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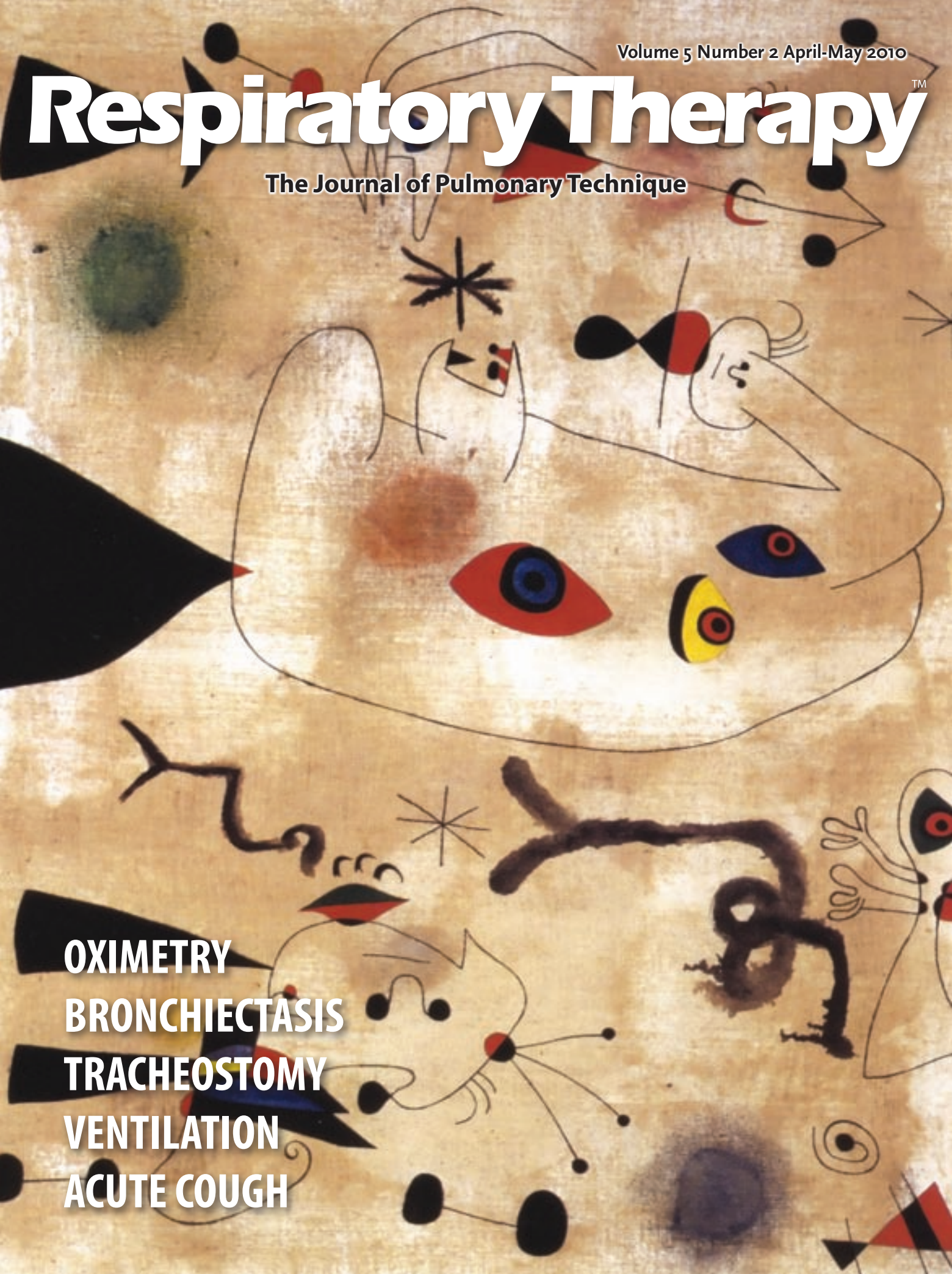
Respiratory Therapy™

The Journal of Pulmonary Technique



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The Journal of Pulmonary Technique

Vol. 5 No. 2
April-May 2010

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Editorial

What Disaster? Mass Casualty Preparation or Slow Motion Crash and Burn?

Dave Swift, RRT

Dave Swift is a member of Respiratory Therapy's Editorial Advisory Board.

Since SARS made its appearance in 2003, we have been preparing for a pandemic and potential mass casualty incidents. Many hospitals and healthcare organizations have developed emergency response plans to deal with the sudden surge in patients. These plans are based upon a premise that the surge will be short lived (<7 days and ideally <72 hours). Most plans are based upon the organization being self sustaining for 72 hours and if the situation persists beyond this time, it is expected that the municipal, state/provincial governments and federal government will be available to help.

With the advent of the novel H1N1 virus, mass casualty events took on a new form. Facilities were encouraged to be self sustaining for 3 months and encouraged to stockpile critical supplies. Instead of a short, brief surge in casualties, we experienced a surge that began slowly but immediately increased on an exponential basis, coming in unpredictable waves. It quickly became evident that three factors were challenging the healthcare system:

• Patient volumes in the emergency department were at unprecedented numbers. It was not unusual to have >10 patients present and arriving each shift. These numbers seem to increase exponentially as the days progressed. With patients failing the FRI (febrile respiratory illness) screening tool and going in to isolation, this required an additional 10 minutes of entry/egress to take the precautions required for each visit and this added substantially to each member of the care team's workload. For example, with the majority of the patients being hypoxic and wheezy/bronchospastic, 15 patients having to be seen only once, it adds an additional 150 (2.5 hours) minutes of workload for each 8 hour shift. This does not take into account any other respiratory care or monitoring required. What could be normally managed by one therapist will easily require twice or more the number of therapists.

• Critical care overload. The numbers of patients being admitted to ICU with H1N1, although not high, utilized a disproportionate amount of critical care resources. Patients required aggressive ventilator management/monitoring through the use of prone ventilation, aggressive conventional ventilation, HFO, nitric oxide or flolan use, APRV(R) and even ECMO. Adding to this increased care/resource demand is the workload associated with isolation PPE. Overall, the H1N1 critical care patient represents a significant increase in additional workload and substantially more in resource utilization.

• Staffing absenteeism. During the H1N1 surge, staff absenteeism was significant in that staff who had symptoms of the flu were required to be off at least for a 5 day minimum and until they were symptom free. This created significant challenges to sustaining the elevated activity levels.

These three factors quickly identified the flaws and assumptions made in the development of our MCI (mass casualty incident) plans. The sustained resource (staff and equipment) requirements tested our ability to maintain supplies, service delivery, workload support and staffing levels.

Most healthcare facilities/organizations have effective MCI plans that can handle a sudden surge associated with a very sudden and short lived incident. The "new" MCI

Continued on page 64…

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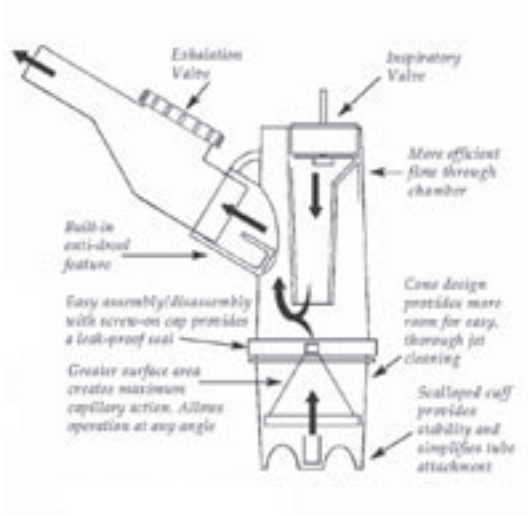

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News

☐ April-May 2010

BIOMED CENTRAL NEWS

SCImago has given high ratings to BioMed Central, with Molecular Pain occupying the top position in its category, coming in first among 88 journals. Other top-rated journals are Molecular Pain and Neural Development, as well as the Journal of Biology… The site recently launched Genome Medicine… Cancer Cell International has been indexed by Thompson Reuters… The journal Silence published its first articles in January. The journal covers biogenesis and RNA… Health Research Policy and Systems has published articles on informed policy-making… Other journals with newly-relevant articles are BMC Musculoskeletal Disorders, Environment Health, and Breast Cancer Research. Data.gov.uk provides a single access point to more than 2,500 government databases for free. The organization has adopted Creative Commons-compatible licensing. Some newer journals for BMC: Harm Reduction Journal, International Journal for Equity and Health; there are new materials available from Parasites & Vectors; Mobile DNA has published its first articles; Genome Medicine offers a new study on genetic risk models; Malaria Journal offers a new thematic series on malaria eradication. Contact bmc.com.

THE BEST COURSE

The ATS is sponsoring 30 postgraduate courses on Friday, May 14, and Saturday, May 15, before the official start of the 2010 International Conference. The postgraduate courses that will be offered at ATS 2010 are: Contributions to Respiratory Disorders in Children & Adults; Practical Issues in the Management of Interstitial Lung Disease; Interventional Pulmonology; Update on Cystic Fibrosis 2010: Pathobiology, Genomics & Treatment; Pulmonary & Critical Care Reviews; Practical Approach to Occupational & Environmental Lung Disease; Challenges & Opportunities for TB Control; Host Defense Mechanisms in Pulmonary Infection; Update in Pulmonary Hypertension: Conventions and Controversies; Advances in the Comprehensive Management of COPD; Conquering Population Biology; Case-Based Pulmonary Function Test Interpretation; OSA Diagnosis & Management; Quality Measurement & Improvement; The Art & Science of Translational Research; Novel Research Opportunities in Clinical Research Utilizing Existing Data; Thoracic Imaging; State of the Art Controversies in COPD: A Pro-Con Debate; Cardiopulmonary Exercise Testing for the Practicing Clinician; ICU-Acquired Weakness; The Science of Healthcare Delivery in the ICU; Gene-by-Environment Interactions on Lung Disease; Challenges in the Management of Pulmonary Infections; A Physiologic Approach to Pediatric Lung Diseases; Grant Fundamentals; The Translational Biology of Lung Cancer; Quantitative Assessment of Lung Structure; Clinical Respiratory Physiology & Pathophysiology Master Class; Respiratory Neurobiology; and Mastering Clinical Teaching Skills for Pulmonary & Critical Care. Contact thoracic.org/go/pg-courses; for registration call (212) 315-8658, e-mail conference@thoracic.org.

THOMAS PETTY DIED

Dr Thomas L. Petty, the pioneer in the use of continuous oxygen therapy for patients with chronic obstructive pulmonary disease and other lung disorders, recently died from pulmonary hypertension. He was 76. His research led to the widespread use of home oxygen therapy, which he used himself. Petty was the first to puncture an artery to measure arterial blood gasses and was the co-discoverer of adult respiratory distress syndrome. The Los Angeles Times reported: in 1963, he realized that compact oxygen canisters developed by NASA were becoming commercially available, and he suspected that they could be used by patients to administer oxygen to themselves at home. Other pulmonologists had been reluctant to attempt such therapy, however, because of the then-prevailing belief that persistent use of oxygen would lead to unusually high levels of carbon dioxide in the blood with deleterious effects. He and his colleagues initially studied six patients with COPD. After a month on the oxygen therapy, all six patients reported less fatigue and a higher quality of life. Petty was also able to demonstrate that there was no buildup of carbon dioxide in their blood. In the 1970s, Petty and his colleagues organized a trial on 203 patients in which oxygen was administered around the clock. They reported in 1980 that the continuous therapy significantly elongated patients' lives. In 1967, Petty and Dr David G. Ashbaugh of the University of Colorado and their colleagues were the first to describe and name ARDS. Petty was summoned to India as a consultant after the 1984 Bhopal disaster, in which the release of pesticide from a Union Carbide plant killed as many as 40,000 people. He wrote more than 30 books and published more than 800 articles in journals. He was also the founding chairman of the National Lung Health Education Program. Thomas Lee Petty was born in Boulder, CO, on Dec 24, 1932. He began working at age 12 delivering the Boulder Camera and held various jobs at the newspaper throughout his school years to pay for his education at the University of Colorado, working as a janitor, operating lead-melting machines for Linotypes and serving as assistant circulation manager. He received his medical degree from the University of Colorado in 1958. He is survived by his wife, a daughter, two sons and eight grandchildren. Reported by Thomas Maugh in the Los Angeles Times, copyright © 2010, The Los Angeles Times. Information from The Los Angeles Times article has been edited.

GOOD LUNGS

Asthmatics with higher blood levels of vitamin D have better lung function than those with lower levels, according to researchers at National Jewish Health, in Denver. Researchers enrolled 54 nonsmoking asthmatics, assessed their levels of serum vitamin D and tested their lung function and airway hyper-responsiveness, as well as the subjects' response to steroid treatment. With decreasing levels of vitamin D, subjects performed more poorly on tests of lung function and airway hyperresponsiveness. Also, the lower the vitamin D level, the worse the subjects tended to perform on tests of lung function and airway hyperresponsiveness, which nearly doubled in subjects with serum levels of vitamin D below the sufficient threshold level of 30ng/ml, when compared to subjects with

higher levels. A lower level of vitamin D was associated with increased production of TNF-α by immune cells in the blood, raising the possibility that low vitamin D levels could be linked to enhanced inflammation in asthma. Vitamin D levels were also inversely correlated with BMI: the higher the BMI, the lower the vitamin D levels. The researchers concluded that vitamin D levels influence lung function, bronchospasm and therapeutic response to steroids.

BREATHLESS

Women with pulmonary arterial hypertension experienced significant reduction in breathlessness using continuous IV treprostinil, according to researchers at the University of Rochester Medical Center, NY. The Rochester study measured patients' feelings of breathlessness during a six-minute walk and how far they could go before having to stop. During 12 weeks of treatment with treprostinil or placebo, researchers found that patients treated with treprostinil could walk an average of 83 meters further in six minutes, a 30% increase. Patients taking the study drug scored Borg scale 2.0 units better on average than patients on placebo. Another measure was whether treprostinil improved PAH patients' New York Heart Association (NYHA) functional class. Most patients started the study with Class III heart failure. Intravenous treatment with treprostinil shifted patients on average from Class III to Class II. As the study was designed, anyone whose condition started to worsen was immediately rescued with a switch from placebo to active therapy. Treatment with treprostinil was also associated with lowers levels of Ang-2. The study was conducted in India, where patients with PAH today experience a disease course much like patients experienced in the United States during the mid-1990s.

Patients were randomized in a 2:1 ratio, so that more patients got the active drug than did not, but researchers were still able to compare the drug's effect against placebo. All patients were offered treprostinil free of charge for life upon completion of the study.

QUICK AND CHEAP

UK anesthetists affiliated with Swansea University have designed and tested three prototype low-cost ventilators that could provide vital support during major healthcare emergencies. The devices could also be used where resources are limited, such as in developing countries, remote locations or by the military. The anesthetists came up with a gas-efficient ventilator that cost less than $200, usable wherever 2-4 bar oxygen was available, with no pressurized air or electrical requirements. The proptotypes operate on the principle that the energy is taken from approximately 1 l.min-1 compressed oxygen at a supply pressure of 2-4 bar to provide the motive force to ventilate the lungs. After the stored energy has been used to provide motive power, the waste oxygen, which is now at atmospheric pressure, is re-used to enrich the air being drawn into the ventilator before it is delivered to the lungs. A mechanical test lung was used to test the three devices and they were also tested over a range of lung volumes and compliances, which indicated that the oxygen consumption was considerably lower than that of the commercially available gas powered ventilators currently on the market. The designers said the devices could be used anywhere that 2-4 bar oxygen is available and could even run on hospital compressed air, using very little air from the hospital's compressor reservoir. For full details on the devices, see: A low oxygen consumption pneumatic ventilator for emergency construction during a respiratory failure pandemic. Williams et al. Anaesthesia.

LONG TERM IMPACT

The impact of COPD on health related quality of life has been studied by researchers at the EVOCA Study Group in Barcelona. The investigation compared the treatment of COPD exacerbations with moxifloxacin (400 mg/day for five days) and amoxicillin/clavulanate (500/125 mg three times a day for 10 days). Eligible patients for the research were adults over 40 years of age, smokers or ex-smokers of at least 10 pack-years, with chronic bronchitis. Family physicians recruited 236 patients with stable COPD. The study population of 229 patients, 218 men and 11 women, with a mean age of 68.2 years and stable COPD, participated in a prospective, observational study of two years' duration. The results show that COPD exacerbations occurred in 136 patients (124 patients received the study medications). The differences between baseline and the final visit were higher for moxifloxacin compared with amoxicillin/clavulanate. The same findings were observed in patients with two or more exacerbations. The conclusions of the study indicate that in COPD outpatients, treatment of exacerbations with moxifloxacin had a more favorable long-term effect on quality of life than amoxicillin/clavulanate. For the complete study, visit Dove Medical Press Ltd.

DON'T INHALE

According to a researcher at the University of Leicester, UK, despite their usefulness in rapidly relieving asthma, relievers may cause asthma to worsen when used too frequently. Moreover, they are not always as effective as predicted. When lung mast cells are exposed to reliever drugs, in the presence of both IgE and stem cell factor, relievers lose their ability to prevent chemical release from mast cells. Interestingly, under

these circumstances, relievers may actually cause mast cells to release more chemicals, causing asthma to worsen. Researchers say their studies might have explained why reliever drugs are not always as effective as predicted, and why they might worsen and destabilize asthma. They noted that if the function of the stem cell factor in the lungs of asthmatic patients can be inhibited, reliever drugs such as salbutamol might be more effective. Scientists at Asthma UK noted that people who use their reliever inhalers too often, without using a preventer inhaler, are putting themselves at risk of worse asthma symptoms.

PREDICTION

The presence of the Streptococcus pneumoniae in samples that can be easily obtained in clinics and emergency rooms may predict risk of severe disease in H1N1 pandemic influenza, according to researchers at Columbia University and Argentina's National Institute for Infectious Diseases. MassTag PCR, a method for sensitive, simultaneous surveillance and differential diagnosis of infectious diseases, found a strong correlation between the presence of Streptococcus pneumoniae and increased risk for severe disease. Researchers examined 199 nasopharyngeal samples of people with H1N1 infections in Argentina, 39 severe and 160 mild cases. They used 454 pyrosequencing and classical Sanger sequencing methods to test for viral evolution toward increased virulence. MassTag PCR found that the presence of S. pneumoniae in the majority of severe cases was associated with a 125-fold increased risk of severe disease. These results imply that S. pneumoniae is important in the pathogenesis and prognosis of H1N1pdm-associated disease. Whether this effect is associated with all S. pneumoniae or only with specific serotypes remains to be determined. Easily accessible samples such as nasopharyngeal swab samples may be used as an index to risk of severe disease. Multiplex diagnostic methods like MassTag PCR can enable rapid detection of a broad spectrum of viral and bacterial agents and inform clinical care. The above study is available online at Plos One.

WEIGHT, HEIGHT, SEX

Researchers from Newcastle University in the UK have found that poor lung function is likely influenced by weight, height and gender. They analyzed health data from 252 fourteen year old patients and followed up for 122 of the patients when they were age 49 to 51. Results showed that several factors were related to poorer lung function at age 14, including lower height, lower BMI, being breast-fed for less than 4 weeks, and childhood respiratory disease. The factors that predicted a decline in lung function between the ages of 49 to 51 years were cigarette smoking, having a higher FEV1 at age 14, and being female. Researchers noted that women reach their maximum FEV1 at a younger age than men, which was perhaps why the lung function of women declines at a higher rate than that of men. For details, see the January issue of Chest.

NATURAL

A naturally occurring lipid in the lungs can prevent RSV infection and inhibit spread of the virus after an infection is established, according to researchers at National Jewish Health. The findings also help explain how the lipid, known as POPG (palmitoyl-oleoyl-phosphatidylglycerol), helps the lung tolerate a daily barrage of inhaled inflammatory irritants. Lipids and proteins in surfactant fluid prevent collapse of the air sacs and contribute to immunity. However, the function of POPGs has been unknown. Previous research has shown that POPG reduces inflammation in the lung and suggested that it might play a role in RSV infection. Researchers showed that inoculation with POPG before RSV exposure prevents RSV infection, as well as cell death and inflammation associated with RSV infection. In mice, prophylactic intranasal inoculation with POPG reduced the RSV infection-rate by a factor of 1,700, and prevented the infiltration of inflammatory cells into the lung that can cause tissue damage. The researchers also showed that application of POPG to cells in culture after a viral infection is established dramatically arrests the spread of infection to neighboring uninfected cells. POPG works by binding to RSV, thus preventing it from binding to receptors on cell surfaces. POPG also binds to CD14 and MD2, cell-surface molecules that detect bacterial endotoxin and initiate inflammatory responses. The suppression of inflammation by POPG helps explain how healthy people can routinely inhale low environmental levels of endotoxin without mounting a robust inflammatory immune response. In essence, POPG sets a high tolerance threshold for endotoxin in the lung, thereby preventing chronic inflammation. It also suggests that supplemental POPG may be helpful in damping down

the inflammatory response and the "cytokine storm" that accompanies severe bacterial infections and sepsis. POPG also has been safely administered to millions of premature infants as part of a lipid mixture to protect their lungs. It is also a small molecule that is easily synthesized and is chemically stable.

GENE GENIUSES

A new gene therapy may prevent the progression of emphysema, according to researchers at Boston University School of Medicine. Alpha-1 Anti-trypsin Deficiency is the most common inherited form of emphysema seen in young people due to a mutation in the Alpha-1 Anti-trypsin gene. This genetic disease predisposes affected individuals to early emphysema and cirrhosis of the liver. According to the researchers, gene transfer into specific cell lineages in vivo remains an attractive yet elusive approach for correcting inherited mutations. Although a variety of techniques have been developed to deliver DNA molecules to cells in vitro, in vivo gene transfer has been limited in many cell types by inefficient gene delivery as well as the limited life-span of differentiated cell types. Using mice, the BUSM researchers discovered a system to deliver genes selectively to as many as 70% of a mouse lung's alveolar macrophages. This method of gene transfer achieved localized secretion of therapeutic levels of human alpha-1 antitrypsin (hAAT) protein in lung epithelial lining fluid. The progression of emphysema in mice exposed to elastase was significantly improved by the gene therapy as evidenced by improvements in lung compliance and alveolar size. After 24 weeks of sustained gene expression, no humoral or cellular immune responses to the human hAAT protein were detected. The results challenge the dogma that lung macrophages are short-lived and suggest these differentiated cells as a target cell that may be considered for in vivo gene therapy applications including the sustained correction of hAAT deficiency.

In another gene study, pediatric researchers have identified a novel gene, DENND1B, involved in childhood asthma. Researchers at The Children's Hospital in Philadelphia, implicated a location on chromosome 1 associated with moderate-to-severe childhood-onset asthma. Previously, researchers had identified only one other asthma-susceptibility gene. In this current study, researchers sampled 793 white North American children with persistent asthma, compared to control group of 1,988 children. They replicated the study in a separate group of 2,400 European subjects and controls, then did further analyses on a third group of 3,700 black children. By analyzing a large cohort of children with moderate to severe asthma, all of whom require controller medications on a regular basis, the researchers managed to enrich the study for genetic signals and achieve sufficient statistical power to uncover and replicate a novel asthma gene. In addition to observing the previous results for chromosome 17, researchers found a novel location on chromosome 1q31, with eight single nucleotide polymorphisms (SNPs) associating robustly with asthma. A "snip" (SNP) is a change to a single chemical base along the DNA helix. Within this region on chromosome 1q31 the gene with an apparent role in asthma is DENND1B, already suspected as a player in the body's immune response. DENND1B expresses a protein of the same name, which is active in particular types of dendritic cells and specific T lymphocytes, including natural killer cells. Both of these immune cell subtypes form cross-talks between them (the antigen presenting synapse) and regulate how the body responds to foreign material such as viruses, bacteria and allergens. Researchers now know that the DENND1B gene and its protein are involved in the release of cytokines. The gene mutations in DENND1B appear to lead to overproduction of cytokines that subsequently drive hyperresponsiveness in asthma patients. Because this gene seems to regulate many different cytokines, intervening in this pathway has great potential for treating asthma.

PRODUCTS

HAITI HELP

Dräger responded to Haiti's earthquake victims by donating 16 ventilators and two anesthesia machines to the University of Miami for use at a 300-bed field hospital, including operating room suites. Dräger provided 16 Carina-home ventilators and two anesthesia machines to aid earthquake victims. This donation came at the request of the University of Miami, where an international effort to create a 300-bed field hospital at the Port-au-Prince airport took place. Dräger was able to respond immediately because the equipment was onsite at the logistics staging center in Miami within 36 hours. Additionally three field staff employees volunteered their time and clinical expertise to assist with the effort to operate the field hospital.

BEST

Dräger's Medical Division won the "Best of Show" Exhibit Award at the 55th Annual AARC Congress held in San Antonio. The AARC Congress is the nation's largest gathering for members of the respiratory care community to share technical innovations and clinical advancements. Approximately 6,000 respiratory therapists, physicians, and other clinicians attend the show annually.

Left to right: Timothy Myers (AARC), Ed Coombs, Sebastian Kassner, Nancy Morrison, Sam Larson, Marion Varec, Arno Wolters, and Karen Stewart (AARC).

CLINICAL UPDATE

Dartmouth-Hitchcock Medical Center and Masimo, the inventor of Pulse CO-Oximetry and Measure-Through Motion and Low Perfusion pulse oximetry, jointly announced the peer-reviewed publication of an in-depth, 21-month clinical study on the impact of the Masimo Patient SafetyNet remote monitoring and clinician notification system. The study, featured in the February 2010 issue of Anesthesiology, is the first published report to demonstrate that continuous pulse oximetry monitoring and clinician notification in post-surgical patients on the general floor leads to a "significant drop" in key clinical outcome

measures, including 65% fewer rescue events, 48% fewer ICU transfers, and reduced annualized ICU time by 135 days.[1] In the study, orthopedic patients were monitored by measure-through motion and low perfusion pulse oximetry finger probes connected to a computer that notified nurses when physiological abnormalities were detected. These abnormalities are often the first sign that a more serious situation may be developing. Dr Andreas Taenzer and a team of clinicians at Dartmouth-Hitchcock Medical Center used Masimo Patient SafetyNet which combines the gold-standard performance of Masimo SET pulse oximetry at the point of care with remote monitoring and wireless clinician notification via pager, in a 36-bed post-surgical orthopedic unit. When comparing data collected for 11 months before and 10 months after implementation of Patient SafetyNet in the 36-bed unit as well as two other post-operative units with only standard monitoring equipment and protocols in place, researchers found that Patient SafetyNet-monitored patients experienced approximately 65% fewer rescue events (1.2 vs 3.4 per 1,000 patient discharges) and 48% fewer ICU transfers (2.9 vs 5.6 per 1,000 patient days), freeing up 135 ICU days per year, while the two comparison units had no change. In an accompanying editorial about the impact of the study, John P. Abenstein, MSEE, MD, at the Department of Medicine, Mayo Clinic, in Rochester, MN, wrote that the "implications of this study are broad" and its results could "have important implications for hospital wards throughout the country."[2] According to Abenstein, "The literature and each of our own clinical experiences have examples of physicians on rounds, or nurses coming to check patients who have been dead for hours." He continued, "We believe that Taenzer et al have shown us a glimpse of the future," and, "Not only will such systems allow us to improve the quality of care of our patients, but will also be a key to lowering costs." Masimo Founder and CEO, Joe Kiani, stated, "There have been other studies that have shown the positive clinical and cost outcome in neonates and infants by using Masimo SET pulse oximetry, but this is the first time with adults. Over 20 years ago, we set out to solve the motion artifact and low perfusion problems of pulse oximetry, which were the bane of pulse oximetry and were thought to be unsolvable at the time. We thought by overcoming the motion artifact problem, we could improve patient outcome and reduce cost of care by taking noninvasive monitoring to new sites and applications... With this groundbreaking study, our vision is that in the near future, hospitals will utilize this important Patient SafetyNet technology to care for all of their patients, the same way airbags have become ubiquitous in cars today." *1. Taenzer, Andreas H.; Pyke, Joshua B.; McGrath, Susan P.; Blike, George T. "Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers: A Before-and-After Concurrence Study." Anesthesiology, February 2010, Vol. 112, Issue 2. Available online at: http://journals.lww.com/anesthesiology/Abstract/publishahead/Impact_of_Pulse_Oximetry_Surveillance_on_Rescue.99692.aspx. 2. Abenstein, John P.; Narr, Bradly J. "An Ounce of Prevention May Equate to a Pound of Cure: Can Early Detection and Intervention Prevent Adverse Events?" Anesthesiology, February 2010, Vol. 112, Issue 2. Available online at: http://journals.lww.com/anesthesiology/Citation/publishahead/An_Ounce_of_Prevention_May_Equate_to_a_Pound_of.99693.aspx.*

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CONTRACT

Radiometer America announced a new agreement with Amerinet Inc, a leading national healthcare group purchasing

organization, to supply blood gas products and services. Through December 31, 2012, the contract offers significant savings to Amerinet members on products including laboratory analyzers, reagents, consumables, and blood gas/electrolytes. Contact radiometeramerica.com.

TOP RATED

In the recent MD Buyline Quarterly User Satisfaction Report, Hamilton Medical's ventilation systems have earned the top ratings for ventilation system performance and reliability in the ventilation industry. Once again, Hamilton Medical has earned the top composite score in ventilation as it has in the previous eight quarterly User Satisfaction Reports published. Hamilton is in its 26th year of serving the ventilation industry. As of this year, all new ventilation systems purchased from Hamilton Medical, Inc include a one year labor and two year parts warranty on every system. Contact (800) 426-6331, hamilton-medical.com.

CLEARANCE

Masimo, the inventor of Pulse CO-Oximetry and Measure-Through Motion and Low Perfusion pulse oximetry, announced FDA clearance of its latest innovation—Masimo Rainbow SET Acoustic Monitoring, providing noninvasive and continuous respiration rate (RRa) that is accurate, easy-to-use, and enhances patient compliance. Masimo Rainbow SET Acoustic Monitoring may enable earlier detection of respiratory compromise and patient distress—offering a breakthrough in patient safety for post-surgical patients on the general floor. The limited market release allows select hospitals to be the first to benefit from the new technology. Continuous monitoring of respiration rate is especially important for post-surgical patients receiving patient-controlled analgesia (PCA) for pain management, as sedation can induce respiratory depression and place patients at considerable risk of serious injury or death.[1-4] Although the Anesthesia Patient Safety Foundation (APSF) recommends continuous oxygenation and ventilation monitoring in all patients receiving opioids,[5,6] current methods for respiration rate monitoring are limited by accuracy and patient compliance. Masimo Rainbow SET Acoustic Monitoring features an innovative adhesive sensor with an integrated acoustic transducer that is easily and comfortably applied to the patient's neck to detect upper airway acoustic vibrations on the surface of the skin during the respiratory cycle. Using patented acoustic signal processing that leverages Masimo's revolutionary Signal Extraction Technology (SET), the respiratory signal is separated and processed to display continuous respiration rate. When Masimo Rainbow SET Acoustic Monitoring is used in conjunction with Masimo Rainbow SET Pulse CO-Oximetry and the Masimo Patient SafetyNet Remote Monitoring and Clinician Notification System,[2] clinicians can follow key indicators of oxygenation with Masimo gold standard SpO_2, ventilation with the breakthrough RRa, circulation with Masimo measure through motion pulse rate (PR), and bleeding with Masimo noninvasive and continuous hemoglobin (SpHb)—enabling them to monitor more patients, more safely, than ever before. *1. Joint Commission on Accreditation of Healthcare Organizations. Sentinel Event Alert: Patient controlled analgesia by proxy. Chicago: JCAHO, 2004; 2. Institute for Safe Medication Practice. Safety issues with patient-controlled analgesia: Part 1-How errors occur. Huntingdon Valley: ISMP, 2003; 3. Institute for Safe Medication Practices. Safety issues with patient-controlled analgesia: Part II–How to prevent errors Huntingdon: ISMP, 2003; 4. Bird M. Acute pain management: a new area of liability for anesthesiologists ASA Newsletter. Park Ridge: American Society of Anesthesiologists, 2007; 5. Weinger MB. Dangers of Postoperative Opioids: APSF Workshop and White paper address prevention of postoperative respiratory complications. APSF Newsletter, 2006;21:61-7, http://www.apsf.org/assets/Documents/winter2007.pdf; 6. Stoelting RK, Weinger MB. Dangers of Postoperative Opioids—Is There a Cure? APSF Newsletter, 2009;24:25-26. http://www.apsf.org/assets/Documents/summer2009.pdf.*

SAFE CPAP

Mercury Medical, recognized as a leader in providing the highest quality of respiratory, anesthesia and critical care products and service, introduced its Flow-Safe CPAP System. Mercury notes that this is the "first disposable CPAP system with built-in safety features for less." It incorporates a built-in manometer and pressure relief valve on all units. Flow-Safe is the latest innovation for treating Acute Pulmonary Edema (APE). Each unit is completely disposable and highly portable, making it ideal for hospital and pre-hospital use. Contact mercurymed.com.

INFLAMED

A group of asthma clinicians and researchers has issued a consensus paper recommending that inflammation monitoring using exhaled nitric oxide should be part of the routine clinical management of asthma in conjunction with other conventional methods. The results were announced by Aerocrine AB. The panel recommended that FENO should be used to determine the presence or absence of eosinophilic airway inflammation, to determine the likelihood of steroid responsiveness, to measure response to steroid therapy and level of inflammation control. In addition, the panel concluded that FENO is a useful tool to monitor patient ICS treatment adherence and allergen exposure. The panel also noted that private payer resistance is still common, and some insurance carriers refuse reimbursement for FENO testing on the grounds that it is investigational, experimental or unproven. However, the consensus panel disagreed. Aerocrine develops medical devices and the method to monitor airway inflammation by measuring FENO. Aerocrine's first device received CE marking in Europe in 2000 and FDA clearance in the US in 2003. NIOX MINO, the first and only handheld device for FENO monitoring in clinical practice, received CE marking in 2004 and FDA clearance in early 2008. To date, more than three million patient tests have been performed around the world using Aerocrine's FENO monitoring systems.

CLEAR AND EASY

ndd Medical Technologies announced 510 k clearance on its Easyone Pro Respiratory Analysis System. EasyOne Pro is the first lung function instrument to allow single breath DLCO measurement outside of the lung function laboratory. ndd's unique ultrasound technology eliminates complex calibration and maintenance procedures as required in today's laboratory equipment. The device allows physicians to provide patients with prompt and accurate diagnosis and treatment. Contact nddmed.com.

FINGER ON THE PULSE

The GO_2 personal finger pulse oximeter from Respironics is an accurate, affordable, and durable personal finger pulse oximeter that monitors oxygen saturation and heart rate. GO_2 delivers accuracy comparable to professional oximeters, and features a patient-oriented, easy-to-read display. It is manufactured in North America and backed by Philips Respironics service and warranty support. GO_2 uses one AAA battery for approximately 2,400 spot checks. For more information, contact go2.respironics.com.

THE EASY LIFE

WHAT: Philips Respironics has introduced the EasyLife nasal mask for the treatment of obstructive sleep apnea (OSA). With its patented Auto Seal technology and minimal number of parts, EasyLife is an extraordinarily easy mask for both health care professionals and patients to use. **WHY**: The innovative, lightweight design of EasyLife features a unique dual-cushion construction—the inner cushion creates an instant, self-adjusting seal that adapts to patient movements, while the outer cushion provides comfortable support. Because the forehead pad adjusts automatically, a number of traditional mask adjustments are nearly eliminated except for intuitive headgear adjustments. With only four parts—mask frame, headgear, outer support cushion, and inner seal cushion—the mask is easy to assemble and clean. "The EasyLife mask is so easy, it practically fits itself," said Gretchen Jezerc, director, US Marketing, Sleep Disordered Breathing, Philips Home Healthcare Solutions. "From assembly to fitting to adjusting, sleep labs and homecare providers will find it an easy choice for a set-up mask. Patients will appreciate its comfort and the way it maintains a seal throughout their nighttime movements. It is truly a breakthrough in the patient interface market." The four available cushion sizes—small, medium, medium wide, and large—each fit one of two frames. To further simplify fitting and inventory management, FitPacks with two sizes of cushions are available. DuoPacks with multiple cushions of the same size also are offered to support supply replacement initiatives for patients. Contact respironics.com.

SLEEEEP

Royal Philips Electronics announced the introduction of BiPAP autoSV Advanced, its latest device for treating complicated sleep-disordered breathing patients. The enhanced system combines clinically-proven technologies in one compact device to more effectively manage and treat the most challenging sleep apnea cases. These range from complex sleep apnea, which occurs when patients being treated for Obstructive Sleep Apnea develop Central Sleep Apnea when Continuous Positive Airway Pressure (CPAP) is administered, to Cheyne-Stokes Respiration, a periodic breathing disorder. When Respironics released the first bi-level positive airway pressure device in the late 1980s, it made a significant clinical impact for treating sleep apnea, a role it continues today. BiPAP autoSV Advanced is Philips Respironics next generation servo ventilation (SV) device, updated to make patient management nearly automatic and optimize therapy for complicated patients. It has the unique ability to manage the airway and assure proper ventilation by continually monitoring and adjusting to patients' changing therapy needs. A major advancement in BiPAP autoSV Advanced is an auto adjusting EPAP, utilizing at its core the clinically proven REMstar Auto titration algorithm.[1,2] With this addition, BiPAP autoSV Advanced enhances treatment by automatically distinguishing between obstructed and clear airway apneas and adapting pressure to patients' needs as their conditions change due to weight, alcohol use, or lifestyle. The automatic adjustment of EPAP simplifies titration and achieves efficacy at the minimum pressure levels. In addition, BiPAP autoSV Advanced adds the proven Bi-Flex technology[3] which assures patient comfort by providing pressure relief during exhalation and at critical transition points. "Unlike standard CPAP and bi-level therapies, this highly developed system is specifically designed to take on challenges of managing complicated sleep apnea cases," says Eli Diacopoulos, Director, Global Product Marketing, Sleep Therapy, for Philips Home Healthcare Solutions. "Combining our core technologies into one unit furthers our efforts to make the complex simpler to manage and assure the very best treatment possible for these patients." Respironics advanced technologies, such as Digital Auto-Trak, match flow to the patient's own breathing. The clinically proven SV algorithm[4] monitors peak flow and can rapidly normalize breathing patterns of patients with complex sleep apnea conditions with breath-to-breath adjustments of pressure support. In the presence of central apneas, when care must be taken not to over- or under-ventilate a patient, the delivery of automatically calculated back-up breaths encourages spontaneous breathing at the patient's own natural rate. BiPAP autoSV Advanced also offers integrated heated humidification and built-in digital data storage. The Encore patient management system automatically collects vital patient information and enables the entire care team to continuously monitor and track treatment progress and transfer new or updated prescriptions. Contact philips.com. *1. Fietze, I., et al., Respiration 2007;74:279-286; 2. Mulgrew, A., et al., Sleep Breath 2007;11:31-37; 3. Ballard, R., et al., JCSM; 2007;3:706-712 4. 4.*

Arzt, M., et al., Chest 2008;134;61-66. Respironics, autoSV, Auto-Trak, Bi-Flex, BiPAP, and Encore are trademarks of Respironics, Inc. and its affiliates.

WEBBED

Siemens Healthcare announced a one-stop shop for ultrasound application upgrades and options, now available through Siemens Healthcare's webShop at usa.siemens.com/webshop. By providing ultrasound users with the opportunity to browse through and sample new applications for their Siemens ultrasound imaging equipment, webShop offers a smart and easy way to discover the clinical benefits of the latest ultrasound applications. webShop provides on-demand access to a variety of clinical application upgrades, including a selection of syngo workstation applications such as automated measurement packages, image enhancement technologies, and contrast-enhanced ultrasound. Customers can quickly discover the latest applications to suit their need for specific products. Before purchasing, users can request trial licenses for the options they are interested in and experience the benefits of new upgrades firsthand, for a limited time. Contact usa.siemens.com/webshop.

RECOVERY

Radiometer's Economic Recovery Program enables you to purchase new equipment while reducing your operating costs by up to 10%. With this program, you can benefit from the latest Radiometer technology while controlling your costs well into the future. Radiometer sponsored several POC Network webinars in January, including two featuring Geisinger Health System's Jay Jones and one featuring Massachusetts General's Kent Lewandrowski. Topics will include lean point-of-care testing and implementing POCT for better patient outcomes in the ED. Webinars are free to participants; PACE credits are available. Radiometer also announced the availability of a training DVD for the ABL800 FLEX analyzer. The DVD contains step-by-step video demonstrations of the analyzer. Competency exams are included on each DVD. Call (800) 736-0600, opt 1, and ask for part # CD-ABL800. Contact radiometer.com.

DOSE PROTECTION

Recognized as one of the leading pediatric healthcare centers in the United States, St Louis Children's Hospital in St Louis is further enhancing its nationally renowned pediatric care program with the installation of a SOMATOM Definition AS computed tomography (CT) scanner from Siemens Healthcare. The SOMATOM Definition AS is the world's first adaptive scanner, which intelligently adapts, on the fly, to the patient, for aiding in dose protection, as well as adapting to new dimensions and space. Even though CT is a crucial medical imaging tool in diagnosing illness and disease in children, there is always a concern over the amount of radiation dose a pediatric patient receives. Medical institutions, such as St Louis Children's Hospital, strive to provide the best medical imaging exams as possible, while ensuring one of the best methods for its patients. The addition of the SOMATOM Definition AS provides the link between dose protection and imaging excellence for Children's Hospital's young patients. In the July 2009 issue of Radiology,* a team of researchers evaluated the potential effectiveness of adaptive collimation in reducing CT radiation dose owing to z-overscanning (one of the factors responsible for radiation burden in spiral CT examinations) by using dose measurements and dose simulations. The data revealed that by using adaptive section collimation, a substantial dose reduction of up to 10 percent was achieved for cardiac and chest CT when measurements were performed free in air and of 7 percent, on average, when measurements were performed in phantoms. For scan ranges smaller than 12 cm, ionization chamber measurements and simulations indicated a dose reduction of up to 38 percent, according to the team's findings. The research team concluded that adaptive section collimation allows substantial reduction of unnecessary exposure owing to z-overscanning in spiral CT. It can be combined in synergy with other means of dose reduction, such as spectral optimization and automatic exposure control. CARE Dose 4D, Siemens' real-time dose modulation, assists in guaranteeing an unparalleled combination of maximum image quality at minimum dose for every patient in every spiral scan. The entire SOMATOM Definition AS family of scanners comes with adaptive dose shield and set of pediatric protocols to provide optimal patient care. In addition to its extraordinary performance, the SOMATOM Definition AS is able to adapt to the space constraints many facilities face today. Featuring a large bore and high-capacity patient table, the scanner requires very little floor space, with an 18-m^2 footprint. This allows the Definition AS to fit into rooms that have traditionally been too small for high-end CT scanners. The technology couples components in a dynamic manner, such as a large-volume coverage area with a 200 cm scan range and up to 330 msec rotation time. These features allow even the most clinically challenging patients (ie, trauma patients) to be imaged rapidly, from head to toe, with minimum difficulty. **Deak P, Langner O, Lell M, Kalender W. Effects of adaptive section collimation on patient radiation dose in multisection spiral CT. Radiology: Volume 252: Number 1–July 2009. Contact usa-siemens.com.*

A HELPING SPONSOR

Clinical Foundations, a patient-focused education program dedicated to helping respiratory care professionals stay current on clinical trends, has recently published a new edition titled "Pathogens Associated with the Intensive Care Unit Environment–Considerations for the Respiratory Therapist." This program has been approved for 2.0 contact hours of continuing education (CRCE) by the American Association for Respiratory Care (AARC). The edition is authored by John Davies, MA, RRT, FAARC a registered respiratory therapist and Clinical Research Coordinator at the Duke University Medical Center, Durham, North Carolina. Hospital-acquired infections are associated with increases in ICU and hospital length-of-stay, costs, morbidity and mortality.[1] The risk of developing pneumonia increases from 3 to 10 times when the patient is intubated and receiving mechanical ventilation.[2] In particular, the reported mortality attributable to ventilator associated pneumonia (VAP) is in the neighborhood of 20% to 30% higher than with the underlying disease alone.[2] Clinical Foundations provides a comprehensive review of the pathogens associated with hospital-acquired infections, methods to prevent ventilator associated pneumonia, and available equipment to limit the likelihood of infection. A panel of four experts discuss the role of the respiratory therapist in ventilator associated pneumonia diagnosis and treatment as well as strategies for preventing and treating VAP. As part of a commitment to helping healthcare professionals improve their skills, each edition of Clinical Foundations is fully accredited by the AARC for Continuing Respiratory Care Education (CRCE). The program is sponsored by Teleflex Medical. Teleflex Medical, through the Hudson RCI brand of respiratory products, has been delivering products that make breathing easier for over 50 years. *1. Beardsley JR, Williamson JC, Johnson JW, Ohl CA, Karchmer TB, Bowton DL. Using local microbiologic data to develop institution-specific guidelines for the treatment of*

hospital-acquired pneumonia. Chest 2006;130(3):787-793. 2. Craven DE, Chroneou A, Zias N, Hjalmarson KI. Ventilator-associated tracheobronchitis: the impact of targeted antibiotic therapy on patient outcomes. Chest 2009;135(2):521-528. Contact clinicalfoundations.org or teleflex.com.

BLOOD GAS

Siemens RAPIDLab 1200 series of blood gas analyzers offers neonatal bilirubin (nBili) point of care testing with 60 second turnaround time, and detects elevated levels of bilirubin. If undetected, this condition can lead to a variety of health issues in newborn infants, from jaundice to neurological disorders, and in severe cases, brain damage. Siemens neonatal bilirubin (nBili) test requires 100uL sample of whole blood, measuring 2-30 mgdl and does not require any sample preparation, while providing fast and accurate results and does not increase monthly operating costs. Siemens RAPIDLab systems, nBili testing is conducted as part of a neonatal test panel that includes blood gas, pH, electrolytes, metabolites, total hemoglobin and CO-oximetry, with no additional reagents needed for nBili testing. For additional information, visit usa.siemens.com/bloodgas.

HOLD YOUR NOSE

The NG Tube Holder from Dale Medical Products, Inc is an easy to use naso-gastric tube holder that is individually packaged and designed to remain in place comfortably for up to three days is available from Dale Medical Products, Inc of Plainville, MA. The Dale NasoGastric Tube Holder is a woven fabric nose pad that securely holds naso-gastric feeding and aspiration tubes such as: Salem sump-, Levin stomach-, naso-entric feeding- and naso-gastric intestinal tubes. Designed to prevent nasal irritation, erosion or necrosis, this comfortable alterna-tive to taping has dual tabs for holding two tubes at once and can remain in place for up to three days. Providing maximum tube security, without compromising patient comfort, the Dale NasoGastric Tube Holder is a "one size fits all" latex-free solution. Easy to apply, the nose pad stretches and conforms for a custom fit that won't slide off the nose, uses a skin-friendly adhesive, and the tips on each tab are non-adherent to let care-givers remove them without scissors. The Dale NasoGastric Tube Holder is priced at $1.60 each (suggested list) and comes individually unit packaged and supplied 50 per box. Free samples are available upon request. For more information contact dalemed.com.

NEWS FEATURE

Intravenous Infusion Sedation Among Mechanically Ventilated Patients

Jeff Borrink, BS, RRT

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

Patients in ICUs often require invasive monitoring and support, which can lead to anxiety, agitation, pain, etc, and subsequently intravenous infusion sedation is often considered to be an important element in the care of these patients, especially for those patients requiring mechanical ventilation.

Many studies compare the efficacy of different forms of intravenous infusion sedation for critically ill patients, but little is known about the actual usage rates of these medications. Recent guidelines for sedation in the United States cite Lorazepam (eg Ativan) as the sedative of choice for use in most ICU patients. However, existing studies that try to quantify sedation practice rely on surveys, and surveys are poorly equipped to address the issue of stated practice vs actual practice, and perception of practice can often times differ from reality of practice.

The authors of a recent article published in Critical Care Medicine, Waunsch et al, sought to describe the actual current use of IV sedation in mechanically ventilated patients in ICUs across the United States. One hundred seventy-four ICUs contributed data on all patients who received mechanical ventilation from 2001 through 2007. Intravenous sedatives examined included benzodiazepines (midazolam and lorazepam), propofol, and dexmedetomidine. Use was defined as having received an intravenous infusion for any time period during the stay in the ICU.

The study looked at whether IV infusion sedation choices changed based on the duration of mechanical ventilation (<96 hours vs >96 hours). They also assessed trends in the use of IV infusion sedation over time and they assessed the use of IV infusions of narcotics (fentanyl, morphine, or hydromorphone) alone, and in patients who received IV infusion sedation.

Of 109,671 mechanically ventilated patients, 56,443 (51.5%) received one or more intravenous infusion sedative drugs. Sedative use increased significantly over time, from 39.7% of patients in 2001, to 66.7% in 2007. Most patients who received intravenous infusion sedation received propofol (82.2%) vs benzodiazepines (31.1%) or dexmedetomidine (4.0%). Of the patients who received intravenous infusion sedation, 66.2% received only propofol, and 16.2% only benzodiazepines. Among patients mechanically ventilated >96 hrs, propofol infusions were more common. Intravenous infusion of narcotics (fentanyl, morphine, or hydromorphone) was used more frequently among patients who received benzodiazepines (70.1%) compared with propofol (23.9%).

The authors concluded that the percentage of mechanically ventilated patients receiving intravenous infusion sedation has increased steadily over time. The majority of the increase in sedation appeared to be due to the increase in the use of propofol, but the overall use of both benzodiazepines and dexmedetomidine went up as well. Propofol infusions were associated with much lower overall use of IV infusion narcotics. Sedation with an infusion of propofol was much more common than with benzodiazepines or dexmedetomidine, even for patients mechanically ventilated beyond 96 hours. These results suggest that propofol is the preferred IV infusion sedation agent in most ICUs in the United States, and has been steadily gaining in popularity compared to other sedatives, even among patients requiring prolonged mechanical ventilation.

Editor's comment: I was somewhat surprised that 1/3 of ventilated patients don't receive any IV sedation at all. Upon further review, the patients receiving no sedation had much lower ventilator LOS (0.8) days and were more likely to be surgical patients. These patients likely already had some anesthesia and sedation "on board" from the OR. The high rate of propofol usage was also associated with much shorter ventilator LOS, which likely reflects the use of propofol to rapidly wean post-operative patients or patients expected to

be rapidly weaned due to the faster wake up time properties of propofol. —Paul Garbarini MS, RRT

Reference: Waunsch H, Kahn J, Kramer A, Rubenfeld G: Use of intravenous infusion sedation among mechanically ventilated patients in the United States. Crit Care Med 2009: 37:3031-3039.

What Happens to ARDS Patients Who Survive?

Paul Garbarini, MS, RRT

Paul Garbarini is Clinical Applications Manager, Hamilton Medical, Inc. This article is from the company's newsletter.

Increasing awareness of the need to implement lung protective strategies for ARDS patients has improved outcomes. As clinicians, we are naturally focused on the acute management of ARDS. Recently an article in Critical Care Medicine reported on the effects of critical illness on adult ARDS survivors and caregivers.

Over 70% of patients reported terrifying vivid dreams or flashbacks of the the ICU. Events such as suctioning and restraints along with the inability to communicate were commonly reported.

On a personal note, recently my mother was intubated for several days due to airway compromise associated with an anaphalytic reaction to a medication. She, however, has absolutely no recall of being in the ICU as of yet. During her stay, we noted increasing doses of sedation due to "agitation," which was concerning due to the known side effects and potential for increasing ventilator length of stay. It was only when we, as a family, were able to explain to her where she was and why, that the anxiety could be reduced. This was despite the fact that both the RNs and RTs did communicate well to her. It seemed that only the familiar voice of a family member had any effect.

The study patient's average ventilator length of stay was 17 days and the average hospital length of stay was 27 days. All the survivors in the study experienced prolonged disability with weakness and cognitive deficits for weeks to months after discharge being most common. The article contains interview quotes from patients and caregivers. Many of these are profound and I'd recommend reading these so we gain an appreciation of the human cost of surviving a critical illness. Indeed, while my mother has no cognitive deficits, she clearly, even with her short ICU stay, is having prolonged weakness. The authors concluded that the profound impact on caregivers' lives and the predominance of weakness after surviving ARDS needs to be further studied as to what interventions can improve the quality of life post-discharge. The study referenced above is from Crit Care Med 2009 Vol. 37, No. 10.

OXIMETRY ROUNDTABLE

Masimo

Tell us about your latest oximetry products.
We recently initiated limited market release of our latest innovation, Masimo Rainbow SET Acoustic Monitoring, offering breakthrough acoustic respiration rate that when used with other clinical variables, may help clinicians assess respiratory status and help determine treatment options. Developed specifically to overcome the limitations of existing methods, Masimo Rainbow SET Acoustic Monitoring provides noninvasive and continuous respiration rate that is accurate, easy-to-use, and enhances patient compliance. As the first-ever acoustic respiration rate technology, it features an innovative adhesive sensor with an integrated acoustic transducer that is easily and comfortably applied to the patient's neck to detect acoustic signals that indicate the respiratory cycle. Then using signal processing that leverages Masimo's patented revolutionary Signal Extraction Technology (SET), the respiratory signal is separated and processed to display the continuous RRa measurement. Select hospitals around the world can begin incorporating this revolutionary new technology into their care pathways and clinical workflows as part of the limited market release initiated December 2009.

How does your oximetry product improve patient care?
Masimo Rainbow SET Acoustic Monitoring has been added to our standard oximetry offering as a way to help clinicians better assess, continuously monitor and track/trend their patient's respiratory status. Continuous monitoring of respiration rate—defined as the number of breaths per minute—is considered a critical vital sign in assessing the physiological status of hospitalized patients because a change in respiratory rate is one of the earliest and most sensitive indicators of patient distress. This is especially important for post-surgical patients receiving patient-controlled analgesia (PCA) for pain management, as sedation can induce respiratory depression and place patients at considerable risk of serious injury or death.[1] Direct monitoring of respiratory status may offer additional significance in patients receiving supplemental oxygen, compared to pulse oximetry monitoring alone. Masimo Rainbow SET Acoustic Monitoring offers several key benefits over existing respiration rate monitoring methods, with the potential to greatly improve monitoring and patient safety in a variety of patient care settings. Current methods for respiration rate monitoring have significant limitations, including patient compliance with capnography, accuracy with impedance pneumography, and intermittent updates with visual monitoring. Masimo Rainbow SET Acoustic Monitoring uses a noninvasive Acoustic Respiration Sensor that is unobtrusive and virtually unnoticeable to the patient, leading to enhanced patient compliance. In fact, an initial compliance study conducted at Loma Linda University Medical Center showed that 14 out of 15 pediatric patients dislodged the capnography nasal cannula in less than 20 minutes, but they all left the Masimo Rainbow Acoustic Respiration Sensor intact.[2] The accuracy of Rainbow Acoustic Monitoring has been shown to be similar to capnography, in a comparison of over 21,000 data points.[3] And lastly, unlike intermittent visual monitoring, Masimo Rainbow SET Acoustic Monitoring provides an automated, continuous measurement of breaths per minute—alerting clinicians of compromised breathing that could indicate airway obstruction or respiratory distress.

Discuss the range of your oximetry product's applications.
Rainbow SET Acoustic Monitoring may have the greatest clinical impact in the general care setting, where patients receiving PCA and opioids for pain relief are at increased risk of life-threatening respiratory depression. By helping to more accurately, reliably,

and automatically detect respiratory changes, clinicians on the general care floors may be able to efficiently monitor more patients, more safely than ever before. Additionally, in recovery settings and post-anesthesia care units (PACU), the combination of Masimo Rainbow SET Pulse CO-Oximetry and Acoustic Monitoring will allow clinicians to noninvasively and continuously measure key indicators of oxygenation (SpO_2), circulation (pulse rate), breathing (RRa), and bleeding (SpHb) to meet current Anesthesia Patient Safety Foundation (APSF) guidelines and increase patient safety for post-surgical patients.

Discuss the cost effectiveness of oximetry and of your product.
Because RRa is available as part of the Masimo Rainbow SET technology platform, there is no additional hardware to purchase. A simple upgrade to existing Masimo Rainbow-compatible devices and an Acoustic Respiration Sensor is all that hospitals will need to incorporate RRa into their patient monitoring protocols—making it broadly available and extremely cost-effective to implement.

What type of training and customer assistance do you offer?
With one of the largest teams of pulse oximetry clinical specialists available, we provide comprehensive customer training and support services, including in-depth "super user" and continuing education training. Our clinical specialists provide the breadth of customer support necessary to ensure unparalleled installation processes and resources. In addition, our dedicated Technical Support Team is available 24/7 to answer questions and help resolve clinical issues related to pulse oximetry equipment. MasimoU (available online at: masimo.com/MasimoU/index.htm), provides accredited and non-accredited courses in a convenient, self-paced online learning environment that allows clinicians to learn about noninvasive pulse oximetry and Pulse CO-Oximetry monitoring capabilities and patient applications. MasimoU modules accredited for Continuing Respiratory Care Education (CRCE) credit include: • Monitoring in Critical Care; • Use of the Pulse Oximeter Waveform as a Noninvasive Functional Hemodynamic Monitor; • Oxygen Transport and Neonatal Pulse Oximetry; • Retinopathy of Prematurity; and • Carbon Monoxide Poisoning. MasimoU non-accredited learning modules include a variety of sensor application and product training courses that help clinicians to maximize the impact of Masimo technologies, features and products on patient care. *1. Weinger MB. "Dangers of Postoperative Opioids." Anesthesia Patient Safety Foundation Newsletter, 2006; Vol 21 No.4.; 2. M. Macknet MD, P. Kimball-Jones MD, R. Applegate II MD, R. Martin MD, M. Allard M.B.Ch.B FRCA. "An improved sensor for monitoring respiration in pediatric patients." Loma Linda University, Department of Anesthesiology; 3. Masimo FDA Submission Data.*

Maxtec

Tell us about your latest oximetry products.
Maxtec offers a lineup of pulse oximeters ranging from simple spot checks oximeters to high quality monitors capable of recording data. The latest spot-check available from Maxtec is the all new OxyWatch MD300 C63 pulse oximeter. This new model features new advanced features such as a shockproof design, a reinforced battery door for increased durability, finger slip resistance, and automatic compensation for any decrease in infrared signal.

How does your oximetry product improve patient care?
Our oximetry products provide professionals with accurate patient SpO_2 monitoring tools in multiple areas of care. Our Pulsox-300i monitor provides high resolution readings that will enable border-line patients to qualify for oxygen therapy. Moreover, the 300i is easy to use and its all-in-one design can improve compliance, thus improving patient care. We offer a full range of oximeters including product that is affordable for approved individual use, and oximeters that are more suitable for professional use.

Discuss the range of your oximetry product's applications.
Our oximetry products are suitable for use within multiple areas of the hospital including areas of pulmonary rehab and cardiac rehab, pre-hospital, home care, physician's offices, surgery centers and even during exercise.

Discuss the cost effectiveness of oximetry and of your product.
As mentioned above, the testing facility obtains a quicker return on investment by way of the Pulsox-300i because it enables them to qualify more patients while reducing overall cost of ownership.

What type of training and customer assistance do you offer?
Maxtec sales representatives are available for product demonstrations. Product manuals and literature are available on our website for download. Lastly, Maxtec offers long warranties and the availability to always speak directly with a customer support team member via our toll-free number should any questions or concerns ever arise.

Nonin Medical

Information provided by Yvonne Leonard, Consumer Products Marketing Manager.

Tell us about your latest oximetry products.
Nonin Medical developed the GO_2 line of personal fingertip pulse oximeters to give chronic respiratory disease patients the choice of a home-use oximeter that is as dependable as the one their respiratory therapist uses. With an influx of unreliable off-brand oximeters, we felt it important that patients have an affordable prescription fingertip oximeter that both they and their respiratory therapist can trust. The GO_2 line empowers these patients with the knowledge of reliable oxygen saturation and pulse rate values without compromising the quality and accuracy that have made us the most trusted name in fingertip pulse oximetry. The GO_2 line offers two different style products (GO_2 and GO_2 LED) to choose from depending on a patient's needs. Both styles are uniquely designed to face the patient during use and are built with Nonin's proven PureSAT SpO_2 technology, (the same technology used in our professional oximeters) while being durable and water-resistant. The GO_2 is our smallest fingertip pulse oximeter and has an LCD screen that displays numbers in black on a light-colored background. It has a built-in automatic backlight that turns on in low light conditions. The GO_2 LED is uniquely designed to rest comfortably across multiple fingers

and has an LED screen that displays numbers in red on a dark-colored background for ultimate contrast and easy viewing in all light conditions.

How does your oximetry product improve patient care?
An accurate SpO_2 measurement is an important factor for successful management of chronic respiratory diseases. The GO_2 line empowers patients to respond in situations where they find themselves feeling strained or short of breath and allows them to take the appropriate action, such as pursed lip breathing or titrating their oxygen, as taught to them by their Respiratory Therapist. And for respiratory therapists, the GO_2 line provides trust in the oxygen saturation and pulse rate values reported by their patients since it's engineered with our proven PureSAT SpO_2 technology—enabling a more effective partnership throughout the course of therapy. With over 20 years of manufacturing, engineering and research experience, we have a long-standing reputation for excellence. In fact, 96% of pulmonary rehab facilities use Nonin.

Discuss the range of your oximetry product's applications.
Having the necessary information is essential for patients to successfully manage their oxygen in order to stay within their prescribed oxygen saturation and pulse rate range. With a GO_2, they are better prepared to: • Adjust their oxygen to meet their daily activity levels; • Get instant feedback on the effectiveness of their breathing techniques; • Improve communication with their clinician due to the reliability of accurate readings. A chronic lung disease diagnosis often requires that adjustments be made in a patient's daily activities, but it does not have to mean a life of limitation. With the ability to know their oxygen saturation at a moment's notice, the GO_2 line provides peace of mind and enables patients to go out for a night at the movies, or up their activity level by walking those extra blocks around the neighborhood, or to simply feel safe around the house. It can also help to promote exercise compliance. With the reassurance of a trusted oxygen monitor by their side, patients will have a level of assurance and be more apt to comply with an exercise regimen.

What type of training and customer assistance do you offer?
Nonin realizes that a pulse oximeter is only one piece of the puzzle when it comes to managing a patient with a chronic respiratory disease. We are committed to offering clinical and patient education resources and are continually developing new materials to help patients better understand their condition. We are especially proud to have worked with the late Dr Thomas Petty to develop the patient booklet, "Your Personal Oximeter: A Guide for Patients." In terms of service, we are dedicated to providing live, real-person customer support from friendly and knowledgeable specialists. We will be here long after the sale and provide an industry-leading 2-year warranty.

Smiths Medical

Information provided by Theresa A. Sikac, Product Marketing Manager

Tell us about your latest oximetry products
Backed by over 20 years experience, the New $SPECTRO_2$ Pulse Oximetry Portfolio draws on proprietary BCI technology to deliver accurate, trustworthy readings across a full range of patient care settings. The portfolio features three pulse oximeters offering spot check and continuous monitoring capabilities, a clinical software analysis application and an array of optional accessories. With its unique features and optional accessories, this BCI family of pulse oximetry devices facilitates improved patient care and clinical efficiency, while providing the flexibility and convenience required by today's healthcare professionals. The portfolio's array of optional accessories makes it possible to customize a solution to suit each clinical environment's specific needs. Unique features of the $SPECTRO_2$ Pulse Oximetry Portfolio include: • Pulse amplitude Index (PI) bar-graph indicator: Based on a strong pulse signal, the PI helps the clinician identify a good test site, giving the clinician confidence in the results. • Patented BCI Serial Autocorrelation technology provides low perfusion performance and motion tolerance. • Durable, rugged design for everyday use. • Large, bright LED display—more than 50% larger than comparable hand held devices: Allows easy at-glance-patient assessment. • On-board cradle to store and protect the sensor—helps reduce damage and unnecessary replacement costs. • New BCI spot check finger sensor designed with a 20-inch cable to minimize frustrating tangled cables.

How does your oximetry product improve patient care?
Empowering clinicians with confidence and reliability in a wide range of clinical settings, the $SPECTRO_2$ Portfolio combines advanced BCI technology and an array of features and optional accessories to help improve patient care by: • Displaying the Pulse amplitude Index (PI) bar graph to visually confirm a reliable test site, enabling confidence in results; • Operating from advanced BCI technology, with various models utilizing patented Serial Autocorrelation digital technology, providing reliable performance in low perfusion or motion conditions; • Offering the optional clinical analysis software program to assist with detailed analysis of patient data to assist in identifying the proper care plan for each patient.

Discuss the range of your oximetry product's applications.
The $SPECTRO_2$ Pulse Oximetry portfolio delivers reliable performance, while allowing healthcare providers to customize their pulse oximeter solution to meet a variety of clinical needs in a wide range of settings: • $SPECTRO_2$ | 10–reliable spot check results at an affordable cost. • $SPECTRO_2$ | 20–patented BCI serial autocorrelation technology delivering reliable spot-check results in the most challenging clinical settings, including low perfusion or motion. • $SPECTRO_2$ | 30–continuous monitoring of pulse rate and oxygen saturation levels during sleep screening and overnight oxygen evaluation as well as ambulatory testing. This device features the patented BCI serial autocorrelation technology with low perfusion performance and motion tolerance. Equipped with audible and visual alarms and the availability of a nurse call system to allow healthcare providers with remote monitoring, the $SPECTRO_2$ | 30 helps ensure patient safety. • $SPECTRO_2$ | LOGIX Clinical Analysis Software—A clinical analysis software application to assist in the interpretation of pulse oximetry data. • Sleep Screening Analysis features our proprietary Sleep Disorder Probability Index to help determine the relative probability a patient suffers from sleep disordered breathing such as obstructive sleep apnea. • Ambulatory analysis and 6-minute walk tests for ambulatory oxygen needs evaluates patients exercise tolerance, or Rate of Perceived Exertion. • Supplemental oxygen qualification and evaluation assesses whether supplemental oxygen is needed.

• Trending displays raw pulse oximetry data numerically and graphically, so the clinician can make his or her own assessment of data. • Optional Accessories of the SPECTRO$_2$ Pulse Oximetry Portfolio includes: A docking station that converts hand-held device to bedside device, recharges the device and back-up Lithium Ion battery; Convenient device storage when not in use; Attachable printer which prints stored or real-time data and graphical or numerical trends and helps reduce documentation errors. The unit offers multiple power choices and backup power solutions. Other power options reduce replacement costs on disposable batteries. Other features include auto-charge with AC power or rechargeable battery, protective rubber glove in a range of bright and friendly colors; a choice of four colors for identification and provides protection for the device. The universal mounting bracket is a quick and easy attachment to the IV pole, bed and chair rails.

Discuss the cost effectiveness of oximetry and of your product.
Smiths Medical is committed to meeting customer needs by improving global strategies that will ensure a profitable company, able to produce state-of the-art goods at realistic prices, identified by intelligent market analysis. Through processes such as our Article Quality Assessment whereby we ensure the best possible costs and quality from our vendors to our Value Analysis/Value Engineering process with which we continually evaluate opportunities to reduce costs, we are able to deliver competitively priced products to the market without sacrificing quality. Additional elements of value are also realized in the support we provide for our devices to include experienced and dedicated Customer Service and Marketing Teams, a Clinical Education Group and a team of qualified Service Technicians. The SPECTRO$_2$ Pulse Oximetry Portfolio offers a range of products varying in price from $395 to $795. In addition, the portfolio offers an array of unique, optional accessories to choose from. A clinician can choose only the product(s) by which they want to meet their needs in each clinical setting. By having the ability choose only the products they need, this will help to stay within their price range.

What type of training and customer assistance do you offer?
Smiths Medical has a dedicated sales team addressing the various needs of our customer segments targeted, as well as a Clinical Education Group with dedicated clinicians on staff to provide field customer support, continuing education and product in-servicing. We also offer the services of experienced Product Specialists who assist with product evaluations and in-servicing. In addition to the operation manuals that accompany the products, Quick Reference Guides are also available to customers for speedy education needs on the operation of our products.

EXECUTIVE PROFILES

Teleflex Medical

Describe your products and their unique features.
Hudson RCI is a key part of a strong family of Teleflex Medical brands including Arrow, Rüsch, Beere, Deknatel, KMedic, Pilling, Pleur-evac and Weck. At Teleflex Medical, we are driven by a singular mission: improving patient outcomes. For our customers, this means we provide respiratory medical devices and solutions aimed at reducing infections, enabling less invasive procedures and improving patient and provider safety. Through partnerships and product innovations, we've made several exciting advancements in core areas of our respiratory business to support changes in clinical practice guidelines.

In humidification, we continue focusing on products that allow caregivers to maximize humidification and minimize challenges. Specific examples include our ConchaTherm Neptune Heated Humidifier, Gibeck Humid-Flo, Comfort-Flo High Flow Nasal Cannula System, and OSMO for maintenance free water removal. In aerosol and oxygen therapy, we offer the Neb-U-Mask System, a combination product that allows for the concurrent delivery of aerosolized medications and high concentrations of oxygen or heliox. In ventilation management, we've entered into a partnership with ResMed Corp that gives us exclusive distribution rights in the US acute care market for ResMed Non-Invasive Ventilation products. As a world leader in mask design, ResMed NIV masks provide the proven comfort and seal of Mirage dual-wall cushion technology in a disposable mask.

Tell us about the latest advances in the area your products serve.
We're proud of the progress we've made with innovations to add value to the care and treatment of respiratory patients. ConchaTherm Neptune is our heated humidifier that offers simplicity, versatility and universal performance. Featuring an adjustable patient airway temperature, the Neptune allows the caregiver to customize humidification based on unique patient, ventilator and environmental conditions. The temperature gradient control and custom breathing circuit components minimize circuit condensation and improve clinician efficiency. The Neptune can be used for Invasive Ventilation, NIV and High Flow Oxygen Therapy from neonates to adults. For passive humidification, we offer the Gibeck Humid-Flo HME, designed to remain in-line during aerosol treatments, allowing medication to be delivered without breaking the ventilator circuit. OSMO, our most recent product introduction, addresses one of the biggest challenges with heated humidification—condensation control. The management of condensation can be labor-intensive and can lead to multiple circuit breaks, ventilator alarms, increased filter usage, interruptions in ventilation and cross-contamination concerns. Featuring a revolutionary media, OSMO allows for maintenance-free water removal from the expiratory limb during mechanical ventilation.

Discuss your R&D process, including clinical user input.
Our goal in product design is to incorporate the needs of the caregiver into every product we offer. In turn, we involve multi-disciplinary respiratory care specialists and key opinion leaders in both new product development and product improvement programs to ensure we're meeting the needs of caregivers.

Discuss the educational services you offer for use of your products.
We field a multi-disciplinary team of clinical specialists who provide in-service education, clinical and product trouble-shooting and consultation. Additionally, we offer a broad variety of clinical education programs for the respiratory therapist. These programs include Clinical Foundations (www.clinicalfoundations.com), a patient-focused education program for respiratory care professionals, AARC accredited CRCE programs and the website firstdonoharm.com, that provides

clinical and patient education and information on hospital acquired conditions.

What new technology do you see as having the greatest impact on your area of expertise?
Companies will continue focusing on products that address AARC and SHEA guidelines. Ultimately, we believe new humidification technologies will be a focus as companies look to introduce easier to use and more effective products. Additionally, products focused on VAP prevention and reduction of hospital acquired infections will continue to be important, along with products that deliver effective patient therapy in non-invasive applications with a focus on reducing overall cost and patient length of stay when possible.

Salter Labs

Information provided by David Wilson, Director of Marketing & Sales.

Describe your product and its unique features.
Salter Labs, based in Arvin, CA, the provider of the broad line of Salter-Style cannulas—the worldwide standard for comfort and clinical efficiency, has also developed leading edge technology in the field of inhaled drug delivery. Its unique breath-enhanced NebuTech HDN high density small volume nebulizer provides superior clinical outcomes, faster treatment times (3 to 5 minutes), better patient compliance and reduced medication waste. The NebuTech HDN high density nebulizer accomplishes this by collecting and storing a plume of high density aerosolized medication in a patented 50cc tower during exhalation. Then, at the very beginning of inhalation, this stored 50cc bolus of aerosolized medication is delivered very deep into the patient's lungs, resulting in demonstrated superior aerosol deposition. With no moving parts to overcome, the HDN is appropriate for adults as well as pediatrics and is used in leading hospitals and institutions across the US and Europe.

How does your product directly affect patient care?
While providing patients with superior clinical outcomes, the NebuTech HDN high density nebulizer also can significantly improve patient compliance in the homecare environment by reducing treatment times to as little 3 to 5 minutes. In institutional settings, patient compliance is also improved as a result of the significantly reduced treatment times which have been demonstrated to also allow the elimination of concurrent SVN therapy.

Discuss your R&D process, including end-user input.
With the objective of supplying users with useful products that meet customers' specific needs, Salter Labs engages in continual, in-depth consultations with end users including physicians, therapists and patients while developing new products and modifying existing products. A prime example of this is the ongoing development of the NebuTech HDN high density nebulizer product line. The ongoing dialogue with users allowed the company, over time, to develop the NebuTech device and its various accessories into the most versatile aerosol product available. Initial customer feedback led to the development of two different NebuTech HDN nebulizers—a cost effective reusable unit for homecare use and a less expensive disposable version for hospital use. These units were further modified so that they can deliver treatments either by a mouthpiece or via an aerosol mask. After much user feedback and consultation, a broad line of Salter aerosol masks were designed for use with the NebuTech HDN device. These masks are now available in a broad range of configurations to meet a wide range of specific patient and customer needs. Available are both over the ear and headband style masks in a variety of sizes ranging from infant through pediatric to adult and extra large adult sizes. Additionally in response to professional concerns regarding aerosolized medication depositing in the patients' eyes, Salter Labs developed a line of valved aerosol I-Guard masks. These unique valved aerosol masks direct any exhaled aerosol medication away from the patient's eyes and help with patient compliance and health by preventing unnecessary eye irritation.

Discuss the role of critical care providers in developing and upgrading your product.
Another example of designing products to meet specific customer needs is the company's aerosol filters. When Salter personnel, through consultations with respiratory professionals, became aware of concerns regarding long term occupational exposure to exhaled airborne aerosol particles, the company designed a special, inexpensive filter system for use with the NebuTech HDN nebulizer. These dual membrane filter sets capture 99.56% of all aerosol particles larger than 0.14 microns in size. The optional NebuTech filter sets are currently being used by numerous medical facilities worldwide to significantly reduce the potential risks of cross contamination from patient exhalation and aerosol droplets.

Talk about how you test and evaluate your product in actual day to day use.
All of Salter Labs' products are subjected to intense bench and clinical testing both prior to and subsequent to their release. As part of Salter's continuing product testing and day to day evaluation, a very recent (2009) study was conducted on the NebuTech HDN high density nebulizer at a well known institution in Ohio. The results of this study provide new evidence of the superior aerosol deposition provided by the NebuTech HDN device. In this study, scintigraphic imagery was used to graphically show that the device provided uniform aerosol distribution in the lungs and periphery. Another example of the results of the day to day evaluation and testing of Salter products in a real world environment is a recently published study conducted at the Cleveland Clinic that demonstrated that the use of the NebuTech HDN high density nebulizer could significantly reduce SVN (small volume nebulizer) workload and associated costs without adverse events and demonstrated that the device would permit improved patient care and long-term cost savings over traditional T-piece nebulizers.

Tell us how you utilize conferences, seminars and such to promote your product.
To assist in educating clinicians about Salter products and their uses, the company employs a large staff of highly trained professional service representatives and independent reps to call on, work with and in-service the staffs of hospitals, alternate care facilities and homecare providers both in the US and abroad. To supplement these efforts Salter Labs participates in and attends over 175 national, international and regional professional meetings and trade shows each year. Patient educational materials, product data sheets, clinical reprints, etc regarding Salter products are routinely provided to professionals by the Salter Labs' representatives or are available from the company's customer/professional service department by phone (800) 421-0024.

Passy-Muir, Inc

What are your products and their unique features?
The Passy-Muir Tracheostomy and Ventilator Swallowing and Speaking Valves are patented, closed position speaking valves that were invented by David Muir, a 23 year old quadriplegic patient with muscular dystrophy. David invented the closed position "no leak" design in 1985 to assist his own communication needs while on the ventilator. The product line consists of the PMV 005, PMV 007, PMV 2000, PMV 2001, PMV 2020 and the PMA 2000 Oxygen Adapter for use with the PMV 2000 series. The Passy-Muir valves are small, lightweight, and designed to fit the universal 15mm hub of tracheostomy tubes. All Passy-Muir valves, with the exception of the PMV 2020, can be used interchangeably by tracheostomized and ventilator dependent patients. They are easily adapted for use in-line with a ventilator circuit and can be used in conjunction with closed suctioning systems, swivel adapters, supplemental oxygen, and humidification. The PMV 2020 is used with metal tracheostomy tubes and is not indicated for ventilator use. All other one-way speaking valves available have an open position design that requires expiratory pressure to close them. There is always some air leakage through these valves during expiration which precludes the benefit of a "closed system." Increased work of breathing can also occur with open position speaking valves because the patient must both open and close these valves. In addition, an open position design allows secretions to travel up the tracheostomy tube and potentially occlude these valves. The Passy-Muir valve has the only patented closed position "no leak" design which enables the valve to close automatically at peak inspiration, not requiring expiratory pressure to close it. This design restores a "closed system" on expiration and creates a buffer to secretions to resist occlusion. Over the past 20 years clinicians and physicians have observed several other clinical benefits for their tracheostomized and ventilator dependent patients when using the Passy-Muir valve. These clinical benefits and FDA indicated uses of the Passy-Muir valves are supported by numerous independent research studies which report restored communication, improved swallow and decreased aspiration, improved secretion management, improved oxygenation and expedited weaning and decannulation.

Do you provide technical and clinical support?
Passy-Muir Clinical Specialists are available by phone, (949) 833-8255 or through email (info@passy-muir.com) to answer technical and clinical questions from patients, family members, caregivers, and medical professionals. Whether it is deciding which valve to order, troubleshooting issues with assessment and placement, or answering ventilator related questions, our Clinical Specialists are ready to assist. If additional education or clinical support is required they can schedule a private webinar or on-site visit.

What educational services do you offer?
Passy-Muir, Inc has a nationwide team of clinical specialists and educational consultants who are independent clinicians in the fields of speech-language pathology, respiratory therapy and nursing. Each clinical specialist and consultant has extensive experience specializing in tracheostomized and ventilator dependent patients and has utilized the Passy-Muir valves in their clinical practice. These consultants provide clinical inservices at medical facilities, and presentations at college and university programs, clinical seminars, and local, state, and national conferences. Passy-Muir, Inc has a comprehensive website, www.passy-muir.com, which provides clinical information and support for our medical and educational products. Healthcare providers are able to request complimentary research literature packets, clinical instruction booklets, patient education handbooks, pocket-sized clinical reference guides with web key technology, clinical videos and DVDs. Available on-line are free downloadable resources, streaming video of medical animation and patient stories, and continuing education programs. Free live and pre-recorded webinars as well as self study courses are available and registered for CEUs with American Association of Respiratory Care, American Speech Language and Hearing Association and the California Board of Nursing. Course topics include application and assessment, pediatric issues, dysphagia issues, team-building and ventilator applications.

What is your R&D process?
Improvements in design and functionality of the Passy-Muir products have been driven by direct feedback from healthcare providers and patients using the Passy-Muir valves. Passy-Muir, Inc maintains a very close relationship with the medical community. The team of Passy-Muir Educational Consultants consists of respiratory therapists, speech language pathologists and nurses who are practicing at their respective facilities, but who make themselves available to provide clinical inservices at hospitals and schools across the nation. This provides direct feedback on Passy-Muir products from patients, colleagues and physicians. These close clinical ties to the medical community have provided increased safety of use, cost saving measurements for the patient and healthcare facility and improved educational opportunities for patients and clinicians. The valuable feedback

from this closely-knit network of experienced clinicians allows Passy-Muir, Inc to continually meet the needs of the end user and provide state of the art care for tracheostomized and ventilator dependent patients.

What are the latest advances in the area your product serves?

Although Passy-Muir valves have been used on ventilator dependent patients for over 20 years, the costs saving benefits of expedited weaning have promoted early intervention in the ICU in recent years. This trend has been reflected in the increased use of the Passy-Muir valves in the critical care setting. This clinical need has prompted ventilator manufacturers to update their ventilator software with appropriate alarm settings and modalities to allow Passy-Muir valve use on acute care ventilators. Many hospitals now have respiratory therapy driven protocols which allow the cardiopulmonary team the latitude to make the necessary adjustments to the ventilator during Passy-Muir valve use. In addition, the early use of the Passy-Muir valves for tracheostomized and ventilator dependent patients allows the dysphagia clinician to complete an early assessment of swallowing, leading to improved vocal fold function, laryngeal treatment exercises and improved nutritional intake, all of which assist with expediting the weaning process.

TUTORIAL

Waveform Essentials – Is My Patient Autocycling The Ventilator?

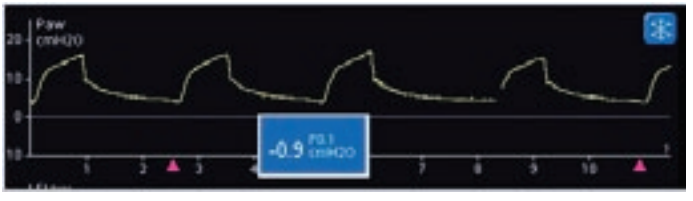
Paul Garbarini, MS, RRT

Paul Garbarini is Clinical Manager, Hamilton Medical, Inc. This article is from the company's newsletter.

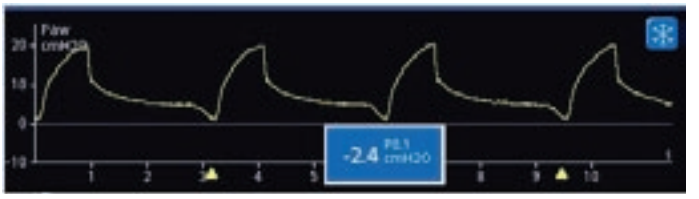
Current generation ventilators trigger system performance has significantly improved.

Flow triggering, proximal airway triggering and engineering are examples of the reduced imposed work of breathing associated with triggering breaths in current generation ventilators. My observations over the years are such that auto-cycling or self-triggering of the ventilator is now more common than the inability to trigger breaths as trigger performance has improved. This can lead to adverse consequences such as respiratory alkalosis, air-trapping/autopeep, hemodynamic compromise etc. Fortunately, examination of the pressure and flow waveforms can help us rapidly distinguish between auto-cycled and patient triggered breaths. We focus just on assessing the pressure waveforms rather than the flow waveform.

Note, the triangles on the waveforms indicate a triggered breath.



The circle is the trigger phase. Note the minimal length and depth of the pressure drop. It's important to note the change in slope at the start of the trigger phase. This represents minimal imposed trigger work with a flow trigger setting of 2lpm. WOB as represented by PO.1 (pulmonary occlusion pressure) is -0.9 cm (less negative being more work).



The trigger has now been changed to a pressure trigger of -2cm. Note the increased length and depth of the pressure drop. This represents increased trigger work. Note the increased PO.1. Decreasing the pressure trigger setting to -1cm or switching to flow triggering as above would reduce imposed WOB due to trigger.

In this case triggering is present as indicated by the yellow triangle trigger symbols. But is the patient really triggering these breaths? Examining the pressure waveform, we don't see the change in slope seen at the the trigger phase as seen in the above examples. This then would represent auto-cycling until ruled out.

Troubleshooting steps could include:

• Assess for leaks. The very gradual drop in pressure during the expiratory phase may be causing the pressure to drop below the trigger threshold (same would apply if flow triggering as ventilator can't distinguish between "leaked flow" vs the patient drawing flow.

• Observe/palpate the patient's chest/abdomen for respiratory efforts. If none are present then autocycling is present. At times, it may be hard to distinguish patient effort from the motions of the chest due to breath delivery. In this case, set the trigger to a less sensitive setting (eg, go from -1cm to -3cm pressure trigger or flow trigger setting 2lpm to 6lpm). If the triggering stops and there's not patient negative drop on the pressure waveform then autocycling is present. Also note the PO.1 is extremely low, so this is unlikely patient effort, unless the patient was extremely weak and/or sedated.

• Rule out external factors—is this occurring when the ICU bed is in "percussion" mode? Is the patient on an intra-aortic balloon pump, having cardiac palpations? All of these can cause motion which can cause small pressure/flow oscillations in the airway and cause autocycling.

Non-Cystic Fibrosis Bronchiectasis Update: Breaking The Vicious Circle With High Frequency Chest Compression

Jane Braverman, PhD; K. James Ehlen, MD

Medicine is a science of uncertainty and an art of probability.
—Sir William Osler

A paradigm shift is underway in the understanding of non-cystic fibrosis bronchiectasis (NCFB). NCFB is distinguished from the CF-related bronchiectasis that is omnipresent in advancing stages of that disease. Emerging data indicates that the prevalence of NCFB has been markedly underestimated. A study of relevant medical literature confirms the escalating recognition of NCFB as an increasingly serious chronic respiratory problem.[1-6] NCFB is now viewed as a major factor secondary to a broad variety of underlying pulmonary and systemic etiologies. Currently, chronic lung disease (CLD) ranks fourth in the US in terms of utilization of healthcare resources and consumption of healthcare dollars.[7] New evidence suggests that a significant proportion of CLD patients have or are at risk for bronchiectasis.[8-12] The prevalence of NCFB rises both with age and pre-existing risk factors. When matched for age, sex, geographic region and several selected comorbidities, patients with NCFB use significantly more medical resources than their cohorts.[13] Runaway healthcare costs are now on track to consume one-fifth of the American economy. This projection cannot be altered without aggressive implementation of targeted initiatives to detect, treat and prevent NCFB.

Until quite recently, inattention to NCFB was entirely warranted. The condition is truly a re-emerging pathology, comparable to historically prevalent diseases—most notably tuberculosis—that were at one time thought to have been largely eradicated. The decline and near disappearance of bronchiectasis in the industrialized West is largely attributed to advances in medicine and public health policy.[1-4] By the mid 1950's, previously high rates of bronchiectasis-related morbidity and mortality declined sharply following the advent of mass immunization campaigns and easy access to effective antibiotics. In the post mid-century medical literature, NCFB is often described as an "orphan" disease.[14] Physicians were identifying fewer and fewer cases. Until the emergence of widespread use of high resolution imaging techniques as routine diagnostic tools, bronchiectasis was rarely considered in diagnostic workups except among discrete subsets of patients—such as those with cystic fibrosis and immotile ciliary disorders—with historically high rates of the condition.[15-18]

This article was provided by Respirtech.

Pathophysiology

NCFB is not a specific disease entity. It is a pathological process characterized by generally irreversible dilation of the large airways, bronchi and bronchioles and by progressive destruction of parenchymal tissue.[1-4,19,20] Bronchiectatic lesions may involve a single pulmonary segment or lobe, or may be diffusely distributed throughout one or both lungs. Three morphological classifications are recognized—sacccular, cylindrical and varicose.[1,17,21] These distinctions are less important than the degree of mucociliary clearance impairment.[8,19] Because chronic or recurrent airflow limitation is a distinguishing feature, bronchiectasis is classified generically under the rubric "obstructive lung disease."

In his definitive 1986 paper, "Inflammation: A Two-Edged Sword—The Model of Bronchiectasis," the eminent pulmonologist P.J. Cole posited a "vicious circle" image to illustrate the cascade of pathophysiological events that define bronchiectasis.[20] This description remains unsurpassed:

"An initial insult to the tissue, usually a pneumonitis, must occur. The resulting damage to the respiratory tract compromises mucociliary clearance mechanisms and allows propagation of microbes that are not eliminated by normal inflammatory response. The poor clearance of the microorganisms, therefore, and their longer stay in the damaged area, allow them to gain a foothold with resultant colonization. These resident organisms then provoke an increased inflammatory response in the area of the bronchus. This response itself is damaging, through delivery of destructive enzymes by inflammatory cells. Increased destruction leads to further damage, and the situation is perpetuated. In addition, the microorganisms themselves might be the cause of damage to the clearance mechanisms, by disrupting the normal ciliary function necessary to clear the lumen of debris and secretions."

Bronchiectasis, then, is a pathological process that occurs as a consequence of diminished pulmonary defenses and, most critically, impaired mucociliary clearance mechanisms. Once bronchiectasis is established, its normal pattern is to progress. Bronchiectasis may be viewed as the final common pathway triggered by a broad range of antecedent diseases or conditions.

Any patient presenting with clinical symptoms consistent with the pattern described by Dr Cole's Vicious Circle should be evaluated for bronchiectasis. Most cases found in clinical

practice are post-infectious in origin and include primary and recurring infections.[1,19-26] Other causes involve impaired host defense, exaggerated immune response, certain congenital abnormalities, and extrinsic injuries that damage the airway wall. Notably, a specific underlying etiology is identified in fewer than half of all NCFB cases.[23-26]

Diagnosis of bronchiectasis; tip of the iceberg?

Because bronchiectasis typically arises as a complication of an antecedent condition, it is rarely cited in medical records as a chief—or even secondary—complaint. Thus, reliable estimates of its prevalence are currently unavailable. Usefully, a retrospective cohort study of patients with NCFB, published in 2005, established important baseline information.[27] Data extracted from a health care claims database that included more than 30 US insurance plans covering 5.6 million members showed that 52.3/100,000 had bronchiectasis listed as an admission diagnosis. Mean age was 61 years, prevalence increased with age, and, at 68%, female gender was dominant. These numbers were then extrapolated to represent the US population as a whole, yielding an overall prevalence number of approximately 110,000 adult cases nationwide. Because this study excluded the now presumed majority of individuals with unrecognized and/or undocumented NCFB, it exposes only the tip of the iceberg. Scores of studies representing diverse patient populations support much higher numbers.[9-12,16,28-38]

Bronchiectasis Research and Consortium Registry

Growing awareness of the clinical importance of NCFB has prompted creation of a nation-wide research consortium to develop a consolidated database of NCFB patients seen at multiple clinical institutions. The consortium consists of a collaboration of the COPD Foundation—supported by the Richard H. Scarborough Bronchiectasis Research Fund—the University of North Carolina at Chapel Hill, and ten academic and medical centers distributed across the country. Physicians directing the enterprise are recognized authorities on bronchiectasis. Consortium goals include use of the Bronchiectasis Registry to support collaborative research and to participate in the planning of multi-center trials for the treatment of NCFB. Emerging information will also be used to provide better insight into the etiology, pathophysiology and diagnosis of the disorder. Information and site locations are found on the Bronchiectasis Research Registry Website link.[39]

A sea change in diagnosis

A resurgence of interest in NCFB has been prompted by the superior ability of advanced imaging techniques to detect early or unsuspected disease.[1,2,17] Just as the advent of the achromatic microscope in the early nineteenth century opened a new universe of cellular pathology, computed tomography (CT) technique—especially high-resolution computed tomography (HRCT)—has transformed the science of diagnostic chest imaging. HRCT/CT detects and characterizes NCFB with a high degree of sensitivity and specificity. The degree to which these techniques have enabled precision pulmonary diagnosis cannot be overstated. Recently, magnetic resonance imaging (MRI) technology has been shown to perform as well as HRCT/CT, but without exposure to radiation.[40]

COPD: A public health nemesis

COPD ranks high among conditions shown to have a large component of secondary bronchiectasis. The prevalence of COPD in the US is currently estimated to exceed 30 million.[7] The condition ranks as the fourth leading cause of death and is expected to reach third place by 2020. According to the Centers for Disease Control (CDC), in 2005 nearly one in 20 deaths had COPD as the underlying cause; it is the only major disease with an increasing death rate, showing a rise of 16% of between 2000 and 2008. Overall costs for 2002 were estimated at $32.1 billion, up from $30 billion in 2000.[7] By any standard, the burden of COPD-related care and costs are soaring. When NCFB is a comorbidity, expenditure is significantly higher than for COPD patients with less advanced disease.[27,41]

COPD: A major healthcare challenge

Three studies, although small, suggest that an astonishing number of COPD patients have NCFB and that many more are at risk.

- In a limited study, Munro, et al performed CT scans on 27 COPD patients with a history of significant daily sputum production. Eleven were former smokers; ten had forced expiratory volume in one second (FEV1) scores below 80% predicted. Bronchiectasis was identified in 56%.[12]
- In the largest screening of COPD patients for bronchiectasis, O'Brien et al examined 110 stable patients aged 40-80 drawn from primary care clinics. CT scans and lung function testing revealed a wide range of disease patterns and severity; 29% showed some form of bronchiectasis.[9]
- Patel and his East London group have published numerous studies of their COPD clinic patients, all of which excluded those with a known history of bronchiectasis. Despite this, CT scans performed on 54 older (mean age: 69) patients with severe obstructive lung disease (mean FEV1= 38.1% predicted) found some degree of bronchiectasis in 50%.[10]

Robert Wilson, a leading British authority on COPD and bronchiectasis, reported recently that observational data at the Royal Brompton Hospital, London is consistent with the findings of the studies cited above.[8] He found this pattern unsurprising given the high incidence of recurrent bacterial respiratory exacerbations in these patients associated, in particular with Pseudomonas aeruginosa.[42] Rapid disease progression has a poorer prognosis and has been shown to be associated with increased bronchial wall thickening (BWT), colonization with P aeruginosa, and high concentrations of certain proinflammatory markers.[42-45]

HRCT reveals widespread NCFB

Because COPD itself is so common, the unanticipated prevalence of NCFB in COPD has ominous implications for the American healthcare system. Other important disease categories contribute to this evolving picture. In study after study, similarly high proportions of the condition are demonstrated in numerous diagnostic categories. Although in many instances patient populations are much smaller, the cumulative numbers are sobering. Selected examples include...

- Asthma (severe): In 185 subjects with severe asthma, 80% demonstrated HRCT abnormalities including BWT; 40% showed frank bronchiectasis.[11]
- Common variable immunodeficiency disorder (CVID): In 65 CVID patients; HRCT scans showed abnormailites in 94%, including BWT in two-thirds; 57% showed some degree of bronchiectasis.[32] Similarly high prevalence rates are found in individuals with acquired immunodeficiency conditions, including infants, children and adults with HIV-AIDS.[29,31,37]
- Primary ciliary dyskinesia (PCD): Twenty children and adults (4.6-27.5 years) evaluated by HRCT for evidence of

BWT, mucous plugging and bronchiectasis showed positive findings for BWT in 80%, for mucous plugging in 75% and for bronchiectasis in 80%.[16]

- α1 - antitrypsin deficiency: Seventy-four subjects with α1-antitrypsin deficiency screened by HRCT for evidence of bronchiectasis revealed bronchiectatic changes in 70 (94.5%); 20 subjects (27%) had radiologic bronchiectasis in 4 or more bronchopulmonary segments.[34]
- Autosomal dominant polycystic kidney disease (ADPKD): ADPDK affects between 1/400 and1/1,000 Americans and accounts for 5-10% of all cases of end-stage renal disease. The condition is associated with abnormal ciliary motility. Ninety-five ADPKD and 95 non ADPKD kidney patients were screened by CT scan for bronchiectasis. A threefold-increased prevalence of bronchiectasis was found in the ADPKD group vs the control group (37% vs 13%), suggesting the increased risk for airway disease in patients with a variety of cilia-associated disorders.[30]
- Coal-workers' Pneumoconiosis (CWP), aka black lung disease: Coal workers and others at risk for inhalation of industrial, occupation and disaster-related fine particulate matter have high prevalence of CLD. To ascertain the extent and severity of bronchiectasis among coal workers, 78 subjects (43 with CWP and 35 without CWP) underwent CT evaluation. Overall, 20% of the non-CWP subjects—all of whom had significant occupational exposure—showed bronchiectasis; those diagnosed with CWP had, at 44.1%, NCFB rates that were more than double.[28]

Airway clearance treatment

"It has long been speculated that mucus clearance is important for airway defense, but only recently have important details of this system become available...as long as mucus clearance is maintained, chronic airway infections do not occur.
—Knowles MR, et al., J Clin Invest 2002; 109 (5): 571-577.46

All cases of bronchiectasis share the common denominator of mucus plugging and superimposed bacterial colonization. The mucus plugging is a result of abnormal physical consistency and/or impaired clearance. Poor clearance of mucus from bronchiectatic airways is the proximate cause of bacterial colonization. Once the airway is colonized, prognosis is sharply worsened. Although the bronchiectasis itself generally will not revert, the clearance of the airway will improve any post obstructive pneumonia and may prevent progression of the airway damage.[1-2,8,20,46,47]

Airway clearance therapy (ACT) is widely accepted as standard of care for bronchiectasis.[48,49] This conclusion is based upon both clinical judgment and empirical observation. Practicing pulmonologists generally appreciate the daunting practical difficulties of conducting adequately powered, randomized, controlled (RCT) studies of ACT in a population so etiologically and demographically diverse. Despite the paucity of data from such studies, clinical outcomes strongly support its routine use in NCFB care plans.[48] Effective ACT can mitigate factors that favor disease exacerbation, relieve bronchial obstruction, improve ventilation and gas exchange, improve patients' quality of life, and help control long-term healthcare costs.[2,8,46-49] Comprehensive disease management may eliminate the need for drastic, costly interventions including mechanical ventilatory support, lung reduction surgery of lung transplantation.

In a recent study, Sheehan, et al "assessed in patients with NCFB serial changes lung function and CT scan interpretation over time." Changes observed in FEV1 correlated closely with positive or negative changes in CT estimates of the extent of mucus plugging (small and large airways). Likewise, increased standardized bronchectasis scores corresponded with increased mucus plugging and BWT. Both are strong indicators of airway inflammation and worsening bronchiectasis.[50]

Which modality?

Although is generally agreed that treatment of NCFB should focus on efforts to improve mucus clearance, confusion prevails concerning how this is best accomplished. Practice guidelines do not identify as superior one ACT over another.[48] However, clinical and practical factors rule out most modalities for bronchiectasis patients.

- Chest physiotherapy (CPT): Under ideal conditions, CPT can be used successfully in some individuals with bronchiectasis. To be fully effective, treatments should be administered at least twice daily in sessions lasting from 30-45 minutes. CPT protocol involves manual percussion applied to each lung segment for 5 minutes with each interval separated by positioning the patient in 9-12 specified postures. The objective is to facilitate gravitational drainage of loosened secretions from smaller to larger airways for clearance by coughing or expectoration. Head-down, or Trendelenburg positioning, is required. Caregiver limitations, including inconsistent or non-availability, technique deficiencies and physical limitations preclude CPT as a viable choice for most patients. Likewise, patient factors such as treatment contraindications, inability to tolerate required positioning and a variety of physical, cognitive and behavioral problems are often predictive of CPT failure.[8,49,51,52] Of concern, mounting evidence demonstrates that gastroesophageal reflux (GER)—common in many bronchiectasis patients—increases risk for aspiration lung injury, pneumonia and subsequent respiratory failure. In such patients, CPT is contraindicated on the basis of risks that may outweigh the likelihood of benefit.[53-56]
- Technique-dependent modalities: Patients with clinically significant bronchiectasis typically lack the lung capacity and expiratory force sufficient to fully benefit from effort-dependent ACTs including positive expiratory pressure (PEP) and oral high-frequency oscillatory devices. Significant comorbidities may be contributing factors.[49,56]
- High frequency chest compression (HFCC): HFCC is the only therapy able to provide consistently effective secretion clearance regardless of individual limitations and treatment obstacles.[49,57] Increasingly, HFCC is recommended in the medical literature for patients with bronchiectasis of all etiologies.[58-60] Treatments are administered by means of an air pulse generator attached by two lengths of tubing to an adjustable, inflatable jacket/vest garment fitted over the user's thorax. The jacket component of the device transmits compressive forces to the chest wall to produce increased airflow and oscillatory effects within the airways, thus enhancing mucus mobilization and clearance. The therapy is technique-independent and requires no active effort from the user. During HFCC, all segments of the lung are treated simultaneously. Most aerosolized medications may be administered during therapy, thus reducing time and burden of treatment.

High Frequency Chest Compression (HFCC): A simple solution

"Clearing... sputum from the airways is a consistent problem

in managing bronchiectasis... A newer way to administer CPT is through the use of high-frequency chest compression (HFCC)... Studies have shown HFCC to be equally safe and effective when compared to CPT.... easier to administer, less expensive, and less time consuming."
—Silverman, et al. J Heart Lung 2003; 32: 59-64.[58]

For patients with NCFB, ACT is the most arduous component of the daily treatment regimen. The long-term value of prescribing a method that minimizes burden of treatment and maximizes benefit cannot be overstated. When treatment demands overwhelm patients' physical capacities, family resources and emotional reserves, adherence wanes. A decrease in adherence to critical therapies may paradoxically lead to worse outcomes and negate benefits. For this reason alone, HFCC cannot be surpassed as a prudent therapeutic decision. Just as public health efforts at mid-century held NCFB at bay for several decades, we now have a clear indication for an aggressive call to action as the frequency, morbidity, cost and treatment options for NCFB are better recognized. The American healthcare crisis demands nothing less.

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Methods for Improving the Standard of Care for Patients with Tracheostomy: Why It's Important

Mary Spremulli, MA, CCC-SLP

Why should you be focused on patient outcomes?

As emphasis on costs and patient outcomes continue to be used as measures of system effectiveness, health care professionals caring for patients with a tracheostomy will increasingly be held accountable for their own practice patterns through the development of quality assurance activities and evidence based standardized processes to care.

What is the frequency and cost of tracheostomy?

Tracheostomy is the most frequently performed surgical procedure in the intensive care unit (ICU) and has undergone substantial change in the last few years.[1] A tracheostomy is performed to gain access to the airway, and is typically performed because of: upper airway obstruction such as with head and neck lesions or flaccid upper airways; pulmonary toilet for patients unable to clear secretions from the lower airways; and when the need for mechanical ventilation exceeds 7-10 days in the acute care patient or is permanent as with patients with a progressive neuromuscular disease.

It is known that acute care patients who require a tracheostomy have a high consumption of resources and a high patient cost.[2] The tracheostomized patient has the third most costly hospital stay, with an average length of stay of 31 days and an average cost of $219,217 (From HCUP 2006 National Statistics). Therefore, once a patient is viewed stable, issues of tracheostomy care and management become paramount to improving patient safety and outcomes, including reducing length of stay.

What are the safety issues associated with tracheostomy?

Safety issues can be characterized two ways: 1. Those that have to do with the actual care of the tracheostomy, and include suctioning techniques, understanding the different types of tubes, role of cuffs, etc. Also included would be the lack of understanding professionals often have regarding how a tracheostomy tube and other artificial airways may alter the functions of the aerodigestive tract, including speech and swallowing.[2] The second way safety issues can be characterized has to do with "team issues." There is often much variability in educational preparation and training among the staff that care for tracheostomized patients.[3] Training that does occur, is often done in isolation. That is, speech-language pathologists, nurses, and respiratory therapists all receive their formal education in isolation, don't read each others' journals or research, and then, graduate and begin a job, where they are suddenly part of a multidisciplinary team treating these patients. Some team members, such as physical therapist and occupational therapist are even less "hands-on" when it comes to the tracheostomy, and yet should be involved in placement of speaking valves and other treatment modalities that could actually facilitate weaning and decannulation and reduce further muscle disuse atrophy. On a daily basis, the team should be asking: "Why does the patient still require a tracheostomy?" and "What are the criteria and goals for decannulation?"

Why a team approach?

Implementing a team approach and creating a standardized process or pathway for care is likely to yield the best overall patient outcomes, including patient safety and reduced length of stay. Authors have noted clinical and professional benefits such as reduced variability of tracheostomy tube selection, increased ability to meet patient and professional needs, and improved communication between team members.

The Performance Improvement Process, which is already a requirement for JCAHO facilities, can be a great vehicle for clarifying specific institutional problems which have risen as obstacles to safety and care of tracheostomized patients, and also for development of multidisciplinary policies and procedures to address those concerns. The PI (Performance Improvement) team needs to include physicians, of course, who are directly involved with this population, but, also representatives of the various disciplines, such as nursing, speech and respiratory.[5]

Accountability

Even once a process is developed, the ongoing need for staff education, training, and accountability measures seem to be necessary. Outcomes are affected not only by the care provided, but also by the factors related to the patient, to the interpersonal

Continued on page 39…

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New Treatment on the Horizon for Asthma

Justin Tse, BS, RRT

Asthma affects people of all ages, but it most often starts in childhood. In the United States, more than 22 million people are known to have asthma.[1] Nearly 6 million of these people are children. Asthma is a chronic lung disease that inflames and narrows the airways (See Figure 1).[2] Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. The coughing often occurs at night or early in the morning. Current therapies for asthma include both short acting medications to contol acute exacerbations and long acting medications to prevent exacerbations from occurring.

Quick relief, or rescue medications are used to relieve symptoms during an attack. These include:

- Short-acting bronchodilators (inhalers) such as Proventil, Ventolin, Xopenex and others.
- Corticosteroids (such as prednisone or methylprednisolone) given by mouth or into a vein.
- Long-term control medications are used on a regular basis to prevent attacks, not to treat them. Such medicines include:
- Inhaled corticosteroids (such as Azmacort, Vanceril, AeroBid, Flovent) prevent inflammation
- Leukotriene inhibitors (such as Sinfulair and Accolate)
- Long-acting bronchodilators (such as Serevent) help open airways
- Cromolyn sodium (Intal) or nedocromil sodium (Tilade)
- Aminophylline or theophylline (not used as frequently as in the past)[2]

The FDA recently approved a new, non drug treatment for asthma. "The AIR2 Trial evaluated the safety and efficacy of bronchial thermoplasty in patients with severe asthma. Performed using the Alair Brochial Thermoplasty System, bronchial thermoplasty is an investigational outpatient procedure that uses thermal energy to reduce the airway and smooth muscle in the lung, with the goal of reducing the severity and frequency of asthma symptoms by limiting the airway's ability to constrict."[3]

The Alair system uses radio frequency energy to apply a controlled temperature to the airway's smooth muscle to inhibit the muscle from contracting. The study conducted by Asthmatx was an outpatient trial. "The objective of this randomized, double blind, sham-controlled study is to evaluate the safety and efficacy of Bronchial Thermoplasty with the Alair System

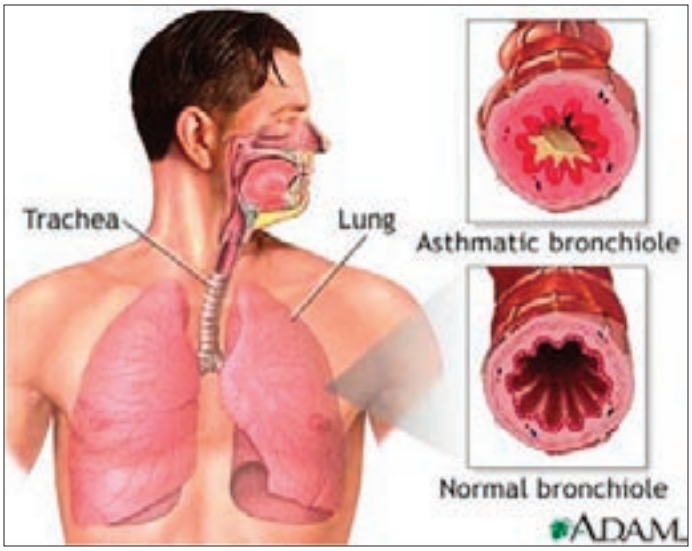

Figure 1. Normal and Asthmatic Bronchiole

in a population of subjects with severe asthma who are still symptomatic despite being managed on conventional therapy."[4] To view an animation of the procedure, you can go to the Asthmatx website.

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Justin Tse is Clinical Support Specialist, Hamilton Medical, Inc. This article is reprinted from the company's newsletter.

Noninvasive Ventilation: A Primer for Medical Center Administrators

Adam Seiver, MD, PhD, MBA, FACS, FCCM

Introduction

It is rare for a medical technology to simultaneously improve mortality, address patient discomfort, and reduce costs. Noninvasive positive pressure ventilation achieves this unusual health services "hat trick." Unfortunately, noninvasive ventilation appears to be underutilized at many hospitals.

This paper presents noninvasive ventilation for an intended audience of CEOs, Chief Nursing Officers, and other medical center executives. The goal is to provide background information from a non-technical perspective that will help the medical center leadership team facilitate the appropriate use of noninvasive ventilation.

Invasive ventilation

Endotracheal tube: The distinction between noninvasive and invasive ventilation derives from the fact that noninvasive ventilation does not require an endotracheal tube. An endotracheal tube is a plastic tube, typically 7 to 9 mm in diameter that is placed through the mouth, past the hard and soft palates, through the vocal cords and into the windpipe, or trachea (Figure 1). A soft balloon, the cuff, near the tube tip creates a seal against the trachea allowing a ventilator to blow air into the lungs to provide respiratory support.

Placement of the endotracheal tube is usually done by an experienced physician (such as an anesthesiologist, an emergency department physician, a pulmonologist, a surgeon, or an intensivist) to ensure that the tube is placed into the trachea and not into the esophagus. A mal-positioned endotracheal tube—if not immediately rectified—can harm the patient.

Side effects of the endotracheal tube: Even a properly-placed endotracheal tube has undesirable side effects linked to its "invasive" nature. First, the tube irritates the throat and windpipe. To manage the discomfort, patients require medication for pain and anxiety. This anesthesia contributes to immobility, with its own set of deleterious effects. Second, the tube is a foreign body that interferes with normal expectoration of pulmonary secretions. Saliva that is contaminated by bacteria from the stomach drips past the endotracheal tube into the lungs. The result can be a lung infection frequently referred to as ventilator-associated pneumonia, although a more appropriate term would be "endotracheal tube-associated pneumonia." Ventilator-associated pneumonia not only has clinical consequences for the patient but soon may have financial consequences for the medical center. The Centers for Medicare and Medicaid Services (CMS) has indicated that it is considering adding ventilator-associated pneumonia to the hospital acquired conditions for which it intends to deny reimbursement. The typical cost for a patient hospitalization with ventilator-associated pneumonia is greater than $130,000, creating substantial financial incentive for hospitals to prevent this potentially life-threatening, expensive complication.

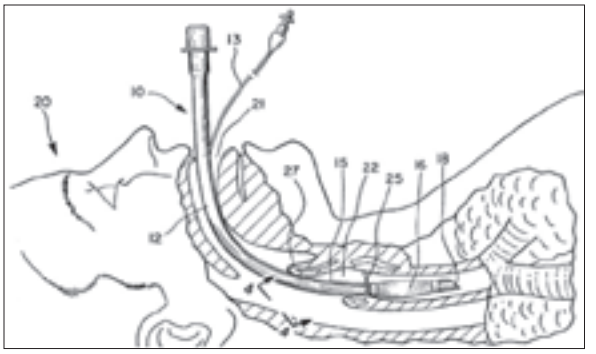

Figure 1. The endotracheal tube is placed through the mouth, past the tongue (at #21) and into the trachea (starts at #25). The cuff (#16) is a balloon that is inflated with the pilot tube (#13) to create a seal with the trachea. The invasiveness and discomfort of an endotracheal tube should be apparent.

It is important to note that some patients, such as those with severely altered cardiopulmonary function, can only be managed with endotracheal intubation. For these patients there will continue to be the need for invasive ventilation. The disadvantages of the endotracheal tube, however, have driven the development of noninvasive ventilation, which can provide superior respiratory support in properly selected patients.

Noninvasive ventilation

A bit of history: noninvasive negative pressure ventilation: Noninvasive ventilation encompasses respiratory support using alternatives to the endotracheal tube. There are two types of noninvasive ventilation. First, there is negative pressure ventilation, exemplified by the iron lung. The iron lung is a box in which the patient is placed and which draws air into the lungs by decreasing the pressure in the box. Essentially, the iron

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Figure 2. Patients with polio and respiratory muscle paralysis are treated with the iron lung at Rancho Los Amigos Hospital, Downey, CA, in the early 1950s.

lung sucks the patient's chest out and air rushes into to fill the vacuum created in the patient's lungs. The iron lung was used extensively during the polio epidemics of the 1950s and 1960s (Figure 2).

The patient in the iron lung is physically inaccessible, making nursing care burdensome. Better outcomes achieved with invasive ventilation in the 1960s led to the rapid disappearance of negative pressure ventilation in the 1970s. It is rarely used today.

Current approach: noninvasive positive pressure ventilation

The noninvasive interface: The other type of noninvasive ventilation is noninvasive positive pressure ventilation. This is similar to invasive ventilation in that air is blown into the lungs rather than sucked in by a vacuum created around the chest. Instead of using an endotracheal tube, however, noninvasive positive pressure ventilation uses an "interface" to make a connection between the ventilator and the patient. A wide variety of interfaces are available to accommodate variation in face anatomy and patient preferences (Figure 3).

The noninvasive ventilator system

The noninvasive positive pressure ventilation system consists of both an interface and a noninvasive ventilator device. Unlike invasive ventilators, which operate with the air-tight seal created by the cuff of the endotracheal tube, noninvasive ventilators must manage air leaks that occur between the mask and the patient's face. The present generation of noninvasive ventilators calculates the changing leak and rapidly adjusts the airflow to replace the lost air in milliseconds. This feature is called leak compensation.

Even more important, noninvasive ventilators sense when a patient's breathing starts and stops, synchronizing the mechanical respiratory support with spontaneous patient effort. Identifying patient effort in the midst of flow variation caused by leaks requires special software algorithms—a distinguishing feature of noninvasive ventilators (Figure 4).

The noninvasive program

Good outcomes from noninvasive programs require attention not only to equipment but also to staff training. A protocol can facilitate appropriate selection of patients and consistent management through the noninvasive care cycle. The protocol shown in Figure 5 was developed at the Tufts-New England Medical Center by Nicholas Hill, MD, to guide physicians, respiratory therapists and nurses. The protocol, together with a

Figure 3. A variety of interfaces are available for use in noninvasive ventilation of patients with acute respiratory failure, including the total face mask (top, also Figure 4), full face mask (bottom left), and the nasal mask (bottom right).

Figure 4. A patient is supported by a noninvasive ventilator using a total face mask. The noninvasive ventilator consists of a blower, to generate airflow, linked to a computer-based control system that automatically compensates for leaks around the mask and uses sophisticated algorithms to ensure synchronization with patient breathing.

comprehensive training program, can address what appears to be underutilization of noninvasive ventilation at many institutions. The protocol explicitly defines how to: (1) identify patients who are suitable for noninvasive ventilation, (2) initiate support, (3) adjust support to patient breathing needs, and (4) remove support when it is no longer needed. Importantly, it provides guidance on how to recognize that noninvasive ventilation is not meeting patient needs so that the clinician can transition to invasive ventilation safely. Dr Hill has shown that a program of education coupled with standardized physician order forms can enhance adherence to the protocol and increase the appropriate use of noninvasive ventilation.

Patients for whom noninvasive ventilation has proven benefit

There are over 1,000 articles on the use of noninvasive

Management of acute respiratory distress/failure using Noninvasive Positive Pressure Ventilation (NPPV)

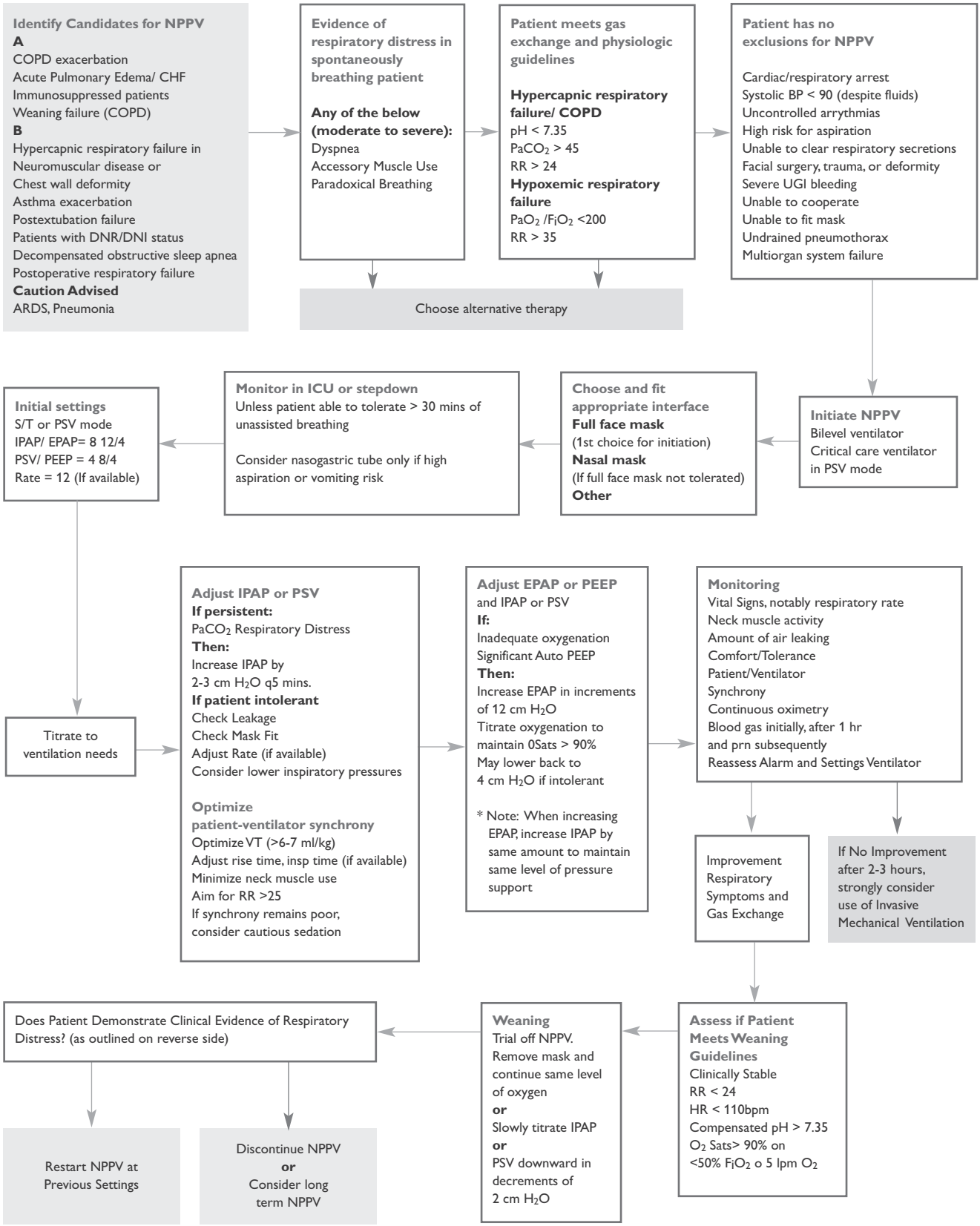

Figure 5. This protocol ensures consistent identification of patients who are suitable for noninvasive ventilation, guides the initiation of support and its adjustment to support individual patient breathing needs, and clarifies when support is no longer needed and thus can be removed. (Protocol courtesy of Nicholas Hill, MD).

ventilation, with over 100 of these reporting randomized, controlled trials. The literature identifies three groups of patients for which noninvasive has proven benefit.

Chronic Obstructive Pulmonary Disease (COPD): Patients with exacerbations of chronic obstructive pulmonary disease (COPD) form the most important group of patients for which noninvasive ventilation has proven beneficial. COPD is a lung disease in which the breathing passages become blocked making it difficult for air to pass in and out of the lungs. Smoking is an important contributing factor, with asthma, bronchitis, and emphysema as frequently associated conditions. Patients with COPD can develop infections, which make their chronic breathlessness acutely worse. These exacerbations of COPD can be marked by life-threatening drops in oxygen levels in the blood (hypoxemia) and excessive levels of carbon dioxide (hypercapnea and acidosis). Invasive ventilation, with its risk of ventilator-associated pneumonia, has a high mortality when used for COPD exacerbations. There are multiple randomized, controlled studies showing that noninvasive ventilation reduces mortality, patient discomfort, and length-of-stay for exacerbations of COPD compared to invasive ventilation. There is also literature showing that not only is noninvasive ventilation more effective in terms of clinical outcomes, but it is also less costly.[1]

Pulmonary edema from congestive heart failure: Patients with pulmonary edema from heart failure are a second group of patients for which there is strong evidence to support the application of noninvasive ventilation. In congestive heart failure the heart muscle pumps blood inefficiently, requiring high pressures during the filling portion of the cardiac cycle. Fluid is forced out of the lung blood vessels and fills the lung air sacs, interfering with respiration. Patients can experience extreme breathlessness that can be life-threatening. Noninvasive ventilation can help re-expand lung segments that have collapsed with fluid, reduce patient effort, and augment heart performance, giving time for drugs to correct the underlying cardiac failure. There are multiple randomized, controlled studies showing mortality benefit over invasive ventilation for noninvasive ventilation in pulmonary edema from heart failure. A recent study by Denise Wilfong, MD has highlighted the importance of early management of pulmonary edema by pre-hospital caregivers, showing a cost saving of over $4,000 per pre-hospital application of CPAP, a form of noninvasive ventilation.[2]

Impaired immune function: The third group for which there is compelling evidence for the benefit of noninvasive ventilation includes patients with impaired immune function. Patients with transplants take drugs to combat rejection. These drugs diminish immune function and reduce resistance to infection. Invasive ventilation is thus hazardous for patients with impaired immune function due to the high risk of ventilator-associated pneumonia. There are randomized, controlled studies that show reduced intensive care unit mortality rates and lengths of stay for patients with transplants treated with noninvasive ventilation compared to conventional therapy.

Patients for whom noninvasive ventilation is an option

While the evidence is strongest for patients with acute respiratory failure from COPD exacerbation, pulmonary edema, and impaired immune function, there are other groups for whom noninvasive ventilation is an important option. These other groups include patients with the following conditions:

- Postoperative respiratory failure
- Asthma
- Pneumonia
- Acute Respiratory Distress Syndrome

In these patients close monitoring is mandatory. The clinical team must be prepared to immediately intubate the patient and initiate invasive ventilation in patients who fail noninvasive ventilation.

Conclusion

Noninvasive ventilation is one of those rare medical technologies that both improves patient outcomes and reduces treatment costs. The technology requires an organized and well-trained team of physicians, nurses, and therapists. For selected groups of patients with acute respiratory failure—with the focus on COPD exacerbations, heart failure pulmonary edema, and immunocompromised hosts—noninvasive ventilation is preferred to conventional therapy with invasive ventilation.

Key Ideas

- Noninvasive ventilation is the standard-of-care for treatment of severe exacerbations of chronic obstructive pulmonary disease (COPD).
- There is substantial evidence to support the use of noninvasive ventilation for patients with the following conditions:
  - pulmonary edema resulting from cardiac disease
  - impaired immune systems.
- There is evolving evidence for the use of noninvasive ventilation in other conditions or disease states, such as pneumonia, asthma, and the acute respiratory distress syndrome.
- Particularly for chronic obstructive pulmonary disease, there is compelling evidence that noninvasive ventilation reduces mortality, morbidity, and costs.

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aspects of care, and to the setting or environment in which care is provided.

Maintaining department data that measures outcomes may be one of the best ways to demonstrate the benefit of a program to the administrative staff, and also a mechanism for the team leaders to correct their course if outcomes are different than what was anticipated.

What are the ongoing needs of any program?

Communication and Education: Formal and informal communication among team members is essential. Developing hand-off communication methods to ensure patient safety as they move within a facility or are discharged to tertiary care centers is equally important. Identifying educational needs, maintaining competencies, and accessing external sources (Webinars, Online CEs, product resource specialists) are necessary to facilitate training. Networking with facilities that already have demonstrated success with a tracheostomy team, and formation and sharing of policies and procedures may be another method for supporting the process.

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Acute Cough: A Diagnostic and Therapeutic Challenge

Peter V. Dicpinigaitis, Gene L. Colice, Mary Jo Goolsby, Gary I. Rogg, Sheldon L. Spector, Birgit Winther

Abstract

Background: Acute cough is one of the most common complaints prompting patient visits to healthcare professionals. Despite the broad repercussions of acute cough on patient quality of life, school and work productivity, and public health resources, research on this condition is minimal, as are the available treatment options. Many patients use over-the-counter medicines, which are often ineffective for symptom relief. Some therapies may achieve antitussive activity, but at the expense of unpleasant or intolerable side effects.

Unmet needs: When considering the treatments currently available for the management of acute cough, the multiple limitations of such treatments are quite apparent. Most of these treatments lack clinically proven efficacy and reliability to support their use. This reinforces the need for the generation of quality scientific data from well-performed clinical trials. Hopefully, the result will be the development of safer, more effective and more reliable therapeutic options in the management of acute cough.

Cough assessment and management: Acute cough can be due to a variety of causes, and it is worthwhile to consider these pathogenic factors in some detail. It is also important to be familiar with the effects that acute cough has on patients' quality of life, work productivity, and the healthcare system; proper awareness of these effects may contribute to better understanding of the social impact of cough. In reference to the available treatments for the management of acute cough, adequate knowledge of the type of over-the-counter and prescription products in the market, as well as their mode of action and advantages/disadvantages, may provide expanded pharmacotherapeutic opportunities and facilitate better clinical decisions. However, due to the drawbacks of current treatment options, ideas for future cough management and newer products need to be considered and tested.

Conclusion: In view of the socio-economic impact of acute cough and the limitations of available treatments, a renewed interest in the management of acute cough needs to be encouraged. The current strategies for acute cough management need to be reassessed, with a focus on developing new, reliable products and formulations with proven efficacy and safety.

Review

Introduction to acute cough: Acute cough is one of the most common symptoms for which patients seek medical attention and spend healthcare dollars,[1] the most common new presentation in primary care,[2] and the most frequent reason for visits to hospital-based outpatient clinics.[3] In the USA, acute cough accounted for 26 million office visits in 2004.[4] In the vast majority of cases, acute cough is due to acute viral upper respiratory tract infection (URTI), i.e., the common cold. Notably, over the past 50 years, pediatric immunization has dramatically decreased pediatric pertussis cases, from 157 to less than 1 per 100,000 persons,[5] but has not decreased the incidence in adults. In fact, during the 1990s, the number of pertussis cases in adolescents and adults more than doubled in the USA and Canada.[6] In a 2.5-year study, the incidence of pertussis in 2,444 healthy people, aged 5–65 years, ranged from 370–450 cases per 100,000 persons per year. Extrapolated to the USA population, nearly a million pertussis cases occur per year.[7]

By definition, acute cough is one lasting <3 weeks, sub-acute cough lasts 3–8 weeks, and chronic cough lasts >8 weeks.[9] Most acute coughs raise minimal concerns among health practitioners as they are generally caused by URTIs, usually have a short duration, and are self-limited. However, acute cough may be a symptom of a serious underlying condition, such as pneumonia, acute pulmonary embolism, pulmonary edema, or lung cancer. It is the most common symptom associated with acute exacerbations and hospitalizations with asthma and COPD (Table 1).[2] Despite the significance of cough in clinical practice, the clinical interest and research efforts in the study of cough have been historically sparse,[9] and there have been no new antitussive treatments in the past 50 years.[10]

However, recent years have seen a heightened scientific, clinical, and pharmaceutical interest in cough, along with a

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Table 1. Causes and estimated frequencies of acute cough in the adult

Common	Less common
Common cold	Asthma
Acute bacterial sinusitis Pertussis	Congestive heart failure Pneumonia
Exacerbations of COPO Allergic rhinitis	Aspiration syndromes Pulmonary embolism
Environmental irritant rhinitis	

Reproduced with permission from: Irwin RS et al. Chest 1998, 114: 1335-181 S.

Table 2. Adverse symptoms associated with cough [25]

Physical	Psychological	Social
Syncope Vomiting Chest pain Hoarse voice Headache Incontinence Hernia Sleep deprivation Lethargy	Depression Anxiety Embarrassment Fear of serious illness Frustration	Relationship tensions Fear of public places Avoidance of social events Interference with work Interrupt telephone calls Interrupt meals

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steady increase of publications on this subject.[9,11] Recent years have also witnessed the release of evidence-based guidelines for the diagnosis and management of cough from the American College of Chest Physicians (ACCP),[12] the European Respiratory Society,[13] the British Thoracic Society,[2] and the Japanese Respiratory Society.[14]

This article reviews the limited research in acute cough, the impact of acute cough on quality of life and health economics, current treatment options, and potential treatments to satisfy unmet needs in the management of this common ailment.

Pathology: Cough is a forced expulsive maneuver, usually against a closed glottis, and is associated with a characteristic sound.[2] In most healthy individuals, cough is an important natural reflex and defense mechanism that helps to clear excessive secretions and prevent foreign matter from entering the airways. However, when the respiratory system becomes compromised, cough can become excessive, nonproductive, disturbing to the patient, and potentially harmful.[15] Although many factors can induce acute cough, URTIs, usually of viral origin, are the most common.[16] While the common cold is the most frequent cause, other factors causing acute cough include viral rhinosinusitis, acute bronchitis/sinusitis, and acute exacerbation of COPD.[1] Acute cough can be induced from the upper airways by rhinovirus, which primarily infects the nasopharynx, and can be cultured from the nasopharynx for up to 3 weeks.[17] Patients on anti-inflammatory treatment may shed the virus for a longer time.[18] Patients with asthma may also shed rhinovirus from the lower airways. Of note, cough reflex sensitivity, as measured by capsaicin inhalation cough challenge, is transiently enhanced during an URTI.[19,20]

A study of children aged 5–12 years found that symptoms of rhinovirus colds differ in children and adults. In symptom diaries completed with the assistance of parents, children more frequently report cough during the first 5 days of illness, whereas adults primarily report nasal discharge, persisting only through day 4. Rhinovirus-induced acute cough peaks at about 40% in adults on days 3–5 and drops to about 20% by day 10. In children, cough peaks on day 2 at over 70% and is still reported in more than 40% of children through day 9, when it finally falls below 40%.[21]

Cough is commonly triggered when sensory cough-inducing receptors in the respiratory tract are stimulated by mechanical or chemical irritation.[1] Mechanical irritation can be due to factors ranging from inhaled irritants (eg, dust, dandruff,[22] smoke), to excess and tenacious mucus, and somatic conditions such as infections. Particle exposure to common allergens (eg, dust mites, animal allergens, and pollen) can induce cough after eliciting upper or lower respiratory tract reactions, such as allergic rhinitis and asthma.[23] Exposure to chemicals, such as chloramines in swimming pools, may also affect a large number of individuals.[3,24] Cough can also be chemically induced by angiotensin-converting enzyme inhibitors. This typically nonproductive cough is associated with an irritating, tickling or scratching sensation in the throat, and will disappear or substantially improve within 4 weeks of discontinuing the drug.[1]

Quality of life and economic impact: Acute cough can be very disruptive to patients' well-being and adversely affect family members and co-workers as well. Most patients seek medical attention because of concerns or complications related to the cough syndrome, such as worries about the intensity of cough symptoms, perceptions of fatigue associated with cough, feelings of self-consciousness, and symptoms of sleep deprivation, hoarseness, musculoskeletal pain, sweating, and urinary incontinence in women. Some serious complications associated with vigorous coughing may require prompt assessment and treatment, eg, cough-related syncope, cardiac arrhythmias, pneumothorax, splenic and venous ruptures, seizures, loss of consciousness, and disruption of surgical wounds and intravascular catheters.[1]

Other factors prompting patients to seek professional healthcare are socially avoidant behaviors, vomiting, depression, and excessive perspiration.[1] Some patients experience symptoms for many weeks, even years, before they seek medical help and, in some cases, the patient's relatives or partner initiates the medical referral.[25] The potential benefits of treating cough early could be preventing the vicious cycle of cough perpetuating cough[26] and decreasing the infectious spread of viruses by decreasing cough.

A study investigating the impact of acute cough on health-related quality of life revealed that cough had an adverse effect on well-being in both men and women. However, significantly more women complained of urinary incontinence and exhaustion, whereas significantly more men noted a concern of cancer and having to make lifestyle changes as a result of their cough.[27] Table 2 summarizes the most common adverse symptoms associated with cough.[25]

URTIs also impose a significant economic burden. Studies done in Europe and Australia have shown that the healthcare costs of acute cough and URTIs in children are substantial.[28,29] Similarly, an analysis of hospital admissions in the UK from 1990 to 2005 documented a considerable increase in hospitalizations in the elderly from respiratory episodes in winter, with acute bronchitis (for which the main symptom is acute cough) being the primary and most consistent reason for the hospitalizations.[30] The annual cost of OTC cough medicines in the USA is estimated to be in the several-billion dollar range, despite a lack of efficacy for

Table 3. Over-the-counter and prescription medicines available for the therapy of acute cough

Type of product	Component	Available in combinations with	OTC or prescription; formulation
Cough suppressant	Benzonatate	–	Prescription; perles and capsules
	DXM polistirex	–	OTC; extended-release suspension
	DXM	Antihistamine: *promethazine*	Prescription; syrup
	Hydrocodone	Agent to discourage overdose: *homatropine*	Prescription; tablet and syrup
	Hydrocodone	Antihistamine: *chlorpheniramine*	Prescription; extended-release suspension and extended-release capsule
Antihistamine	Brompheniramine	–	Prescription; elixir and injection
	Brompheniramine	Cough suppressant + decongestant: *DMX + pseudoephedrine*	Prescription; syrup
	Chlorpheniramine	Cough suppressant: *codeine*	Prescription; extended-release suspension
	Clemastine	–	OTC or prescription; tablet and syrup
	Desloratadine	–	Prescription; tablet and syrup
	Desloratadine	Decongestant: *pseudoephedrine*	Prescription; extended-release tablet
	Dexbrompheniramine	Decongestant: *pseudoephedrine*	OTC; extended-release tablet
	Dexbrompheniramine	Decongestant + antipyretic: *pseudoephedrine + acetaminophen*	OTC; extended-release tablet
	Diphenhydramine	–	Prescription; injection, elixir and capsule
	Loratadine	–	OTC; tablet and syrup
	Loratadine	Decongestant: *pseudoephedrine*	OTC; extended-release tablet
	Promethazine	Cough suppressant: *codeine*	Prescription; syrup
	Promethazine	Cough suppressant + decongestant: *codeine + phenylephrine*	Prescription; syrup
	Promethazine	Cough suppressant + decongestant + antihistamine: *codeine + phenylephrine + triprolidine*	Prescription; syrup
Expectorant	Guaifenesin	–	OTC; tablet
	Guaifenesin	Cough suppressant: *DXM*	OTC; tablet
	Guaifenesin	Decongestant: *pseudoephedrine*	OTC; tablet

OTC=over-the-counter; DXM=dextromethorphan

many of these medicines.[31] In addition to the direct and indirect healthcare costs of acute cough, there is a significant morbidity with cough syndromes that imposes additional burdens and healthcare expenditures.[31,32] Considering the high socioeconomic impact of reduced productivity associated with acute-cough syndromes, URTIs are one of the most common reasons for work and school absenteeism,[32] and there is a cascade of productivity losses by caregivers when a child is sick.[28]

A study to quantify the cost of viral respiratory tract infections in the USA found that when survey results of 4,051 respondents who experienced cough in the past year were extrapolated to the population, the total economic burden approaches $40 billion annually. This includes $17billion in direct healthcare resource (medications, medical services) costs and $22.5 billion in indirect costs (productivity losses), per year.[33]

Acute cough management: Appropriate management of acute cough includes sequential evaluation and treatment of the likely causes of cough, using both diagnostic tests and appropriate empiric therapy. The most important initial decision is to determine whether the cough is a sign of a serious, potentially lifethreatening condition, such as pneumonia, pulmonary embolism, congestive heart failure, asthma, COPD, bronchiectasis, or lung cancer, or, as is commonly the case, a result of the common cold or exposure to an environmental allergen or irritant.[34]

Treatment of acute cough caused by viral URTIs tends to be symptomatic, with the aim of suppressing the hypersensitized cough reflex while the underlying cause is cleared naturally. A medical history and physical examination are usually sufficient to determine whether the acute cough is due to a non–life-threatening URTI, a lower respiratory tract infection, exacerbation of an existing condition, or an upper airway cough syndrome.[34]

In some cases, acute cough may be indicative of a serious illness, requiring further investigation. An acute cough that is productive may be a sign of acute bronchitis due to a lower respiratory tract viral infection such as influenza A, bacterial infection, or another condition that mimics acute bronchitis.[34] If a patient remains symptomatic despite evaluation and treatment for 8 weeks, the cough is considered chronic and the primary care clinician should consider referral to a specialist. An algorithm showing differential considerations during the assessment of acute cough is shown in Figure 1.[8]

Current OTC treatments: Most patients initially use OTC cough and cold medicines to relieve acute cough and other symptoms associated with URTIs. However, a Cochrane review of OTC cough medicines, based on randomized controlled trials in children and adults, failed to clearly demonstrate the effectiveness of these medicines. For example, two Cochrane-reported trials on adults with 356 participants compare antihistamine-decongestant combinations with placebo. One trial comparing loratadine/pseudoephedrine (5 mg/120 mg twice daily for 4 days) with placebo (n=283) did not show statistically significant differences in cough scores reported in patient diaries between both groups.[35]

The second trial (n=73) compared dexbrompheniramine/pseudoephedrine (6 mg/120 mg) twice daily for 1 week) with placebo. The mean severity rank of cough on a scale of 0–4, obtained through a patient diary, was less in the active group (1.4) than in the placebo group (2.0) on days 3–5 (p _ 0.05).[36] There was an increased severity of dizziness and dry mouth in the active drug group on days 5–7 and 2–10, respectively. The Cochrane review was inconclusive because the number of trials was small and often with few patients.[37,38] An overview of OTC and prescription cough medicines is given in Table 3.

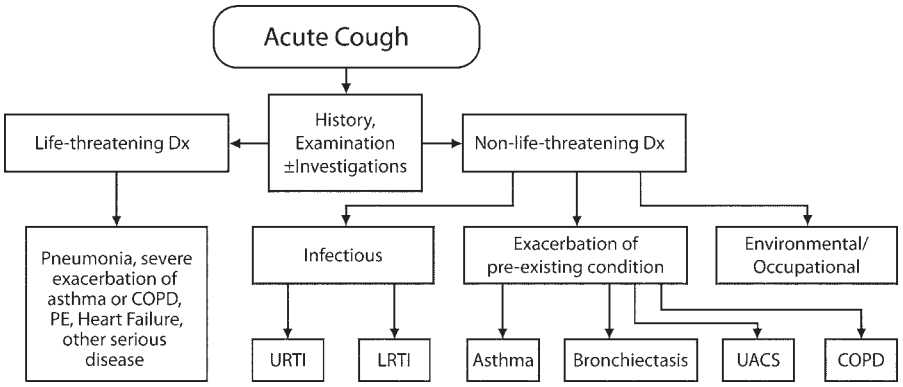

Figure 1. Algorithm for assessment of acute cough in patients ≥15 years of age (adapted with permission from Irwin et al., 2006) [8]. (URTI = upper respiratory tract infection; LRTI = lower respiratory tract infection; UACS = upper airway cough syndrome; COPD = chronic obstructive pulmonary disease).

Most OTC cough medicines are short-acting syrups in two basic categories: cough suppressants (antitussives) and expectorants. Suppressants attempt to dampen the cough reflex to normal levels when its intensity is in excess of that is required to defend the airways.[39] The most commonly used OTC suppressant is dextromethorphan (DXM), which is considered generally safe at recommended doses. However, it can cause hallucinations when taken in large doses. Products containing DXM are rapidly becoming substances of abuse in the USA.[40]

Expectorants may be useful in cases of excessive mucus production, by increasing the volume of mucus and facilitating the removal of secretions by ciliary transport and/or cough.[38,41] The only FDA-approved expectorant in the USA is guaifenesin, which has an established and benign safety profile when used as directed. Although guaifenesin is not typically known as a cough suppressant, it has been shown to inhibit cough-reflex sensitivity in patients with URTI in whom cough receptors are transiently hypersensitive,[42,43] and to reduce subjective measures of acute cough due to upper respiratory infections (URIs).[39,44]

Many OTC products offer combinations of centrally acting cough suppressants (eg, DXM) and expectorants (eg, guaifenesin), as well as combinations of either drug with analgesics, decongestants, and/or antihistamines. Effective antihistamines in combinations are firstgeneration agents, such as dexbrompheniramine and chlorpheniramine. Non-sedating newergeneration antihistamines are considered ineffective for reducing cough in patients with the common cold.[16]

Prescription treatment options: Prescription cough remedies usually contain higher doses of cough suppressant than expectorant agents, and are typically prescribed when OTC remedies have failed to relieve disruptive cough symptoms. Relatively few drugs have been shown to suppress acute cough by an action on mucociliary factors, and none has been shown to do so consistently.[39] Inhaled anticholinergic agents have had inconsistent effects on acute cough, and some of their adverse effects can present challenges in clinical management and adherence.[39] However, a recent study has demonstrated the ability of inhaled tiotropium to suppress cough reflex sensitivity in subjects with acute viral URI.[45] The clinical significance of this finding remains to be elucidated. Similarly, first-generation antihistamines (brompheniramine, chlorpheniramine, clemastine, etc) share a number of adverse effects with anticholinergic agents and may induce drowsiness and gastrointestinal distress.

Although benzonatate, which is believed to work by decreasing the sensitivity of stretch receptors in the lung, is effective for temporary relief of cough, there have been reports of severe adverse reactions to this product, including bronchospasm, laryngospasm, and cardiovascular collapse. Seizures and cardiac arrest are possible following an acute ingestion.[46]

Studies of opiates in acute cough due to URTIs have shown mixed results. Although the antitussive effects of codeine in patients with chronic bronchitis were established in small patient populations, and there have been no double-blind, placebo-controlled studies of codeine in cough due to acute bronchitis, it is reasonable to presume that codeine is effective under these circumstances.[39] When administered orally, codeine has a short duration of action, and up to 95% of a single dose is excreted within 48 hours. Current ACCP guidelines do not recommend the use of peripherally or centrally acting cough suppressants for the treatment of cough due to URTIs, and discourage the use of OTC combinations for the treatment of acute cough due to the common cold, except for an older combination of a first-generation antihistamine plus a decongestant.[39] Patients with acute cough or upper airway cough syndrome can also be administered naproxen to help reduce cough symptoms.[16]

Discussion and future direction of cough management: While there are no established guidelines for when patients should seek medical attention for cough, the authors believe that adults should see a healthcare professional after 8 weeks, at which time the cough is considered chronic. Prior to that, a visit to a professional will depend on cough severity, patient discomfort, and impact on quality of life. However, medical attention should be sought immediately if acute cough is accompanied by certain symptoms that may indicate serious underlying problems: cough with fever and purulent sputum (pneumonia), cough with significant dyspnea (pneumonia, pulmonary embolism, congestive heart failure), and cough with hemoptysis (pneumonia, active TB, endobronchial lesion). Clear guidelines and public education on when patients should seek medical attention for cough, as well as an improved patient-reported cough severity measure, and consideration of the quality-of-life impact in cough management are warranted.

Historically, there has been a dearth of scientific evidence and research in acute cough treatment. When it may be preferable to suppress viral-induced acute cough and when it may be preferable to enhance it utilizing expectorants has not been adequately investigated. Currently available cough-suppressant

therapy is limited by a paucity of effective agents and/or their unacceptable side effects. There is also a lack of clinically useful tools to measure the effect of cough suppressants and drugs that address symptomatology.

Most current treatments are liquid formulations, which share common problems with all medicines not dispensed in tablet form, including difficulties with precise measuring of doses and the common practice of exceeding recommended doses, which can lead to significant unintended complications. Storage and transportation are other relevant disadvantages of liquid formulations, especially when traveling.

The ideal treatment for acute cough would not only have a well-established safety profile, but also provide rapid and long-acting relief, with sufficient effectiveness to allow patients to sleep throughout the night. In the future, longer-acting formulations of cough-suppressing agents using extended-release technology to deliver sustained relief, or existing agents used in novel combinations may play an important role in developing more optimal treatments for acute cough. Current research is also investigating alternative cough suppressants that may have improved side-effect profiles. These include large-conductance calcium-activated potassium channel openers and agents selectively targeting various receptors (eg, vanilloid receptor antagonists, selective opioid or opioid-like receptor agonists, tachykinin receptor antagonists, endogenous cannabinoid type-1 receptor agonists and antagonists, 5-hydroxytryptamine receptor agonists).[47]

Conclusions

Acute cough is a serious problem that has an adverse impact on the well-being of patients, families, and caregivers, and on health economics. The clinical morbidity and quality-of-life and economic issues associated with acute cough warrant increased attention to this common syndrome.

Most current treatments for acute cough lack evidence-based proof of efficacy to support their use. Many are short-acting liquid formulations, and many contain anticholinergics, firstgeneration antihistamines, or DXM. Guaifenesin, the only available OTC expectorant with antitussive effects is short acting, but more recently long-acting guaifenesin formulations and combination products have been launched. Codeine, the most common prescription opiate antitussive, is only available in a short-acting form and requires frequent daily dosing. Treatment with a prescription medication is frequently necessary to control disruptive cough symptoms, even if the underlying cause of symptoms, the acute viral infection, is self-limiting.

There is a need for a reliable, longer-acting formulation in solid form that can safely and consistently deliver relief of cough for extended periods, particularly at night, as well as for combinations of agents with complementary mechanisms of action. Due to the ineffectiveness of current therapies to suppress cough episodes in many patients, the combination of an expectorant to facilitate productive cough and an extended-release opiate to decrease cough frequency may bring incremental and clinically desirable results.

The current strategies for cough suppression should be reassessed through the implementation of controlled clinical trials in large populations. Evidence-based medicine should guide the development of novel treatments that can more effectively reduce the social and healthcare burden associated with acute cough.

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Intubation and Mechanical Ventilation of the Asthmatic Patient

Jeff Borrink, Paul Garbarini

In the United States, there are approximately 2 million emergency department visits for acute asthma per year.[1] Approximately 2% to 20% of admissions to intensive care units (ICUs) are attributed to severe asthma with intubation and mechanical ventilation deemed necessary and mortality rates in these patients range from 10% to 20%.[2]

The American Thoracic Society recently published an article with recommendations for intubation and mechanical ventilation of the asthmatic patient in respiratory failure. The article by Brenner et al, part of a Joint Emergency Department (ED) Task Force from several different schools of medicine, reviews the recent evidence-based data regarding the indications, techniques, and complications of intubation and mechanical ventilation in the treatment of acute asthma in the ED. Strategies are discussed for possibly preventing the need for intubation in patients with severe exacerbations who are not responding to conventional therapy. Recommendations for the practical management of these patients in the clinical setting are provided.[3]

The Joint ED task force identified 7 key areas for discussion from their review of the literature and their clinical experience:
1. Prevention of intubation
2. Criteria for intubation
3. Recommendations for intubation technique
4. Recommendations for appropriate ventilator settings
5. Management in the immediate post intubation period
6. Medical management of asthma in the ventilated patient
7. Prevention and treatment of complications

The Joint ED task force discussion includes recommendations for appropriate ventilator settings, management of auto-positive end expiratory pressure (autopeep), and permissive hypercapnia vs hyperinflation, which will be the focus of this discussion.

The severe asthmatic patient being mechanically ventilated presents challenges to the clinician. Dynamic hyperinflation from breath stacking, and autopeep often occur, putting the patient at risk for hypotension and barotrauma, and often causing significant patient discomfort and asynchrony. Clinicians should therefore be alert for and anticipate these complications, and take measures to reduce them.

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Positive end-expiratory pressure is the pressure in the alveoli at the end of exhalation that is greater than the atmospheric pressure due to ventilator set PEEP level. Normally, during passive exhalation, the lungs empty by elastic recoil, and at the end of exhalation the alveolar pressure is the same as the PEEP setting. The severe asthmatic patient requiring mechanical ventilation has diminished expiratory flow causing incomplete emptying of alveolar gas. The lungs may not deflate fully prior to the beginning of the next breath delivery, and the end-expiratory pressure and volume and remains elevated. As end-expiratory lung volume increases, so does end-inspiratory volume for a given tidal volume, predisposing the patient to dynamic hyperinflation.[4,5] This elevated pressure above the PEEP setting measured at end exhalation is termed "autopeep."

Three ventilator strategies are offered by the ED task force to reduce autopeep and dynamic hyperinflation in the intubated asthmatic patient. The first and most effective strategy is to reduce the respiratory rate. If one is unable to reduce the rate enough for reduction of autopeep and dynamic hyperinflation to acceptable levels, inspiratory time can be shortened to allow for a proportionately longer time for exhalation. Tidal volume reduction may also be appropriate, but it is limited by its progressive effect on the dead-space fraction (eg the biggest bang for the buck is to increase the time available for exhalation which is most efficiently achieved by reducing the rate vs adjusting the inspiratory time setting). Alternatively, one could state that reducing the minute volume setting achieves the same purpose.

Decreasing respiratory rate in an attempt to reduce autopeep and dynamic hyperinflation can cause hypercapnia in the intubated asthmatic patient. Fortunately, hypercapnia is often well tolerated in these patients, even with arterial $PaCO_2$ values as high as 90 mm Hg, and in selected, critically ill patients it might be safer to accept hypercapnia than to over ventilate to a normal $PaCO_2$ at the cost of critical hyperinflation.

One way to recognize autopeep is by examining the graphic display of the flow vs time waveform on the ventilator. Exhalation that continues until the next breath starts, or expiratory flow that does not return to baseline prior to the initiation of the next breath suggests the presence of autopeep.

If autopeep is recognized or suspected, it should be measured. Autopeep can be measured by employing an end-expiratory hold maneuver, which terminates expiratory flow and allows

equilibration of the alveolar pressure and the airway pressure. Accurate and reliable measurements require patient-ventilator synchrony without active respiratory effort. The resulting airway pressure measurement represents the average total PEEP present, and autopeep is then calculated by subtracting external PEEP from total PEEP. Efforts should be made to try to keep autopeep less than 15cmH_2O.[6]

There is some disagreement/confusion in regards to terminology; ventilators as noted above, will typically calculate "autopeep" as the end-expiratory hold pressure-external (set) PEEP. In reality, depending on whether the autopeep is due to flow limitation vs "inappropriate" ventilator settings, the set PEEP may or may not be contributing to the total PEEP measured with an expiratory hold. One can assess this in individual patients by turning the set PEEP to 0cm and repeating the expiratory hold. This then is the actual autopeep and at times may be equal to the total PEEP measured even with PEEP set on the ventilator. In other words, if the total PEEP is no higher as you increase set PEEP, you know the external PEEP setting is not exacerbating or contributing to further increases in autopeep. If one examines a pressure volume loop in volume control mode with a constant flow, in these cases you may observe pressure rising with no volume delivered until the peak pressure exceeds the patient's intrinsic autopeep level. So often there's a net effect of intrinsic autopeep and set PEEP which the clinician should be aware of.

In severe asthmatic patients with airflow obstruction, external PEEP may be employed to decrease work of breathing (WOB) and relieve dyspnea, but not as a treatment for the underlying condition. In a patient with autopeep, during patient-initiated breaths, the inspiratory muscles have to produce an initial effort to overcome the opposing recoil pressure before the ventilator can be triggered and inspiratory flow can begin. Autopeep acts as an inspiratory threshold, and therefore creates additional work that the respiratory muscles must overcome to initiate a ventilator breath. In this situation, applying external PEEP during mechanical ventilation may reduce the patient's WOB. In addition, external PEEP may increase expiratory flow and reduce WOB by stenting collapsible airways, much like pursed lip breathing does for patients with chronic obstructive pulmonary disease. External PEEP should not be applied to all severe asthmatic patients with airflow obstruction who are being mechanically ventilated-only those with autopeep, with flow limitation and dynamic airway compression. If external PEEP is kept below 75%[7] to 85%[8,9] of the autopeep level, worsening hyperinflation or circulatory depression are unlikely to occur. Note, if the patient is synchronous or paralyzed, some would argue there's no benefit to adding external PEEP as the patient is not working to trigger the ventilator. We would argue, ok, speculate that allowing flow to start entering the lung earlier in the inspiratory phase potentially provides for a more even distribution of ventilation as long as the set PEEP is not raising the total PEEP level.

If dynamic hyperinflation is suspected, the plateau pressure should be measured as well so as to assess potential for baro/volutrauma due to hyperinflation. Plateau pressure is measured by applying an end-inspiratory hold maneuver, temporarily stopping flow at end-inspiration during a single delivered breath. Pplat estimates average end-inspiratory alveolar pressure, and many experts agree that complications are rare when Pplat is less than 30cmH_2O.[6]

The article also recommends using volume control mode with a constant flow rate (square or decelerating). Those recommendations are sound; however others would argue that Pressure control modes offer an advantage. If the severity of obstruction increases, in VC mode the pressures will increase and potentially increase risk of hyperinflation unless ventilator setting changes are made or other interventions made. Whereas in pressure control mode, the tidal volume will be sacrificed and hypercapnia worsen.

The Joint ED task force goes on to discuss each of the other key areas mentioned earlier for intubation and mechanical ventilation of the asthmatic patient including prevention of intubation, criteria for intubation, recommendations for intubation technique, management in the immediate post intubation period, medical management of asthma in the ventilated patient, and prevention and treatment of complications. In addition, different tables are included that offer alternative therapies for possible prevention of intubation, consensus indicators for intubation, benefits/risks of intubation methodology, initial ventilator settings, and guidelines for the use of metered dose inhalers and nebulizers in mechanically ventilated patients.

To see the full article on-line or to download a full text pdf file of the article, please go to pats.atsjournals.org/cgi/content/full/6/4/371.

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Public Perceptions Of Quarantine: Community-Based Telephone Survey Following An Infectious Disease Outbreak

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Abstract

Background: The use of restrictive measures such as quarantine draws into sharp relief the dynamic interplay between the individual rights of the citizen on the one hand and the collective rights of the community on the other. Concerns regarding infectious disease outbreaks (SARS, pandemic influenza) have intensified the need to understand public perceptions of quarantine and other social distancing measures.

Methods: We conducted a telephone survey of the general population in the Greater Toronto Area in Ontario, Canada. Computer-assisted telephone interviewing (CATI) technology was used. A final sample of 500 individuals was achieved through standard random-digit dialing.

Results: Our data indicate strong public support for the use of quarantine when required and for serious legal sanctions against those who fail to comply. This support is contingent both on the implementation of legal safeguards to protect against inappropriate use and on the provision of psychosocial supports for those affected.

Conclusion: To engender strong public support for quarantine and other restrictive measures, government officials and public health policy-makers would do well to implement a comprehensive system of supports and safeguards, to educate and inform frontline public health workers, and to engage the public at large in an open dialogue on the ethical use of restrictive measures during infectious disease outbreaks.

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Background

Long considered an anachronism from a bygone era, quarantine has re-emerged in the 21st century as an important (albeit controversial) tool in the battle against infectious disease. Prior to the 2003 outbreak of severe acute respiratory syndrome (SARS), it had been more than 50 years since mass quarantine measures had been invoked in North America.[1] The SARS containment measures imposed in Canada and Asia, and on a lesser scale in the U.S., provoked a heated debate within the public health community regarding the ethics and legality of quarantine.[2-7]

Likewise, the SARS experience has sparked a renewed research interest in the ethics and effectiveness of quarantine. The findings of two recent retrospective studies of the 1918 Spanish flu pandemic strongly suggest that it was non-pharmaceutical inventions such as quarantine and other social distancing measures that were most effective in slowing the rate of spread and minimizing the rate of death.[8,9] And data from SARS-affected regions have pointed to the enduring value and effectiveness of quarantine and other restrictive measures.[10,11] In contrast, there are those who argue that the use of quarantine during SARS was both ineffective and inefficient.[6,7] The advent of advanced statistical modelling has added a new dimension to this long-running debate.[12,13]

Toronto experienced the largest outbreak of SARS in North America, with investigation of 2,132 potential cases and identification of 23,103 contacts of SARS patients who required quarantine.[11] Post-SARS investigations have detected myriad adverse effects among those quarantined: significant feelings of uncertainty, anxiety, and isolation;[14] experience of stigma, fear, and frustration;[15] symptoms of depression and post-traumatic stress disorder;[16] and loss of anonymity.[17]

Despite the long and controversial history of quarantine, little is known about lay perceptions of and attitudes toward its modern-day use. In view of the evidence of potential adverse effects on individual well-being and psychosocial health, and owing to the critical necessity of high compliance in the event of a major infectious disease outbreak, it is increasingly important to understand how quarantine is perceived by the general public.

Therefore, the objective of the present study was to determine prevailing public attitudes toward the use of quarantine as a means of infectious disease control.

Methods

Participants and setting: The study was conducted in two regions of the Greater Toronto Area (GTA), specifically the City of Toronto proper and the Regional Municipality of York located directly to the north of Toronto. The GTA is among the largest metropolitan areas in North America with a population exceeding 5.5 million.[18] As the urban centre of the GTA, the City of Toronto is a denselypopulated, cosmopolitan city (population estimate: 2,500,000; population density: 3,972/km2; visible minority population: 46%). In contrast, York is a much less-densely populated suburban region comprised of several small cities and towns (population estimate: 900,000; population density: 506.7/km2; visible minority population: 30%).

The study sample was stratified to include an equal number of participants from Toronto and York. There was no age or gender stratification. All participants provided verbal consent over the telephone prior to the survey interview. Research ethics approval was obtained from the University of Toronto, Toronto Public Health, and York Region Public Health Unit.

Survey instrument: The survey instrument was developed by Toronto Public Health for use in a telephone survey of the general public following the SARS outbreak. The data reported in this paper are derived from a subset of 15 survey items specifically designed to measure public attitudes towards the use of quarantine during infectious disease outbreaks. These items addressed issues ranging from the legality of restrictive measures, the perceived effectiveness of quarantine, and the supports that should be supplied to those affected by quarantine orders. Respondents were asked to indicate their level of agreement/disagreement with each item; the response format was a 5-point Likerttype design (1="Strongly Disagree"; 2="Somewhat Disagree"; 3="Neutral"; 4="Somewhat Agree"; and 5="Strongly Agree").

After the response format was explained and before the first survey item was asked, all participants were provided standardized definitions of 'quarantine' ["Quarantine means that you must stay in a separate area away from others because you were around someone with a serious illness and so you might have it, too."] and 'infectious disease' ["Infectious disease means a sickness that you can catch from another person, like the flu or tuberculosis.]. At the conclusion of the survey, respondents were asked to supply general demographic information.

Data collection and analysis: Data collection occurred between April 25, 2005 and May 16, 2005. The survey was administered using computer-assisted telephone interviewing (CATI) technology. The 15 interviewers received training in advance and worked with the assistance of two project supervisors. Potential participants were screened for eligibility at the beginning of each call. Inclusion criteria included the following: minimum age of 18 years, primary residence located within the study area during the SARS outbreak, English comprehension skills, and ability to provide informed consent. Those who did not meet the minimum age criteria were asked if another member of the household aged 18 or above was available to participate in the survey. A final sample of 500 individuals was achieved through standard random-digit dialing.

Table 1. Demographic profile of survey respondents

	Female	Male	Total
Personal Characteristics			
Age group			
18-35 yrs	94	55	149
36-65 yrs	176	104	280
>65 yrs	51	19	70
Total	321	178	499
Location			
Toronto	153	97	250
York	169	81	250
Total	322	178	500
Quarantine Status			
Was anyone in your home quarantined during SARS?			
No	307	172	479
Yes, myself but nobody else in my home	8	1	9
Yes, myself and someone else in my home	5	3	8
Yes, not myself but someone else in my home	2	1	3
Total	322	177	499

The survey response rate varied slightly by study region. Excluding calls to ineligible participants (i.e., did not meet inclusion criteria) and disqualified numbers (eg, not in service, wrong number, fax/computer/business line), the final response rate was 27% for the City of Toronto and 31% for York Region. A factor analysis using Varimax rotation with Kaiser Normalization was performed on the data yielding four factors. Composite index scores were then computed for each factor by summing the responses on items loading on the respective factors. Thus, if a factor comprised five items then individual composite scores for that index could range from 5 to 25. Bi-variate and multivariate analyses were performed to investigate the inter-relationships among variables. All analyses were performed using SPSS 11.0 for Windows. No statistical weighting of the data was performed.

Results

Descriptive analysis: A total of 500 participants were administered the subset of survey items on quarantine. Table 1 presents a summary of the demographic characteristics of this sample. The majority were middle-aged (56%) and female (64%). Within this sample, 4% of participants were personally impacted by quarantine during the SARS crisis (ie, either they or someone else in their home was ordered into quarantine).

Table 2 presents the distribution of responses for each of the 15 Likert-type survey items (from "Strongly Agree" through to "Strongly Disagree"). In the table, the wording of the individual items is precisely as appeared on the survey instrument; however, for the purposes of presentation, the items are clustered according to the findings of the factor analysis (as described below). As there were no significant differences between respondents from Toronto versus York, the overall results are shown. The vast majority of respondents indicated agreement (either "Strongly Agree" or "Somewhat Agree") that sufficient justification exists for the use of quarantine during infectious disease outbreaks. Similarly, most respondents agreed that public health authorities and government officials should endeavour to lessen the burdens endured by those ordered into

Table 2. Public attitudes toward quarantine (Qx) by factor

	Strongly Agree	Somewhat Agree	Neutral	Somewhat Disagree	Strongly Disagree
Justification					
Public Health should have the power to order people into Qx during outbreaks	77%	18%	3%	1%	0%
Qx is a good way to stop the spread of infectious disease outbreaks	76%	18%	3%	3%	0%
If someone is given a Qx order by Public Health, they should follow it no matter what else is going on in their life at work or home	70%	22%	5%	2%	1%
If I go into Qx, my family/friends/community will be protected from becoming sick	66%	22%	4%	5%	3%
Sanctions					
People who break Qx orders on purpose should face legal penalties like a fine or jail	53%	25%	14%	4%	3%
Public Health should be able to lock people up if they fail to obey Qx orders	28%	30%	19%	11%	12%
Public Health should use electronic bracelets and in-home surveillance cameras for people who disobey Qx orders	27%	23%	20%	12%	18%
Burdens					
Public Health needs to explain to everyone why they should be allowed to use Qx	84%	13%	2%	0%	1%
Government should pay for nurses and counselors to help people who are in Qx	77%	16%	4%	2%	1%
Public Health should ensure that people have food and shelter while in Qx, and pay for it with public money if need be	68%	19%	7%	4%	3%
Government should pay for counselors and support groups so that people coming out of Qx have someone to talk to about it	43%	29%	14%	9%	6%
People in Qx should get money from the government to pay for missed time at work	43%	26%	17%	9%	6%
Safeguards					
Public Health should ensure that there is no discrimination in the use of Qx	91%	8%	1%	0%	0%
It is reasonable for some rights to be taken away during an infectious disease outbreak	52%	30%	8%	4%	6%
People who disagree with their Qx order should be able to request a review to have it ended early	43%	35%	10%	3%	9%

quarantine. Likewise, there was majority support for the use of various legal sanctions, penalties, and/or coercive measures in order to maximize compliance with quarantine orders. And, finally, the vast majority of respondents were in favour of safeguards against unwarranted and/or inappropriate use of quarantine. While these high percentages suggest a certain degree of convergence of opinion, it is important to note that the proportion of respondents indicating "Strongly Agree" versus "Somewhat Agree" varies significantly across the 15 items, as indicated in Table 2.

Finally, survey participants were asked to indicate, by way of forced choice, their response to this statement: "Breaking or not obeying a quarantine order is most like which of the following [choose 1 only]: (a) parking in a no-parking zone; (b) driving way above the speed limit on a busy street; or (c) physical assault." Fully 59% responded that breaking quarantine is most like "physical assault," whereas 27% selected "driving above the speed limit" and 8% chose "parking in a no-parking zone"; (6% did not answer).

Factor analysis: Principal components factor analysis of the survey data yielded an underlying factor structure of four independent factors. Based on a subjective analysis of the content of items loading on each individual factor, the four factors were labelled as follows: 'Justification,' 'Sanctions,' 'Burdens,' and 'Safeguards' (as shown in Table 2).

Bivariate/multivariate analysis: Four sub-scales were computed by summing scores for the items within each of the factors identified in the factor analysis. In addition, a total composite index was computed by summing scores across the four sub-scales. Scores on the four sub-scales and composite scale were submitted to age, gender, and regional analysis. Analysis of variance testing revealed a number of statistically significant age and gender differences. On the "Justification" sub-scale, female respondents scored significantly higher than males [$F=11.456$ ($df=1$), $p<.001$], thereby indicating greater agreement that the use of quarantine is justified in the context of an infectious disease outbreak. With respect to age, older respondents (>65 yrs) indicated greater agreement that use of quarantine is justified than did the young (18-35 yrs) [$F=4.514$ ($df=2$), $p<.01$]. Also, older respondents agreed more strongly that the use of sanctions for quarantine absconders is appropriate when compared both with the young and with the middle-aged (36-65 yrs) [$F=4.577$ ($df=2$), $p<.01$]. There were no significant differences by region.

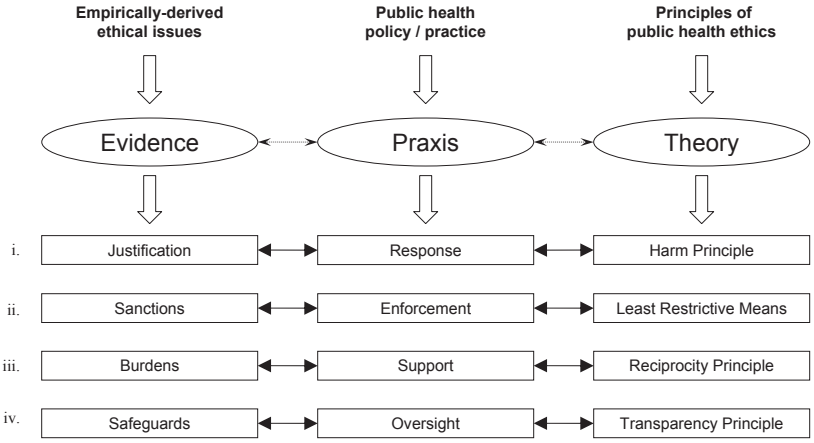

Figure 1

Discussion

The quarantine of exposed persons (along with the isolation of infected persons) has been properly described as the most complex and most ethically and legally controversial intervention within the jurisdiction of public health.[19] Complexity and controversy notwithstanding, the present data indicate a very high rate of public acceptance of quarantine as a means to control the spread of infectious disease. Indeed, the vast majority of respondents indicated strong support for the use of quarantine in an infectious disease outbreak, for legal penalties against absconders, for social supports for those affected, and for public safeguards against potential inappropriate use.

Data on public attitudes toward quarantine in the wake of SARS are scarce. Public opinion polls have indicated high levels of acceptance of quarantine among samples of Torontoarea residents (97%) and US citizens (93%).[20] These findings are supported by an observed non-compliance rate of only 0.1% among Torontonians requiring quarantine during SARS.[11] A qualitative study of factors influencing compliance with quarantine in Toronto identified protection of the health of the community as a prominent motivating factor. The authors of the study concluded that while the overall compliance rate among residents of the GTA appears to have been high, the influence of civic duty and social responsibility may not be as significant in other countries and cultures.[21]

Comparative data from international studies do lend support to the theory that cultural values and societal norms impact upon quarantine compliance rates. Researchers at the Harvard School of Public Health and the U.S. Centers for Disease Control and Prevention surveyed residents of Hong Kong, Taiwan, Singapore, and the U.S. and found significant regional variability.[22] The proportion of survey respondents favouring the quarantine of persons suspected of having been exposed to a serious contagious disease was as follows: 76% in the US, 81% in Hong Kong, 89% in Singapore, and 95% in Taiwan. By way of comparison, in the present study, 94% of respondents agreed that quarantine is a good way to stop the spread of infectious disease outbreaks. Interestingly, in our study, significantly fewer (58%) agreed that public health officials should be able to detain those who fail to obey quarantine orders. Likewise, in the Harvard study, the proportions favouring the use of quarantine decrease significantly if people could be arrested for refusing (to a low of only 42% in the US to a high of 70% in Taiwan). The authors partially attributed the observed differences to prior experience with infectious disease outbreaks in which quarantine and other restrictive measures were implemented.[21]

In view of this inter-region variability, it is not surprising that the global community of public health experts is itself conflicted about the use of quarantine and other restrictive measures that impinge upon the intrinsic rights of individuals. Those who favour the consideration of quarantine during infectious disease outbreaks maintain that it is prudent public health policy,[23] whereas those in opposition argue that quarantine is inherently paternalistic and an unnecessary breach of basic human rights.[24] Despite the difference of opinion, however, there does appear to be general agreement on this: "ultimately, public health must rely not on force but on persuasion, and not on blind trust but on trust based on transparency, accountability, democracy, and human rights."[24]

With a view to fostering further deliberation and constructive debate, we are proposing a conceptual framework for the ethical use of restrictive measures in public health emergencies (see Figure 1). Building upon previous theoretical work on the justification for public health intervention,[25] our model is designed to reflect the dynamic interplay among theory, empirical evidence, and policy/practice that is inherent to public health. To that end, we have incorporated the empirical data from the public opinion survey described in this paper. The model explicitly contemplates the four primary functions of public health as regards the use of restrictive measures in infectious disease outbreaks, namely, response, enforcement, support, and oversight. For instance, with respect to the enforcement of quarantine orders, the model illustrates how the specific function of enforcement aligns with the ethical principle of the 'least restrictive means' and is likewise concordant with empirical evidence indicating strong public support for the use of sanctions to promote compliance with quarantine orders (survey data reported here). This conceptual framework for the ethical use of restrictive measures in public health emergencies should be considered provisional and, as such, is open to further testing and refinement.

Implications

Much has been learned from the unexpected arrival of SARS in the spring of 2003.[26,27] Likewise, we continue to learn from historical analyses of the 1918 influenza pandemic, with one recent study providing strong support for the hypothesis that early implementation of public health measures such as

quarantine can significantly reduce influenza transmission.[9] Given the current threat posed by pandemic influenza, it is incumbent upon the public health community including ethicists and legal experts to delineate both the limits to individual liberty and the obligations of public health authorities in the context of an infectious disease outbreak. It is noteworthy that the concept of 'voluntary quarantine' features prominently in many of the current plans for pandemic influenza. As contrasted with the classic quarantine order, which is typically enforceable by law, voluntary household quarantine refers to compliance based on the individual's own free will without legal compulsion.

Owing to the global threat of pandemic influenza, considerable planning and preparation for infectious disease outbreaks has been undertaken.[28] There remains a pressing need, however, to engage the citizenry more fully in the process of preparedness planning in order to ensure that the plans reflect the common will and that the policies serve the common good.[29] In this regard, the continuing growth in interest and activity in the subfield of public health ethics is certainly welcome and holds great promise.

While we believe the data reported here contribute to the goal of better planning and better preparedness, the present study is limited by its sample of respondents who were drawn only from the Greater Toronto Area. Our goal was to assess the attitudes and perceptions of those living in an area significantly impacted by the SARS outbreak, but further research is now required to determine the generalizability of the present findings to other geographic regions and other populations. Also, our survey was conducted after the conclusion of the outbreak; it is conceivable that public perceptions and attitudes toward the use of restrictive measures could be different during the course of an outbreak. Finally, a relatively small proportion of our survey respondents were directly affected by quarantine during SARS, which precluded any analysis of differences between those who were directly affected and those who were not.

Conclusions

The use of restrictive measures such as quarantine draws into sharp relief the push and pull of opposing forces that characterize the dynamic interplay between the personal autonomy of the citizen on the one hand and the collective rights of the community on the other. As Bensimon and Upshur[3] have argued, justification for quarantine cannot be founded upon scientific evidence alone; rather, the decision to implement quarantine should be equally informed by the values, preferences, and practices of the affected communities. The present findings indicate strong public support for the use of quarantine in the context of an infectious disease outbreak and for serious sanctions against those who fail to comply. Our data further suggest, however, that public support for quarantine is contingent on the implementation both of legal safeguards to protect against inappropriate use and of psychosocial supports to provide for individuals who are adversely affected. This tension between individual rights and the greater public good is precisely the challenge that infectious disease presents to public health ethics. In order to engender strong public support for the use of quarantine and other restrictive measures, government officials and public health policy-makers would do well to implement a comprehensive system of supports and safeguards, to educate and inform frontline public health workers, and to engage the public at large in an open dialogue on the ethical use of restrictive measures during infectious disease outbreaks.

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Experience Talks: Physician Prioritization of Contrasting Interventions to Optimize Management of Acute Cough in General Practice

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Abstract

Background: Uptake of interventions to improve quality of care by clinicians is variable and is influenced by clinicians' attitudes. The influence of clinicians' experience with an intervention on their preference for adopting interventions is largely unknown.

Methods: Thematic analysis of semi-structured interviews exploring views and attitudes towards an illness-focused intervention (specific communication skills training) and a disease-focused intervention (C-reactive protein, or CRP, point-of-care testing) to optimize management of lower respiratory tract infections (LRTI) among general practitioners (GPs) who had used both interventions for two years in a randomised trial (exposed GPs), and GPs without experience of either intervention (non-exposed GPs).

Results: All but two of the ten non-exposed GPs indicated that they would prioritize implementation of the disease-focused intervention of CRP testing over communication skills training, while all but one GP in the exposed group said that they would prioritize the illness-focused approach of communication skills training as it was more widely applicable, whereas CRP testing was confirmatory and useful in a subgroups of patients.

Conclusion: There are differences in attitudes to prioritizing contrasting interventions for optimizing LRTI management among GPs with and without experience of using the interventions, although GPs in both groups recognized the importance of both approaches to optimize management of acute cough. GPs' experiences with and attitudes towards interventions need to be taken into account when planning rollout of interventions aimed at changing clinical practice.

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Introduction

Achieving effective uptake of new evidence into routine clinical care is challenging. Several barriers and enablers to evidence uptake have been identified. These range from practice environment and organisational factors to professional knowledge and attitudes.

Continuing professional development is concerned with the acquisition, enhancement, and maintenance of knowledge, skills, and attitudes. Learning and improving practice, including uptake of new interventions, is mainly governed by individual clinicians' motivation and perceived needs. However, clinicians may not choose to adopt the most effective or important interventions and identifying factors influencing health professionals' behaviors is challenging.

For example, contrasting approaches have been suggested for enhancing physician antibiotic prescribing practices. A disease-focused perspective promotes interventions to decrease diagnostic uncertainty such as diagnostic tests. An illness-focused perspective promotes interventions aimed at addressing the patients' agenda, such as physician communication skills training. However, it is not known how experience with one or other of these broad approaches influences GPs perceptions about which intervention type they would prioritize for adoption into their own practice.

We therefore studied the role of experience with interventions in influencing clinician prioritizing of intervention uptake. We focused on two contrasting interventions for improved management of the exemplar condition of lower respiratory tract infections (LRTI) in general practice. We describe the attitude of physicians with experiences of implementing both approaches and the attitude of physicians who have no practical experience of either intervention. Our goal was to highlight the influence of physician exposure to contrasting approaches when considering prioritizing interventions for adoption into their clinical practice.

Methods

IMPAC^{3}T trial: We analyzed qualitative interview data obtained from general practitioners (GP) who participated in the IMPAC^{3}T trial (Improving Management of Patients with Acute Cough by C-reactive protein testing and Communication skills Training). This study was a factorial, cluster randomized clinical trial assessing the effect of two contrasting interventions, singly and combined, on antibiotic prescribing for LRTI. These interventions were: 1. Disease-focused: C-reactive protein (CRP)

Table 1: Preferences of exposed and non-exposed GPs towards illness or disease-focused interventions to improve LRTI management

Exposed GPs	Preference
'You can't take them apart, I want them both.' (GP1)	Undecided
'I found CRP less useful than communication skills training.' (GP2)	CST
'Communication is the key component of our profession. If not doing it [communication skills as thought in the training] yet, one should immediately consider it. The other thing [CRP] is an addition, but a very useful one in my opinion.' (GP7)	CST
'Communication, as I think this is the most important in consultations, either in LRTI or another condition... CRP as a value is wonderful, but it doesn't tell you everything.' (GP8)	CST
'Communication skills training.' (GP9)	CST
'If I really need to choose I need to say communication skills training.... That was great fun to do, to systematically use it, it works.' (GP10)	CST
'The communicative bit has my preference yes. I always try to do without the test, but well, if I don't succeed I pull out CRP to convince patients.' (GP13)	CST
'Communication. I try to structure my consultation to give attention to all aspects, and CRP can be one of them.' (GP14)	CST
'Communication training... in the majority of patients you do well with these skills, and when in doubt with CRP.' (GP17)	CST
'You'll achieve most by doing communication skills training.' (GP18)	CST
Non-exposed GPs	**Preference**
'I'd choose CRP. Two reasons: I'm a games person, so I love such a test very much... and because I feel that communication skills training thing, well... I don't think I need to improve that much in that field... I don't feel communication is the problem in antibiotic prescribing.' (GP3)	CRP
'Yes, CRP.' (GP4)	CRP
'CRP, as it is useful in my practice and because I feel I can get patients on my side with it. I think that the magic of the machine is more than the magic of my words.' (GP5)	CRP
'Most obvious would be CRP, easier and less time consuming.' (GP6)	CRP
'CRP, as I think that I will not improve that much when knowing how to give information back to the patient, but I would find it useful to have such a test in my practice.' (GP11)	CRP
'I think communication training, as I can buy CRP myself.' (GP12)	CST
'CRP, it is useful to know that it is there to be used.' (GP15)	CRP
'CRP could help me in case of doubt, I don't see how communication would help me in that regard.' (GP16)	CRP
'In the end communication skills training will benefit the most. It is, in any form, always an eye-opener and even if only small bits are remembered, it is nice.' (GP19)	CST
'CRP for sure. Much easier, much faster. I expect more of it than of communication skills training. Such a training will offer some extra, but not much.' (GP20)	CRP

CST = Communication skills training (Illness focused approach)
CRP = C-reactive protein point-of-care testing (Disease focused approach)

point-of-care testing, assisting GPs to differentiate serious from self-limiting LRTI. 2. Illness-focused: Clinician communication skills training, assisting GPs to provide evidence-based information on the natural course of LRTI and setting realistic expectations on the role of antibiotics for LRTI.

The trial protocol and description of the clinician communication skills training as well as the effectiveness and cost-effectiveness of the two interventions have been described elsewhere. In brief, both interventions were effective at reducing antibiotic prescribing for LRTI, without compromising clinical outcome or patient satisfaction. Both interventions were cost-effective from the health care perspective. As part of the process evaluation, we interviewed all participating GPs after trial completions to explore their experiences with and attitudes towards the interventions.

Because GP practices were randomized in the trial, we had the unique opportunity to explore views and attitudes towards these contrasting interventions of two distinct groups of GPs: 1. GPs exposed to both interventions: 10 GPs had used both interventions (CRP and communication skills) for at least two years (exposed GPs); 2. GPs not exposed to either intervention: 10 GPs practicing as usual without either of the two interventions during these two years (non-exposed GPs)

Interview procedure: We used qualitative research methods as these are best suited to achieving a deep understanding of experiences and views from the perspective of the physicians (rather than quantifying the pre-conceived notions of researchers). We conducted individual, semi-structured interviews in GP surgeries. The average length was 30 minutes. Interviews were audio taped and took place in the first winter after the end of the trial. The GPs were told that our purpose was not to audit or pass judgement on practice but to understand their experiences and views. At the time of the interview, GPs were unaware of the trial results. Two trained interviewers conducted semi-structured interviews. For unexposed GPs, we extensively described the interventions and asked them about the possible impact on their own practice and about their preferences for prioritizing the interventions. The interview guide was piloted in one videotaped interview. All questions were open, followed by predetermined prompts when there was no response to the initial question. We aimed to interview all 20 study GPs. The main question in the interview schedule that generated data for the present analysis was: Which intervention would help you most improving your management of LRTI and why?

Data analysis: The audiotaped interviews were transcribed by an experienced medical typist. Three researchers then read

the transcripts. Analysis and data collection were conducted in parallel. Coding schedules were agreed upon and piloted. Seventy percent of the interviews were double coded, with the remaining transcripts coded by only one researcher. Discrepancies were resolved by discussion whenever possible. Where disagreement remained, a third researcher was consulted who made the final decision. We sought to identify commonly expressed themes as well as unusual cases using thematic content analysis. This method of analysis is essentially a process of summarization, categorization, and counting frequency of responses. Data analysis and reporting was assisted by NVivo software.

Results

All 20 GPs in the relevant randomisation groups in the cluster randomised controlled trial agreed to be interviewed. GPs' characteristics in each group were similar and comparable to average Dutch GPs. The quotations in Table 1 illustrate that GPs in the two groups expressed contrasting initial reactions in answer to the key question (Which intervention would help you most improving your management of LRTI and why?)

All but two of non-exposed GPs indicated they would prefer to adopt the disease-focused intervention of CRP testing to optimise management of LRTI in their practice. This contrasted with the exposed GPs, where all but one indicated they favored the illness-focused approach of enhanced communication skills training for LRTI management. The one exception in this group declined to make a choice, as he felt both approaches should always be integrated.

Non-exposed GPs expressed favorable attitudes to CRP point-of-care testing relating to the professional context of their working environment. "I'm convinced that it will enhance diagnostic certainty" (GP5, non-exposed), and "I'm sure that half of all prescriptions are not necessary and CRP is useful for confirming this assumption before actually making the decision about prescribing" (GP19, non-exposed). These attitudes arise from a disease-focused concern to rule out serious disease. Yet, achieving shared decisions with patients not to prescribe antibiotics was also frequently mentioned by nearly all non-exposed GPs. "CRP would be useful in my practice and because I feel I can get patients on my side with it. I think that the magic of the machine is more powerful than the magic of my words" (GP5, non-exposed).

This last quote is typical of non-exposed GPs who attached greater value to CRP testing compared to enhanced communication skills training. A typical quote from a non-exposed GP addressed barriers: "I don't think that this is where my weakness is" (GP3, non-exposed), and "it [communication skills training] is never real life, training only tells you how you could or may do it" (GP16, non-exposed). Four non-exposed GPs stated that communication skills training was not a priority for them, and four others said they already deployed excellent communication skills. Non-exposed GPs were sceptical of the value of the time investment required for enhanced communication skills training. They were also concerned by the potential negative impact on consultation length of focusing on communication about antibiotics with their patients. So, many non-exposed GPs did not feel any compulsion to act in this regard. "What we want as GPs must fit in 10-minute consultations. So as long as we aim to do these things [communication skills] within the time restriction of 10 minutes, implementing communication skills will not be feasible" (GP5, non-exposed).

Despite the overwhelming preference for CRP testing as their priority intervention, all but one of the non-exposed GPs also expressed positive attitudes towards illness-focused communication in LRTI. Typical comments were: "In the end it [good communication] will lead, so we hope, to a satisfied patient, a satisfied GP, and less antibiotic use" (GP12, non-exposed), and "I always do it, I find it the most important part of my professional practice" (GP15, non-exposed).

All but one of the GPs exposed to both interventions indicated that if they had to choose, they would select the illness-focused intervention over the disease-focused intervention. The remaining GP preferred not to make a choice as he felt both approaches should always be integrated. However, all exposed GPs also saw a place for CRP testing as for some, but not all, patients with LRTI. Typical quotes are: "I think these communication skills are more essential, with CRP giving additional guidance" (GP10, exposed), and "communication is of utmost importance in general practice. More important even than drugs, so I find this communication skill training crucial and CRP is a useful addition" (GP18, exposed). Eight GPs indicated that they used their enhanced communication skills with all patients and used CRP only when faced with particular problems: "It depends on the patient. For some patients, [CRP] could be of additional value, but some I think will do fine without the test and the communication bit is more than adequate, while some patients want more objective measures [like CRP]. It certainly depends on the patient which strategy I choose" (GP13, exposed).

The best of both worlds?

Despite differences in prioritizing the interventions, both groups acknowledged a central role for both approaches to optimize management of acute cough, albeit from different perspectives.

In general, exposed GPs stressed the value of having both approaches. One-half suggested the interventions would be synergistic, and all agreed that having the combination available would be ideal. "I think you can combine both quite nicely, it is additive, like I said before. It is a very natural combination, very complete indeed" (GP7, exposed). "Management decisions are more robust if you combine them" (GP9, exposed), and "CRP is a confirmation of your account of things. If they [patients] hear that their blood test was also normal, your explanation becomes even more credible to patients" (GP2, exposed). Although the dominant view was that good communication skills would be adequate for optimal handling of most consultations, the GP's own agenda, including dealing with diagnostic uncertainty, was not forgotten and here CRP testing had a role: "You can use it when patients are in doubt [not convinced], but certainly also when you yourself are uncertain" (GP17, exposed). Time constraint was the only commonly mentioned disadvantage of utilizing both approaches within LRTI consultations. However, GPs in this group did not see this as a barrier to implementing the approaches. "It takes a bit more time, but I do think that we then confirm the decisions from two angles, which provides more satisfaction and reassurance" (GP2, exposed).

Non-exposed GPs recognised the value of both approaches but were nevertheless inclined to express a preference for the CRP approach over the other. On the one hand, to decrease diagnostic

uncertainty, but also to convince patients: "CRP would be useful in my practice and because I feel I can get patients on my side with it. I think that the magic of the machine is more powerful than the magic of my words" (GP5, non-exposed). However, they saw good communication skills as a key competence for daily practice anyway, for example: "I have been [a] GP for a long time and this is something I have always been mindful of, structured and focused communication. That's always something I strive for, time and time again, and I'll keep doing it until you get sick of it" (GP15, non-exposed).

Discussion

This study found differences in GPs' expressed preferences for prioritizing contrasting interventions to optimise LRTI management. Those GPs who had experience of both an illness-focused intervention (communication skills training) and a disease-focused intervention (CRP point-of-care test) indicated that they would choose to prioritize enhanced communication skills. Conversely, GPs without access to CRP point-of-care testing and enhanced communication skills training indicated they would prefer to have access to the CRP disease-focused intervention.

The views and attitudes expressed in this study must be considered in the context of the quantitative findings from the randomized factorial trial. Here, our primary analysis considered an issue of discrete choice about which intervention GPs would prioritize. Apart from the striking differences between the exposed and non-exposed clinicians in relation to the study question, many similarities between the two groups were identified. Both recognized a place for both approaches in the management of acute cough.

These findings may be helpful when considering barriers to, and incentives for achieving evidence-based practice and implementation, a process which is receiving greater research and policy attention. Although non-exposed GPs saw skilled communication as a core competency for daily practice, our data did not indicate a hunger for improving specific communication skills to better manage LRTI. Such professional barriers will determine whether or not an intervention is successfully adopted into routine care. On the other hand, GPs who had been exposed to the interventions saw a role for enhanced communication skills in all LRTI consultations. They stated that the CRP disease-focused intervention could be useful in managing a subgroup of patients.

This study included selected GPs -- those that had recently participated in a RCT. Their views may no be typical of GPs' views on prescribing decisions and antimicrobial resistance. GPs' accounts of their experiences of CRP point-of-care testing for LRTI in this trial have been reported elsewhere. While non-exposed GPs did not have access to the interventions, they had been recruiting LRTI patients into the trial over two winters, and some contamination may have occurred. We did not explore patients' views in this research. However, we do know from the trial data that participating patients were highly satisfied with their consultations, irrespective of the intervention their managing clinician was exposed to during the study.

Exposed GPs recognized that effective communication is the foundation of good medical practice. They also recognized the importance of the enhanced communication skills intervention for optimizing the management of a specific condition, LRTI. Nevertheless, they did indicate that differentiating serious from self-limiting disease is a crucial component of their professional role. They found CRP testing valuable in a specific subgroup of patients, namely those who were not convinced of management decisions based on history and physical examination alone. It would be erroneous to conclude that exposed GPs would only want to use their communication skills and never use CRP point-of-care testing. All exposed GPs indicated that CRP testing had a useful role in LRTI management. Similarly, non-exposed GPs recognized the value of communication skills training in general, although they considered that they would find CRP point-of-care testing more useful. This may also be explained by how enhanced communication skills and a diagnostic test were conceptualized by this non-exposed group. Because communication is seen as already essential to good medical care, an intervention to further expand these skills may be seen as less important than a new diagnostic test, which adds to the physician's agenda of increasing diagnostic certainty. Similarly, a test result can also be seen as an aid to persuade patients to accept certain management decisions, exemplified by a striking quote by non-exposed GP5 (see Table 1). Both interventions can affect the communication dynamics within a consultation and, despite the fact that a diagnostic test is a disease-focused intervention, it may affect the illness experience of the patient as well.

As with previous research, GPs in this study were concerned about the impact of using enhanced communication skills and shared decision making on consultation length. Implementing communication skills did not increase consultation time beyond feasible limits during competence assessment. Nonetheless, exposed GPs recognised that extra time invested in combining both approaches would be synergistic, providing enhanced reassurance from two directions.

Setting priorities for uptake of contrasting interventions may differ substantially between GPs with and without previous exposure to the interventions. GPs' level of experience with and attitudes towards interventions to improve clinical practice need to be taken into account when planning widespread dissemination.

Long-Term Particulate Matter Exposure and Mortality: A Review of European Epidemiological Studies

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Abstract

Background: Several studies considered the relation between long-term exposure to particulate matter (PM) and total mortality, as well as mortality from cardiovascular and respiratory diseases. Our aim was to provide a comprehensive review of European epidemiological studies on the issue.

Methods: We searched the Medline database for epidemiological studies on air pollution and health outcomes published between January 2002 and December 2007. We also examined the reference lists of individual papers and reviews. Two independent reviewers classified the studies according to type of air pollutant, duration of exposure and health outcome considered. Among European investigations that examined long-term PM exposure we found 4 cohort studies (considering total and cardiopulmonary mortality), 1 case-control study (considering mortality from myocardial infarction), and 4 ecologic studies (2 studies considering total and cardiopulmonary mortality and 2 studies focused on cardiovascular mortality).

Results: Measurement indicators of PM exposure used in European studies, including PM10, PM2.5, total suspended particulate and black smoke, were heterogeneous. This notwithstanding, in all analytic studies total mortality was directly associated with long-term exposure to PM. The excesses in mortality were mainly due to cardiovascular and respiratory causes. Three out of 4 ecologic studies found significant direct associations between PM indexes and mortality.

Conclusion: European studies on long-term exposure to PM indicate a direct association with mortality, particularly from cardiovascular and respiratory diseases.

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Background

Data from European epidemiological studies on the relation between long-term exposure to particulate matter (PM) and mortality are still limited, as most research on health effects of air pollution has focused on short-term exposure.[1] Besides information on the issue from a few US cohort studies, including the American Cancer Society Cancer Prevention Study II (ACS-CPS),[2] the Harvard Six Cities Study,[3] and the Women's Health Initiative Observational Study,[4] a few European studies provided new data during the last 5 years.

Ambient levels of several air pollutants are more variable within Europe than in the USA, and in some areas they are comparably high compared to US levels.[1] In a previous report, we reviewed the evidence of the association between long-term exposure to ambient PM and risk of lung cancer in Europe.[5] In this report, we provide a comprehensive review of European epidemiological studies considering the relation between long-term PM exposure and total mortality as well as mortality from cardiovascular and respiratory diseases. Studies conducted in North America and other areas of the world are mentioned in the Discussion whenever relevant for comparison purposes. The rationale for restricting analyses to Europe is based on differences in population density, exposure and characteristics of pollutants (eg, due to a larger proportion of diesel vehicles as compared to North America or Japan), as well as in available measures of pollutants.

Methods

This work is part of a wider project on air pollution and various health outcomes in Europe. We retrieved from PubMed the abstracts of all the journal articles on European epidemiologic studies included in the EPA report.[1] We identified the MeSH terms common to all the 96 papers, and defined a search string to select the scientific literature. We used these strings to search the Medline database for papers published from January 2002 to December 2007. Furthermore, reference lists of a number of published papers (original articles and reviews) were examined. We retrieved 4497 papers, which were then included in an electronic database using Endnote (version 9). On the basis of title, abstract (when available), and keywords (MeSH terms), two independent reviewers independently classified all the papers, in order to identify studies of high interest, using a 5-point score. From the first selection, 3122 papers were eliminated (both reviewers' score <3). The other 1375 papers, over 100 of which were scored 5 by both reviewers, were further evaluated and classified—using a 10-point score—according to type of

Table 1: Analytical studies investigating the relation between long-term PM exposure and total mortality.

Reference, Study design, Country	Sex, age at enrolment	Number of deaths	Risk indicator, measurement unit	Relative risk (95% CI)
Hoek et al., 2002, NLCS cohort, the Netherlands	MF, 55-69	489	- Model 1[a]	- Model 1[a]
			BS, 10 μg/m^3	1.04 (0.65-1.64)
			Living near a major road	1.53 (1.01-2.33)
			- Model 2[b]	- Model 2[b]
			BS, 10 μg/m^3	1.31 (0.95-1.80)
Beelen et al., 2007, NLCS cohort, the Netherlands	MF, 55-69	17,674	- Model 3[c]	- Model 3[c]
			BS, 10 μg/m^3	1.05 (1.00-1.10)
Filleul et al., 2005, PAARC cohort, France	MF, 25-59	2396	TSP, 10 μg/m^3 (24 areas)	1.00 (0.99-1.01)
			TSP, 10 μg/m^3 (18 areas)[d]	1.05 (1.02-1.08)
			BS, 10 μg/m^3 (24 areas)	0.99 (0.98-1.01)
			BS, 10 μg/m^3 (18 areas)[d]	1.07 (1.03-1.10)
Gehring et al., 2006, cohort, Germany	F, 50-59	399	Average 1-year concentration PM_{10}, 7 μg/m^3	1.08 (0.94-1.25)
			Average 5-year concentration PM_{10}, 7 μg/m^3	1.13 (0.99-1.30)
Naess et al., 2007a, cohort, Norway	M, 51-70	NA	$PM_{2.5}$, quartile 4 vs 1	1.44 (1.32-1.58)
	F, 51-70	NA	$PM_{2.5}$, quartile 4 vs 1	1.41 (1.27-1.43)
	M, 71-90	NA	$PM_{2.5}$, quartile 4 vs 1	1.18 (1.10-1.26)
	F, 71-90	NA	$PM_{2.5}$, quartile 4 vs 1	1.11 (1.05-1.17)

BS: black smoke; CI: confidence interval; NA: not available; NLCS: Netherlands Cohort Study; PAARC: Pollution Atmosphérique et Affections Respiratoires Chroniques; PM: particulate matter; TSP: total suspended particulate
[a] Model 1: Local and regional effects were separately included in the model
[b] Model 2: Local and regional effects were combined in a single variable
[c] Model 3: Exposure was calculated according to local, urban and regional components
[d] Six areas for which the NO/NO_2 ratio was >3 were excluded

air pollutant, duration of exposure (acute, short- or long-term) and health outcome considered. From the second selection we eliminated 738 papers with both reviewers' score <5 (or one reviewer's score=5 and the other's one <5). Among the other 637 papers, 186 were considered original European studies by both reviewers. Most of these studies evaluated the association with short-term exposure to ambient pollutants, including PM. For this review, we selected all European studies investigating long-term exposure to PM and total, cardiovascular and respiratory mortality, ie, 3 cohort studies from the Netherlands, Germany and France, 1 record linkage study from Norway, 1 case-control study on myocardial infarction from Sweden, and 4 ecologic studies.

Analytic Studies on Total Mortality

The major results of four European analytic studies that investigated long-term PM exposure and total mortality are described below and are summarized in Table 1. A cohort study conducted in the Netherlands[6] was based on a random sample of 5,000 subjects selected from the over 120,000 participants to the Netherlands Cohort Study on Diet and Cancer (NLCS). All subjects were 55-69 years old at enrolment (in 1986), and were recruited from 204 of 714 municipalities with computerized population registries and covered by a cancer registry. Ninety percent of the sample (4,492 subjects) was successfully followed up until 1994. Two different models were used to estimate relative risks (RR). In the first model, average regional background concentration of black smoke (BS) and distance of the residence from a major road were analyzed separately, while in the second model these two factors were combined by adding the background and the estimated contribution from living near a major road to air pollution concentrations. Subjects who had lived 10 years or longer at the same address near a major road had an increased risk of all cause mortality, the RR being 1.53 after adjustment for several confounders. According to the second model, the RR for a 10 μg/m^3 increase in BS concentration was 1.31. Additional analyses of the Netherlands study have been reported in an abstract form.[7] Using the case-cohort approach, the adjusted RR of mortality for all natural causes for a 10 μg/m^3 increase in BS was 1.03. The corresponding RR in the full cohort analysis, including covariate information only on age, gender, active smoking and area-level socio-economic status, was 1.05.

The Pollution Atmosphérique et Affections Respiratoires Chroniques (PAARC) cohort study[8] included 14,284 adults residing in 7 French cities, aged 25-59 years at enrolment in 1974 and followed-up until 2001 for vital status. The average exposures to BS and total suspended particulate (TSP) were estimated for the period 1974-76. Long-term exposure to BS or TSP did not affect the risk of mortality from all non-accidental causes. However, when the analyses were restricted to subjects from the 18 areas with a ratio of NO/NO_2 <3 (ie, excluding the 6 areas where the exposure measure was likely influenced by a busy roadside near the air monitor station), the RRs for total non-accidental mortality for a 10 μg/m^3 increase were 1.07 for BS and 1.05 for TSP.

Table 2: Analytical studies investigating the relation between long-term PM exposure and cardiovascular and respiratory mortality.

Reference, Study design, Country	Sex, age at enrolment	Number of deaths by cause	Risk indicator, measurement unit	Relative risk (95% CI)
Hoek et al., 2002, NLCS cohort, the Netherlands	MF, 55-69	185 cardio-pulmonary	- Model 1[a]	- Model 1[a]
			BS, 10 μg/m^3	1.34 (0.68-2.64)
			Living near a major road	1.95 (1.09-3.51)
			- Model 2[b]	- Model 2[b]
			BS, 10 μg/m^3	1.71 (1.10-2.67)
Beelen et al., 2007, NLCS cohort, the Netherlands	MF, 55-69	7325 cardio-pulmonary	- Model 3[c]	- Model 3[c]
			BS, 10 μg/m^3	1.06 (0.98-1.15)
		1046 respiratory	BS, 10 μg/m^3	1.22 (0.99-1.49)
Filleul et al., 2005, PAARC cohort, France	MF, 25-59	546 cardio-pulmonary	TSP, 10 μg/m^3 (24 areas)	1.01 (0.99-1.03)
			TSP, 10 μg/m^3 (18 areas)[d]	1.06 (1.01-1.12)
			BS, 10 μg/m^3 (24 areas)	1.00 (0.97-1.02)
			BS, 10 μg/m^3 (18 areas)[d]	1.05 (0.98-1.12)
Gehring et al., 2006, cohort, Germany	F, 50-59	139 cardio-pulmonary	Average 1-year concentration PM_{10}, 7 μg/m^3	1.34 (1.06-1.71)
			Average 5-year concentration PM_{10}, 7 μg/m^3	1.59 (1.23-2.04)
Rosenlund et al., 2006, case-control, Sweden	MF, 45-70	272 myocardial infarction	All MI deaths PM_{10}, 5 μg/m^3	1.39 (0.94-2.07)
			In-hospital MI deaths PM_{10}, 5 μg/m^3	1.21 (0.75-1.94)
			Out of hospital MI deaths PM_{10}, 5 μg/m^3	1.84 (1.00-3.40)
Naess et al., 2007a, cohort, Norway		Cardio-vascular		
	M, 51-70	2007	$PM_{2.5}$, quartile increase	1.10 (1.05-1.16)
	F, 51-70	946	$PM_{2.5}$, quartile increase	1.14 (1.06-1.21)
	M, 71-90	4531	$PM_{2.5}$, quartile increase	1.05 (1.01-1.08)
	F, 71-90	7480	$PM_{2.5}$, quartile increase	1.03 (1.00-1.05)
		COPD		
	M, 51-70	233	$PM_{2.5}$, quartile increase	1.27 (1.11-1.47)
	F, 51-70	203	$PM_{2.5}$, quartile increase	1.09 (0.94-1.25)
	M, 71-90	503	$PM_{2.5}$, quartile increase	1.10 (1.00-1.21)
	F, 71-90	516	$PM_{2.5}$, quartile increase	1.05 (0.96-1.16)

BS: black smoke; CI: confidence interval; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; NLCS: Netherlands Cohort Study; PAARC: Pollution Atmosphérique et Affections Respiratoires Chroniques; PM: particulate matter; TSP: total suspended particulate

[a] Model 1: Local and regional effects were separately included in the model

[b] Model 2: Local and regional effects were combined in a single variable

[c] Model 3: Exposure was calculated according to local, urban and regional components

[d] Six areas for which the NO/NO_2 ratio was >3 were excluded

In a German study conducted in various towns of North Rhine Westphalia,[9] about 4,800 women aged 50-59 years who participated in several cross-sectional surveys between 1985 and 1994 were followed-up until 2002-2003. The overall response rate to the surveys was 70%, and data on follow-up and address were obtained for 97% of the sample. A similar approach to the Dutch study was used, ie, background exposure and distance of the residence from a road with >10,000 cars/day were estimated independently. Background exposure was computed as average concentrations for the year of recruitment and for the four years preceding recruitment. The adjusted RRs for all cause mortality for a 7μg/m^3 increase in PM_{10} were 1.08 for average exposure measured in the baseline year and 1.13 when average exposure was measured on five years. Mutual adjustment of PM_{10} level and proximity to major roads did not materially change these estimates.

A record-linkage study was conducted on all inhabitants of Oslo aged 51-90 years in 1992, followed-up until 1998 (n=143,842).[10] Hazard ratios (HR) were calculated according to approximate quartiles of long-term $PM_{2.5}$ and PM_{10} exposure, separately by sex and age at enrolment (51-70 and 71-90 years). Compared to those in the lowest exposure category, the HRs were 0.96, 1.12 and 1.48 in subsequent quartiles of $PM_{2.5}$ exposure for men aged 51-70 years. Corresponding estimates in older men were 0.99, 1.10 and 1.19. Estimates in women were very similar to those of men of the corresponding age group. Adjustment for education and occupational class (HRs given in Table 1) did not materially modify the results.

Analytic Studies on Morality from Cardiovascular and Respiratory Diseases

Besides total mortality, the cohort studies described above also presented data on mortality from cardiopulmonary diseases. Further, a Swedish case-control study provided results on the relation between long-term PM exposure and fatal (and non-fatal) myocardial infarction. A summary of European studies providing data on mortality from cardiovascular and respiratory diseases is presented in Table 2. In the Netherlands Cohort Study,[6] most of the excess risk observed in total mortality appeared to be attributable to cardiopulmonary causes of death. The RR of cardiopulmonary mortality for subjects living near a major road was 1.95. Updated analyses[7] showed RR near to unity for high traffic intensity on the nearest road using the case-cohort approach, and RRs of 1.06 for cardiopulmonary mortality and 1.10 for respiratory mortality in the whole cohort. With reference to BS exposure, the RRs for a 10 μg/m^3 increase were 1.04 for cardiopulmonary and 1.16 for respiratory mortality using the case-cohort approach. The corresponding RRs calculated on the whole cohort, adjusted for age, sex, smoking and area-level socio-economic status, were 1.06 and 1.22. In the PAARC study,[8] causes of death were available until 1998 for 96% of the sample. No association was found between cardiopulmonary mortality and long-term exposure to BS and TSP. When the analysis was restricted to 18 areas, the RRs for all cardiopulmonary causes were 1.06 for a 10 μg/m^3 increase in TSP and 1.05 for BS. Similarly to the findings of the Netherlands Cohort Study, in the German study conducted in North Rhine Westphalia the effects of PM and traffic appeared stronger for—or limited to—cardiopulmonary mortality.[9] The adjusted RRs for a 7 μg/m^3 increase in PM_{10} in the baseline year was 1.34, while the RR was 1.59 when exposure was measured for five years. Women living near a major road had a 70% increased risk of dying from cardiopulmonary causes. Mutual adjustment of PM_{10} level and proximity to major roads did not materially change these estimates. Another analysis was conducted on the same data to investigate the impact of respiratory health on the association between PM_{10} exposure and cardiovascular mortality.[11] Findings from that study suggested that impaired respiratory health and long-term exposure to air pollution are independently associated with an increase in cardiovascular mortality.

A population-based case-control study on 1,397 cases with first myocardial infarction and 1,870 population controls resident in Stockholm county, aged 45-70 years, was conducted between 1992 and 1994.[12] Response rates to the mailed questionnaire varied between 70% and 81% depending on sex and case-control status. For each subject, exposure to PM_{10} and $PM_{2.5}$ was reconstructed from 1960 to a year prior to enrolment (1992-1994), ie, for over 20 years, using data on traffic around the home address. Only data for long-term exposure to PM_{10} were used in the analysis, given the high correlation between PM_{10} and $PM_{2.5}$. Logistic regression models adjusted for the matching variables, ie age, sex and hospital catchment area, smoking, physical inactivity, diabetes and socio-economic status were used to compute odds ratios (OR). Hypertension, body mass, job strain, diet, passive smoking, alcohol and coffee intake, and occupational exposure to motor exhaust and other combustion products were also evaluated, but did not appear to confound the relation with PM. With reference to fatal cases of myocardial infarction the OR was 1.39 for an increase of 5 μg/m^3 in PM_{10} exposure. A borderline significant association was found when fatal cases were further restricted to 84 subjects who died out of hospital, while the OR was 1.21 for in-hospital deaths. Though this finding can be interpreted as supportive of an association between air pollution exposure and mortality, random variation in small subgroups cannot be excluded. The Norwegian record-linkage study presented cause- and sex-specific HRs for PM_{10} and $PM_{2.5}$ (and NO_2).[10] The crude HRs for cardiovascular mortality for a quartile increase of $PM_{2.5}$ were 1.11 in 51-70 year old men, 1.06 in 71-90 year old men, 1.16 in 51-70 year old women, and 1.02 in 71-90 year old women. With reference to mortality from chronic obstructive pulmonary disease, the corresponding HRs were 1.32, 1.14, 1.18, and 1.09. Further, the HRs for $PM_{2.5}$ exposure adjusted for occupation and education (given in Table 2) and those for PM_{10} exposure were almost unchanged. In the same record-linkage investigation, another study considered the socio-economic correlates of PM exposure in subjects aged 50-74 years.[13] Overall, the risk of death from cardiovascular diseases and COPD was associated with $PM_{2.5}$ exposure. When deprivation indicators were included in the models, however, the RRs became closer to unity. The authors concluded that more deprived neighbourhoods have higher levels of air pollution, and thus deprivation accounts for some of the excess mortality from several diseases, including cardiovascular and respiratory conditions, associated with air pollution in these neighborhoods.

Ecologic Studies

An Irish study compared mortality rates before and after the ban of coal sales in Dublin.[14] Given the deterioration of the air quality in the 1980s after a switch from oil to other fuels, mainly bituminous coal for domestic water and space heating, the Irish Government banned the marketing, sale and distribution of bituminous coals within the city of Dublin on September 1990. After the ban, the average BS concentrations declined by 35.6 μg/m^3 (70%). The authors compared age-adjusted death rates for the 72 months before (September 1984 to August 1990) and after (September 1990 to August 1996) the ban. Significant decreases were observed for all non-accidental and cardiovascular mortality in all seasons, and the decreases were more marked in winter. Significant decreases were observed for respiratory mortality overall, in winter and spring, while no significant change was observed overall for other causes. The authors concluded that control of PM could substantially diminish daily mortality. However, during the same period, mortality declined in several other European countries. Thus, a causal link between the decline in mortality and the ban of coal sales cannot be established. On the other hand, the authors interpreted the fact that the biggest declines were observed in winter, when the use of coal was highest, as supportive of their hypothesis.

Two studies compared air pollution levels in 1030 census enumeration districts in Sheffield, UK, to mortality and emergency hospital admission rates from coronary heart disease[15] and stroke.[16] For each district, a 5-year average PM_{10} concentration for the period 1994-1999 was computed. The districts were then divided according to quintiles of PM_{10} concentrations. The mean PM_{10} concentration in the highest quintile was 23.3 μg/m^3, and 16.0 μg/m^3 in the lowest one. Mortality and emergency hospitalization rates were then computed for the districts' quintiles. For coronary heart disease, the rate ratios (adjusted for sex, age, deprivation and smoking prevalence) for the highest quintile compared to the lowest one were 1.08 for mortality and 1.01 for hospital admissions. Corresponding values for stroke were 1.33 and 1.13.

An ecologic study conducted in Great Britain,[17] based on small residential areas, investigated the association between long-term

BS and SO_2 exposure and mortality overall and from selected causes, including cardiovascular and respiratory diseases. This study found a significant excess risk of total, cardiovascular, and particularly respiratory mortality. Stronger associations were reported between recent exposures (0-4 years) and respiratory mortality, with adjusted excess relative risk of 3.6% for 10 µg/m^3 of BS.

Discussion

In European analytic studies conducted between 2002 and 2007, mortality was associated with various measures of long-term exposure to PM. The excesses were mainly attributed to cardiovascular and respiratory causes.

Major North American studies on the issue found associations between fine particles and total mortality somewhat stronger than those of European investigations. In the Harvard Six Cities study,[3] including 8096 white participants from various cities of the USA followed since the mid-1970 to 1998, the adjusted RRs for an increase of 10 µg/m^3 of $PM_{2.5}$ were 1.16 for total mortality, 1.28 for cardiovascular diseases, and 1.08 for respiratory causes. The Women's Health Initiative cohort study, including 65,893 post-menopausal women, found a RR for cardiovascular mortality of 1.76 for an increase of 10 µg/m^3 of $PM_{2.5}$.[4] The corresponding RR for incidence of cardiovascular diseases was 1.24. In the ACS-CPS-II study,[2,18] that linked air pollution data with the individual data of approximately 500,000 adults from the USA, followed from 1982 to the end of 1998, the adjusted RRs for an increase of $PM_{2.5}$ of 10 µg/m^3 were 1.06 for all-cause mortality, 1.12 for cardiovascular diseases plus diabetes, and 0.92 for respiratory causes.

Efforts have been made to analyse the consistency of findings from European and North American studies, and to assess reasons for heterogeneity, also on the effect of short-term PM_{10} exposure on daily mortality.[19] The "Air Pollution and Health: A Combined European and North American Approach" (APHENA) study found comparably increased mortality risk estimates for European and US cities, whereas the acute effects of PM exposure were greater in Canadian cities. Some differences between geographic areas were noticed according to effect modification factors of the relation between PM_{10} and short-term mortality, including level of co-pollutants and climate (ie, temperature and humidity).

In investigations of long-term effects of PM, the modifying effect of selected socio-economic factors varied across studies. In the USACS-CPS-II study, no association was found between $PM_{2.5}$ and total and cardiopulmonary mortality for subjects in the highest category of education (>high school), while there was an association in less educated subjects.[2] This is in contrast with the findings from a French study,[8] where the highest point estimates were observed in more educated subjects. Apart for chance and bias, at least part of the discrepancies could be explained by the different PM measure investigated, as most European studies did not provide data on $PM_{2.5}$. Interestingly, an analysis of socio-economic correlates of PM exposure conducted in the Norwegian record-linkage study found that deprivation explained part of the excess mortality from cardiovascular and respiratory diseases associated with air pollution, as poor city areas experienced higher levels of air pollution. On the basis of these and other findings,[2,8,13] one of the major issues to be addressed in future studies will be the role of socio-economic covariates (ie, concurrent confounder and determinant of exposure) on the association between PM exposure and mortality.

With reference to morbidity from respiratory and cardiovascular diseases, European studies in adults do not provide consistent evidence of an association between PM exposure and chronic bronchitis or asthma, nor cardiovascular conditions.[12,15,16,20-22] Studies on PM_{10} and lung function, on the other hand, reported positive results.[23,24]

The number of analytic European studies that investigated the long-term effects of PM exposure on mortality is limited. Furthermore, for all the studies, exposure assessment was estimated only on the home address, without considering the characteristics of the home (eg, floor of residence) or other possible sources of exposure. The French study, however, excluded from the sample heads of households who were manual workers, to avoid confounding from other exposures, and occupation was controlled for in some studies. In short-term time series, comparisons are ideally made between different days within individuals, and adjustment for day of week and holidays is often performed. In contrast, studies on long-term exposure are necessarily based on comparisons between individuals, and on cumulative exposure assessment. Misclassification of exposure is likely to occur and to affect results. There are indications that exposure measurement errors affect risk estimates, in most instances leading to attenuated findings.[1] Measurement error might be lower for major urban areas, where more detailed information is generally available, and higher outside the urban setting.[25] Measurement indicators were heterogeneous across European studies, as several PM indexes were used, including PM_{10}, $PM_{2.5}$, BS and TSP. Their results may therefore be not comparable in various studies, particularly if fine or ultrafine particles have a major role. Among other potential limitations, spatial autocorrelation should be taken into account in the analyses of air pollutants and health, but only two studies considered the issue.[8,25] However, updated data from the NLCS investigation found no material difference in the original estimates when spatial autocorrelation in neighbourhood and municipality was accounted for.[25] On the other hand, ecologic studies are suggestive and hypothesis generating, but, given the potential bias inherent in their design, they cannot provide a solid base for inference.

Conclusion

European studies on long-term exposure to PM indicate a direct association with mortality, particularly from cardiopulmonary diseases. Further studies relying on uniform methods to measure air particles, addressing the effects of socio-economic correlates of PM exposure, and considering the role of the chemical components of PM besides its mass[26] are however needed. Priority should be given to the inclusion of populations living in areas where PM is high (such as those from some regions of Central and Eastern Europe), among whom adverse health effects may be detected sooner than in less polluted areas of Europe.

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associated with progressive exponentially increasing casualties and resource demands necessitates the need to develop a plan to recognize and respond to this type of incident. This plan requires a new approach to address the staffing, prioritization of care plans and workload challenges.

"The PLAN"

Staffing and prioritization of care plans are essentially linked. Every day, respiratory therapy departments face significant staffing challenges between staff shortages, attrition, the high reliance on per diem workers and absenteeism. Using more-with-less is the hallmark of most successful respiratory departments but with this new MCI a more realistic approach is necessary. Reviewing your absolute functional staff numbers, including those in non-bedside roles (eg PFT, non-invasive cardiology, clinics) is an essential first step. These therapists represent your hidden reserve and the only real source of "on hand" staff you have that is over and above the regular bedside therapists. To utilize this hidden reserve, an urgent in-house training program must be developed, license restrictions reviewed and addressed, contractual/union issues addressed and scheduling limitations reviewed for each staff member.

With the staffing issue addressed, the next step is to define your service delivery commitments and priorities. The ability to meet your service commitments starts with defining what they are.

The first step is to develop a comprehensive list of all of the client services your department provides. This list must include all non-bedside commitments such as educational support, student mentoring, administrative duties and orientation of new staff. Once this list has been developed, a priority weighting must be assigned to each service. The highest priority weighting is assigned to your critical care services and the lowest to routine diagnostic services. This list must reflect what is deferrable and what is the absolutely essential.

Utilizing this list you will be able to determine to what extent you can support your commitments using the staffing resources available. An expected 150% and 200% increased activity level should be used as part of the planning process and allow you to prepare two plans.

The first plan reflects your ability to sustain a 150% increase in workload demands with minimal deferred services. The second plan reflects the need to reduce services to all but critical levels and represents a significant reduction in services that can only be sustained for very short periods of time. Both of these plans must be designed to be able to flex with the situational demands so should employ options for your staffing response. An example would be to utilize an emergency response team model instead of fixed assignments on noncritical care units to address stat or urgent calls. Routine services may have to be given to the ward nursing following a pre-MCI educational training blitz. A second option would be to utilize therapists from non-bedside areas who have received additional training, orientation and support to maintain the noncritical care ward services.

Once you have undertaken the process to develop an exponential MCI response plan you now need to run it by the staff tasked with implementing it; only they can make it work. The line staff's input in refining the plan(s) is essential to the development of a plan that can actually work. Upon completion you will have a plan that you can pull-off-the-shelf and put into play and successfully achieve your patient care and service goals.

The process of developing and refining the plan(s) themselves serves as a very effective training and educational process. On completion you have staff who can mentally put themselves in the mass casualty response mode (due to their participation in the development) and utilize a plan that they are familiar with. Only by having completed the exercise/process can your facility be prepared to handle an exponentially increasing MCI. The next few years will present increasing challenges, as we have been very lucky with the Monkey Pox, SARS, West Nile Virus and now H1N1. It is essential that we prepare for this "new" MCI.

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