests over 7% of its annual revenue in R&D efforts. This commitment to our customers has been in place for over 100 years. Our research and development teams are constantly focused on the future as it relates to how patient care is impacted. This leadership paves the way for the best solutions possible. Specifically regarding mechanical ventilation, Draeger sees the future in providing seamless technology from emergency care to intensive care, to recovery. The ability to provide high-end technology while addressing portability and disaster management situations will remain on the forefront.

Smiths Medical PM, Inc.

Information provided by Brian Eisner, RRT-NPS, Product Manager, Patient Monitoring and Ventilation, Smiths Medical PM, Inc., Waukesha WI.

What products does your company offer for emergency planning and /or implementation?
The Smiths Medical family provides the clinician with a complete solution for emergency and disaster planning. Smiths Medical PM, Inc offers the complete line of Pneupac ventilators and BCI patient monitoring products for emergency planning and implementation, while Smiths Medical ASD, Inc provides ventilation accessories with the Portex and Medex brand products. Clinical specialists are also available to provide assistance in developing custom solutions for disaster preparedness plans and requirements.

What hand-on experience does your company have dealing with emergencies?
Pneupac ventilators have been used worldwide in a variety of emergency situations, and in the harshest of environments and situations. In the aftermath of natural disasters and mass causality events, Pneupac ventilators have proven to be a reliable and easy to use device.

What type of educational materials and opportunities do you offer for users and /or potential users of your products?
Smiths Medical PM, Inc provides a variety of training opportunities for Pneupac ventilators. Every ventilator shipped includes a training DVD explaining its simple features, operation, and maintenance. Additional printed materials are available highlighting the user application and device features, and service and technical support is available via phone or email.

Discuss the role of the critical care product providers in researching, developing and implementing strategies for emergency planning and execution.
Device manufacturers and product providers should play an active role in the research, development, and implementation of emergency planning strategies. They need to actively participate on planning committees in an effort to assess needs and provide custom products to meet the individual emergency plans.

What trends do you see in new products and product applications for emergency planning and preparedness?
Recent experiences and trends in emergency preparedness have

forced manufacturers to examine the complexity and usability of their devices. Clinicians have demanded safe and easy to use devices that require minimal competency training. Instead of feature laden devices that demand a high level of training and competency, smaller easy to operate devices have been proven to be more useful in mass casualty situations.

Praxair

Information provided by Paul Garvey of Praxair.

What products does your company offer for emergency planning and/or implementation?
Hospital Emergency Management Standards, Utilities Management EC 4.17 requires that access to key utilities be maintained without interruption during an emergency. Oxygen and other medical gases are a meaningful consideration. Seismic events, floods, tornados, fire, bio terrorism and pandemic outbreak are examples of scenarios where proper planning will reduce the likelihood of a supply shortage or interruption. Since no single solution is appropriate for every contingency, Praxair provides a number of products including portable liquid supply and multi-cylinder emergency carts, services and on-site consulting to ensure solutions are appropriate to the likely event.

What hands-on experience does your company have dealing with emergencies?
Praxair was the key oxygen supplier to the City of New York during 9/11. In the immediate floodwater aftermath of Katrina, we accompanied the National Guard and provided university hospitals in downtown New Orleans with liquid nitrogen for the uninterrupted cryogenic preservation of their irreplaceable specimens.

What type of educational materials and opportunities do you offer for users and/or potential users of your product?
Praxair offers its users written, multi-media and web-based training programs as well as on-site consultation.

Discuss the role of critical care product providers in researching, developing and implementing strategies for emergency planning and execution.
Security of supply for oxygen and other critical medical gases is very important. Numerous critical care products depend on the availability of oxygen supply. With more than 100 years of experience, and as the largest supplier of medical gases to hospitals in North and South America, Praxair has a variety of oxygen related products and services for emergency supply to ensure the most appropriate solution for an individual facility.

What trends do you see in new products and product applications for emergency planning and preparedness?
The inclusion of oxygen, medical gases and cryogens as an essential part of emergency planning continues to increase, in part due to the focus being placed on these utilities by regulatory authorities. We expect oxygen, medical gases and cryogens will be part of emergency planning with a focus on testing and real-world exercise scenarios to ensure plans are truly adequate.

Newport Medical

Information provided by Cyndy Miller, RRT, Director Clinical Education, Newport Medical.

What products does your company offer for emergency planning and/or implementation?
Newport Medical offers the Total Solution Program. This program enables our customers to face ventilation emergencies with strength, consistency and confidence. The Total Solution Program consists of four elements:

1. The Newport HT50 Ventilator
2. customized, flexible purchasing programs
3. personalized training and education programs
4. superior clinical and technical support services

Following are some notable points about the HT50 Ventilator:

Clinical proficiency

- HT50 came out on top in Department of Defense-funded performance comparison of 15 transport ventilators (Respiratory Care. 2007 Jun;52(6):740-51).
- Seamless continuum of care from ground zero to hospital to alternate care site to home.
- Pediatric to adult application for invasive and non-invasive ventilation.
- Safer use of pressure control modes because back up ventilation is based on monitored minute volume.
- Exceptional infection control: unlike blower and turbine based ventilators, Newport Medical's patented, dual micro-piston gas generator uses viral and bacterial gas intake filtering to ensure protection from airborne pathogens for all patients.
- Expanded protection: attach CBRN adapter and NATO-style filter to the gas intake port.

Electrical and gas efficiency

The HT50 has the most flexible power options of any ventilator:

- Built-in, automatic, power converter system accepts any AC voltage from 110-240 VAC or any battery from 12-30 VDC.
- Runs from household/industry (50/60) or aircraft (400) Hz.

The HT 50's patented, dual-micro-piston uses the least power of any gas generating ventilator:

- New, fully charged internal battery lasts up to 10 hours at standard vent settings, external battery adds 12-15 more.
- Any battery you use will power HT50 longer than it would power any other gas generating ventilator.
- HT50 outperformed other major competitors when tested for oxygen conservation during long distance transport of ventilated patients (Oxygen conservation during long-distance transport of ventilated patients: assessing the Modified Circle System. Air Med J. 2006 Jan-Feb;25(1):35-9.).

The HT50's stockpiling/emergency preparedness (EP) advantages:

- Quick set up guide makes setup easy for any operator.
- Stackable hard case, on wheels, with power plug that is accessible from outside. This allows the integrated battery to be charged without removing the ventilator from the storage case.
- Low cost non-proprietary, universal, disposable or reusable circuit.
- Quick and easy field software upgrade via RS232 port.

- Message window displays a reminder when service is needed.

What hands-on experience does your company have dealing with emergencies?
Newport Medical has extensive experience in dealing with emergencies. The Newport HT50 was deployed throughout China during the SARS crisis. Newport Medical embraced this challenge and exceeded the product production, product performance and customer support expectations of users and government agencies throughout the process. In recognition of our efforts, Newport Medical received a beautifully framed Certificate of Appreciation from the Shanghai Red Cross, "for Humanitarian Aid and Relief." We have also worked with many other government agencies both domestically and internationally to assist with the preparation, training and equipment procurement needed to plan appropriately for the possibility of disasters. Newport Medical's flexible production program allows us to dramatically increase production and delivery of the HT50 Ventilator when an emergency arises.

What type of educational materials and opportunities do you offer for users and/or potential users of your product?
Newport Medical works side by side with our users and potential users to help them plan for successful deployment of ventilators in the case of a disaster. Newport Medical's training programs include:
- Clinical and technical service "Train the Trainer" sessions
- Interactive CD with built-in competency assessment tool
- Web-based support
- Friendly quick-guide included with each "EP" Ventilator
- 24/7 hotline to reach a highly trained clinician or technician

Discuss the role of critical care product providers in researching, developing and implementing strategies for emergency planning and execution.
Critical care product providers understand the need for ventilators that help caregivers of all experience levels meet the challenges of ventilating acutely ill and recovering patients. Newport Medical has over 26 years of experience in providing ventilators into many countries where caregivers may have very little or no ventilation experience. We also have ventilators in the home market where "mom" is the only caregiver. These users find our products easy to learn and safe to operate. For emergency use, the KIS (keep it simple) strategy is still the best pathway to help ensure that ventilator patients get the best care when conditions may be less than ideal.

What trends do you see in new products and product applications for emergency planning and preparedness?
There are higher expectations for capabilities in the devices purchased for emergency planning and preparedness. In the past, the ventilators that were sold for this application offered gas or power efficiency or clinical proficiency or ease of use. There was little expectation that one device would offer all of these assets. This expectation has changed since respiratory care practitioners got involved with EP planning. They know what their patients need and aren't willing to give that up in exchange for portability or ease of use. They want it all. Newport Medical has met this challenge. Our critical care experience combined with new gas generator and power system technology has allowed us to offer EP planners a ventilator that meets the elevated requirements for clinical proficiency with improvements in portability and durability. The Newport HT50 is the right product for ground zero, for transporting stricken individuals, and for effectively ventilating sick and healing individuals in alternate care sites where power and gas supplies are scarce. The HT50 Ventilator enables a seamless continuum of care for pediatric to adult patients within the limitations imposed by emergency response and recovery.

Hamilton Medical, Inc

David Costa
David Costa is Vice President and COO, Hamilton Medical, Inc.

By the way of background, describe your product and its unique features, including the latest in product development and applications.
Intelligent Ventilation by Hamilton Medical, offers one very unique advantage in the event of an emergency or disaster. That unique advantage is automation. In the best of circumstances, there is a well recognized shortage of qualified healthcare professionals. In an emergency or disaster that shortage will be even more severe. It is bad enough that our clinical teams are pushed to the limit on a normal work day, but add the threat of contamination themselves, and you multiply the stress exponentially. Should a pandemic strike, the challenge will be getting healthcare workers to report for work, period.

Many have cited the need for more ventilators in the event of an emergency or pandemic. I believe that unless the ventilator that you select is a "force multiplier" by offering a "ventilation autopilot" you have wasted precious capital resources. In a recent New York Times article, the statement was made that, "Hospitals operating on thin profit margins, say they cannot afford to buy and store hundreds of units that may never be used. Cheaper alternatives can be deployed in a crisis, but doctors say they are grossly inadequate to deal with a flu pandemic." Hamilton Medical is the only ventilator company that offers a ventilator that can provide either a sedated or spontaneously breathing patient correct support without the need for constant supervision by a clinician. In an emergency situation, clinical teams will need to be caring for the casualties, not the equipment. Hamilton Medical also offers a simple and unique scavenging system that can filter expiratory gasses from infectious patients. Hamilton Medical responded in full force during the SARS outbreak in Asia, where this product was proven highly efficient. The Hamilton ventilators stay completely isolated from patient contamination. The scavenging system is completely disposable.

How can your company help an area stricken by a disaster or in an emergency situation?
Hamilton Medical is always available to assist anyone during a time of a disaster or emergency situation. If they don't ask, we will call. We are offering a very unique disaster/emergency program that allows health care facilities to participate in a shared ownership program of sorts. The Hamilton Emergency Life-support Program (HELP) allows a hospital to invest minimum dollars for access to a specific number of mechanical ventilators, clinical staff, and virtually everything needed to support the ventilator (including disposables). Participation in HELP allows the healthcare facility to leverage their available funds. In the event of an emergency or disaster, a complete Hamilton Medical team arrives to set-up, train and support the

equipment during those initial hours or days of an emergency when the situation is the most tense. The hospital need not worry about stockpiling equipment. Hamilton Medical makes sure that the equipment is always in patient ready condition. Since training on Intelligent Ventilation is so simple, the team of Hamilton Medical Respiratory Care Professionals can get virtually anyone basic competency with the "ventilation autopilot" in very short order. This allows the hospital Respiratory Care Professionals to focus on the most critical tasks right away, without compromising patient safety with transport or portable ventilators that require manual ventilator settings and do not adapt to a dynamic patient.

What products does your company offer to assist in this type of effort?
HELP is only available to facilities that have taken the opportunity to sign up in advance. These customers are triaged by our disaster management team to top priority. All other response from Hamilton Medical is directed on a first come, first serve basis. HELP is a new initiative and will be expanded based upon interest from government, military and individual health care facilities.

Has your company had any experiences with dealing with man-made or natural disaster situations?
Yes. Two examples of Hamilton Medical's experience with dealing with man-made or natural disasters are the SARS outbreak in Asia (2003) and Hurricane Katrina (2005). HELP is a totally new initiative and has not yet been implemented in support of an emergency or disaster.

What contingency plans does your company have to boost production of your product in case of a disaster or emergency?
Hamilton Medical believes that the best way to address a disaster or emergency is to plan in advance. This is the main reason behind HELP. This allows for a no-hassle implementation of support on minimum notice. In the event of an unplanned demand for ventilators, Hamilton Medical is ready. We can increase our production five-fold in very short order and maintain that for several months. Hamilton Medical has set up a hierarchy of action that ensures existing Hamilton Medical customers are always served first before we address needs outside of the current owner group. We are obligated to those facilities that have been the leaders in incorporating Intelligent Ventilation. They are the ones who are changing the mechanical ventilation paradigm forever.

What types of education do you provide, relevant to emergency services or disaster planning, for both your own personnel and for those using your products?
Intelligent Ventilation from Hamilton Medical is the primary educational focus of the organization. When health care professionals realize how Intelligent Ventilation from Hamilton Medical benefits them, and more importantly the patient, we can have "next step" conversations like disaster planning and emergency preparedness. Intelligent Ventilation provides dramatic improvements in patient safety, staff efficiency, risk reduction and quality improvement. Hospitals that have interest in, or participate in the Hamilton Emergency Life-support Program (HELP) have the opportunity to receive specialized training and consulting services relevant to the scope of the program. This mission specific training provides the highest level of readiness to both parties.

What mechanisms relevant to your product are in place to assist hospitals, clinics and users in the event of emergency use of your products?
HELP redefines disaster preparedness for mechanical ventilators. The program is simple, and designed to address localized disasters and emergencies. In the event of a national pandemic or national emergency no one program can address all needs, but history has shown that regional emergency events are by far the most prevalent. Hamilton Medical makes a great many analogies with commercial aviation. As a former airline pilot, I learned early on that you cannot address emergencies correctly unless you train, evaluate and critique performance on a regular basis. Many times our first step with a Hamilton customer is product training. That is simply not enough. Hamilton Medical is now focused on Human Factors Training. Put simply, our role is not to teach clinical practice but to train correct interaction between the human operator and the ventilator itself. Common elements like a pre-flight check, crew briefing, procedures, flows and checklists are incorporated into this kind of training. Hamilton Medical's Human Factors Training is applicable to any facility that manages ventilators, regardless of manufacturer.

Discuss the role of critical care providers in research, development, and improvements and/or new applications of your products in emergencies and for disaster preparedness.
Hamilton Medical has implemented a comprehensive customer and clinical feedback system. Intelligent Ventilation is so dramatically changing the "clinical standard" that it demands that Hamilton Medical catalogue all feedback for analysis. Intelligent Ventilation is all about protecting the patient from harm due to mechanical ventilation. Intelligent Ventilation is also focused on making the ventilator as hassle-free as possible for the clinician as well. Those involved in serving the patient, need to be free from the limitations that medical instrumentation imposes on their already hectic day. In June, Hamilton Medical launched a new initiative to discuss the clinical issues around new technology's role in patient safety, staff efficiency and quality improvement. We are the first ventilator company in the world to do this. Hamilton is calling this new program the "Initiative for Patient Safety in Mechanical Ventilation." I consider it my personal mission to put together an industry consensus meeting on closed-loop control: impact on safety, efficiency and quality in critical care. I thank you for allowing me this opportunity to invite executives from other ventilator companies, clinicians in all fields of critical care practice, patients, healthcare executives and clinical associations and organizations to join me in putting together an un-biased consensus meeting on a paradigm whose time is already upon us. As an airline pilot who has always been one to "fly by hand," I can tell the readers that appropriate automation combined with better situational awareness and human factors analysis will benefit the patients that we all serve. An airline captain must follow strictly evidence-based procedures, protocols and report deviations to those established criteria. We fought these initiatives at first, but soon learned that this in no way limited our command authority, but by embracing this change, greatly improved safety for our passengers. There may be a reason why we adopted this more quickly in aviation. We are sitting in the same aircraft as our passengers! There is a huge benefit for the clinical team with Intelligent Ventilation and Hamilton is taking great care to educate our clinical experts (customers) of "what's in it for them as well!" It is our obligation in industry to separate

gadgets and features from what makes the best sense for the patient, the clinician that dedicates themselves to the patient and the already strained healthcare system as a whole. Anyone with interest in moving ahead with this initiative, please contact me directly.

Talk about how you test and/or evaluate your product in-house and in the field.
Hamilton Medical does a majority of its initial product testing at top institutions in Europe and elsewhere. Our product development team is in Bonaduz, Switzerland. The evaluation of our devices is on-going and never stops. Information from users is constantly re-evaluated to determine the next step in the improvement process. This is a big reason for our high grades with industry watchdog groups. We are never satisfied with "good enough."

Discuss your R&D process, including clinician and user input, both in terms of emergency and day-to-day applications.
Intelligent Ventilation from Hamilton Medical will never have an "end point," so R&D continues every day. We are well along the road to a fully automated ventilator that allows the clinician to choose from several "autopilots" depending on the situation. Imagine a ventilator that can assess proper ventilation, oxygenation AND lung recruitment status. Imagine the RT now able to look only at caring for the patient, managing a dynamic and automatic system that protects that patient from harm while they perform the high level management functions that only a human can perform (looking at the big picture). Would this be helpful and dare I say, required, in an emergency situation? You bet.

Tell us about how you're promoting your product as it relates to emergency usage and applications.
Intelligent Ventilation is perfect for emergency applications. We are currently developing our next step… the world's first portable ventilator with Intelligent Ventilation, due out in the near future. In the meantime, Hamilton Medical is focused on promoting Intelligent Ventilation; now, any ventilator with simply manual control or traditional waveforms is obsolete.

SPOTLIGHT ON VENTILATION

VENTILATION FEATURE: DISUSE ATROPHY

Mechanical ventilation has been a critical component in saving the lives of many critically ill patients. Once a patient is intubated and mechanically ventilated, we should be trying to liberate them from mechanical ventilation as soon as possible to prevent additional complications. However, some patients can be difficult to wean from mechanical ventilation. One possible explanation for having difficulty weaning from mechanical ventilation was just published in the March 27, 2008 edition of the New England Journal of Medicine. The study by Levine et al describes "The combination of complete diaphragm inactivity and mechanical ventilation (for more than 18 hours) elicits disuse atrophy of myofibers in animals."[1] They hypothesized the same occurs in humans. The study included 22 patients (14 brain-dead organ donors and 8 patients undergoing surgery [control group]). The patient group was broken down into elective surgical patients for the control group and stroke and trauma for the case subjects. The donor subjects underwent diaphragm inactivity for 18 to 69 hours where as the control group underwent 2 to 3 hours of inactivity. Biopsy samples were taken from the subject's diaphragm. Histological, biochemical, and gene-expression studies were conducted on these specimens. Levine et al concluded that "the combination of 18 to 69 hours of diaphragmatic inactivity and mechanical ventilation was associated with marked atrophy of both slow-twitch and fast-twitch fibers of the diaphragm."[1] Levine et al also discussed limitations to their study and concluded that further studies are necessary. One way to help prevent disuse atrophy is to allow for spontaneous breathing as soon as possible. By allowing spontaneous activity, diaphragmatic atrophy may not occur or may occur to a lesser degree. As clinicians, we must select the appropriate amount of support for our patients, and allow spontaneous activity as soon as possible. One possible solution is a closed loop mechanical ventilation controller allowing the ventilator to react to the patient's earliest efforts at spontaneous breathing. By reducing time on a ventilator as well as decreasing the use of sedation, disuse atrophy may be minimized. Closed loop ventilation can help achieve these goals. Reference: 1. Sanford Levine, M.D., Taitan Nguyen, B.S.E., Nyali Taylor, M.D., M.P.H., Michael E. Friscia, M.D., Murat T. Budak, M.D., Ph.D., Pamela Rothenberg, B.A., Jianliang Zhu, M.D., Rajeev Sachdeva, M.D., Seema Sonnad, Ph.D., Larry R. Kaiser, M.D., Neal A. Rubinstein, M.D., Ph.D., Scott K. Powers, Ph.D., Ed.D., and Joseph B. Shrager, M.D. Rapid Disuse Atrophy of Diaphragm Fibers in Mechanically Ventilated Humans. N Engl J Med March 27, 2008; 358: 1327-1335. Justin Tse, BS, RRT-NPS. The above was written by Justin Tse, Hamilton Medical. This article is from the company's newsletter.

SPOTLIGHT CASE STUDY: GOING HOME

Jim Hamrick, a 55-year-old former paramedic, was diagnosed with polio when he was a toddler. As a result of his illness, Hamrick had to spend an entire year in the hospital before he was fully recovered. In 2003, he began experiencing post polio syndrome, a condition that affects polio survivors years after recovery from an initial acute attack of the poliomyelitis virus. Symptoms can include slowly progressive muscle weakness, fatigue and muscle atrophy. Hamrick later began experiencing severe headaches as well as obstructive and central mixed apnea; his muscles would collapse and his brain would forget to tell his lungs to breathe. His pulmonologist, Peter L. Fort, MD, FCCP of University Sleep Specialists in Bradenton, FL, suggested he use a partial ventilator at night to combat his sleep apnea. Hamrick was initially placed on a CPAP machine but was soon transferred to BiPAP, which allowed him to get more air in and out of his lungs without the natural muscular effort needed to do so. While the BiPAP was a success, Hamrick experienced discomfort during sleep. His doctor wrote a prescription for a home ventilator with an assist-control setting because of his post polio and neuromuscular weakness. The assist-control mode minimizes patient effort by providing full mechanical support with every breath. In this mode, inspiratory effort from the patient triggers the delivery of a breath from the ventilator. If the patient does not trigger the ventilator, the ventilator initiates a breath, ensuring the desired respiratory support. Hamrick made the switch from his previous device to the Carina *home* ventilator in the spring of 2007. Carina *home* provides both invasive and non-invasive ventilation, enabling a great deal of independence and choice of care settings for many patients with respiratory disorders. The Carina *home*, with its pressure- and volume-oriented modes, presents both professional and non-medical

caregivers with their own interfaces. This unique user interface concept means that while a full-access interface is available to professional users, a dedicated patient-friendly screen reduces patient access to a limited number of settings and only as enabled by the professional user. "I used to be afraid to go to sleep at night because I didn't know if I'd ever wake up," Hamrick said. "Thanks to the Carina *home* ventilator and the support of Draeger, I feel much more comfortable now, and I don't go to bed worried." He also noted, "The BiPAP was much noisier. Carina *home* doesn't wake my wife up. It's a much smoother system and doesn't make the loud roar that other machines do." Information provided by Draeger. Individual results concerning the use of Carina *home* may vary from patient to patient.

AT YOUR SERVICE

SERVO-i from Maquet, Inc is designed for the future of ventilation. It is easy to use and highly adaptive, with a plug-and-play platform, and easy to upgrade—maximizing your investment in the future. The SERVO-i supports the latest innovations in ventilation technology from MAQUET, including NAVA—Neurally Adjusted Ventilatiion Assist, a new, unique way to monitor your patients and improve synchrony. The MR Environment option allows critically ill patients to stay connected to the same SERVO-i ventilator in the ICU, MR examination room or during transport to and from the MR room. Contact maquetusa.com.

NEW PNEUPAC

Smiths Medical PM, Inc, today announced the availability of the Pneupac VR1 emergency and transport ventilator with a new air mix feature. This lightweight, ergonomically designed, palm-sized oxygen powered ventilator will still provide 100% oxygen when necessary but can now, with a flick of a switch, provide approximately 50% oxygen for patients who don't require that high of a concentration. Similar to the Pneupac VR1 without the air mix feature, the unit has a single control for setting the frequency and tidal volume, including a click-stop setting at the recommended adult position to enable rapid setup in demanding circumstances. The addition of the air mix feature, combined with auto/manual controls, a patient demand system, MRI compatibility, and other features, provides a better means to manage respiratory emergencies. The paraPAC is a compact, portable and rugged gas powered, controlled ventilator. The ventiPAC is similar to the paraPAC, and specifically designed for use by paramedics and other qualified persons for adult, child and infant ventilation. The babyPAC is designed for delicate neonate and infant lungs. All are MRI compatible. Contact smithsmedical.com.

OVER A CENTURY

For over 100 years, Draeger has continued to bring advanced ventilation technology to hospitals around the world. Our world class products serve a multitude of care areas—our ventilation product line is multifaceted to meet the specific needs of the user. The Oxylog 3000 is a compact and rugged transport ventilator that is designed to bring advanced care to the pre-hospital/transport environment. Our Babylog 8000+ serves the neonatal population with advanced features such as dynamic leakage compensation and volume guarantee for VLBW babies. The Evita XL ventilator is our flagship product—the latest technology advancement is SmartCare/PS—our automated weaning system. For chronic care areas, the Savina offers a wide range of treatment options designed for this patient population. Designed with the caregiver in mind, our Savina ventilator has recently undergone a "facelift" with color graphics and easy to read controls. Our Carina *home* ventilator is designed for patients at home. Our Carina *home* includes "SynchPlus" technology which aids the patient's work of breathing and automatically compensates for leakage. Contact draeger.com.

NONINVASIVE

BiPAP AVAPS is Respironics' newest noninvasive ventilator for use in the home, and features AVAPS (Average Volume Assured Pressure Support) technology. The AVAPS algorithm guarantees an average tidal volume by automatically adapting pressure support to meet the patient's needs on a breath-by-breath basis. The algorithm achieves this by estimating the patient's tidal volume over several breaths and calculating the change in pressure needed to achieve the target tidal volume. AVAPS slowly increases or decreases the IPAP pressure to achieve the proper pressure support. Additional features include BiPAP technology, Digital AutoTrak Sensitivity, SmartCard for use with Encore Pro and integrated alarms.
http://bipapavaps.respironics.com.

HOSPITAL TO HOME

The LTV 1150 and LTV 1200 from Viasys are the newest generation in the LTV Series. A patient may go from the hospital/transport LTV 1200 ventilator to home on the LTV 1150 using the same settings. Both these next generation ventilators offer presets for the initial patient set-up for infant, pediatric and adult with integrated spontaneous breathing trial, internal PEEP compensation, pressure and volume control. Flexible therapy options including non-invasive ventilation and enhanced monitoring capabilities combined with a wide selection of convenient power accessories make the LTV Series the preferred ventilation platform across the entire continuum of care. Contact viasyshc.com.

ENHANCED

The new HAMILTON G5 ventilator was designed to enhance patient safety. Unique is a "cockpit" display to give clinicians situational awareness of patient status, the only 'autopilot' closed loop ventilation system applicable from intubation through extubation and automated recruitment maneuvers. Its Ventilation Cockpit integrates complex data into object-oriented intuitive graphics and provides 24/7 "wean screening." The G5 features ASV closed-loop control, which adapts to the patient's drive and pulmonary mechanics. ASV requires fewer user interactions, facilitates shorter ventilation times, and provides ventilation at least as safely and effectively as international ventilation experts using conventional modes. ASV automatically implements lung protective strategies and spontaneous breathing trials. Contact hamiltonmedical.net.

PERFORMANCE

The portable, battery operable, turbine driven iVent201 adult & pediatric invasive & non-invasive ventilator is designed to deliver ICU grade performance, modalities and monitoring to a broad group of patients virtually anytime and anywhere. Fully featured alarms, graphics and trending can be complimented by optional integral SpO2 monitoring. Contact versamed.com.

High-Frequency Chest Compression: Optimizing Sputum Induction

Jane Braverman, PhD

Abstract
Concomitant use of high-frequency chest compression (HFCC) during sputum induction (SI) is a safe, non-invasive, reliable and cost effective method of obtaining high quality specimens. Recovered samples are ideal for an array of investigative and clinical purposes. The additive effect of HFCC during SI yields superior specimens: sputum samples are larger, cell counts are higher and percentages of diagnostically important cells are greater. Specificity and sensitivity compares favorably with "gold standard" bronchoalveolar lavage (BAL). HFCC should be a part of every sputum cytology program seeking optimal results.

For more than a century, sputum has been used to investigate the nature and extent of lung diseases. Unfortunately, owing to methodological deficiencies, most studies performed before 1970 are of doubtful value.[1] Expectorated sputum (ES), the only practical source of study material at that time, was qualitatively and quantitatively unreliable. Moreover, analytic techniques were limited to the examination of stained smears. Absence of standardized protocols for collection, assessment and analysis of ES led to poorly reproducible results and unconvincing conclusions.[1, 2]

In recent decades, rapid advances in sputum studies have revolutionized the understanding of pulmonary disease. Improved collection methods have made such studies feasible. Progressively refined technical methods have exponentially increased knowledge of complex relationships between inflammatory cells and related mediators.[3-5] New insights have improved diagnostic accuracy, assessment of disease severity and treatment response monitoring.[6-8] Inflammation monitoring in clinical practice has shown the potential to significantly reduce illness exacerbations and related care costs.[9-10] On an investigational level, sputum analysis has shown exciting potential to advance studies of experimental agents that may help prevent or reverse some disease processes, such as lung cancer.[11-13]

Investigational/clinical applications of SI

Sputum biomarkers of infection and inflammation enable quantification of complex pathophysiological processes. Numerous studies have validated such biomarkers as correlates of disease severity; others have applied biomarker results to assess disease severity and to monitor treatment in patients with asthma, bronchiectasis, COPD, CF, HIV/AIDS, lung cancer, lung transplantation, pulmonary tuberculosis and a host of other conditions.[6, 23-31, 43-48]

Cystic fibrosis
Chronic airway inflammation and infection begin early in life and are central to the pathophysiology of cystic fibrosis (CF).[49] Interleukin (IL)-8, neutrophil elastase (NE) and neutrophils are increased in bronchoalveolar lavage (BAL) fluid by age 2 months, and are associated with early viral and bacterial infection.[8] Aggressive treatment may initially eradicate Pseudomonas aeruginosa, the most prevalent pathogen found in young children with CF, but chronic infection leads to worsening prognosis. Frequent assessments of infection and inflammation are important to tailor appropriate treatment which may be initiated before an exacerbation takes hold and to monitor treatment response. For routine monitoring, only non-invasive methods are practical.

- Ordonez et al [2003] correlated treatment-related changes in several biomarkers in induced sputum with improvements in FEV_1. FEV_1 improved significantly after approximately 2 weeks of IV antibiotics, chest physiotherapy (CPT) and bronchodilators, corresponding to proportional decreases in biomarker levels.[23]
  - Among 55 CF subjects with pulmonary exacerbation completing the study (mean age ± SD 18.2 7.9 years; FEV_1 > 40% predicted; O_2 sat > 92% on room air, and no history of Burkholderia cepacia):
    - FEV_1 increased by an average of 0.3 ± 0.3L (10.4% ± 8.7% predicted); $p < 0.0001$
    - Density of Pseudomonas aeruginosa decreased by 2.4 + 3.1 log10 cfu/g ($p < 0.0005$)
    - Density of Staphylococcus aureus decreased by 4.0 + 2.3 log10 cfu/g ($p < 0.0001$)
    - Neutrophil count decreased by 0.4 + 0.6 $\log_{10}$ cells/ml ($p < 0.0001$)
    - Interleukin – 8 concentration decreased by 0.5 + 1.3 log10 pg/ml ($p < 0.05$)
    - Neutrophil elastase (NE) concentration decreased by 0.4 + 0.7 log10 µg/ml ($p < 0.005$)

Asthma

The value of SI in asthma lies in its potential to directly and non-invasively assess airway inflammation. Applications of SI in asthma treatment monitoring show significant clinical and economic benefit.[9,10]

- Covar, et al [2004] used SI to determine whether a management strategy that minimized sputum eosinophils would reduce asthma exacerbations compared with a standard management strategy. The sputum management group experienced fewer hospitalizations versus the standard management group, with no increased steroid burden.[9]
- Green, et al [2002], extended these observations by evaluating applicability of monitoring sputum eosinophils to reduce asthma exacerbations. They showed that treatment designed to "normalize" the percentage of sputum eosinophils reduced the number of asthma exacerbations, thus precluding the need for additional anti-inflammatory therapy.[10]
  - In this randomized placebo-controlled trial, 74 subjects with asthma were assigned to either a management strategy aimed at normalizing their sputum eosinophil count or standard clinical care. Patients in the sputum management group had:
    - Significantly fewer severe asthma exacerbations than patients in the control group (35 exacerbations vs 109 exacerbations, P = 0.01)
    - Significantly fewer hospital admissions (one admission vs. six admissions; P = 0.047)
    - Outcomes in the treatment group were achieved without an increase in total corticosteroid dose

Non-Cystic Fibrosis Bronchiectasis

Non-cystic fibrosis bronchiectasis (NCFB) is rapidly emerging as an increasingly prevalent, under-recognized diagnosis. While bronchiectasis may develop from a range of underlying causes, about 30-50% of cases remain idiopathic. Currently, high-resolution computed tomography (HRCT) is the usual method for detecting and assessing the anatomic extent of bronchiectasis. Although HRCT cannot help identify the etiology of individual cases, it has an 84% sensitivity and 82% specificity for diagnosis of the condition.[49] However, the method is too expensive to use for routine monitoring of disease progression and response to therapy.

- Sepper, et al [1995] have used SI to identify significant correlations between symptoms, lung function tests, HRCT severity scores and sputum inflammatory markers in NCFB. Like CF and COPD, bronchiectasis exacerbations produce intense neutrophilic inflammation.[50]
  - In this study, the degree of lung function impairment and the number of neutrophils recovered in lung lavage appear to be strongly correlated in most patients. Thus, lung function impairment may express both the degree of neutrophilic inflammation in the airway lumen and the extent of the disease. Results showed a significant correlation between the following parameters:
    - HRCT severity and lung function tests, sputum IL-8 and TFN α levels
    - Symptom scores and spirometry findings and IL-8 levels
    - Sputum IL-8 levels and lung function tests and TFN α levels
  - These observations, confirmed by others, show that the inflammatory process in NCFB is strongly associated with both severity and anatomic extent of the disease and that SI offers several disease-monitoring advantages over HRCT and bronchoscopy/BAL.[24]

Current sputum collection techniques: pros and cons

With any diagnostic procedure or laboratory test, the reliability of results depends directly upon the quality of the specimen. For a sputum sample to be useful, it must contain exfoliated or circulating cells from target areas of the lung, including both peripheral and central airways. For sputum analysis to be clinically practical, collection methods must be safe, simple, and cost-effective. Several methods are currently used for sputum sample procurement.[1-3] Although each collection technique has distinct advantages and disadvantages, one method, sputum induction (SI) with hypertonic saline (HS) and concomitant high-frequency chest compression (HFCC), yields specimens of the highest quality safely, consistently and cost-effectively.[12, 14-16]

Expectorated sputum (ES)

Expectorated sputum (ES) is collected by asking patients to make an effort to raise a bolus of airway material by clearing the throat and then spitting into a prepared container. Although quality assessment of ES has improved, the method remains problematic. In cystic fibrosis (CF), for example, identification of lower-airway pathogens is critical to timely initiation of antimicrobial therapy. In a representative study, nearly half of CF patients over 6 years and a much larger number of younger children could not produce sputum on demand during clinic visits.[17] Moreover, an astounding proportion of ES specimens do not meet adequacy criteria. A review of 16,716 consecutive sputum cytology specimens collected by ES over 3 days found that only 44% represented adequate deep cough samples.[16] When ES fails, clinics often substitute nasopharyngeal suction or throat swab specimens. Those specimens are a poor proxy for sputum as they deceptively over-represent oronasopharyngeal flora and under-represent lower airway pathogens and inflammatory markers.[17]

Bronchoscopy with bronchoalveolar lavage (BAL)

Bronchoscopic techniques have significantly advanced the science of sputum analysis. Most procedures are performed with a flexible instrument inserted orally; nasal or stoma insertion is also done. Bronchoscopy allows sampling of cells and fluid in airway lumens by means of BAL and/or biopsy of mucosal tissue. Although information thus obtained is greatly superior to ES, the method is far from ideal. Among its technical limitations: 1) BAL specimens distinguish only those lung segments distal to the bronchus into which the instrument is inserted; 2) mixing of distal, alveolar and proximal bronchial compartments occurs; 3) inflammatory mediators are diluted in the large volumes of saline used to obtain washings and; 4) some contamination with blood is common.[2,3] Because samples are usually obtained from one or two lung segments, they may not be representative of the whole lung.[18]

Bronchoscopy/BAL also has several practical limitations.[2,3,18] Because it is invasive and uncomfortable, topical anesthetic and mild sedation is used routinely. Young children or uncooperative patients require general anesthesia. The technique requires appropriate facilities and highly skilled personnel. It is both labor-intensive and expensive. Although relatively safe, bronchoscopy is risky for patients with conditions including severe asthma, bulbous emphysema, tracheal obstruction, coagulopathy or severe system illness. Furthermore, it is absolutely contraindicated for patients with unstable angina,

uncontrolled arrhythmias, or refractory hypoxia unresponsive to oxygen.[19,21] The procedure itself may cause injury or inflammation.[20] Because the bronchoscope picks up upper airway commensal or colonizing organisms when it is inserted into the bronchus, infection may result. For obvious reasons, the technique is not suitable for screening of large patient populations or for routine follow-up examination. However, because of its versatility and technical capabilities, bronchoscopy/ BAL remains the "gold standard" for recovery of pulmonary material.[2,22]

Sputum induction (SI) with hypertonic saline (HS)
The easy availability of SI specimens has transformed the study and management of lung disease. SI is typically accomplished by inhalation of an HS aerosol (3% to 5%) generated with an ultrasonic nebulizer at 3-7 mL/minute for about 20 minutes.[22] Although SI specimens tend to contain many squamous epithelial cells, most specimens are adequate for analysis. Comparative efficacy analyses show the superiority of IS to alternative techniques for assessing biomarkers for airway inflammation.[1-8] Scores of high quality studies have validated the usefulness of cellular and inflammatory indices both to clinically differentiate subpopulations of pulmonary patients and as correlates of disease severity.[6, 23-31]

SI studies on subjects with diverse diagnoses and degrees of illness severity confirm its relative safety.[9,20,32,33] Although a small minority experience bronchospasm and transient reductions in FEV_1 and SaO_2, these effects are readily reversible with bronchodilator therapy.[6-9,20-21] Unlike BAL, IS is non-invasive. In contrast to ES, results are highly reproducible.[6-9]

Although SI is superior to alternative sputum collection methods, it is less than ideal. Recovered sputum volume may be too small to perform a full battery of tests, necessitating prioritization. Specimen quality may be subpar as well; total cell counts and the proportion of alveolar macrophages are frequently disappointing.[21] Despite limitations, the advantages of SI make it the method of choice for basic research as well as for routine clinical monitoring, large clinical trials and screening programs.[6-9]

High frequency chest compression (HFCC) + SI
High frequency chest compression (HFCC), used in combination with SI, offers a simple, low cost, highly effective way to improve both the quantity and quality of induced sputum specimens. In 1988, the FDA cleared the use of HFCC as an intervention to evacuate pulmonary secretions when normal clearance mechanisms are ineffective. The product expectorated or suctioned following HFCC therapy contains material representative of the entire lung.[34]

HFCC's basic technique is uncomplicated and its mechanisms of action are thoroughly studied.[35] Currently, three companies manufacture and distribute HFCC equipment: the inCourage system, aka ICS [RespirTech, St. Paul MN]; the SmartVest [Electromed, New Prague, MN]; and the Vest airway clearance system [Hill-Rom, St Paul MN]. All HFCC machines consist of 1) an inflatable jacket, vest or wrap-like garment; 2) one or two interconnecting hoses and; 3) an air pulse generator. The therapy works by administering rapid but gentle compressive forces to the chest via the inflatable garment. These forces produce increased airflow and oscillatory effects within the airways, thus enhancing mucus mobilization and clearance.[34]

HFCC is the only secretion clearance modality shown to mimic all the mucokinetic and mucolytic effects of a healthy MCC system.[35] More than 25 basic research and clinical studies demonstrate that HFCC:

- Mobilizes secretions from peripheral towards central airways[36]
- Promotes mucus clearability by the air-liquid interactions associated with cephalad airflow bias[37-38]
- Reduces viscoelastic and cohesive properties of mucus, thus enabling more effective ciliary and cough clearance[39]
- Increases tracheal mucus velocity (TMV) up to 340x that of spontaneous breathing[40-41]

The combined effects of HFCC + SI + nebulized hypertonic saline (HS) or nebulized water (NW) produce excellent sputum samples. By generating increased airflow velocities and decreasing mucus viscosity, secretions moving through the airways collect exfoliated cells in a bolus rich in diagnostically important material.

Several studies show that the addition of HFCC during SI with HS or NW yields specimens of the highest quality yet achieved:[12,16,42,43]

- Jones et al [1995] showed that the combination of a 30 minute treatment with HFCC and simultaneous inhalation of a 3-5% solution of ultrasonically nebulized hypertonic saline (HS) increases the yield of induced sputum compared to either HFCC or HS alone.[42]
  - In a study of sputum samples from 22 patients being evaluated for lung cancer, the cytological quality of HFCC + SI + HS specimens compared favorably with those obtained via "gold standard" bronchoscopy/BAL. HFCC + SI + HS samples showed:
    - A cytological sensitivity of 71%,
    - A cytological specificity of 80%
    - A positive predictive value of 63%
    - A negative predictive value of 86%
    - An accuracy of 77%.
  - Two of 22 patients yielded cells diagnostic of lung cancer with HFCC + SI + HS but had negative bronchoscopies
- Agostinis, et al [1995] assessed the sputum-induction efficacy of 30 minutes of HFCC combined with SI with nebulized HS (3-5%) compared to SI + HS alone. A higher percentage of cells derived from peripheral lung regions and a greater percentage of alveolar macrophages were obtained with combined HFCC + SI + HS than with SI + HS or HFCC alone.[14]
  - Samples from 9 subjects showed that HFCC + SI + HS yielded:
    - Greater sputum volumes (4.9 ml vs. 3.7 ml with SI + HS alone [$p < 0.05$] and 0.76 ml with HFCC alone [$p < 0.001$])
    - Higher cell counts (2.6x 109 vs. 2.1x 10^9 with SI + HS alone and 2.2x $10^9$with HFCC alone)
    - Higher percentages of macrophages: 33% vs 29% with SI + HS alone and 30% with HFCC alone
- McKinnon et al [1995] reviewed 16,716 consecutive sputum cytology specimens collected by ES over 3 days and found that only 44% were adequate deep cough samples. A randomized controlled trial was performed to investigate the yield of adequate specimens by SI using ultrasonically nebulized water (NW) with and without simultaneous HFCC.[16]
  - Fifty-two heavy smokers were randomized to produce

sputum after 20 minutes of inhalation of NW or with 20 minutes of HFCC + SI + NW. Specimen adequacy was determined by presence of alveolar macrophages.
  - HFCC + SI + NW produced better specimens with higher yields of diagnostically important cells
    - Specimen adequacy: SI + NW + HFCC = 90%; SI + NW alone = 74%
    - Ratio of normal, atypical and malignant bronchial epithelial cells (BEC): HFCC + SI + NW = 1.3 + 1.5% ; SI + NW alone = 0.97 + 1.0%
    - All HFCC + SI + NW samples contained BEC; SI + NW alone contained 93% BEC
- Lam et al [2003] described significant success with HFCC + SI + HS to obtain specimens with high specificity and sensitivity in phase II trials of promising lung cancer chemo preventive agents. The method showed enormous potential to advance a broad range of experimental and/or investigational studies.[12]

Conclusion

HFCC + IS + HS/NW is safe, non-invasive and reliable. It can be used repeatedly for an array of investigative and clinical purposes including assessment of inflammatory patterns and treatment response. The additive effect of HFCC combined with HS/NW during SI are consistently shown to yield superior specimens: sputum samples are larger, cell counts are higher and percentages of diagnostically important cells including alveolar macrophages are greater. Sample specificity and sensitivity compares favorably with "gold standard" BAL. HFCC should be made a part of every sputum cytology program seeking optimal results.

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Potential Hazards of Mechanical Ventilation

Melissa Turner, BA, RRT

In the February issue of the SCCM's Critical Connections newsletter, an article by Albert Fantasia[1] addresses some topics that may lead to injury from mechanical ventilation. Those topics are inclusive of mechanical function, communication, evidence-based practice, staffing, and reporting of medical errors. Each of these topics must be carefully scrutinized and addressed in order to make mechanical ventilation safer for all patients.

Ventilator malfunction is certainly an area of concern as this can cause harm to any patient. It is important that ventilators pass their self-check during boot-up as well as a safety check that clinicians must conduct before placing the ventilator on a patient. In a hurry, clinicians sometimes choose to forego the safety check, although it should be a routine and mandatory step in ensuring the safety of the patient. All ventilators have a system of alarms, both audio and visual, to alert clinicians to any potential problems. Clinicians must take the time to set alarms appropriately as the patient's condition warrants. Placement of ventilators in relation to staff location is also important as some locations make it harder for staff to hear alarms. Ventilators that have an adjustable alarm volume are beneficial in this instance. The G5, a new ventilator from Hamilton also incorporates a large alarm lamp on top of the screen that is visible from 360 degrees around the ventilator. This makes it easy to identify an alarm when an alarm condition exists.

The Joint Commission had reported in 2002 that communication breakdown among staff members was a cause of 16 out of 23 ventilator related injuries or deaths. All members of the health care team should understand the care plan for each patient. Many ventilators include trending which can help clinicians to see what happened before they arrived on shift. It is important for staff members to have a clear picture of the direction they are heading based on the individualized care plan.

Evidence based practices are being implemented more than ever today. Doctors are beginning to stick to techniques and methods that have been proven to work and proven safe. For example, evidence based strategies for ARDS ventilator management today includes using low tidal volumes in the range of 4-6cc/kg of ideal body weight, use of optimal recruitment pressures, and use of plateau pressures limited to less than 30 cm H_2O. Lung protective strategies have been shown to produce more favorable outcomes. Even though the evidence shows that these approaches have better outcomes, they are still not applied routinely.

Applying the ventilator bundle for prevention of VAP has also been shown to have significantly better outcomes when all components, which include elevation of head of bed, daily sedation vacations, peptic ulcer prophylaxis, and DVT prophylaxis, are used together.

Another cause of ventilator induced injury listed by Joint Commission in 2002 was insufficient staffing. Many hospitals today are operating understaffed. Historically, clinicians spent their time with patients based on departmental policy. Generally, each ventilator patient was to receive ventilator checks every 2 hours. In adhering to this type of policy, the sickest patients receive the same amount of clinician time as do the patients who do not have high acuity levels. Fantasia proposes the following table to help allocate clinician time more appropriately.

Using the table in this article, clinicians are better able to allocate time to patients according to acuity.

Combining the use of the ventilator triaging table with closed loop ventilation such as ASV, clinicians can be sure that all patients are being ventilated safely as well as being able to wean when appropriate even though the lower acuity patients are visited less frequently. These patients are able to wean as they are ready and not be held up by a redistribution of clinician time.

Reporting of medical errors was also found to be a factor in mechanical ventilation injury whether due to equipment malfunction or clinician error. Closed loop control systems and new clinician friendly interfaces and graphical presentations of data may help minimize clinician errors. There are less knobs

The author is with Hamilton Medical. Reprinted from Hamilton Medical's newsletter.

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Ventilator Triaging Table[1]

LEVEL I	LEVEL II	LEVEL III	LEVEL IV
Documentation required once per 8 hour shift	Documentation required twice per 8 hour shift	Documentation required 3 times per 8 hour shift	Documentation required 4 times per 8 hour shift
Floor patient	Stable patient requiring ICU level of care for other than respiratory illness	Patient actively weaning	Patients on unconventional modes of ventilation: *Volumetric diffusive respiration *HFOV
Patient whose status has been changed to « comfort measures only »	Patient not actively weaning	Recently intubated (12 hours) and patient has not established severity of illness or level of trauma	Patients with acute unstable disease: *ARDS *sepsis *Status asthmaticus *New intubation with hemodynamic instability
ICU or step-down patient who is flagged to floors		Essentially stable patient who may be requiring frequent intervention to establish adequate ABG's	
Patient who is intubated for airway protection (no other medical issues) and not weaning			

Using this table, clinicians are better able to allocate time to patients according to acuity.

or settings to be manipulated with a closed loop system which leaves less room for error.

One such aid in the prevention of errors is Hamilton's G5 ventilator through its use of the Ventilation Cockpit. The cockpit allows users to visually identify their patients' status in a matter of seconds through use of graphics such as the Dynamic Lung and the Vent Status Panel. With the use of these new tools, clinician time is more productive and patient safety is in the forefront.

Reference

1 Fantasia, A. Preventing Injury from Mechanical Ventilation. Crit Conn. 2008; 7(1): 18-19.

The Clinical Utility of Bilirubin Testing With ABGs in the Neonatal Setting

Doug Wilder, RRT

Introduction

Jaundice is a yellowish discoloration of the whites of the eyes, skin and mucous membranes caused by deposition of bile salts (bilirubin) in these tissues. Increased bilirubin in neonates and premature infants, if left untreated can cause mental retardation and death. In jaundice of newborns this occurs when total bilirubin values are greater than 12 mg/dL.[1] This condition is known as hyperbiliruinema. Jaundice is common in 25-50 % of all full term neonates and there is an increased occurrence in premature babies, that is infants born after a gestation period of less than 37 weeks. It is important to determine if this condition is due to physiologic conditions which is normal or an underlying pathologic condition which is abnormal and requires immediate intervention.[2]

Pathology

Bilirubin is a bi-product of red cell breakdown. The total bilirubin is metabolized into two bi-products, carbon monoxide and unconjugated bilirubin. Once released into the blood stream the unconjugated bilirubin is transported to the liver for conversion. The unconjugated bilirubin enters the liver and undergoes a series of reactions with glucose and oxygen. The converted conjugated form of bilirubin is then removed from the neonate or infant.

Contributory factors to hyperbilirubinemia in neonates and premature infants are poor liver function due to liver development, increased red cell volume and reduced oxygen or glucose levels due to delayed lung development. The result can be an increased level of bilirubin in the blood stream. And since unconjugated bilirubin is not water soluble but is very soluble in fat, the excess bilirubin is deposited in the fatty tissues, mucous membranes and especially brain tissue.[2]

Discussion

With the increasing number of cases of hyperbilirubinemia in neonates and premature infants, the American Academy of Pediatrics and JCAHO guidelines recommend transcuteanous monitoring of all neonates and premature infants for hyperbilirubinema. They require any monitoring value that excesses 12 mg/dL to be verified by an accepted clinical chemistry method.[3] By running a complete ABG panel with metabolites this enables the healthcare provider to determine the root cause of hyperbilirubinema and immediately map the best course of treatment by not only assessing the bilirubin level but also by assessing the glucose, PO_2 and O_2 saturation.

Recommendation

The cobas b 221 < 6 > blood gas system correlates with accepted clinical chemistry methods for bilirubin testing and can provide a much larger clinical picture from just one blood draw reducing blood loss and improving patient care and outcomes at the point of care.

References

1 Clinical Guide to Lab Tests, Third Edition, Nobert Tietz, M.D., 1995
2 Basic Pathology, Stanley L. Robbins, M.D., 1976
3 JCAHO Sentential Event Alert, Issue 31 August 2004

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Planning For Disaster—A Starting Guide

Dave Swift RRT

"In preparing, I have always found that plans are useless, but planning is indispensable." D. Eisenhower (1890-1969)

"Planning is to make up for wasted time….." W. Shakespeare, King Henry IV, part 1, act 1, scene 2

Until the 1990s, mass casualties had a very different meaning. The change in what is perceived as mass casualties changed from 10 or more patients to tens, hundreds and thousands. This represents a change in the scope and type of event.

From transport vehicle crashes (planes, trains & automobiles), building/structural collapse and natural catastrophic events, the actual type of event has not changed but the numbers of casualties has increased, reflecting the exponential growth in population.

As population growth continues, more and more people move into what was previously viewed as high risk areas—flood plains, earth quake fault areas, known wild fire areas, geographically unstable areas and high risk terrorist targets. Add to the mix, the risks associated with diseases and pandemic concerns and it only further serves to underscore the need to have an effective, timely and flexible action plan.

"You may delay, but time will not." Benjamin Franklin 1706-1790

The first step in preparing for a possible event is to inventory what resources are actually available:

- Medical gas supplies (eg bulk, cylinders)
- Ventilator resources
- Automatic or manual resuscitators
- Medical gas related supplies (eg masks)
- Staffing resources
- Training/certification
- Existing "off the shelf" emergency response plans
- Medical/legal support

200%

The Key number to remember is 200% capacity. US strategic planning and the AARC have suggested that the expected capacity for hospitals in an MCI/ pandemic situation to be on the order of 200% or more.

STEP 1: You need to differentiate between immediate on-hand and in-house supplies—how long to resupply?

Medical Gas Supplies

- What is your bulk oxygen capacity? Is it sufficient to meet 3 days, 7 days? Or 2 weeks consumption? During an emergency, you can expect a 200-300% in use of medical gases. This reflects the suggested expected capacity a hospital is expected to accommodate. Cylinders (K, E, D cylinders) are a finite resource that can quickly be exhausted.
- How many tanks are available for transport, OR use and bedside use. Where are they stocked? What is your daily consumption? If you are expected to meet a 200-300% increase in demand, how long can you sustain this level?
- You have cylinders but do you have enough regulators? Alternate supply planning—if you have to reduce supply to maximize resources, what is your plan (ex. back feed critical care areas, concentrators, oxygen generators)?
- NOTE: Back feeding—utilizing a "K" cylinder equipped with a 50 psi regulator to power a small group of outlets. Process: attach the 50 psi gas line from the regulator to the DISS gas outlet on the wall & turn on the tank. Close the zone valve, the outlets downstream from the zone valve are now powered by the "K" cylinder. Multiple cylinders can be used to create a "mini" manifold and extend the duration of the supply between cylinder replacement cycles.
- Can your supplier assure you of resupply and in what time frame?
- Are the phone numbers, contact information and contract information readily available?
- Do you have a contract or memorandum of understanding covering emergencies and emergency resupply? Have a copy in emergency preparedness manual and educate staff on contents.

Mechanical Ventilators

- How many adult, pediatric capable and neonatal ventilators do you have on hand?
- How many are in daily use?
- How many are in biomed for service? What is your average turn around time for service?
- How many of your daily use units can be freed up by canceling elective surgery or by being changed to alternative methods (eg noninvasive)? NB: The AARC recommends volume capable ventilators as the primary/best choice (2004 Working Group on Emergency Mass Critical Care).
- What Biomedical Engineering support do you have after-hours or on weekends? Have you planned and discussed this with the department?
- Is there an alternate supply for ventilators (eg Strategic reserve, local college/university)? Home care companies or educational facilities are a resource. Do you have an agreement with them? Contact or contractual arrangements? What biomed resources are required to bring in outside resources?

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Ventilator ID	Location	Status	Availability
Evita XL #3	Biomed	P.M.	5 hrs
PB 7200 #12C	ICU bed 27	In use	0
Avea	PACU	Stby	Immediate
Babylog #6	SCN	Stby x 2hrs	1-2 hours

Ventilator Supplies

How many circuits do you have? HME's or humidifier supplies? Filters (reusable or disposable)? Closed suction? Nebulizers? Do you have a 3, 7 or 14 day supply on hand?

Supply	On-hand	In-house
Adult universal circuit	20	200
Neo.ciruits	50	300
Disp. filters	50	300
HME	100	400

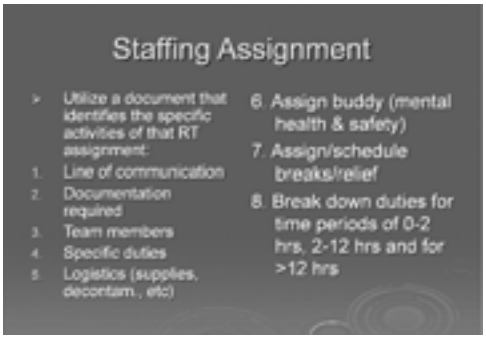
Supply levels

- How many manual rescuscitation bags (eg Laerdal, Ambu) do you have (re-usable and/or disposable) on hand or in-house?
- How many automatic resuscitators are available (eg Vortran Resp Tech Pro, Ambumatic)?
- How many pandemic/surge capacity ventilators (eg MCV 200 portable ventilator by Allied Healthcare Products Inc, Carina ventilator by Draeger Medical, etc) do you have available?
- Aerosol delivery devices (eg Nebulizers and MDI)?
- Airway supplies—ET tubes, laryngoscope blades and handles, stylettes, and related suction supplies?
- PPE supplies—what is available on-hand?
- Medical gas delivery equipment (eg masks) what is available on-hand?
- Battery or gas powered suction—how many are available?
- Do you have a reference catalogue with all needed items identified, stock numbers and quantities available?
- Do you have preprinted logistics supply order forms?

Staffing

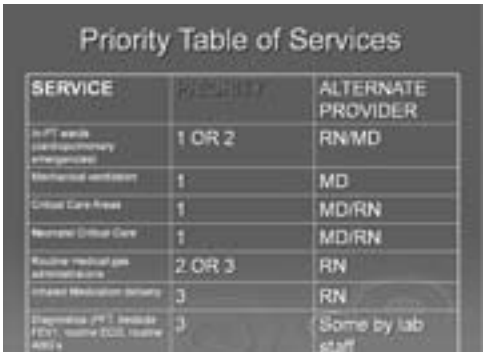
- Immediate on hand staffing—what is your normal staffing level?
- Does it vary for weekends or holidays?
- What is your daily number of sick calls or no-shows? This needs to be considered—working short and then having a MCI event can leave you even further behind with staffing resources.
- How is your staff deployed?
- How many staff can you get in-house from allied services (eg PFT, diagnostic areas, and clinical instructors)?
- What cross training & certification has been carried out?
- How many staff can you call in immediately? Over the next 12 hours, 24 hours, 3 days, 7 days?
- Is your phone/contact list up-to date? Have you tried to call them in? Who is the designated caller (on-duty/off-duty)? Do you have a phone fan-out list? It is recommended that your call-in list be based upon geographic staff distribution (zones) as defined by geography or transport corridors. A typical staff zone distribution map identifies distance and response time. If there is an infrastructure failure, due to the MCI event, using zones allow you to shift resources that are accessible and timely.
- What arrangements do you have with alternate staffing resources? Is there a list of retired staff, students, and home care company staff (including written agreements, insurance and license coverage)?

No plan, no matter how well planned and conceived, ever survives its first real implementation. The key to success is to build in the ability to flex and to utilize the strength of those who will have to implement and make the plan work.



Services

- What services require 100% commitment and which can be deferred?
- For how long can you defer which services? Diagnostic vs. therapeutic?
- What is your priority of service—do you have a list from highest to lowest priorities? This needs to be predetermined before an event and needs the support and agreement of senior management/team members.



Ethics—resource allocation

One of the major issues during an MCI is sufficient ventilator resources. The recognized standard is basic volume ventilation and this is the backbone of most RT/Critical Care departments. However, with a patient surge expected of >200%, ventilator resources will quickly become depleted. Once all ventilators are in use, what plan do you have to provide ventilatory support? Manual resuscitator bags are labor intensive, requiring one-on-one staffing. Automatic resuscitators (ex. Ambumatic or Vortran Automatic resuscitator) and Pandemic/surge capacity ventilators (ex. MCV 200 portable ventilator by Allied Healthcare Products Inc., Carina ventilator by Draeger Medical, etc.) require additional training and experienced clinicians to closely monitor the units.

The final issue is to have a triage system to identify which patient gets a ventilator and which patient is assigned expectant (ie soon to be fatal) status and does not get a ventilator. This needs to be developed in advance by the physician group and medical-legal resources, staff trained and fully cognizant of the implications. There needs to be clear guidelines when this triage system will be implemented. You absolutely need a buddy system to monitor staff—the situation will result in extreme stress. RTs are not trained to withhold ventilators when they are required.

Once you have your inventory completed you can now begin planning. The first step is to break down your planning into three primary levels. Each of the levels builds upon the previous one.

Level 1

Utilizes only in-house resources and involves shifting staff and service levels to handle a small event. You need to establish what a small event for your facility is. At level 1, you would utilize existing staff and redeploy to meet existing, immediate needs. This activity level is only able to be sustained for short periods and is dependant upon the MCI type. Services would be scaled back in low priority areas and enhanced in others, as the need arises. Identify services that can be scaled back (eg diagnostics, elective therapeutics).

Identify which services would need to be enhanced (eg critical care, emergency/trauma, and triage).

Services
Priorities

SERVICE	PRIORITY	ALTERNATE PROVIDER
Cardiopulmonary emergencies	1	MD
Mechanical ventilation	1	MD
Intensive care services	1	MD/RN
Neonatal ICU	1	MD/RN?
Routine medical gas administration	2	RN
Inhaled Medication delivery	2/3	RN
Arterial blood gases (puncture & analysis)	2	MD (puncture) Lab tech (analysis)
Pulmonary diagnostics (ex. PFT, bedside spirometery)	3	None
ECG	3	ECG tech's/nsg/MD

Staffing allocation

MISSION: Organize and deliver Respiratory Therapy Services to Clinical Areas

Date: Start: End: Position assigned:

Position Reports to: PRP/ Charge Therapist->campus co-coordinator-Director
Hospital Emergency Operations Center (HEOC) Location:
Phone:

Contact information:
Radio Titles:

Immediate (operational period 0-2 hours)	Time	Initial
Receive notification, briefing and any appropriate supplies required		
Reads this entire job action sheet and review incident management team chart (TOH IMS Form 207). Put on position identification.		
Notify the Charge RT/PRP of your TOH-IMS assignment		
Document all key activities, actions and decisions in an operational log (TOH-IMS form 214) on a continual, on-going basis.		
Identify area assigned to and other RT's assigned. Complete the Branch Assignment List (TOH-IMS form 204).		
Brief Unit/team members on current situation, incident objectives and strategy ;outline action plan and designate time for next briefing		
Ensure each team member has a buddy assigned to ensure that mental health/stress issues are being monitored		
Ensure that each team member comply with safety procedures		
Coordinate activities between unit(s) team members (ex. ER, ICU, Wards & Neo)		
Dispatch pre-designated supplies to casualty care areas. Identify/enlist the assistance of transport team leader as required.		
Establish and communicate the operational status of Respiratory services with Incident Command.		
Identify & place emergency orders for critical supplies as indicated and advise logistical services.		
Report regularly, status of supplies and resources (ex. Ventilators)		
Co-ordinate with Dept/incident command if external resources are required		
Document All communication (internal/external/ on an Incident Message Form (TOH-IMS Form 213). Provide a copy of the incident message form to the documentation unit		

Intermediate (Operational Period 2-12 Hours)	Time	Initial
Meet regularly/communicate with Respiratory/Cardiopulmonary Services Director +/or Critical Care Director for status reports and to relay important information to unit team members.		
Ensure you keep in contact with your designated buddy to ensure both of your mental health status.		
Continue to monitor service delivery, supply levels and resources available (usage & availability).		
Continue to ensure all available resources are maintained at a "ready to go" level and ensure they are secure.		
Ensure that a 72 hour level of supplies is maintained & liaise with Logistic Services to pro-actively ensure that supply availability is maintained.		
Restock/re-order every 8 hours – document activities		
Advise Respiratory/Cardiopulmonary Services Director of any operational/logistic issues that you are not able to correct		
Ensure that Biomedical Engineering is informed of any electromechanical issues (document)		

Extended (operational period beyond 12 hours)	Time	Date
Adjust staffing levels as required		
Continue to provide periodical situation updates to team/command unit		
Continue effective inventory monitoring and resupply activities		
Ensure your physical/mental readiness through proper nutrition, water intake, rest and stress management technique. Keep in contact with with your designated buddy.		
Observe all staff, volunteers, visitors and patients for signs of stress and inappropriate behavior. Report all concerns to occupational Health and safety unit leader or Cardiopulmonary Director.		
Upon shift change, brief your replacement on status of all ongoing operations, issues and other relavant incident information.		

Level 2

Utilizes in-house staff and a limited number of external staff that have been called in.

The first step requires the development of a progressive list of staff assignments based upon established priorities and is subject to the needs of the specific MCI.

As staff arrive at the designated RT headquarters/department, they are asked to sign in and are given their assignment. The movement of staff (including assignments and travel) needs to be tracked so that the ability to locate and re-assign staff can be maintained.

In level 2, staff is only called in numbers sufficient to meet the numbers required to deal with the MCI.

However, attention must be paid to the needs of the department over the next 12/24/48 hours. The department's day-to-day staffing needs must be considered in the context sustained MCI operations and regular service delivery. Patients will continue to arrive and require treatment, babies born, MI's etc will continue. Staffing requirements will continue. Due consideration must be given to appropriate rest periods, meals, drinks, and mental health in how you assign staff for the MCI event and day-to-day activities.

Level 2 activities can be sustained for periods longer than Level 1 as it utilizes only limited numbers of staff. This is the most common level to operate at after the first 12 hours of a MCI.

MCI staff safety advice: Assign a buddy to each on duty staff member. The role of the buddy is to check on each other and assure that breaks are taken and that the mental health of the assigned buddies is monitored. be prepared for on-duty mental health casualties—exhaustion, mental or physical breakdowns can occur when staff has to operate under duress for prolonged periods.

SERVICE	Staffing #'s required (normal = vs MCI =)	Assigned (print & sign)
Cardiopulmonary emergencies (in-pt wards)	(normal level=)	
Mechanical ventilation		
Intensive care services		
Neonatal ICU		
Emergency department (normal, primary assignment)		
Emergency department (assigned for MCI)		
MCI Triage		
Supply management & pt care support (workload flex)		
Relief Position (ensure scheduled breaks are maintained)		
Transfer/transport		

Level 3

Level 3 reflects an "all call" situation in which all available staffing resources are called into play. Careful consideration needs to be paid to departmental operations in the context of service delivery and staffing resources over the next 12 to 72 hours. If you have all-hands-on-deck for the first 12 hours, who will be available to staff the department after that? You need to establish appropriate maximum sustained staffing levels.

The assigned duty list must continue to be maintained but now requires a new category and that is one of relief. Each of the staffing positions must have an incoming staff member assigned for relief and staffing resources must be in place to allow for increases in workload. As the situation surrounding the MCI evolves, sustained level 3 activities may be scaled back to level 2 or even level 1.

Recovery Phase

Normal operations must be maintained and the deferred services re-activated. Normal scheduled shifts need to resume. Reports and documentation need to be assimilated and a post MCI after-action report needs to be completed. A long-term goal is to extract the effectiveness of your planning from the event and adjust to minimize the gaps or challenges.

Careful attention must be paid to the mental health of staff involved in the MCI following the days and weeks after the event. This monitoring must be maintained for an extended period of time (weeks or months) and co-ordinate with Occupational Health Department à PST (post traumatic stress).

Be prepared for increased staff attrition due to the stress of the event- monitoring and pro-actively addressing the signs of stress will help minimize the attrition. This will also help staff in recognizing that there is an effective way to deal with the issues and that they are part of a team.

Training & Certification

As part of your planning process you need to initiate a training cycle to train staff on the implementation of your action plan. Break the plan down into basic components and train staff on these components (example: have a lunch and learn with your medical gas supplier and review your plan and their plan, review emergency contracts or letters of understanding).

Cycle staff through a skills fair to review necessary MCI skills—airway modalities, suctioning, emergency tracheotomy procedures. Include staff that is considered alternate resources—PFT lab, bronchoscopy staff, clinical instructors, supervisors, etc.

This is an opportune time to review the process for Emergency purchasing and what documentation is required. Coordinate this training with senior management (can they attend?) so that emergency management purchasing authorization process is fully understood and clearly supported.

Practice the emergency plan annually and not just table top exercises. For example, staff phone numbers change so frequently that the phone list needs to be reviewed semi-annually to ensure effectiveness. Breaking down the plan to basic components allows you to economically activate the critical sections of the plan and "TRY IT OUT". An integral portion of this process is the reflective critique of each component.

An essential part of your plan is one simple question—does senior management know of your plan? Does it integrate into the corporate plan and the municipal plan?? Review the plans and update accordingly.

Medical/Legal

The key to success in dealing with the medical/legal ramifications of a MCI is documentation. You will need:

- Incident Management Team (IMS) system (who is doing what, who has what responsibility).
- Operational log—documents all key activities (supplies, staffing, resources, etc)
- Assignment List—who is assigned what role and for what time period.
- Communication—document on the incident message form and ensure staff know what is the appropriate method of communicating (i.e. Runner vs. radio vs. phone)
- Biomedical engineering—document all activities and interactions
- Logistics—document all involvement and requests
- Staffing resources—document all requests, all changes and ensure there is a formal complaint system (in writing) for staff. The complaints will be dealt with during the post MCI recovery phase.
- All documentation must be in duplicate—one (original) copy must be retained in a safe and secure place. The second copy can be used in the actual post MCI recovery after action report.

Conclusion

The foregoing document was designed as a template for building an "off the shelf" plan that creates a skeletal structure that your staff can use to flesh out so as to address the needs of a Pandemic/MCI emergency. Remember, it is your staff who will be dealing with the emergency and the emergency preparedness plan developed by you—a team solution in developing the plan offers the ultimate flexibility required to meet the needs of the moment. Seek input, test, critique, assess, finalize and then review/update annually.

Intelligent Ventilation

Bernhart Hochleitner, RRT, AE-C

Last spring I was afforded the opportunity to travel to Reno, NV, to attend a workshop on Intelligent Ventilation, sponsored by Hamilton Medical and held at the opulent Siena Hotel/Spa and Casino. I chose to opt out of the avocado facial and sea grass pedicure offered at the Siena Spa, and instead chose to spend my free time photographing beautiful Reno. The rest of my time was spent at various workshops related to the Galileo ventilator and Adaptive Support Ventilation (ASV).

Do No Harm. It is a fundamental principle for health care providers. Despite the extraordinary hard work and best intentions of caregivers, thousands of patients are harmed in US hospitals every day. The Institute of Healthcare Improvement's 5 Million Lives campaign aims to reduce the nearly 15 million instances of medical harm, which occur in the U.S. each year.[1] The Intelligent Ventilation workshop utilized this theme in presenting ASV as a closed-looped ventilatory tool that has the potential to reduce mortality secondary to medical errors.

Manipulation of ventilator settings by respiratory therapists are minimized in ASV which decreases the likelihood of "dialing in" the wrong settings. Also, the dynamic nature of lung mechanics and the deleterious changes that can occur within the airways may initially be undetectable to the respiratory therapist. Thus the delicate "tweaking" of ventilator parameters needed to address these subtle changes may not occur until after critical ventilator alarms are triggered and injurious events to the lung parenchyma become widespread. Once alarms are activated, there may be a delay in therapist intervention depending on his/her current work-load demands and other patient encounters. ASV continually monitors and detects changing pulmonary mechanics and selects those ventilatory strategies conducive to minimizing the likelihood of Ventilator Induced Lung Injury (VILI). ASV delivers "real-time" ventilatory management and "tweaking" on a breath-by-breath basis.

The Galileo ventilator also offers a tool to optimize Positive End-Expiratory Pressure (PEEP). The P/V Tool is a welcome addition to the respiratory therapists arsenal of assessment tools. As with ASV, the P/V Tool optimizes patient safety by providing the respiratory therapist with the optimal PEEP level for that particular patient. Hence, under-recruitment or over-recruitment of alveoli is avoided and the likelihood of VILI is minimized. The Galileo P/V Tool is an objective measurement, free of operator bias. It provides repeatable and quantifiable patient data allowing for the optimization of ventilation settings with maximum lung protection.[2] The P/V Tool and ASV are relative newcomers to the world of mechanical ventilation.

We should feel proud that we are on the front lines in introducing new ventilatory modalities, such as ASV, to our collaborative clinical teams. As respiratory therapists, we must continue to embrace and evaluate new technology that falls on our doorstop. We must put aside our fears of the unknown, embrace change as an ally for our profession, and recognize our position as national leaders in the delivery of respiratory care.

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1 "Protecting 5 million lives from harm." A resource from the National Institute of Healthcare Improvement. Retrieved July 5th, 2007. http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=1

2 2006 Hamilton Medical AG product guide.

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Bronchial Thermoplasty

Catharine Johnson-Tieck, RCP, RRT.

Bronchial thermoplasty, a new procedure performed with the Alair System developed by Asthmatx, Inc, was named one of the top ten medical innovations of 2007. Featured in the New England Journal of Medicine and a multitude of other clinical journals, it is no wonder it has captured all of our attention. So what is it and how might it change the way we treat severe asthma?

Bronchial thermoplasty is a non-drug treatment that has been under clinical investigation in eight countries and is currently in the pivotal study phase. It has been performed by some of the leading facilities in pulmonary medicine. The pivotal trial sites include a list of over a dozen facilities from coast to coast.

So what is it?
It is a treatment that is done on an outpatient basis and is performed during a bronchoscopy. The procedure involves the controlled heating of airways one by one in segments. This investigational procedure delivers thermal radio frequency energy to the airways via the Alair Catheter, a specially designed catheter that passes through a bronchoscope. Once the bronchoscope is advanced to the desired area of the airways, the catheter is advanced, deployed and treatment begins. When fully deployed, the four electrodes of the catheter are exposed making even contact in the airway.

Once in the area that is to be treated, the catheter is deployed and radio frequency energy is delivered to the airways. This process is done at a target temperature that does not cause or show any signs of injury. The temperature is comparable to coffee with cream and is warm to the touch.

How does it treat asthma symptoms?
There are many components to asthma including muscles in the airway wall that contract, and inflammation, both of which reduce the size of the airways. Currently we have been treating these with bronchodilators and steroids. The bronchodilators open the airways by relaxing the muscles and the steroids open up the airways by reducing the inflammation.

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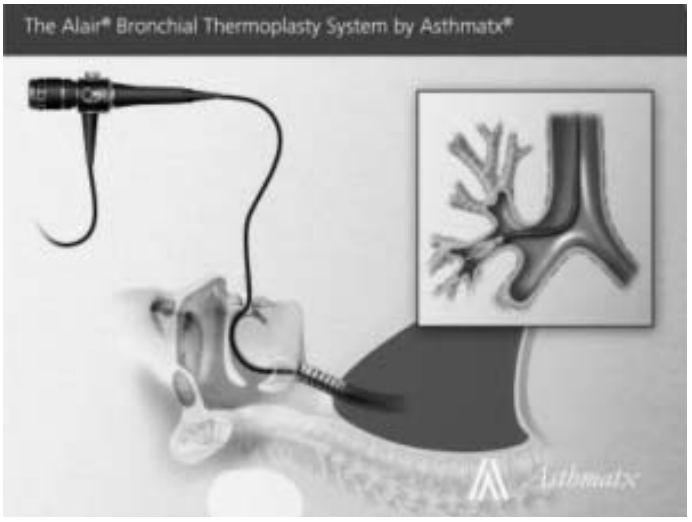


Bronchial thermoplasty is not trying to relax the smooth muscle but instead it is reducing the amount of muscle present in the airway. The heat works by reducing the cells in the muscle. With fewer cells in the muscle, the potential to contract is reduced. Taking a few steps back at the process in the airways that cause the symptoms, we see how simple this procedure really is.

What about scarring the airway?
The radio frequency controller provides a precisely controlled temperature for treatment. It leads to the cell injury that reduces the cells, but not enough to cause scarring. The test subjects that have undergone the procedure have not shown any airway scarring.

Let's walk through the procedure
It takes approximately one hour per session and takes three sessions to complete the therapy. This can be shorter or longer based on the amount of airways and number of branches in the smaller airways.

- A section of the lung is selected (right lower lobe)
- The catheter is advanced and expanded.
- It is treated for a period of 10 seconds then the catheter is

collapsed.
- It is pulled back, re-positioned, and re-expanded. The next section is then treated.
- The process is repeated several times to treat sites continuously along the airway wall for about one hour.
- The patient then returns in approximately 3 weeks to repeat the procedure, treating the next designated area (left lower lobe).
- The 3rd procedure will be repeated in approximately 3 more weeks (both upper lobes).

Additional follow-up is done during the 3 weeks between the procedures. Some participants in the study had an increase in symptoms the week after the treatment, which is expected given that the group is composed of mostly severe asthmatics. For some, it was comparable to typical post-bronchoscopic effects.

Outcomes

Outcomes were measured at 6 months and 12 months in the study published in the NEJM.
- Improved Peak flow.
- Reduced need for rescue medications, on average 25 fewer puffs per week.
- Overall improved asthma control.
- Improved quality of life.

Researchers evaluated 16 patients after 5 years.

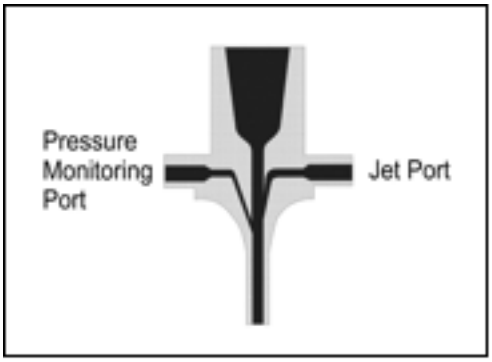
The results of Bronchial thermoplasty were presented most recently at the 2008 AAAAI Annual Meeting as a potential treatment for patients with asthma.
- Reduction of rescue medication use.
- Fewer night awakenings.
- No hospital stays for respiratory events.
- Reduction of asthma symptoms, cough, shortness of breath, and sputum production.

"Computed Tomography Scans were taken at the baseline and annually throughout the study, and showed no significant changes in the airways, including stenosis or bronchiectasis."

The Alair Bronchial Thermoplasty System is a device limited in the US for Investigational Use Only by qualified investigators. The following states are participating in the pivotal trial: California, Illinois, Iowa, Kansas, Maryland, Massachusetts, Michigan, Minnesota, Missouri, North Carolina, Ohio, Pennsylvania, Texas, and Washington. For more information on Asthmatx or the Alair Bronchial Thermoplasty System visit asthmatax.com.

High Frequency Ventilation

The LifePulse is pressure-limited and time cycled with adjustable PIP and rate. Inspiratory time (I-time) is kept as short as possible (0.02 sec.). Exhalation is passive. The LifePulse delivers small tidal volumes (VT) at rapid rates via a special ET tube adapter with built-in jet nozzle. Connecting this adapter to a patient's endotracheal or tracheotomy tube enables tandem use of CMV. Gas flow is feedback-controlled by matching monitored PIP with set PIP. Monitored servo-controlled driving pressure (Servo Pressure) is used to detect changes in lung compliance and resistance and mishaps such as accidental extubation, pneumothorax, bronchospasm, etc.



Ventilation Controls
Pressure amplitude (PIP-PEEP) produces VT and controls PaCO2. VT ≈ 1 mL/kg body mass is about half the size of anatomic dead space. The LifePulse high velocity inspirations penetrate through the dead space instead of pushing the resident deadspace gas ahead of fresh gas as we do when we breathe normally. Exhaled gas cycles out in a counter-current helical flow pattern around the gas jetting in, which facilitates mucociliary clearance in the airways. PIP may be set as high as that used during CMV. However, because inspirations are so fast and brief, PIP falls quickly as HFV breaths penetrate down the airways, and peak alveolar pressure is much lower than peak airway pressure.

The LifePulse uses passive exhalation. Thus, airway pressure at end-exhalation, PEEP, is constant throughout the lungs, as long as rate is set slow enough to avoid gas trapping. Rate is usually set 10 times faster than CMV rates, in proportion to patient size and lung time constants (lung compliance x airway resistance). Keeping I-time constant at its shortest value (0.02 sec.) allows exhalation time (E-time) to be proportionally longer at lower LifePulse rates, which aids in the treatment of larger patients and infants with restricted or obstructed airways.

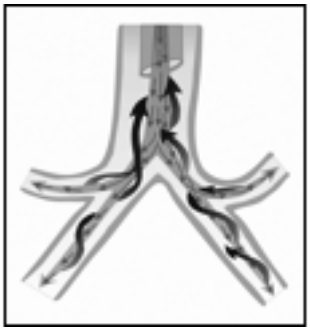
At 240 bpm (4 Hz) for example, I:E = 1:12. Smaller patients may be treated at rates up to 660 bpm (11 Hz) where I:E = 1:3.5. Lowering rate may require raising PIP to maintain $PaCO_2$, because LifePulse VT is independent of rate. But, LifePulse VT s are still ~10 times smaller than CMV VT s because of the 0.02 sec. I-time.

Oxygenation Controls:
CMV settings control oxygenation. CMV at 2-5 bpm facilitates alveolar recruitment with its larger VT s. PEEP is the primary determinant of mean airway pressure (MAP) and lung volume. Optimal PEEP may be found using CMV breaths and pulse oximetry. MAP on CMV prior to starting the LifePulse is reproduced at start-up by raising PEEP 1-2 cm H_2O initially. Patients are then stabilized with CMV = 5 bpm and FIO_2 adjusted to produce appropriate SaO2. CMV is then switched to CPAP mode, and PEEP is increased until SaO_2 is restabilized. Thus, CMV breaths are only used intermittently.

This approach produces an HFV version of "lung protective ventilation," where alveoli are opened, kept open with appropriate PEEP (usually in the range of 8 - 10 cm H_2O), and ventilated as gently as possible. Gas for the patient's spontaneous breathing is provided by the CMV in CPAP mode.

Gas Trapping Considerations:
Gas trapping occurs when tidal volumes have insufficient time to exit the lungs. Thus, larger CMV tidal volumes represent a greater threat of gas trapping compared to much smaller HFV breaths. CMV rate should therefore be reduced before HFV rate whenever there are indications of gas trapping, such as hyperinflation on chest xray or when the LifePulse monitored PEEP exceeds CMV

This paper was provided by Bunnell.

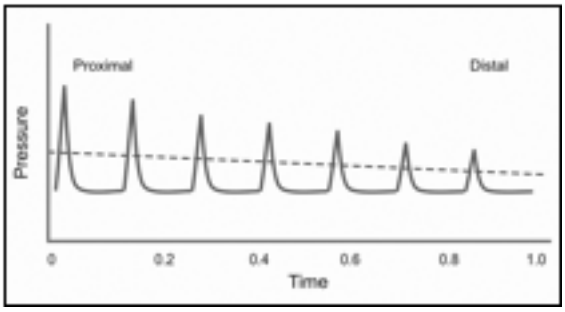


set PEEP. If hyperinflation persists once the CMV is in CPAP mode, decrease the LifePulse rate in 60 bpm increments to improve the I:E ratio and lengthen the exhalation time.

Tidal volumes necessary to produce adequate ventilation at high rates are very small, and lung compliance is often poor in very low birth weight infants, so gas trapping is unlikely to occur with the LifePulse. However, the maximum rate of 660 bpm is rarely used even in preemies weighing less than 1000 grams. Most LifePulse users limit rate to 540 bpm (9 Hz) where I:E = 1:4.5. The minimum I-time of 0.02 sec. usually works best for all patients at all rates.

Applications

While some clinicians use the LifePulse for premature infants with uncomplicated RDS, it is most often used to rescue infants and children with lung injury. PIE is the most common indication for the LifePulse, because it automatically improves ventilation/perfusion matching and facilitates healing by reducing mechanical ventilation of the most affected areas of the injured lungs.



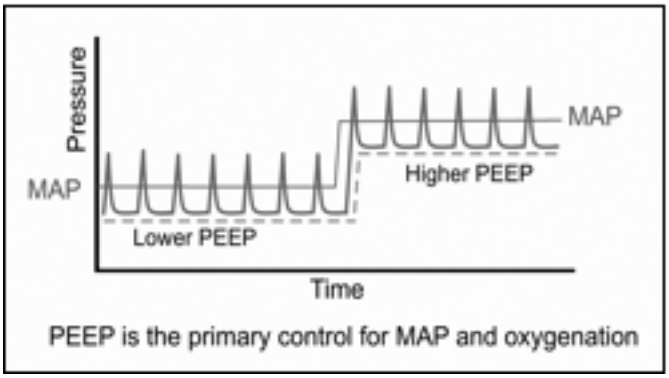
PIE is characterized by inflamed airways with high airway resistance that creates gas trapping, pulmonary overdistension, and alveolar disruption when other forms of mechanical ventilation are used. Since high airway resistance deters high velocity inspirations, resolution of PIE is much more likely using the LifePulse.

Other airleaks, meconium aspiration and other pneumonias (especially those accompanied by excessive secretions), congenital diaphragmatic hernia, and PPHN are other common applications of the LifePulse in NICUs, while trauma and severe pneumonia are typical applications in PICUs. Some institutions also use the LifePulse during and after pediatric cardiac surgery (e.g., Fontan procedure), especially when complicated by respiratory failure.

A pilot study using the LifePulse was recently initiated for "evolving" chronic lung disease in prematurely born infants at 1 to 3 weeks of age. Strategy for these patients is low LifePulse rate (240 bpm), no CMV breaths, and moderate PEEP (~8 cm H_2O). [Note: PEEP is needed to keep airways as well as alveoli open. Reducing PEEP to lessen gas trapping may make matters worse by allowing small airways to collapse during exhalation.] Previous randomized controlled trials support use of the LifePulse for uncomplicated RDS, RDS complicated by PIE, and PPHN.

Complications

Hyperventilation with the LifePulse is associated with increased incidence of cystic periventricular leukomalacia in premature infants with RDS. A single center study revealed such increased adverse effects when the LifePulse was used with low PEEP (5 cm H_2O) where hyperventilation and inadequate oxygenation occurred during the first 24 hours of life. (Inadequate PEEP leads to using higher PIP to generate more MAP, which causes hyperventilation.)



Servo Pressure

Servo Pressure auto-regulates gas flow to the patient to keep monitored PIP = set PIP. The following examples are typical of what automatically set upper and lower Servo Pressure alarms indicate.

Servo Pressure Increases with:

- Improving lung compliance or airway resistance, which can lead to hyperventilation
- Leaks in ventilator circuit leading up to the patient

Servo Pressure Decreases with:

- Worsening lung compliance or airway resistance (eg, bronchospasm), which can lead to hypoxemia
- Obstructed ET tube (e.g., from a mucus plug)
- Accumulating secretions at the end of the ET tube (ie, patient needs suctioning)
- Tension pneumothorax
- Right mainstem intubation

Monitoring Servo Pressure helps you determine if the patient is getting better or worse after you administer surfactant, make a change in ventilator management strategy or reposition the patient. For more information, visit bunl.com, (800) 800-4358.

On the Front Lines: The Vital Role of Respiratory Care In Preparedness and Response (Part 1)

Frank G. Rando

In the wake of September 11, an explosion occurred at a chemical and agricultural fertilizer facility in Toulouse, France leaving 29 dead and generating 3,000 related injuries. Due to 9-11, officials ruled the explosion as a possible terrorist attack. After much deliberation and investigative efforts, planners, first responders, public officials as the public braced themselves for further terrorist attacks, officials determined that the explosion was due to a catastrophic industrial accident. More recently, catastrophic events such as the Indonesian tsunami, Mynamar cyclone and massive earthquake in the Sichuan region of China, demonstrated the devastating effects on infrastructures and human health and safety. Hurricanes Katrina and Rita laid a path of death and devastation that rivaled some of the battlefields of major wars.

Immediately and simultaneously, a major high impact event and complex humanitarian emergency was created that disrupted critical infrastructure, created a multi-jurisdictional public health emergency and overwhelmed healthcare delivery systems throughout the Gulf Coast region. The creation of increased patient surges and disrupted healthcare systems led to the activation of the National Disaster Medical System and the FEMA Disaster Medical Assistance Teams to augment local and regional medical response activities, and in some areas, to replace devastated healthcare facilities and personnel.

Evacuation of the affected population to other regions required the setup of medical evacuation and reception staging areas, alternate care sites and mass care facilities with adequate resources to meet the needs of displaced individuals with medical conditions. Pre-existing medical conditions such as chronic lung disease, asthma, diabetes and hypertension are exacerbated due to a variety of factors and external stressors during disasters and high impact events. Healthcare systems and health professionals must contend with primary illnesses and injuries generated by the event, complicated by aggravated, pre-existing pathologies and other medical emergencies that may arise. This constellation of clinical situations was observed during and in the aftermath of Hurricane Katrina and other documented disasters. It is obvious that we must not only prepare quantitatively, but qualitatively, as well. In high impact events, we must expect high patient volumes and influxes and complex illness and injury matrixes. Clearly, respiratory care clinicians and other healthcare providers will be required to provide services outside of the realm of the controlled chaos of the normal day-to-day operations of their respective facilities. Clinicians will be required to work in austere operational settings, possibly requiring an expanded scope of practice. The aforementioned examples also serve to illustrate the need for healthcare preparedness that addresses all hazards, despite the prevalence of certain types of threats.

In 1993, the World Trade Center bombing, coupled with the 1994 and 1995 Sarin nerve agent attacks in Japan served as a series of clarion calls to US and foreign emergency management officials.

Also in the 1990s, terrorism took the shape of the Murrah Federal building in Oklahoma City and the Centennial Olympic Park bombing in Atlanta.

Efforts centered around terrorism preparedness and enhancing emergency response capabilities to meet the challenges of unconventional weapons utilizing chemical, biological, radiological, nuclear and high-yield explosive and incendiary mechanisms of harm—the so-called CBRNE agents.

Senators Nunn, Lugar and Domenici accelerate counterterrorism and preparedness efforts in the US. The 1996 Defense Authorization Act provided funding for responder training and equipment to meet the challenges of WMD-CBRNE incident management via the Domestic Preparedness Program. This initiative provided initial training in the nation's largest 120 cities, followed by similar programs for smaller communities that included healthcare facility staff at all levels.

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In the aftermath of the September 11 attacks, terrorism preparedness overshadowed preparedness efforts for natural disasters... until Hurricanes Katrina and Rita struck the Gulf Coast. As clinicians and medical planners, we must not sacrifice preparedness efforts for one contingency over another.

While it is prudent to address asymmetric and unconventional threats in institutional and community strategic emergency planning, it is equally important to assess our response capabilities for conventional scenarios such as natural disasters and technological hazards, eg toxic chemical releases, industrial explosions and nuclear power accidents. It's fair to say that hydro-meteorological and geohazards represent the bulk of natural phenomena that can lead to catastrophic events and that these tend to be more prevalent than technological and terrorist events. Therefore, we need to be very judicious, prudent and realistic in our prevention and preparedness efforts. It is the function of risk assessors, emergency planners and the local emergency first response agencies to conduct institutional and community risk and threat assessments and vulnerability analyses.

Often, local law enforcement, Department of Homeland Security and even military planners conduct threat assessments and construct a vulnerability profile for a particular community. Healthcare facilities and healthcare professionals need to become more proactive in the strategic emergency planning and risk assessment processes and offer their input and expertise. This includes respiratory care professionals and their respective departments.

Risk and threat assessments will identify credible threats which may pose an immediate or likely risk of occurrence in your community that could also impact your facility. Internal threats include loss of the facility's critical resources and infrastructure, eg, power failure, loss of communications, flood, other essential utility loss, loss of medical gases, chemical spills, major communicable disease/nosocomial infection outbreak, violence, bomb threat, fire, explosion, elevator malfunction, etc. External threats include any natural or manmade condition such as terrorism, civil disorder, transportation accidents, hazardous weather, earthquakes, hazardous materials incidents, etc.

Other examples may include hazardous industrial operations in the area, criminal activity such as clandestine drug (methamphetamine) laboratories, propensity for hazardous weather conditions or earthquakes. Risk and threat assessments and vulnerability analyses can also assist with pre-planning for asymmetric and unconventional threats, eg, terrorism. In general, respiratory care professionals can also consult with institutional safety managers industrial hygienists, and security managers to obtain information regarding appropriate personal protective equipment (PPE), decontamination operations, chemical, biological and radiological hazard control, community hazards, and appropriate training. Local and state emergency management offices and first responder emergency services are excellent sources of information, guidance and training in emergency response. Federal resources such as the Department of Health and Human Services (DHHS),Centers for Disease Control and Prevention(CDC),US Agency for Toxic Substances and Disease Registry (ATSDR), Environmental Protection agency(EPA), the Occupational Safety and Health Administration (OSHA) and the Department of Homeland Security all offer a plethora of valuable information and training resources for health professionals. Another excellent resource are occupational and environmental medicine/preventive medicine physicians and medical toxicologists who are experts on the clinical manifestations and treatment of toxic exposures and conducting environmental exposure assessments.

Emergency medicine physicians, military medicine specialists and civilian traumatologists are also excellent planning and clinical resources for mass casualty preparedness and response. Clinicians must also interface with external agencies to augment healthcare emergency preparedness. Fire departments, EMS agencies, public health departments, emergency management agencies and other stakeholders need to be involved in planning and response operations, and health professionals, including RCPs/RTs, should embrace these relationships. The respiratory care profession can add value and exceptional expertise to the overall planning process when medical threats and medical countermeasures are discussed and when institutional and community safety and health needs are addressed.

The Surge

Surge capacity is defined as the ability of a healthcare facility to accept and manage increased patient influxes above normal operational capacity and capabilities. Generally, HCFs should be expected to receive and manage an average of fifty additional patients during a mass casualty event. Many HCFs plan to utilizing this initial expected surge. This is not to be construed as a steadfast number, and is only to be used as an initial guideline for pre-planning. However, simulation models for bioterrorism and large-scale communicable diseases suggest capabilities to meet surges of 500 patients per one million population.

A National Disaster Medical System (NDMS) trauma-related surge projection model expects the healthcare system to manage 300-600 patients per one million population. Many experts agree that these are conservative figures that are not based on worst-case scenarios and are dependent on type, magnitude and severity of an event. In the 1995 Tokyo subway sarin nerve agent attack, for example,500 patients presented to the St Luke's Hospital emergency department within the first hour of the incident. In a 24-hour period, approximately 5,500 patients presented to area hospitals, many of these self-reporting and bypassing decontamination lines and pre-hospital EMS assets. Surge capacity and the facility's casualty management profile should be assessed under various stressors and conditions such as management of chemically-contaminated casualties requiring decontamination and by triage category (immediate, delayed and minor). Estimations and capabilities may be projected and assessed by evaluation ,analysis and critique of real-world responses and exercises. These evaluations, critiques and analyses identify and categorize deficiencies in performance, resources and equipment and will contribute to the correction of deficiencies and enhancement of response capabilities. The respiratory care professional must be included in these drills and exercises and participate in critiques and post-analysis. The respiratory care professional can extrapolate and apply information and data from emergency planning and preparedness activities and determine equipment, consumables, compressed medical gas and pharmacologic needs for multi-casualty or mass casualty response. The RCP can also participate in strategic emergency planning by networking with durable medical equipment vendors (DME), pharmacy resources and other medical facilities to address

emergency preparedness and obtain critical medical equipment and supplies such as mechanical ventilators and additional pharmacologic agents.

The respiratory care team should interface actively with local and statewide public health and emergency management agencies in conducting needs assessments and analysis, drafting recommendations for supplies and equipment, addressing resource allocation and medical logistics, obtaining medical and public health intelligence and formulating realistic medical threat assessments, participating in emergency preparedness training and exercises and training/educating others in emergency preparedness and emergency response. The RCP should serve as a key advisor on respiratory care medical management and equipment and work diligently to maximize and augment the mainstays of respiratory therapeutics during critical incidents/mass casualty events. Healthcare systems, public health authorities and emergency management agencies recognize RCPs as key members of the healthcare team in mass casualty response and critical care medicine in an austere and hostile setting.

The proper function of the cardio-respiratory system is essential for maintaining homeostasis and the human organism's viability and respiratory function is the essential physiological process that drives other physiological mechanisms. Because airway patency and intact respiratory function must be assured as a priority during any medical response and airway maintenance, ventilatory function and respiratory gas exchange are critical concerns, the respiratory therapist will assume the role of provider of life support skills such as airway management, mechanical ventilatory support, pharmacotherapy, medical gas administration, physiological/clinical monitoring, and other aspects of respiratory therapeutics and diagnostics. Because of the RCP/RT role, he or she will contribute significantly to initial resuscitative and stabilization efforts, as well as assessment, treatment and consultation throughout the entire medical response continuum.

This is part 1 of a 2 part article.

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Continued on page 65…

The Beneficial Effects of Inhaled Nitric Oxide in Patients With Severe Traumatic Brain Injury Complicated by Acute Respiratory Distress Syndrome: A Hypothesis

Thomas J. Papadimos

Abstract

Background: The Iraq war has vividly brought the problem of traumatic brain injury to the foreground. The costs of death and morbidity in lost wages, lost taxes, and rehabilitative costs, let alone the emotional costs, are enormous. Military personnel with traumatic brain injury and acute respiratory distress syndrome may represent a substantial problem. Each of these entities, in and of itself, may cause a massive inflammatory response. Both presenting in one patient can precipitate an overwhelming physiological scenario. Inhaled nitric oxide has recently been demonstrated to have anti-inflammatory effects beyond the pulmonary system, in addition to its ability to improve arterial oxygenation. Furthermore, it is virtually without side effects, and can easily be applied to combat casualties or to civilian casualties.

Presentation of hypothesis: Use of inhaled nitric oxide in patients with severe traumatic brain injury and acute respiratory distress syndrome will show a benefit through improved physiological parameters, a decrease in biochemical markers of inflammation and brain injury, thus leading to better outcomes.

Testing of hypothesis: A prospective, randomized, non-blinded clinical trial may be performed in which patients meeting the case definition could be entered into the study. The hypothesis may be confirmed by: (1) demonstrating an improvement in physiologic parameters, intracranial pressure, and brain oxygenation with inhaled nitric oxide use in severely head injured patients, and (2) demonstrating a decrease in biochemical serum markers in such patients; specifically, glial fibrillary acidic protein, inflammatory cytokines, and biomarkers of the hypothalamic-pituitary-adrenal axis, and (3) documentation of outcomes.

Implications: Inhaled nitric oxide therapy in traumatic brain injury patients with acute respiratory distress syndrome could result in increased numbers of lives saved, decreased patient morbidity, decreased hospital costs, decreased insurance carrier and government rehabilitation costs, increased tax revenue secondary to occupational rehabilitation, and families could still have their loved ones among them.

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Background

Traumatic brain injury (TBI) affects 1.4 million Americans annually, which includes 1.1 million emergency department visits, 235,000 hospitalizations, and 50,000 deaths. Approximately 5.3 million Americans are disabled with TBI at a cost of $60 billion annually. The Iraq war has provided additional cases and cost. At least 28% of wounded personnel have TBI resulting in $600,000 to $4,300,000 of care per patient. This is based on 2,824 wounded personnel as of August 2005.

Complications occur frequently in TBI, and respiratory dysfunction represents a primary non-neurological system failure. These patients are confronted with a massive inflammatory response with the release of cytokines and neuropeptides that are deleterious to the brain. Furthermore, this inflammatory response renders the lungs less tolerant of stressors causing ischemia-reperfusion and subsequent mechanical insults, i.e., massive brain injury may incite ventilator induced lung injury. This occurs through neurogenic pulmonary edema, ventilator associated pneumonia, and/or acute lung injury (ALI)/adult respiratory distress syndrome (ARDS) that may be secondary to inflammatory ultrastructural changes in pneumatocyte type II cells through the initiation/migration of activated neutrophils into the lungs. In the face of severe pulmonary insufficiency, such as occurs in neurogenic pulmonary edema, pneumonia, and ALI/ARDS, oxygen delivery to the brain may be compromised. INO delivered at 10–80 parts per million is an effective pulmonary vasodilator that rapidly degrades in vivo and improves arterial oxygenation. However, clinical trials have not shown improved outcomes with its use in ARDS, including a large phase III study in the United States. Nonetheless, inhaled nitric oxide (INO) has been successfully used twice in TBI patients with ALI/ARDS.

In severe TBI it has been recommended that the partial pressure of oxygen in arterial blood be maintained at a minimum of 100 mm Hg, cerebral perfusion pressure maintained between 60–70 mm Hg, and the partial pressure of carbon dioxide in arterial blood maintained at 32–35 mm Hg. Increased intracranial pressure (ICP) may then be prevented from occurring. Effective oxygen delivery and decreased inflammation will assist in meeting these parameters.

Very recent basic science and clinical research has brought into question the results of the above-mentioned ARDS trials, especially as they may relate to TBI. Mathru et al have demonstrated that INO attenuates ischemia-reperfusion injury in the lower extremities of humans, and Gazoni et al have demonstrated such attenuation in animal lungs. Hu et al concluded that INO decreased oxidative damage and inflammation along with reduced alveolar leakage in mature

adult rat lungs. Most importantly, Aaltoren et al have shown that pigs with meconium aspiration have hippocampal neuronal injury, however when INO is administered to pigs with meconium aspiration, hippocampal neuronal injury is inhibited. This occurs through diminished DNA oxidation in the hippocampus and is accompanied by decreased levels of glutathione, a biomarker of oxidative stress. Finally, Da et al demonstrated that INO, with concurrent administration of steroids, will decrease the inflammatory response in porcine sepsis through up-regulation of the glucocorticoid receptor (GR).

Thus, use of INO in patients with severe TBI and ARDS will show a benefit through improved physiological parameters and a decrease in biochemical markers of inflammation and brain injury, leading to better outcomes.

While INO is a potent pulmonary vasodilator, and has been thought to remain only in the pulmonary system, recent work has demonstrated that INO may go downstream to improve other organs in the following manner. The view that red blood cells (RBC) consume NO has been altered to one in which the RBC is a deliverer of NO. NO reacts, not only with heme iron, but also with cysteine (Cys)-93 on the hemoglobin -unit. NO reactions with heme iron cause NO's inactivation, but S-nitrosylation of Cys-93 makes hemoglobin a carrier of NO bioactivity. Also, an increase in S-nitrosothiol proteins occurs in sepsis (including RBC S-nitrosothio-hemoglobin and hemoglobin [Fe]NO). This accumulation of hemoglobin [Fe]NO as a 5-coordinate -heme NO does not allow NO release to the Cys-93 residue. However, dissociation of oxygen from the 5-coordinate -heme-NO occurs so that delivery of oxygen occurs without an extensive vasodilation. Thus, according to Goldfarb and Cinel, NO excess that interacts with hemoglobin will lead to products that prevent NO toxicity. Goldfarb and Cinel also point out that S-nitrosylated albumin can transport NO bioactivity downstream, i.e., to other organs and that NO stabilized through hemoglobin or other proteins by reversible S-nitrosylation may be the way NO extrapulmonary effects get downstream.

INO and glucocorticoid regulation may be important, not only in sepsis, but also in TBI. Da et al have demonstrated that glucocorticoid receptor (GR) up-regulation decreased the inflammatory response in a porcine model of sepsis using INO in combination with glucocorticoids (neither intervention worked well alone). In contrast to Da's work, though, up-regulation of GR in the central nervous system has been considered detrimental in some animal models of TBI, but these studies did not involve INO. In humans high levels of total serum cortisol (CORT), adrenocorticotropic hormone (ACTH), and catecholamines are present early in TBI. However, a low plasma ACTH concentration early in TBI is associated with better intensive care unit survival. This may be part of an adaptive down-regulation as demonstrated by Lee et al in which cortical GR expression was down regulated after 6 hours of injury in the ischemic cortex of rats. Thus indicating an organism's attempt at neuroprotection. It may be that INO reaching the central nervous system allows brain GR to be down regulated.

In view of new findings on its downstream effects and lack of side effects, INO may be delivered to the brain and cause GR expression in the brain/hippocampus to be muted. Thus enhancing a neuroprotective effect while at the same time allowing the rest of the body to up-regulate GR in response to steroids and INO administration, and assisting the body in its anti-inflammatory efforts.

The hypothesis may be confirmed by achieving the following aims: (1) demonstrating an improvement in physiologic parameters, ICP, and brain oxygenation with INO use in patients with severe TBI, and (2) demonstrating a decrease in biochemical serum markers of TBI with INO use. Specifically, glial fibrillary acidic protein (GFAP, which is specific for TBI), inflammatory cytokines (TGF- , TNF- , IL-2, IL-6, IL-1), CORT, ACTH, and cortisol-binding globulin will be evaluated.

A prospective, randomized, non-blinded clinical trial may be performed in which patients meeting the following case definition could be entered into the study: a subject whose GCS is ≥ 8, who has clinically qualified for intracranial pressure monitoring, whose trachea is intubated, whose oxygenation and ventilation is being supported by a ventilator, and in whom the ratio of partial pressure of oxygen in arterial blood to inspired oxygen is less than 200 with radiographic evidence of lung injury. The subjects should be randomized into two groups, those that will receive treatment without INO, and those who will receive INO. Invasive monitoring of CNS, renal, and cardiopulmonary parameters will be necessary. Follow-up at 28 days and 6 months can be through hospital records, an information-gathering tool, and the social security death index.

Biochemical markers will be evaluated by enzyme-linked immunosorbent assays (ELISA). Physiologic monitors shall include: pulmonary artery catheter for cardio-pulmonary-vascular indices (cardiac output (CO), cardiac index (CI), mixed venous oxygenation (SVO2), central venous pressure (CVP), systemic vascular resistance index (SVRI), pulmonary vascular resistance index (PVRI), stroke volume index (SVI), right ventricular ejection fraction (RVEF), right ventricular end diastolic volume (RVEDV), left ventricular stroke work index (LVSWI), right ventricular stroke work index (RVSWI), oxygen delivery (DO_2), oxygen uptake (VO_2), and oxygen extraction ratio (O2ER)), arterial line for blood pressure, foley catheter with abdominal pressure monitor, LICOX Brain Oxygen tissue monitor (records brain partial pressure of oxygen, intracranial pressure, and brain temperature), cerebral oximetry, pulse oximetry, and transcranial doppler monitor for middle cerebral artery velocities. Also arterial blood gases, cerebral perfusion pressure, lactate, and methemoglobin will be monitored.

The subjects' entire physiologic/biochemical/hematologic profiles will be available for analysis, such as hemoglobin, hematocrit, electrolytes, etc., as will the injury severity score (ISS) and Apache II score.

Inhaled nitric oxide in humans with TBI and ARDS has been used successfully on two occasions to improve outcomes. It has also been shown to be effective in hippocampal preservation in animals. Positive results could immediately affect treatment of military and civilian TBI patients worldwide. A decreased inflammatory response and increased arterial oxygen tension in TBI patients with ARDS, through the use of INO, could potentially lead to decreased ICP and better brain oxygenation. This would result in increased numbers of lives saved, decreased patient morbidity, decreased hospital costs, decreased insurance carrier and government rehabilitation costs, increased tax revenue secondary to occupational rehabilitation, and families could stay intact.

Features of Asthma Management: Quantifying the Patient Perspective

John Haughney, Monica Fletcher, Stephanie Wolfe, Julie Ratcliffe, Roger Brice, Martyn R. Partridge

Abstract

Background: In the management of asthma, features of care important to patients may not be fully appreciated. This study quantifies the importance of different features of asthma management from the patient perspective. This may assist in the development of personalized management strategies.

Methods: We used the technique of discrete choice experiment (DCE). Patients over 18 years of age with asthma, prescribed and taking medicine at step 3 of the UK guidelines were recruited from 15 general (family) practices in three areas of the UK. One hundred forty-seven evaluable questionnaires were returned from a total of 348 sent out. The outcome measures were the relative importance to patients of features of asthma management and the impact of changes in asthma management, as measured by utility shift between the features tested.

Results: The largest shift in mean utility values was recorded in number of inhalers and use of inhaled steroid. Use of a personal asthma action plan was ranked next highest.

Conclusion: This study suggests that adults with moderate or severe asthma would trade some improvements in symptom relief in favour of, for example, simpler treatment regimens that use as few inhalers as possible and a lower dose of inhaled steroid.

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Background

Patient self management or self care, a concept that enables patients to take a guided but ultimately personal involvement in the management of their condition, is an increasingly debated element of healthcare provision. It is particularly relevant as the prevalence of long term conditions increases and growing numbers of people desire a more active role in their own care with a less paternalistic approach from healthcare professionals.[1] Effective self care has the potential to improve clinical outcomes and reduce use of healthcare resources.[1,2]

Asthma is an ideal condition in which to strive for improved patient outcomes by optimizing self management because it typically fluctuates over time, with symptoms and exacerbations that can potentially be minimized with self monitoring and appropriate adjustment of treatment.[3,4] Self management of asthma is currently suboptimal in many patients, with around 50% self managing in ways that differ from recommended guidance.[5-7]

A key step in improving the self management of asthma is to understand what patients consider important. Patient education programmes designed to improve self care have traditionally centered on what health professionals consider to be important, for example, lung function, asthma symptoms and bronchodilator use in asthma.[8] Previous research has shown that patients have different perceptions of asthma compared to health professionals and that education tailored to meet patients' perceptions is more likely to change behavior.[7]

This study was designed to quantify the relative importance of features of the management of asthma from the patients' perspective. We used discrete choice experiment methodology, a type of conjoint analysis that has been shown to be a rigorous survey technique for eliciting preferences.[9] It is increasingly being used to identify patient and public preferences for health care.[10,11] The technique allows respondents to choose their preferred option between hypothetical scenarios designed to reflect the different attributes that real world decisions would contain, and to make trade offs between these attributes to

When considering your asthma management, if you were offered the choice between scenario A or B, which would you most prefer?

Choice 3	A	B
Symptom relief provided by your treatment	Complete	A little
Inhaled steroid dose (either in low dosage, plus a long-acting inhaled beta-agonist, or in high dosage)	A high regular steroid use	Always a low steroid dose
Use of a written personalised asthma action plan*	Full written instructions are provided by the doctor or nurse on how to recognise worsening asthma and how to alter your therapy yourself	A brief written note is provided on how to take your medication
Asthma crisis management	You are encouraged to attend hospital in the event of your asthma worsening	You are encouraged to attend your local GP surgery in the event of your asthma worsening
Number of different inhalers	No more than two inhalers are provided to you for the management of your asthma	Three inhalers are provided to you for the management of your asthma
Controlling your asthma symptoms	You are encouraged to change your own therapy as required without having to consult a doctor or nurse	You are encouraged to speak to a doctor or nurse before making any changes to your treatment

*A "personalised asthma action plan" is a written plan, given to you by your doctor or nurse, which tells you how to recognise your asthma is worsening and how you should alter your treatment yourself

Which group A or B mostly fits with your preferences?

Please tick the box A or B that contains the statements that are most important to you. This may not be the column that has the most statements you agree with, but will have the ones you feel most strongly about. You may have to select some statements you would rather not choose because they are linked to the GROUP that you prefer overall.

A ☐ B ☐

reveal their preferences. This technique of revealing preference through choice is a truer representation of real life decision-making and as such may be a better tool for establishing preference than data based on the ranking or rating of individual components of asthma management.[12]

A clearer understanding of such preferences may help healthcare professionals tailor an acceptable personalised management of asthma with their patient and consequently move nearer to controlled asthma.[13]

Methods

We carried out a discrete choice experiment (DCE) to determine the characteristics of long term asthma management that patients consider most important, requiring them to make choices between hypothetical scenarios and thus reveal their preferences.

To ensure a reasonable spread both geographically and socio-economically, 15 general practices from three geographical areas of the United Kingdom (UK) (West of Scotland, Norfolk, Gloucestershire), with a total population of 116 000 patients, took part in the study. Nursing staff at each practice identified all patients on treatment step 3 or above in the British Asthma Guidelines (regular use of inhaled steroid and other therapies)[14] who had received a prescription for asthma in the last 12 months, were over 18 years of age, and were believed to be able to understand and complete the questionnaire used in the study. The patients identified were included in a practice held asthma register. The diagnostic criteria for inclusion in this register were likely to be variable. In many cases, a diagnosis of asthma will have been given and accepted without formal, objective evidence of asthma. This scenario is consistent with standard UK practice. Patients on UK asthma guideline treatment step 3 or above were chosen because their asthma management, by definition, is more complex than those at treatment steps 1 and 2.

A sample was selected by allocating each patient a unique identification number and then by the use of a random number generator computer program. The number selected from each practice varied according to total eligible patient numbers, with a maximum of 30 patients per practice. A total of 348 questionnaires were mailed. A traditional power calculation is not appropriate in calculating a sample size for a DCE, where rules of thumb and experience drive the sample size decision. The accepted rule of thumb for our experimental design (nine tasks and two alternatives per task per respondent and no more than three levels in any one attribute) is that the sample size should be in excess of 83.[15]

The questionnaire presented respondents with nine pairs of choices—the discrete choice experiment. Socio-demographic information was also collected.

The key attributes for this discrete choice experiment were drawn from a previous study which included qualitative interviews with more than 400 patients with asthma.[16] We chose six attributes highlighted by patients as being the most important considerations in their long term asthma management. These were: importance of gaining relief of asthma symptoms from treatment; dose of inhaled steroid; the availability and content of a written personalized asthma action plan; locus of crisis (exacerbation) management; number of inhalers prescribed for routine use; and response to a deterioration.

We chose and assigned what we considered to be plausible and realistic levels for the six attributes that represent scenarios commonly found in asthma management. Table 1 lists the levels chosen for each of the attributes.

Table 1: Attributes and levels included in the study and constraints applied prior to analysis

Attribute	*Levels*	*Description*	*Constraints*
Symptom relief provided by your treatment	➢ Completely ➢ Mostly ➢ A little	ORDINAL	Completely > Mostly > A little
Inhaled steroid dose	➢ Always a low dose ➢ High dose when required but generally as little as possible ➢ High and regular steroid use	NOMINAL (with constraints)	Always low > Always high (no other assumptions made)
Use of a written personalised asthma action plan (PAAP)	➢ Full written instructions are provided by your doctor or nurse on how to recognise worsening asthma and how to alter your therapy yourself ➢ Brief written note is provided on how to take your medication ➢ No written instructions are provided	NOMINAL	None
Asthma crisis management	You are encouraged to: ➢ Manage an asthma crisis yourself whenever possible ➢ Attend your local GP in the event of an asthma crisis ➢ Attend hospital in the event of an asthma crisis	NOMINAL (with constraints)	GP>Hospital Yourself>Hospital (no assumption on Yourself v GP)
Number of different inhalers	➢ A single inhaler is provided to you which contains all the inhaled medication you need for the management of your asthma ➢ No more than two inhalers are provided for the management of your asthma ➢ Three inhalers are provided to you for the management of your asthma	ORDINAL	1>at most 2>3
Controlling your asthma symptoms	You are encouraged to: ➢ Change your own therapy in response to changes in your symptoms without consulting a doctor or a nurse ➢ Speak to a doctor or nurse before making changes to treatment	NOMINAL	None

A design program used in the statistical software SAS[17] was used. This software produces a manageable number of combinations of attributes and their respective levels (or scenarios) to develop a survey questionnaire, balancing the statistical requirements with the need to avoid overburdening the respondent with work. A total of nine pairs of choices were produced. For each pair of scenarios, respondents were asked to indicate the one they would most prefer when considering how their asthma should be managed.

The overall relative importances of attributes at both individual and aggregate (group) levels, and shifts in utility values between each level within each attribute were calculated.

Results

A total of 148 questionnaires were returned from a total of 348 sent out, giving a useable response rate of 43%. Non-responders, by definition, did not consent to their involvement in the study. Consequently, a more detailed comparison of characteristics or features of responders and non-responders was not possible.

The Relative Importance results are presented in Table 4.

The outputs shown throughout are the means of the parameters calculated at the level of individual respondents. Figure 2 shows the importance that respondents placed on changes between different levels within-attributes. The degree of importance is seen by changes in utility values for levels within the attributes. All 11 successive within attribute transitions were statistically significant ($P < 0.05$), with the single exception of changing the management of an asthma crisis from 'yourself' to 'visiting a GP/nurse'. Those changes with the highest relative negative impact on respondents' views of their asthma management were: changing from no more than 2 to 3 inhalers; change in steroid dose from low but high when needed to always high; being encouraged to visit a hospital for crisis management rather than being encouraged to manage yourself or attend the local GP surgery; symptom relief provided by current treatment changing from completely to mostly; and changing from 1 to 2 inhalers.

Discussion

The study emphasizes the importance of keeping treatment regimens simple. The results showed that adults with moderate or more severe asthma considered that a simple treatment regimen was the most important consideration in the long-term management of their condition, rather than symptom control without compromise. For example, two of the top five highest utility shifts between levels related to the number of inhalers they needed to use. Changing from no more than two to three

Table 2: Descriptive characteristics of respondents (n = 147)

Characteristics	*Mean (SD) or n (%)*
Age *(missing = 1)*	53.2 (16.2)
Male gender	48 (32.7)
Asthma duration	
< 12 months	0
1 to 4 years	14 (9.5)
5 to 10 years	33 (22.4)
More than 10 years	100 (68.0)
English is first spoken language *(missing = 2)*	143 (97.3)
Difficulty of questionnaire *(missing = 2)*	
Very	4 (2.7)
Moderately	20 (13.8)
Slightly	29 (20.0)
Not	92 (63.4)

inhalers had the highest relative negative impact on respondents' views of their asthma management. While noting the caveats of the relative importance analysis, number of inhalers was ranked the most important attribute of asthma management at both the aggregate (29.3%) and individual levels (21.9%), suggesting a reasonably homogenous view.

This preference for simpler treatment and fewer inhalers confirms in a more systematic and rigorous way preferences for fewer drug treatments and just one inhaler reported in a previous pan-European study[7] and confirms the findings from patient interviews in our previous study.[16] Asthma is only one part of people's lives and treatments that may need to be taken for decades should be offered in the simplest format. Willingness to pay from the patients' perspective—another factor that may influence treatment preference—was not addressed in this study; the cost of therapy to patients may be less important in the UK than in other healthcare settings; it was not rated highly as an issue in our qualitative study.[16]

The factor that patients rated as being of next highest relative importance, and which had the second greatest utility shift, was the dose of inhaled steroid. Scope for lowering the steroid dose without loss of asthma control has previously been described[18] and the addition of an inhaled long-acting beta agonist often permits better control and use of a lower dose of inhaled steroid.[14]

Use of a personalized asthma action plan came next in patients' ranking of relative importance of the attributes of asthma management that they were asked about. A discouragingly small number, only 12 (8%) of respondents, indicated that they held a written personalized asthma action plan—two centers each accounted for three of these patients and a further six practices each had one patient with a plan. This low number of patients with an action plan is similar to that found in previous studies[19] and is disappointing, especially because it has previously been shown that even those without plans would feel comfortable adjusting therapy themselves.[16] Written asthma action plans have been shown both to improve outcomes[3] and to improve compliance with asthma therapy,[20] to be cost-effective[21] and are strongly recommended in asthma guidelines.[14] It may be that lack of familiarity with the nature and benefits of using a personalised plan, by both medical professionals and patients, may have influenced these results and that a greater knowledge would increase the popularity and use of what may be the single most important non-therapeutic intervention in asthma management. In this study, patients indicate a desire for brief rather than full written instructions.

The next ranked factor was asthma crisis management. The utility analysis showed that patients preferred to avoid attending hospital even in the event of a crisis, a theme we have reported in a different disease area and population.[22] Knowledge of patient preference can inform the clinician but will not, of course, be the only factor to consider when deciding how and where to manage an acute exacerbation of asthma.

Perhaps surprisingly, controlling asthma symptoms was ranked lower in patients' ranking of importance, and relief of symptoms was considered least important in the range of attributes tested. However, this does not mean that people with asthma do not consider symptom relief important, but indicates that respondents considered it less important than the other attributes of asthma management they were asked to rank. This suggests that patients were prepared, at least to some extent, to trade off elements of efficacy for what they perceived to be other benefits, such as lower doses of inhaled steroids.

Both asthma crisis management and controlling your asthma symptoms had higher relative importance statistics when determined by the individual level method than by the aggregate level method. This means that there was a division of opinion within respondents as to which level in each of these two attributes was the most desirable.

There was some variation between respondents in the extent to which they wanted to manage their own asthma symptoms. Nearly two-thirds put a higher utility value on being encouraged to change your own therapy than speak to a doctor or nurse before making changes to treatment in the attribute of controlling asthma symptoms. This indicates a split between patients wanting a collaborative/active role in making changes to their asthma therapy and those wanting a more passive role, at a similar level to that reported previously.[23]

One of the greatest strengths of this study is the use of discrete choice experiment methodology, which is a rigorous method of eliciting preferences. Previous studies have demonstrated that respondents tend to behave in an internally valid and consistent manner when answering DCE questions.[24] The study explored

Table 3: Characteristics of responders compared to non-responders

	Responder		**Non-responder**	
	Number	***Mean (SD) or percentage***	***Number***	***Mean (SD) or percentage***
Age	147	53.2 yrs (16.2)	201	45.2 yrs (15.9)
Female Gender	99	67%	129	64%

Table 4: Relative Importance (RI) of Attribute Ranges Tested

Attribute	Individual Level RI	*Aggregate Level RI*
Number of Different Inhalers	**21.9%**	*29.3%*
Inhaled Steroid Dose	**20.3%**	*21.1%*
Use of a Written PAAP	**17.0%**	*12.3%*
Asthma Crisis Management	**15.2%**	*15.0%*
Controlling Your Asthma Symptoms	**14.4%**	*6.1%*
Symptom Relief Provided by Your Treatment	**11.3%**	*16.3%*

patients' preferences between only the attributes and levels that were offered, but these had been identified as being important from patients interviewed in a previous study.[16] The majority of the respondents found the questionnaire easy to complete, although it is possible that the type of questionnaire and the task, which is likely to have been unfamiliar to recipients, influenced the overall response rate.

Another possible limitation to the study is that the majority of respondents were female (65%) and aged over 55 years (48%). However, this is similar to previous studies exploring adult asthma patients' attitudes to their treatment.[9,23] Responders were generally older (mean age 55 years) than non-responders (mean age 45 years) ($P < 0.01$), but there was no statistically significant difference in gender between respondents and non-respondents ($P = 0.3\%$).

Conclusion

Taking a flexible, patient-centered approach to asthma management means focusing on issues that patients consider important. Our study indicates that this means making treatment as simple as possible, with as few medications and inhalers as can achieve symptom control—ideally fewer than three, or even two, inhalers. It also means using the lowest dose of inhaled steroid that can effectively control asthma and avoiding hospitals for emergency care, as well as minimizing asthma symptoms. There is clearly room for improvement in increasing the number of patients receiving personalised asthma management plans, which should improve outcomes by increasing compliance.

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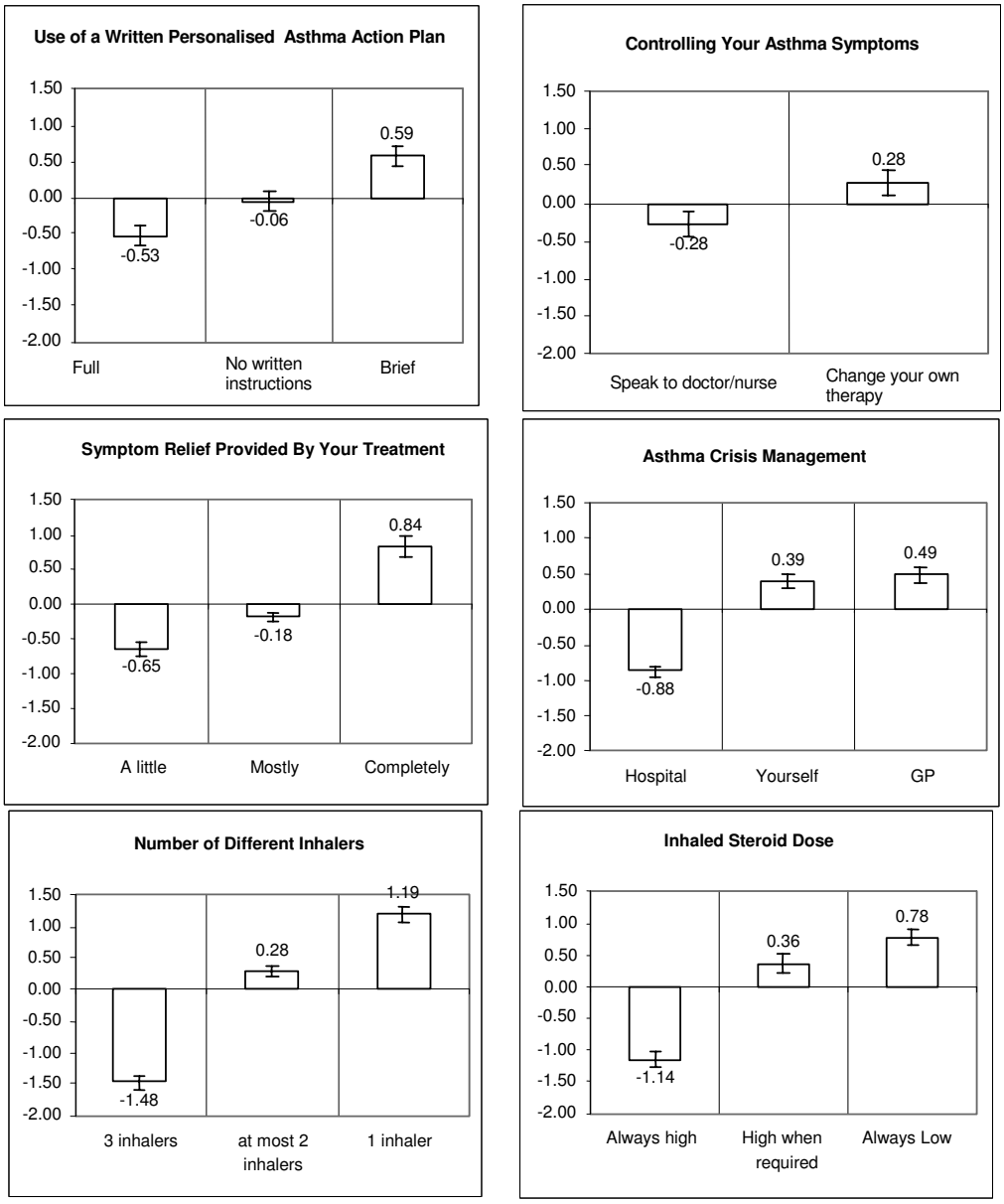

Figure 2
Mean utility values.

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Heliox Therapy: A Clinical Review for Pediatric Use

Airflow through the airways under normal conditions is laminar. Airflow through a constricted orifice or through an obstruction can be turbulent causing increased airway resistance and air trapping. Heliox has been used in many institutions for the treatment of airway obstruction due to its inherent properties. Heliox is a mixture of helium and oxygen. Heliox has a density 3 times less than that of air and 8 times less than that of oxygen. Because of these properties, heliox changes areas of turbulence into areas of laminar flow. Heliox has found its place in the pediatric intensive care unit.

There are many disorders that affect airflow in the lungs in pediatrics. Below is a list of those disorders (this list is not all inclusive).

1. Asthma
2. Post Extubation stridor
3. Croup
4. Bronchiolitis
5. Epiglottitis
6. Tracheitis
7. Laryngitis
8. Tracheomalacia
9. Cystic fibrosis

Heliox therapy can be delivered a number of ways. Mask administration has been used for patients in moderate respiratory distress to buy time for medications such as bronchodilators and steroids to take effect. In other cases, non-invasive ventilation (NIV) with heliox has been used to prevent respiratory failure without endotracheal intubation. Several studies have been shown to improve PCO_2 levels and decrease work of breathing (WOB) with the use of heliox with NIV.

Heliox has also been used with mechanical ventilation where the air supply is replaced with an 80/20 tank of helium and oxygen. The concentration of heliox can change based on the oxygen needs of the patient. Mechanical ventilation has been used frequently in the treatment of acute severe asthma and bronchiolitis. There is only one contraindications of heliox. The need for $FIO_2 > 0.40$ because heliox is not effective with concentrations < 60%; however, FIO_2 requirements may decrease with heliox therapy. Some institutions do not use heliox due to the cost of the necessary equipment as well as the infrequent use of such gases and competencies associated with providing this service.

"The primary indication for heliox therapy is during any clinical situation where airway obstruction prevents or significantly impedes the delivery of gas flow throughout the airways."[1] Failure to maintain pH >7.20 on standard mechanical ventilation with plateau pressures < 35 cm H_2O is another indication of heliox use. This assumes a reduced minute volume is targeted so as to allow permissive hypercapnia.

An assessment of the patient must be done to determine the effectiveness of heliox therapy. The table below describes treatment effectiveness for non-intubated and intubated patients.

Table 1

Spontaneous Breathing Patients	Mechanically Ventilated Patients
1. Decreased use of accessory muscles	1. Decreased wheezing
2. Improved Air entry by auscultation	2. Improved Air entry by auscultation
3. Decreased wheezing or stridor	3. Lower PaCO2
4. Decreased respiratory rate	4. Decreased use of accessory muscles
5. Less dyspnea reported by the patient	5. Improved Vital Signs
6. Improved Vital signs	6. Lower auto-PEEP
7. Lower PaCO2	

The benefit of heliox should be immediate. If no benefit occurs within 30 minutes of start, heliox therapy should be stopped.

Today, heliox is becoming an important part of the medical arsenal. Clinicians need to know the properties of heliox and how these properties interact with physiology. As technology advances and our understanding of disease processes improve, heliox has taken its role as a standard in the treatment of many disorders. I have included studies below for regarding information on heliox and its role in medicine.

Information provided by Hamilton Medical.

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A Picture is Worth a Thousand Words: Reducing Workload in the ICU

We have all heard the proverb "a picture is worth a thousand words." It refers to the idea that complex ideas or situations can be described with just a single image or that the image can provide more information than a large amount of text or data. Tufte states in his text The Visual Display of Quantitative Information, that "graphical excellence is that which gives to the viewer the greatest number of ideas in the shortest time with the least ink in the smallest space."[1] He also says that "graphical excellence is the well-designed presentation of interesting data—a matter of substance, of statistics, and of design…and consists of complex ideas communicate with clarity, precision, and efficiency." Tufte shows criteria for useful versus non-useful display of graphics shown in table 1.

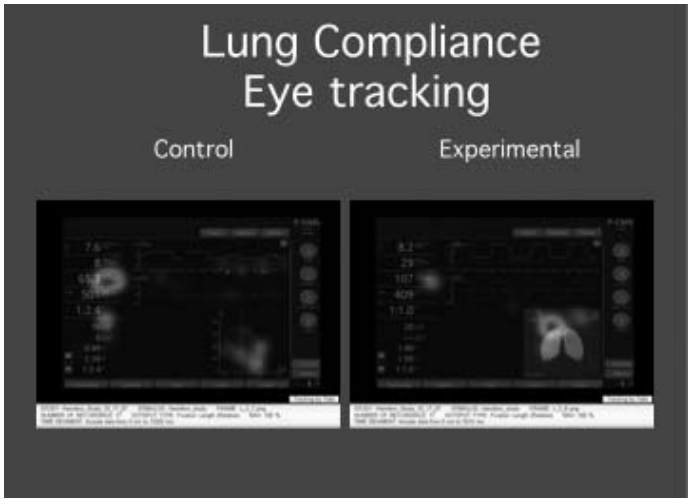
A recent abstract presented to the Society for Technology in Anesthesia by Albert, Syroid, Agutter, and Westenskow showed that graphic representation of information can help clinicians process patient information more quickly and accurately while reducing overall workload. The abstract was the winner of the Clinical Application of Technology Award. The abstract compared a traditional ventilator display to the recently introduced Hamilton G5 ventilator's Dynamic Lung graphical display.

Eight ICU clinicians (2 respiratory therapist, 2 physicians, and 4 nurses) participated in this study. The average experience was 15-plus years. The study comprised of three scenarios where each clinician was asked to determine if certain variables were within normal range. These were respiratory rate, tidal volume, compliance and resistance. The responses were measured using time, accuracy and eye tracking. The results are shown below in table 2.

"Lung Complicance, Eye tracking," shows the results of the eye tracking for lung compliance, as you can see, a graphical display made it easier for clinicians to assess data.

Albert et al concluded that "graphic presentation of information can help reduce the workload associated with the processing of respiratory information and also improve the speed and accuracy of state identification."[2] The participants were able to detect variables with the Dynamic Lung in terms of time and accuracy for Lung Compliance and Airway Resistance than the control display.

Graphical presentation of ICU data can clearly improve interpretation of critical data pertaining to patient care.



Information provided by Hamilton Medical.

Table 1

Useful	Not Useful
▪ no cryptic abbreviations ▪ simple keys, or clear labeling means ▪ no legend or key is required ▪ words run in natural left to right direction simple, upper and lower case font with serifs, modestly and consistently used ▪ clearly printed ▪ graphic enlightens and arouses curiosity	▪ numerous abbreviations requiring searching the text for explanation ▪ elaborate or obscurely coded patterns requiring continual return to legend or key ▪ words run vertically or in several directions. Letters running vertically may be even worse ▪ multiple overbearing fonts, in upper case sans serif ▪ murky and clotted printing ▪ graphic is boring and obscures meaning ▪ strongly patterned shading, cross hatchings and overpowering coloring

Table 2.

ACCURACY	**Traditional Display**	**Graphic Display**	**Difference**	**TIME (seconds)**	**Traditional Display**	**Graphic Display**	**Difference**
Tidal Volume	66.67%	75%	8.33%	Tidal Volume	9.75	10.16	-0.41
Respiratory Rate	95.83%	100%	4.17%	Respiratory Rate	7.66	6.86	0.8
Lung Compliance**	70.83%	95.83%	25.00%	Lung Compliance**	7.91	3.99	3.92
Airway Resistance**	58.33%	87.50%	29.17%	Airway Resistance**	11.22	6.22	5

** Indicates a significant difference between display conditions (P<.001)

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2 Robert Albert; Noah Syroid; James Agutter; Dwayne Westenskow. Improving Patient State Identification with Integrated Graphic Data Presentation

Low Awareness of COPD Among Physicians

Britt-Marie Sundblad, Kjell Larsson, Lennart Nathell

Abstract
Early identification of patients with chronic obstructive pulmonary disease (COPD) in the health care system followed by successful smoking cessation may prevent rapid lung function deterioration, development of severe COPD and respiratory failure.

Objectives: The aim of this study was to determine the frequency of under-diagnosed chronic obstructive lung diseases among current smokers.

Materials and methods: The under-diagnosis of COPD among smokers was determined in subjects who participated in a screening procedure aimed at recruiting COPD patients for a smoking cessation program. In order to identify current smokers, a questionnaire was sent out to persons who had been on sick leave for various reasons certified by a physician for more than 2 weeks. Subjects who stated that they currently smoked more than eight cigarettes per day were invited to perform a lung function test.

Results: A total of 3887 subjects performed spirometry, ie forced expiratory volume in 1 s and forced expirations, and among these, 674 (17.3%) had COPD according to the European Respiratory Society (ERS) consensus guidelines. Of those, 103 (17.3%) had physician-diagnosed COPD. Productive cough was reported by 16.6% of the COPD subjects.

Despite the fact that smokers were on sick leave certified by a physician, more than 80% of those with COPD had no previous diagnosis. As the COPD diagnosis cannot be based on reported symptoms, a spirometry on persons at risk must be performed.

Conclusion: The awareness of COPD among primary care physicians has to increase and smokers above the age of 40, with and without respiratory symptoms, have to undergo spirometry if it is regarded important to establish the COPD diagnosis at an early stage.

The authors are with the Lung and Allergy Research, Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden. The authors wish to thank all the persons involved in this study, from the nine co-operating centres in Umeå, Östersund, Uppsala, Stockholm, Örebro, Göteborg, Kalskrona, Karlshamn and Lund. Reprinted from The Clinical Respiratory Journal 2007; 2: 11–16,

Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by irreversible airway obstruction and is often related to tobacco smoking. The rapid annual decline of forced expiratory volume in 1 s (FEV1) in smokers with COPD usually normalizes.[1]The airway inflammation persists or even increases after smoking cessation in the short term related to repair of tissue damage in the airway, but diminishes in most ex-smokers in the long run.[2] Thus, early identification of the patients with COPD in the health care system followed by successful smoking cessation prevents rapid lung function deterioration, development of severe COPD and respiratory failure.

In an epidemiological study from the northern part of Sweden, under-diagnosis of COPD and chronic bronchitis was reported in adult subjects living in a defined area. Approximately half of the subjects who suffered from chronic bronchitis or emphysema reported that their disease had been diagnosed by a physician.[3] Under-diagnosed COPD is a global problem and has been described in several other studies.[4-6] In a study by Bolton et al, misdiagnosis of COPD was also found when the diagnosis was reviewed in 125 patients after clinical examination with spirometry.[7]

The aim of the present study was to assess the agreement between COPD diagnosed in the present study and physician-diagnosed COPD in a sample of Swedish smokers who were on sick leave prescribed by a physician. The primary reason for the screening of individuals on sick leave was to recruit smokers with COPD to a smoking cessation program.

Materials and Methods

A postal questionnaire containing questions on smoking habits was sent to 43 784 subjects who were between 40 and 60 years of age and who were living in and/or in the vicinity of nine Swedish towns and cities. All had been on sick leave certified by a physician for various reasons for 2 weeks or longer (between April 1998 and November 2000). Subjects were informed that

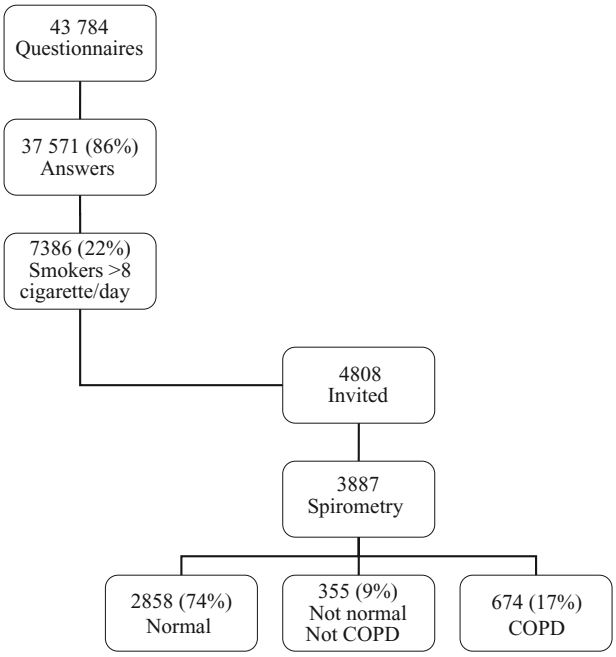

Figure 1. Study design.

this was an insurance supported study and that a decline to participate would not influence their relation to the insurance company. Subjects on sick leave for mental and tumour diseases were excluded. The initial response rate was 55%, which increased to 86% after two reminders. All respondents who smoked more than eight cigarettes per day[8] were contacted at home and invited to perform a spirometry. Those who fulfilled spirometric criteria of COPD were interviewed by telephone by a specially trained nurse.

Spirometry

Spirometry was performed at 10 different laboratories across Sweden by experienced and specially trained technicians. Regular meetings were held to reinforce the recommended techniques. Spirometry was performed according to American Thoracic Society (ATS) recommendations, with a few modifications,[9] and European reference values were used.[10] Spirometry was performed in a sitting position and a nose clip was used. After two to three slow expiratory vital capacity (VC) measurements, at least three forced expirations (FVC) were performed. Spirometry was performed before (n = 3887) and 15 min after inhalation of salbutamol dry powder (4 × 0.2-mg Ventolin Discus; Glaxo Wellcome, Mölndal, Sweden) in all subjects who had a pre-bronchodilator FEV1/(VC or FVC) ratio <0.75 (n = 1581). Short- and long-acting bronchodilator medication was withheld for 4 and 12 h, respectively, before reversibility test.

Definition of COPD

COPD was defined according to recommendations of the ERS consensus statement from 1995, ie FEV1/(VC or FVC) <88% of predicted value for men and <89% of predicted value for women[11] and a FEV1 less than 100% of predicted value. FEV1/VC ratio was calculated using the highest value of either FVC or VC. Severity of COPD were classified according to the ERS guidelines: FEV1 ≥ 70% of predicted value was classified as mild, FEV1 between 69% and 50% of predicted value as moderate, and FEV1 ≤ 49% of predicted value as severe COPD.[11]

Of the 33,765 complete responses, daily smoking was reported by 8,929 respondents (26%) and among these, 7,386 (82.9%) smoked more than eight cigarettes per day. Among the subjects who smoked more than eight cigarettes per day, the criteria of COPD were fulfilled by 674 individuals, with a mean cumulative smoking exposure of 36 pack years (range 5–92). Seventy-eight of these subjects declined to participate in the phone interview and, thus, 596 subjects with COPD completed the study and were included in the final analyses.

In total, 5,337 subjects accepted to undergo a lung function test. For different reasons [mental disorder (n = 363), malignant tumour (n = 87), abuse of alcohol or drugs (n = 40), could not speak, write or understand Swedish (n = 22), other complicated illness, such as recent myocardial infarction (n = 16)], 528 patients were excluded from lung function testing. Of the 4,809 subjects invited to spirometry, 3,887 completed the clinical examinations [1,763 (45.4%) men, aged 52 years (range 46–56 years) and 2,124 (54.6%) women, aged 51 years (range 46–55

Table 1. Lung function, before and after brochodilatation (mean, 95% confidence interval), in subjects with and without previously physician-diagnosed COPD

		COPD			
		No previous diagnosis (*n* = 493)		Previous diagnosis (*n* = 103)	
	No COPD (*n* = 3213)	Before bronchodilation	After bronchodilation	Before bronchodilation	After bronchodilation
VC (L)	3.96 (3.93–3.99)	3.93 (3.85–4.02)	3.97 (3.88–4.05)	3.37 (3.18–3.56)	3.49 (3.30–3.68)
VC (% pred.)	107	102	103	94	97
FEV_1 (L)	3.06 (3.03–3.08)	2.48 (2.42–2.53)	2.59 (2.53–2.65)	1.98 (1.85–2.11)	2.14 (2.00–2.27)
FEV_1 (% pred.)	99	78	81	66	72
FEV_1/VC (%)	77.4 (77.2–77.6)	63.0 (62.5–63.6)	65.5 (64.8–66.2)	58.5 (56.8–60.3)	61.1 (59.2–62.9)
Reversibility (% of pre-bronchodilation)			5.0 (4.4–5.5)		7.8 (6.3–9.2)

Spirometry was performed after bronchodilation if pre-bronchodilation FEV_1/(VC or FVC) was <0.75.
COPD, chronic obstructive pulmonary disease; VC, vital capacity; FEV_1, forced expiratory volume in 1 s; % pred., per cent of predicted value.

Table 2. COPD according to spirometry in the present study in subjects with and without previous physician-diagnosed COPD

	Mild $FEV_1 \geq 70$ % pred.	Moderate FEV_1 50–69 % pred.	Severe $FEV_1 \leq 49$ % pred.	All
No previous COPD diagnosis	372 (88%)	104 (76%)	17 (47%)	493 (83%)
Previous COPD diagnosis	52 (12%)	32 (24%)	19 (53%)	103 (17%)
Total	424	136	36	596

COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 s; % pred., per cent of predicted value.

years)]. The reasons for not participating were: already stopped smoking (n = 22); other illness such as hernia, facial paralysis, low back pain, abuse of alcohol (n = 21); moved from the area (n = 8); deceased (n = 4); not acceptable technique (n = 4); and lost interest or not stating reason (n = 863).

COPD

According to spirometry, 674 (17.3%) of the 3,887 subjects had COPD at the screening test. One hundred three (17.3 %) of the subjects who met the COPD criteria by spirometry reported that they had chronic bronchitis, COPD or emphysema previously diagnosed by a physician. In subjects with severe COPD, about half (52.8%) had a previous smoking-related physician-diagnosed airway disease. Of the subjects who according to spirometry in the present study had COPD, eight (0.2%) had physician-diagnosed asthma.

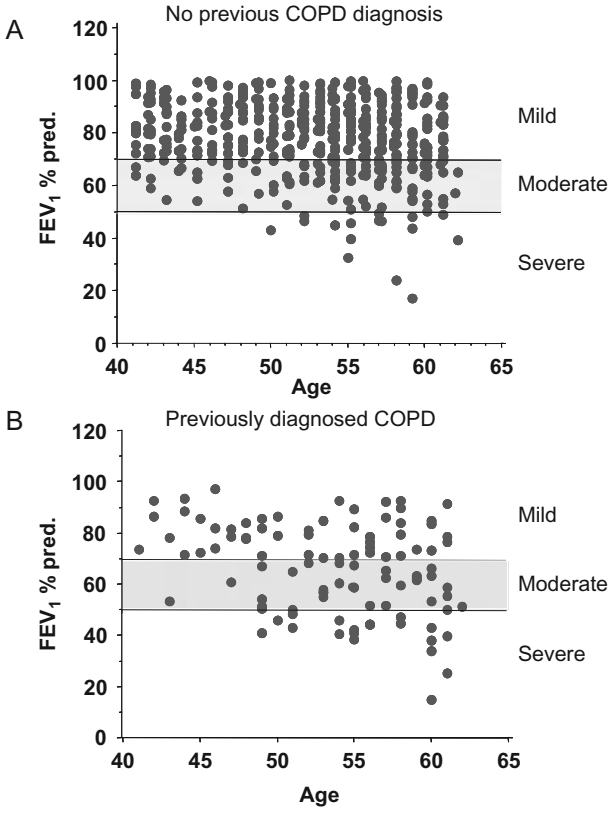

Figure 2. Forced expiratory volume in 1 s in per cent of predicted value (FEV_1 % pred.) in relation to age in 596 subjects with chronic obstructive pulmonary disease (COPD) (post-bronchodilator $FEV_1/VC < 0.70$). (A) 493 subjects who had no previous COPD diagnosis. (B) 103 subjects who had a previous COPD diagnosis.

Subjects who reported symptoms of chronic bronchitis were more common among those with severe COPD. Among the subjects with severe COPD, 36.1% reported symptoms of chronic bronchitis, ie productive cough, most days during a period of 3 months, the latest 2 years. Corresponding numbers in mild and moderate COPD were 14.2% and 18.6%, respectively. There were no significant correlation between productive cough and physician-diagnosed COPD.

Discussion

In the present study, it was shown that only 17% of the smokers with chronic obstruction had physician-diagnosed COPD despite the fact that all patients had been on a physician-prescribed sick leave for more than 2 weeks. It is also noteworthy that approximately half of the subjects with severe disease (FEV1 ≤ 49% of predicted value) had not received a diagnosis despite more than 2 weeks on sick leave certified by a physician.

The diagnosis of COPD highly depends on which guidelines are used for defining the disease. In this study, COPD was classified using the definition of the ERS consensus statement, where the ratio is calculated as FEV1/VC in per cent of predicted value and not with a fixed ratio of 0.7. When our material is classified using the Golden Initiative for Chronic Obstructive Lung Disease, 14% of the subjects were diagnosed as having COPD. The differences between the classifications do not influence the low agreement between COPD diagnosed in the present study and physician-diagnosed COPD.

The majority of sickness certificates in Sweden are drawn up from physicians in primary health care (50%) and in hospitals (20%).[12] The subjects in this study had been on sick leave because of a variety of causes for 2 weeks or longer, and all of them had met a physician. If we had limited the cause of sick leave to respiratory diseases we would have missed a substantial number of cases. Sick leave in COPD has been shown to have a closer relation to fatigue than to lung function assessed as FEV1.[13] Sick leave in workers with asthma and COPD was, in that study, also related to psychosocial variables and work characteristics. Thus, a lot of causes for sick leave, other than respiratory symptoms, may be causally connected to COPD. This emphasizes the importance of an active approach when interviewing smokers about symptoms.

In the present study, subjects who smoked more than eight cigarettes per day were invited to perform a spirometry. The limit of eight cigarettes or more per day was selected based on the fact that answers about the number of smoked cigarettes usually are clustered around multiples of five.[8] Thus, it was preferable to set the border between 5 and 10.

It is most likely that the majority of the patients with unidentified COPD primarily seek a general practitioner. It has

been stated that mild, and even moderate, COPD may occur without complaints or symptoms.[14] Accordingly, our study has shown that many symptom-free individuals with COPD visit a general practitioner because of other reasons. In the present study, more than 83% of the subjects with COPD did not report characteristic symptoms such as productive cough, and there were no significant correlation between productive cough and physician-diagnosed COPD. A more characteristic symptom of moderate and severe COPD is shortness of breath, which was not asked for in the present study. These results raise the question whether you can have COPD without significant symptoms and whether we are asking the right questions. In a previous study of 131 subjects with respiratory symptoms who performed spirometry, underwent a medical examination and answered a questionnaire, 15 subjects (11.5%) had COPD, of whom only three had been previously diagnosed as having a respiratory disease.[15] In that study, it was claimed that one reason for the under-diagnosis of COPD is that a majority of patients with mild COPD seek health care because of an acute exacerbation and the physicians are not always aware of the underlying disease. The diagnosis of the disease is often missed when patients visit the physician because of an infection, which leads to the prescription of antibiotics. At this consultation, spirometry is not often performed despite the fact that the patient is a smoker and has symptoms such as cough with phlegm and breathlessness.[3] Another study from the same group established that the under-diagnosis of COPD was related to disease severity and that all subjects with symptoms and severe COPD had a diagnosis consistent with COPD.[16] Differential diagnosis between COPD and asthma does not seem to be a difficulty, as only eight subjects with COPD were misdiagnosed as asthma by a physician. In conclusion, many physicians do not consider COPD in smokers who seek medical care because of non-respiratory symptoms or respiratory infections.

The COPD diagnosis is based on spirometry,[17] and spirometers are available in most primary care centres in Sweden. In Mid-Sweden, 77% of the primary health care centres have a spirometer.[18] Thus, the reason for not performing spirometry was not the lack of spirometers. Lung function was obviously not assessed despite the fact that the spirometers were available in the primary care. A study from Wales, United Kingdom reported that most care centres had a spirometer (82.4%) and although 85.6% seemed to use the appropriate equipment, COPD diagnosis varied widely, from 0% to 100%, between the care centers.[7] An Italian study showed that 30% of general practitioners do not use spirometry to establish the diagnosis of COPD.[19] It has been shown that the use and handling of a spirometer at a primary care center is improved by educational workshops.[20] In Sweden, COPD also has attracted the attention of the media during recent years and the general impression is that the awareness of COPD has increased. Therefore, we propose that more extensive education and information to nursing staff, physicians and patients is the best way to deal with the problems caused by the under-diagnosis of COPD.

Screening for COPD remains controversial. Depending on the technicians performing the spirometry there are, consequently, differences in misclassification rate.[21] The difference between using medical test for screening the "man on the street" or case-finding in patients consulting a physician is also important. Several criteria have been established for medical tests proposed for the early detection of the disease.[22,23] One of these criteria is that the detected subjects should accept the recommended treatment, in this case smoking cessation, which may pose a problem, as smoking is a lifestyle among COPD patients.

Early detection of the disease is important for the success rate of the intervention (smoking cessation). Early detection also provide a longer time for intervention and treatment failure, such as smoking relapse, which can be dealt with when lung function is still preserved. In addition, early diagnosis allows the reduction of the burden of COPD on the patient and the health care system. According to a recent Swedish study, the cost to the Swedish society of a person with COPD was about 13 400 SEK per year (depending on the severity of the disease).[24]

In conclusion, a lung function test should be considered in smokers above the age of 40, both in the presence and absence of respiratory symptoms. It is quite important to raise the awareness of COPD and to establish the diagnosis in an early stage in order to avoid symptoms, retain a good quality of life and stop the progress of the disease.

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Clinical Summary: Virtual CPAP

Tomasz Golczewski, Marek Darowski

The purpose of this study was to analyze the support efficacy cause in obstructive lung disease localized in bronchi of middle order (OLDMO), esp. the relationship between the CPAP value and optimal BF. Investigations utilized previously built virtual respiratory system. Its most important factors: nonlinear lung compliance and changeability of nonlinear airway resistance (Raw). Influence of BF and the CPAP value on the tidal volume and minute ventilation was analyzed for four exemplary virtual patients: healthy ("standard") and suffering from moderate, severe, and the very severe OLDMO. Minute inspiratory work was as a criterion of the BF optimization.

The study found that CPAP decreased Raw, making breathing easier; however, it shifted the working point of the respiratory system towards the smaller lung compliance, making breathing harder. The final result depended on the Raw value: CPAP improved breathing of patients with serious OLDMO while it worsened healthy breathing. The optimal CPAP value depended on the Raw value. The authors conclude that the CPAP efficacy depends on the level of OLDMO. CPAP is efficient in the severe OLDMO because it increases the optimal BF, which makes possible less energy-consuming breathing with frequency close to normal.

The investigations were conducted on the VRS built-up previously. The VRS data for a healthy human being have been collected on the basis of widely accessible literature. Nonlinearity of the respiratory system compliance and changeability of the nonlinear Airway Resistance (Raw) are those VRS features which are especially important for this paper. Investigation on VRS enables analysis of a problem with the "step by step" method, which is usually impossible in the case of living models.

Results

The value of Raw strongly depends on the bronchi diameter. Therefore, since the diameter depends on the transmural pressure (the difference between pressures inside and outside the bronchus), CPAP influences Raw: the greater the CPAP value, the smaller the Raw value. Hence it appears that CPAP may make breathing easier because a smaller part of the force developed by the respiratory muscles has to be used against Raw. On the other hand, CPAP may make breathing harder. Indeed, if the airflow is equal to zero, as at the inspiration or expiration end, then the pressure inside the lungs is equal to the pressure inside the airways. In particular, the pressure inside the lungs at the inspiration beginning is equal to CPAP, which means that the starting lung volume is greater than it would be for the pressure equal to zero. Since the lung's compliance is nonlinear, CPAP moves the working point towards the smaller differential compliance. As a consequence, the same force developed by the respiratory muscles causes smaller VT. Therefore, the greater the CPAP value, the more horizontal the hystereses.

The analysis suggests that CPAP may either improve or worsen the breathing. CPAP reduces the influence of the frequency on VT because it increases VT in the case of higher frequencies while it decreases VT for lower frequencies. Indeed, if breathing frequency is higher, lungs need less time to empty themselves through the Raw decreased by CPAP. For that reason, CPAP increases VT. On the other hand, if breathing frequency was low, lungs would have enough time to empty themselves without the CPAP support. Hence it appears that CPAP is not helpful in this case. In fact, it appears unprofitable, since it decreases VT because of a shift of the working point toward the smaller lung compliance (as in the case of the normal Raw).

Discussion

It is commonly accepted that a breathing frequency decrease in obstructive lungs disease is connected with an increase of the inspiratory work against Raw. Our simulations, however, suggest that problems of expiration rather than inspiration are the main cause of such frequency fall. The simulations indicated

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that the minute ventilation rises with the breathing frequency increase only if the frequency is smaller than a certain boundary value because of difficulties with lungs emptying during too short expiration. The emptying through the increased Raw needs more time than through the normal Raw, which means that in severe obstructive disease the boundary value is smaller than the normal breathing frequency. Therefore, a patient has to breathe slowly, since more frequent breathing would not increase the ventilation but would increase the minute inspiratory work.

The simulations suggest that CPAP efficacy is connected mainly with possibility of effective breathing with the normal frequency. Therefore, CPAP seems to be helpful only when Raw is increased significantly, ie, when the frequency that is economic without the CPAP support is smaller than the normal one.

CPAP makes breathing easier because it decreases required inspiratory work against the reduced Raw as well as the lungs' compliance, since the work against the compliance is approximately proportional to the squared tidal volume, the tidal volume is approximately inversely proportional to the breathing frequency, and CPAP enables more frequent breathing. The optimal breathing frequency depends on both the CPAP value and the obstruction level.

On The Front Lines…Continued from page 47

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