

Volume 3 Number 1 February-March 2008

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The Journal of Pulmonary Technique



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EDITOR'S NOTE: The New York Times recently reported on COPD, the fourth-leading cause of death in the US, which kills 120,000 people each year. About 12 million Americans are diagnosed with COPD annually, and studies estimate that an additional 12 million residents have the disease but remain undiagnosed. COPD, which costs the US \$42 billion annually in treatment and lost productivity, likely will become the third-leading cause of death by 2020. According to the Times, although COPD is incurable, it is treatable, but many patients, and some doctors, mistakenly think little can be done for it and miss out on therapies that could help them feel better and possibly live longer. As such, you might find the following of interest.

A Patient's Perspective

Julia Pippa, RT, BA

John felt weak, he felt tired. Because of his COPD, the effort of taking each breath drained him of energy. Martha had always accompanied him on these dreadful visits to the doctor. She did the talking when he couldn't, asked the questions he didn't remember to ask and discussed the doctor's findings when they got home. Today, Linda, the receptionist, asked him his name. She had known him for five years. He sat in the office for fifty minutes and then a girl called his name and led him to an examining room. He wondered if she was a nurse. Maybe she was one of those technicians they were using today. He wasn't going to find out from her. She didn't even tell him her name. She instructed him to take off his sweater and his shirt, and the warm undervest he always wore. She handed him a thin gown to put on, open in the back. She had him sit on the edge of the examining table and left the room. After 30 minutes he was shaking with cold and his back hurt. Breathing was becoming more difficult. What was that pursed-lip breathing Martha had him practice? He'd have to ask her. Pain stabbed his heart. How had he forgotten she was in that convalescent home, the stroke having left her virtually devoid of any reasonable life. It was so lonely without her. He hadn't much will to live anymore.

Dr Bennett came into the room, frowning as he read the chart in his hand. "I see you aren't taking good care of yourself. Now, look here, you take your medication as prescribed. You have lost weight. You must start eating regular, healthy meals, three times a day. And most of all, stop smoking! I don't want to see you in the ER anymore. Now go home, uh, (he glanced at the chart,) John, and have a good day." He left the room, the odor of tobacco smoke wafting after him.

"I have this annoying patient, John T." Dr Bennett was complaining to a colleague over scotch and cigars at their club. "He has had three exacerbations of his COPD so far this year. The guy seems to be deliberately noncompliant."

Okay, the above is a liberal exaggeration, but patients see things from their perspective, that being their own lives. Their lives affect their health on many levels. John is sad, he is lonely, he is depressed and he is incapacitated. He has no one to cook him three healthy meals a day. He can't do it. The inconsideration shown in the doctor's office makes him feel unimportant, invisible. For fifty years he owned a business, he was the boss, he made decisions, he was respected. He was useful. Hard to give this up, so he engaged in some understandable denial. He was 83 and felt patronized by the paternalistic attitude of a grandson-aged man. But you say no one could know how John felt, he didn't take responsibility for telling the medical people. Was there any time allotted for this? He would have needed time. He was ill. Why didn't one of the health professionals ask how he was, and then listen?

Julia Pippa is a school nurse with regular and special needs students, many of them severely handicapped.



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Publisher
Steve Goldstein

Editor
Les Plesko

Senior Editor
Carol Brass

Assistant Editor
Laszlo Sandor

Design and Production Management
http://accugraphics.net

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Have You Discarded Measurements of Respiratory Muscle Strength?

Paul Garbarini MS, RRT

Let's go back in time... I recall routinely measuring "NIF" (negative inspiratory force) also referred to as "MIF" (maximal inspiratory pressure) and Vital Capacity along with RR, Vt and minute volume when measuring "weaning parameters."

Let's go to today... Most facilities I visit measure RR, Vt, minute volume and increasingly RSB (rapid shallow breathing index), also referred to as f/V_t . Per previous E-news articles, the value of even doing "weaning parameters" has been questioned as the standard of care. ACCP/AARC weaning guidelines in essence call for a daily (why are we limiting this to once a day?) "wean screen" in which P/F ratio, hemodynamic status, and PEEP level are assessed as to "readiness" to perform a spontaneous breathing trial. Indeed, multiple trials support this strategy. The traditional weaning parameters never really demonstrated good correlation with weaning outcomes, albeit the RSB having the best predictive value of passing a wean trial. If we look at the studies and adhere to the "KISS" principle, then indeed these recommendations are perfectly valid.

What we as clinicians then need to focus on is identifying the underlying causes of spontaneous breathing trial failures. I've previously addressed the value of assessing static compliance and airway resistance measurements in the context of the impedance or load placed on the respiratory muscles. Low compliance/stiff lungs and /or high airway resistance equal higher work of breathing.

What I'd like to address today is the other side of the balance between workload and muscle strength. While oversimplifying, consider the following analogy:

Tom and Jane are asked to continuously raise a 50 lb dumbbell while attempting to walk until they no longer are able. Okay, the dumbbell represents the work due to resistance and/or compliance, while the walking represents the maintenance of an acceptable RSB or breathing pattern.

One of them is going to fail first. Who? Let's say beforehand we assessed what the maximum each could bench press. Tom can bench press maximum 100 lbs while Jane can press 30 lbs. My money is on Jane failing first. Tom is lifting 50lbs/100lbs maximum strength (he's using 50% of his muscle strength) while Jane is only using 50/300 or 17% of her muscle strength to continue walking. Previous studies have indicated that if greater than 40% of the respiratory muscle strength (NIF) is used per breath, fatigue is likely to ensue. So in patients with high loads due to low compliance or high resistance, or who have failed a SBT, assessment of NIF may provide additional insight into the cause of and/or therapy needed to facilitate weaning.

Bernard De Jonghe et al, in Crit Care Med 2007 Vol. 35, No. 9 published an article entitled: Respiratory weakness is associated with limb weakness and delayed weaning in critical illness. This study involved patients with neuromyopathy who were on ventilators longer than 7 days. The researchers were able to correlate measurements of limb weakness with inspiratory and expiratory force measurements. Their main findings were that an inspiratory and/or expiratory force of less than or greater than 30cm were independent predictors of delayed extubation. The risk of extubation delayed greater than 1 week was 8 times higher in patients with a NIF of less than 30 cm. Additionally, septic shock was the only independent risk factor for respiratory muscle weakness.

Perhaps it's time to dust off the NIF manometer.

DO IT RIGHT

Many patients use their inhalers incorrectly, and the older and sicker they are, the more errors they make, according to researchers at Klinikum Offenburg in Germany. In addition, a third of patients never receive direct instruction on how to use the devices, but are simply sent home with their prescriptions and told to read the product inserts. Researchers studied the error rate with inhaler use in 224, with patients whose mean age was 55, diagnosed with asthma or chronic obstructive pulmonary disease, and were prescribed dry-powder inhalers. The overall error rate in this study sample was 32%, with a wide variation, depending on the patient's age and disease severity. The error rate was 20% for patients younger than age 60 years, 42% for those older than 60 years, and greater than 80% for those older than 80 years. The rate was 25% for patients with normal lung function and 64% for patients with severe airway obstruction. Without training the error rate was 53%, versus 23% when users were trained by a healthcare professional.

PAY THE PIPER

In tests of inhalers, results may depend on who pays for the tests, according to a report in *The New York Times*. Studies on adverse inhaler side effects depend in part on who paid for the study, according to a review of more than 500 papers. The *Archives of Internal Medicine* reported that independent studies are four times as likely to find adverse effects as compared to studies paid for by drug companies. Randomized clinical trials were two and a half times more likely to find adverse effects if a drug company didn't pay for the work, and drug company sponsored reports that found adverse effects interpreted them as clinically insignificant. When researchers did a statistical analysis that eliminated aspects of company-sponsored study design, the disparities weren't apparent.

DATA CAPTURE

A recent article in *Respiratory Care* concluded that wireless data capture provided a record of clinical events that could improve surveillance of ventilator use to the benefit of patients. The author noted that this method of data acquisition offered "a higher degree of surveillance with possibilities of producing error free information for research." It was noted that a previous inspection of more than two million ventilator events at the researcher's institution revealed 136,400 transcription errors, including disconnected alarms, inaccurate recordings of readings, and missing entries. For this study, information recorded detections of ventilator changes in the absence of the RT, when adjustments were made, if alarm settings were altered, event duration, and how the ventilator affected the

patient. The study recorded data from a Puritan Bennett 840 Ventilator for several days, with frequency of recordings from two to three hours to 60 seconds. Tests were designed to monitor equipment functionality in the ICU using bluetooth wireless technology and a wi-fi network. See "Wireless On-Demand and Networking of Puritan Bennett 840 Ventilators for Direct Data Capture," William R. Howard, MBA, RRT, *Respiratory Care*, November 2007 Vol 52 No 11.

DON'T GO NUTS

The FDA has recommended that Tamiflu and Relenza should carry warnings about possible side-effects after receiving reports of patients experiencing delirium, psychosis and hallucinations. Reports from Japan indicate that children, particularly, may have a higher risk of experiencing these psychiatric side effects after receiving the flu drugs. Tamiflu and Relenza are the most common medications used for the treatment of flu. The FDA said the warning should be directed at patients of all ages, not just children, but noted that they couldn't tell if the side effects were caused just by the drugs, the flu virus, or the two together. The FDA looked at 596 cases, most of them in Japan, of patients experiencing psychiatric side effects which may have been linked to Tamiflu use. Three Japanese adults committed suicide while on Tamiflu while five children died. Since 1999, when Relenza was approved, there have been 115 reports of psychiatric events, of which 74 were children. The Japanese Ministry of Health warned against Tamiflu use for patients aged 10-19 in March 2007. The ministry then broadened its investigation of Tamiflu to include Relenza and amantadine, after reports came in of abnormal behavior among children. According to Roche, which makes Tamiflu, there is no definite proof of a causal relationship between the drug and abnormal behavior. The company says it has researched this topic at length.

CAN'T BREATHE, EH?

The Lung Association of Canada has released a report on lung disease in Canada that demonstrates the growing burden and deadly impact of lung diseases including asthma, COPD, sleep apnea and lung cancer. "Life and Breath: Respiratory Disease in Canada" released by The Public Health Agency of Canada, highlights the most recent data available for certain major lung diseases. The report cites the important risk factors of tobacco and the environment, and their impact on the lung health of Canadians. Some findings: Respiratory diseases place a considerable economic burden on the Canadian healthcare system, accounting for approximately 6.5% - \$12 billion - of total direct healthcare costs; asthma rates continue to climb, increasing among both sexes and in every demographic; both indoor and outdoor air quality are recognized as significant contributors to respiratory diseases; the increase in smoking among women over the last 50 years has resulted in an increased prevalence of diseases such as lung cancer and Chronic Obstructive Pulmonary Disease (COPD) among women; tobacco usage remains the most important preventable risk factor for chronic lung diseases, demonstrating the need for active smoking cessation policies and programs designed to reduce tobacco-related lung diseases such as lung cancer and COPD. In related news, The Lung Association of Canada reported that as many as three million Canadians may have COPD, which is the country's fourth leading cause of death. This is nearly double previous estimates and includes over one and a half million undiagnosed Canadians and one and a half million who say they currently suffer from this chronic lung disease.

The research also shows that the disease is highly prevalent among younger Canadian baby boomers, one in seven Canadians aged 45 to 49 (375,000), may have COPD. The association recommended spirometry tests for anyone who thinks they might be at risk. COPD awareness among Canadians continues to be low. Only 59% of Canadians have even heard of COPD.

IT'S A GAS

Recent survey results from a study released by Airgas Puritan Medical reveals that while most hospital respiratory therapy directors said their hospitals had a dedicated supply of portable oxygen cylinders for a disaster or pandemic, most said they have less than 24 hours of oxygen to meet a surge need. Most of those surveyed are also counting on suppliers to replenish oxygen supplies within six hours after a disaster. The results of the 2007 Disaster Preparedness Study were unveiled at the recent AARC Convention. The study, conducted by International Communications Researched, surveyed 151 respiratory therapy directors in the US. According to the study, 80% said their hospitals maintained a dedicated supply of portable oxygen cylinders, but 60% said they had less than 100 cylinders on hand in a typical month, and 58% said the supply would be used up by a 40-patient surge in 24 hours. Only 32% reported that they had enough oxygen to last 72 hours or longer for such a surge. The survey also found that 40% of respondents were highly concerned about their ability to maintain an adequate supply of oxygen and were highly concerned about their suppliers' ability to replenish portable cylinders and bulk oxygen tanks. In fact, 58% of hospital RT directors expect that their medical gas supplier will be able to replenish their supply within six hours in an emergency, an unlikely timeframe given the foregoing, according to Airgas senior vp Kelly Justice. "Although Airgas was able to respond within hours after Hurricane Katrina, we were the only medical gas supplier who could," Justice noted. "Hospitals should be planning with the expectation that their suppliers may have difficulty reaching them in the first 24 hours after a disaster."

WAR AND PTSDs

A study by researchers at Columbia University Mailman School of Public Health has linked asthma to post-traumatic stress disorder (PTSD). The study of male twins who were veterans of the Vietnam era suggests that the association between asthma and PTSD is not primarily explained by common genetic influences. The study included 3,065 male twin pairs, who had lived together in childhood, and who had both served on active military duty during the Vietnam War. According to the findings, among all twins, those who suffered from the most PTSD symptoms were 2.3 times as likely to have asthma compared with those who suffered from the least PTSD symptoms. The study included both identical twins who share genetic material and fraternal twins, who share only half of the same genetic material. If there had been a strong genetic component to the link between asthma and PTSD, the results between these two types of twins would have been different, but the study didn't find substantial differences between the two. Several other studies have found a relationship between asthma and other anxiety disorders, but this study was the first to investigate the link between asthma and PTSD. The research also confirmed previous findings that linked asthma with a higher risk of depression. The researchers found the association between asthma and PTSD existed even after they took into account factors such as cigarette smoking, obesity and socioeconomic

status, all of which are associated with both anxiety disorders and asthma.

NOT FOR GRANTED

More than 10% of the nation's healthcare facilities are seeking grants from Cardinal Health through a \$1 million fund set up by the company to help improve patient safety. More than 700 hospitals, health systems and community health clinics responded to Cardinal's announcement about the grant program, which is the largest and first of its kind in the private sector. To support initiatives that enhance patient safety and quality of care, Cardinal Health will grant up to \$50,000 per facility to fund new and innovative programs that establish or implement creative and replicable methods to address challenges in providing quality patient care and to help drive improvements. The company expects to fund up to 40 of the 730 grant requests. In selecting grant recipients, Cardinal Health's selection committee is looking for: projects that respond to a clearly identified, high priority safety issue; projects that apply new thinking and approaches to development of solutions; collaborative programs; demonstrable and sustainable measures to assure that improvements hold up over time; and model programs that can be replicated at other organizations. Contact cardinalhealth.com.

SILVER LINING

The FDA has cleared for marketing a breathing tube coated with a thin layer of silver. The coating, a material known to have antimicrobial properties, reduces the risk that patients on ventilators will acquire pneumonia while in the hospital. The Agento endotracheal tube, manufactured by C.R. Bard Inc, is intended for patients who must rely on a ventilator to breathe for 24 hours or more. Patients requiring such a breathing support system are at risk of exposure to hospital-acquired bacteria that can build up on the breathing tube or pass through the tube to their lungs, eventually causing VAP. Fifteen percent of the patients on ventilators develop VAP every year and 26,000 die from the infection, according to the Centers for Disease Control and Prevention. Silver has been known for its antimicrobial properties for decades and has been used for this purpose on several types of devices. This is the first endotracheal tube coated with silver. In a multicenter clinical trial comparing the Agento breathing tube to an uncoated tube, the percentage of patients who developed pneumonia was reduced from 7.5 to 4.8%. The Agento also delayed the onset of pneumonia.

MICE AND (LITTLE) MEN

Researchers at Washington University School of Medicine in St Louis have pinpointed a key step in the development of asthma in mice after a severe respiratory infection. They suggest that medications designed to interfere with this mechanism could potentially prevent many cases of childhood asthma. Researchers found that mice that developed asthma-like symptoms after a severe respiratory viral infection had an unusual immune reaction. During the infection, the mice produced antibodies and immune signals similar to those produced during an allergic response, instead of those typically made in response to infection. That started a chain reaction that led to asthma. The researchers propose that a similar reaction occurs in some people who suffer severe respiratory viral infections. To investigate the connection between severe respiratory viral infections and subsequent asthma, the researchers used mice genetically selected to have an asthma

susceptibility and infected them with a virus similar to RSV. They found that severe respiratory infections in the mice induced an allergic-type immune response and ultimately caused long-term changes in the airways of the lungs that are hallmarks of chronic asthma. The researchers discovered that certain immune cells in the mouse lungs reacted to severe viral infections by releasing compounds that instigated an inflammatory response. That in turn induced many lung airway cells to transform into mucus-producing cells, which can cause the obstruction of lung passages and shortness of breath characteristic of asthma. The researchers found that interfering with this process by altering the immune cells or removing the inflammatory compounds they secreted prevented overgrowth of mucus-producing cells. The findings promise a new approach to asthma prevention in that it may be possible to prevent many cases of asthma and other chronic inflammatory airway diseases by stopping allergic-type antibody production after a severe viral infection in infants.

DOUBLE LATTE NON FAT IN A BABY BOTTLE, TO GO

Very premature babies who were given caffeine to regulate their breathing had a significantly lower incidence of disabilities at the age of two years, according to an international study led by researchers at McMaster University. Researchers studied more than 2,000 premature babies who were either treated with caffeine or given a placebo. Babies receiving the caffeine were less likely to develop cerebral palsy and cognitive delay. The study involved infants who weighed between 500 and 1,250 grams at birth, and who were at risk of apnea. The ongoing study will continue to follow the children until they reach the age of five. The latest results of the study showed that 46% of the infants receiving the placebo died or survived with a neurodevelopmental disability. Among the babies receiving caffeine therapy, only 40% had an unfavorable outcome by the time they reached the end of their second year of life. Researchers noted that of all the drugs we use in the neonatal intensive care unit, caffeine is the first to have been shown conclusively to reduce long-term disability in very preterm babies. Caffeine reduced the rates of cerebral palsy and cognitive delay but had no significant effect on the rates of death, bilateral blindness and severe hearing loss. The Caffeine for Apnea of Prematurity (CAP) project enrolled 2,006 premature infants who were born between October 1999 and October 2004 in nine countries. The research project was designed to address long-standing concerns about possible adverse effects of caffeine therapy in pre-term infants. Earlier findings released last year by the same research team revealed that babies who received caffeine had a lower incidence of abnormal lung development than infants who were given a placebo.

UNINTENDED CONSEQUENCES

The BCG vaccine, which aims to prevent tuberculosis among children in developing countries, might be causing illness and death among some HIV-positive infants, researchers say. The findings are included in a report about the HIV/TB co-epidemic released by the Forum for Collaborative HIV Research. The report said that the benefits of potentially preventing severe TB among HIV-positive infants are outweighed by the risks associated with the use of BCG vaccine. The World Health Organization previously recommended that all healthy infants receive the BCG vaccine as soon as possible after birth. However, the agency released a report in May 2007 changing its

position because of evidence that HIV-positive infants had an increased risk of developing BCG disease. The BCG vaccine is based on a weakened strain of the bacterium that causes TB in cattle. Many of the infants who receive the vaccine are born HIV-positive and subsequently have compromised immune systems that make them susceptible to BCG disease, which is caused by the bovine bacterium in the vaccine. One study found that the vaccine had a 75% mortality rate among children with BCG disease and that 70% of those children were HIV-positive. In that study, an estimated 400 of every 100,000 HIV-positive infants in South Africa's Western Cape province had become ill from the BCG vaccine, and it was unclear how widespread the problem might be across Africa. This story is copyrighted by the Kaiser Network, The Henry J. Kaiser Family Foundation, originally reprinted in Medical News Today.

KIDDIE ANGST

Young people with asthma are about twice as likely to suffer from depressive and anxiety disorders as children without asthma, according to a study by a research team in Seattle. Previous research had suggested a possible link in young people between asthma and some mental health problems, such as panic disorder, but this study is the first showing such a strong connection between the respiratory condition and depressive and anxiety disorders. The study at the University of Washington School of Medicine, Group Health Cooperative, and Seattle Children's Hospital Research Institute comprised interviews with more than 1,300 youths, ages 11 to 17 who were enrolled in the Group Health Cooperative HMO. Of the participants, 781 had been diagnosed with or treated for asthma, and the rest were randomly selected youths with no history of asthma. About 16% of the young people with asthma had depressive or anxiety disorders, the researchers found, compared to about 9% of youth without asthma. When controlling for other possible variables, youth with asthma were about 1.9 times as likely to have such depressive or anxiety disorders. Researchers tested for several depressive and anxiety disorders, including depression, a mood disorder called dysthymia, panic disorder, generalized anxiety disorder, separation anxiety, social phobia, and agoraphobia. These disorders are somewhat common in youth, and are associated with high risk for school problems, early pregnancy, adverse health behaviors like smoking or lack of exercise, and suicide. Young people with depressive and anxiety disorders often find it harder to manage their asthma and describe more impaired physical functioning because of the combination of asthma and a depressive or anxiety disorder, the researchers said. Youth with asthma and one of the disorders are also more likely to smoke, making their asthma more difficult to treat. Researchers also found that female respondents were at a greater risk of depressive and anxiety disorders, as were youth living in a single-parent household, those who had been diagnosed with asthma more recently, and those with more impairment in asthma-related physical health.

ACHOO

A mutated version of a common cold virus caused 10 deaths in a recent 18 month period. A new variant of an adenovirus has caused at least 140 illnesses in New York, Oregon, Washington and Texas, according to the CDC. The illness made headlines in Texas when a so-called boot-camp flu sickened hundreds at Lackland Air Force Base in San Antonio. The most serious cases were blamed on the emerging virus and one 19-year-old trainee died. There are more than 50 types of adenoviruses tied to

human illnesses. They are one cause of the common cold and also trigger pneumonia and bronchitis. Severe illnesses are more likely in people with weaker immune systems. There are no good antiviral medications for adenoviruses. In the CDC report, the earliest case of the mutated virus was found in an infant girl in New York City, who died last year. The child seemed healthy right after birth, but became dehydrated and lost appetite. She died 12 days after she was born. The Ad14 form of adenovirus was first identified in 1955 and it seems to be growing more common. The strain accounted for 6% of adenovirus samples collected in 22 medical facilities in 2006, while none was seen the previous two years. Reported in the Seattle Times.

BIGTIME

The New York Times recently examined chronic obstructive pulmonary disease, the fourth-leading cause of death in the US, as part of a series on the six leading causes of illness and death. In the US, COPD kills 120,000 residents annually. About 12 million Americans are diagnosed with COPD annually, and studies estimate that an additional 12 million residents have the disease but remain undiagnosed. COPD, which costs the US \$42 billion annually in treatment and lost productivity, likely will become the third-leading cause of death by 2020. Smoking causes about 85% of COPD cases, and symptoms often appear after age 40 in individuals who have smoked one pack daily for at least 10 years. According to the Times, although COPD is incurable, it is treatable, but many patients, and some doctors, mistakenly think little can be done for it and miss out on therapies that could help them feel better and possibly live longer. From the NYT 11/29.

CLASSIFIED

A new classification system developed through research at Cincinnati Children's Hospital and Medical Center is improving diagnosis and treatment of rare lung diseases in infants. The system clears up confusion about how to classify and treat diseases that are rarely seen by most doctors and pathologists. Formerly, doctors used a number of different terms to label the same disease. In some cases, a disease with a favorable prognosis has been confused with a potentially lethal lung disease. The study, funded by the National Institutes of Health through its Rare Lung Diseases Consortium, included data from 11 medical centers in North America. Investigators reviewed 187 biopsies of children under the age of 2 who were being evaluated for diffuse lung diseases like interstitial lung disease (ILD). Children with ILD commonly have prolonged respiratory symptoms of fast breathing and low oxygen levels and exhibit diffuse changes on chest radiographs. When the cause of their symptoms is not identified with blood tests or x-rays, a surgical lung biopsy is often needed for diagnosis. In this study, the researchers were able to classify 88% of the 187 lung biopsy cases, and found a diverse spectrum of lung diseases that are largely unique to young children. One-quarter of the lung diseases studied were grouped together under the label "growth abnormalities." The best-known is pulmonary hypoplasia. Another group of diseases was categorized as "surfactant dysfunction disorders," which refer to genetic abnormalities of surfactant. The new classification system is said to be helping pathologists diagnose children's lung disease more accurately, leading in some cases to more appropriate treatment. For instance, in the past, children with lung growth abnormalities might have been treated as though they had ILD and given steroids, which may not be an effective treatment for them. The

new system also gives doctors more information about an infant's prognosis. In the past, children with ILD were thought to have a high rate of illness and death. The classification system can help doctors distinguish certain children who may appear very ill, but who have a high chance of recovery (such as children with pulmonary interstitial glycogenosis and neuroendocrine cell hyperplasia of infancy), from those with a particular genetic mutation, known as ABCA3, who are unlikely to recover on their own and may need a lung transplant.

TAKE TWO ASPIRINS

Treatment with ibuprofen is associated with a significantly slower rate of decline in lung function in children and adolescents with cystic fibrosis, according to a new study. Researchers found that patients with cystic fibrosis who took high doses of ibuprofen had a 29% reduction in loss of lung function compared to those who did not use the anti-inflammatory drug twice daily over a period of two to seven years. The study, conducted at Rainbow Babies and Children's Hospital, concluded that the benefits of ibuprofen therapy outweigh the small risk of gastrointestinal bleeding. Results are from a study conducted 12 years ago that found ibuprofen reduced the loss of lung function in CF patients, but questions have remained about the safety of regular high-dose ibuprofen use, which in some cases can lead to gastrointestinal bleeding. This study showed that gastrointestinal bleeding was rare, with an annual incidence of 0.37% in those taking ibuprofen, compared with 0.14 percent in those not taking the drug. While the earlier trial was conducted under tightly controlled conditions to ensure that patients strictly adhered to their medication regimens, the new study looked at "real-world" use of ibuprofen. The new study used data from 1996 to 2002 on patients from ages 6 to 17 who were part of the Cystic Fibrosis Foundation Patient Registry. It included data on 1,365 patients who took ibuprofen and 8,960 who did not, who were of similar age and disease severity. Each dose of ibuprofen ranged from 20 to 30 milligrams per kilogram of the patient's weight. Some patients took up to 1,600 milligrams of ibuprofen per dose.

FALLOUT

Findings released by the New York Health Department provide the first broad snapshot of physical and mental health effects among children exposed to the World Trade Center disaster. The survey found that children under five had an increased likelihood of being diagnosed with asthma in the two to three years following the event, though not as sharp an increase as rescue workers. The survey did not find evidence of elevated levels of post-traumatic stress in children. According to the survey, half of the 3,100 children enrolled in the registry developed at least one new or worsened respiratory symptom, such as a cough, between 9/11 and the time of the interview. A follow-up survey now underway will assess whether these symptoms persisted beyond the initial days and months after the event. Prior to 9/11, asthma rates among child enrollees were on par with national and regional rates, but at the time of the interview, about 6% of enrolled children had received a new asthma diagnosis. Children exposed to the dust cloud following the collapse of the towers were twice as likely to be diagnosed with asthma as those not caught in the dust cloud, the survey found. The post-9/11 asthma rate among children under five years old may be as much as twice the regional (northeastern) rate for the same age group. Further research is needed to learn whether some of this increase is due to better detection of asthma in kids with WTC exposure or because parents of

children with asthma symptoms were more likely to enroll their children in the registry. The mental health portion of the survey showed that only 3% of the children surveyed had symptoms suggestive of post-traumatic stress disorder at the time of the interview, a level that is not above that in children elsewhere. As with asthma, however, children who were caught in the dust cloud experienced higher levels. The survey did not assess other mental health problems. This survey included children under 18 years of age on 9/11/01, who lived or went to school south of Canal Street (preschool and K-12) or were south of Chambers Street on 9/11. The Health Department is now working on its second survey of the more than 71,000 enrollees

EFFECTIVE TREATMENT

A specific variation in the glucocorticoid receptor gene is associated with lung disease progression in cystic fibrosis, research published this week in the online open access journal *Respiratory Research* reveals. This finding adds weight to previous research suggesting that specific subgroups of patients with cystic fibrosis may benefit from glucocorticoid treatment. Patients with cystic fibrosis show wide variability both in terms of the inflammatory burden of the lung and in their response to inhaled glucocorticoids. As such, the effectiveness of this therapy in patients with cystic fibrosis remains uncertain. However, previous research has suggested that specific subgroups of patients may benefit from treatment with inhaled glucocorticoids. In several inflammatory diseases, variations in sensitivity to glucocorticoids have been found to be associated with single nucleotide polymorphisms in the glucocorticoid receptor gene. So, a team from Hôpital Trousseau, Assistance Publique Hôpitaux de Paris, Inserm and Université Pierre et Marie Curie (all based in Paris, France) set out to investigate the effect of four polymorphisms in the glucocorticoid receptor gene on disease progression in 255 young people with cystic fibrosis. The BclI glucocorticoid receptor gene polymorphism was found to be significantly associated with a decline in lung function, as measured by the forced expiratory volume in 1 second and the forced vital capacity. The deterioration in lung function was more pronounced in patients with the BclI GG genotype than in those with the CG and CC genotypes. The authors write: "The association of BclI polymorphism and lung disease progression in cystic fibrosis gives support to the concept that specific subgroups of patients with cystic fibrosis may benefit from the use of glucocorticoids preferably by the inhaled route. If true, this should allow discriminatory prescribing which is of tremendous importance."

PRODUCTS

PICK YOUR POISON

Masimo announced that the National Association of EMS Educators (NAEMSE) has issued guidance to all its members advocating carbon monoxide screenings for patients presenting with any of the signs and symptoms of carbon monoxide poisoning or suspected exposure. In addition, the organization is advocating enhanced carbon monoxide training programs for all EMS professionals to help improve outcomes and save lives. In a letter to its membership issued earlier this month, NAEMSE said failing to diagnose carbon monoxide poisoning during the emergency response efforts may lead to poor pre-hospital decisions, including failure to transport, failure to transport to an appropriate facility, failure to properly treat and failure of the

emergency department to diagnose. Too often, even the most skilled first responders can miss the chance to treat carbon monoxide poisoning early because until now there hasn't been a fast, accurate and noninvasive way to detect elevated levels of CO in the blood. However, with the Masimo Rainbow SET Rad-57 Pulse CO-Oximeter, EMS professionals can easily detect carbon monoxide poisoning on the spot in just seconds with the push of a button, allowing for prompt and possibly life-saving treatment. In addition, Rad-57 can also limit the likelihood of long-term cardiac and neurological damage that can result from non-fatal exposures. A training program about CO poisoning is available at naemse.org. Joe Kiani, Chairman and CEO of Masimo noted, "NAEMSE's recommendations for proper EMS training and field screening of carbon monoxide poisoning represents an important milestone in the establishment of new protocols for emergency responsiveness and improved public safety. If implemented nationwide, these recommendations will help reduce morbidity and mortality from unsuspected cases of carbon monoxide poisoning."

GAS IT UP

Airgas Puritan Medical's National Oxygen Kit (NOK) is designed to supply hospitals with immediate access to emergency oxygen during natural disasters or security events. This self-contained product is the first oxygen delivery system designed for immediate large-scale treatment. A single NO is equipped with enough cylinders, regulators and masks to treat up to 40 people for a 24-hour period. Toggle valves allow instant access to oxygen without the need for an "e" key or other tools. NOKs have a guaranteed shelf life of five years for the oxygen and ten years for the cylinders, ensuring a low-maintenance supply for the long-term. For related information, please see our news article, "It's a Gas" in this issue. For more contact airgas.com.

BEHRING STRAIGHT

Siemens is integrating Dade Behring into its existing business of Siemens Medical Solutions Diagnostics, a wholly owned subsidiary of Siemens Medical Solutions USA, Inc, with a transaction that took place this past November. The acquisition will allow Siemens to become the leader in the laboratory diagnostics market and enables Siemens to offer its customers a comprehensive portfolio of innovative solutions across the whole healthcare continuum - from prevention to diagnosis, to therapy and care. The company is bringing together the entire medical imaging, laboratory diagnostics and clinical IT value chain under one roof, offering opportunities for the integration of a comprehensive range of technology, workflows and information that will help deliver an improved quality of patient care at reduced costs. According to Siemens, together with Dade Behring, Siemens Medical Solutions Diagnostics is well-positioned to lead the way in bringing new capabilities to the diagnostics industry. Jim Reid-Anderson will lead the Siemens Medical Solutions Diagnostics global business that has nearly 15,000 employees. Jochen Schmitz will remain Chief Financial Officer (CFO). Primary offices of the company will be located in Deerfield, IL, the current headquarters of Dade Behring. Siemens has 475,000 employees. Contact siemens.com.

NOT FOR GRANTED

More than 10% of the nation's healthcare facilities are seeking grants from Cardinal Health through a \$1 million fund set up by the company to help improve patient safety. More than 700 hospitals, health systems and community health clinics responded to Cardinal's announcement about the grant

program, which is the largest and first of its kind in the private sector. To support initiatives that enhance patient safety and quality of care, Cardinal Health will grant up to \$50,000 per facility to fund new and innovative programs that establish or implement creative and replicable methods to address challenges in providing quality patient care and to help drive improvements. The company expects to fund up to 40 of the 730 grant requests. In selecting grant recipients, Cardinal Health's selection committee is looking for: projects that respond to a clearly identified, high priority safety issue; projects that apply new thinking and approaches to development of solutions; collaborative programs; demonstrable and sustainable measures to assure that improvements hold up over time; and model programs that can be replicated at other organizations. Contact cardinalhealth.com.

KEEPS SOARING

Siemens Medical Solutions helps hospitals and healthcare systems innovate their clinical and financial workflows through Soarian, its next-generation, workflow-engineered healthcare information system. Soarian combines clinical, financial and operational processes to support patient-centered care. By streamlining access to images and data from a variety of medical modalities in one location, Soarian helps facilitate more informed decision-making, leading to improved care delivery, increased staff satisfaction, and more efficient business practices. In addition to helping streamline critical information across clinical, financial and administrative functions, Soarian is assisting many healthcare organizations in improving workflow and patient safety. Currently, more than 100 Soarian-enabled workflows are live across the Siemens global customer base, demonstrating the ability to seamlessly connect clinical, operational, and financial processes in support of patient-centered care. Contact siemens-medical.com.

GO WITH THE FLOW

Vapotherm introduced Precision Flow, its new respiratory care device at the AARC annual conference in Orlando, FL at the AARC meeting. Precision Flow is the first high flow therapy device to integrate humidification, gas blending, flow control, and full alarm functionality into a single device for the delivery of nasal cannula inspired gases. The company has submitted and is awaiting 510(k) clearance for the new product from the FDA. The company's current device, the 2000i, is used in hundreds of hospitals throughout the US. With Precision Flow, the respiratory community will have a new option in high flow therapy that includes broader functionality, additional safety features and ease of use. Contact vtherm.com.

TIE ONE ON

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

available upon request. Contact (800) 647-0172, peppermedical.com.

HOME AND HOSPITAL

Q-Core Ltd, a leading developer of Electronic Drug Delivery Systems for the medical devices market, announced the latest version of multi-therapy pumps that merge hospital and homecare, improving patient quality of life and safety while decreasing cost of care. The Q-Core line of multi-therapy pumps, including infusion pumps, enteral feeding pumps and veterinary infusion pumps, can be worn comfortably in a pouch in virtually any social environment and easily transported to the hospital where it is hooked into a cradle so hospital staff can monitor drug administration. Q-Core's efc Technology (Electromagnetic Flow Control Technology), based on the principles of electromagnetic propulsion, dramatically improves flow accuracy and enhances the continuous nature of the IV flow, thereby increasing patient safety. With an exceptional infusion rate spanning from 0.1-1000 ml/hr, Q-Core pumps can be used for all patients, including infants, enabling hospitals to save on the extra costs typically required when purchasing various sized pumps and IV sets. As the first infusion pump on the market to employ this principle, Q-Core's efc Technology also has a unique ability to perform any linear or non-linear flow profile, in any physical orientation, increasing patient mobility and comfort. Q-Core's detachable touch screen with intuitive programming capabilities provides a new level of simplicity and ease of use for patients who lack medical training. The user-friendly interface reduces the chances of error in configuration, while the Q-core event log, storing up to 5,000 treatment-related events, allows hospital staff to precisely monitor out-patient activity. Q-Core's pumps include the uniquely designed Magic Straw, a disposable module attached to the pump as part of the Administration Set, providing automatic anti-free flow protection and upstream/downstream occlusion protection. The Magic Straw is easy to install, and its design prevents incorrect installation of the tubing.

READY FOR TAKEOFF

The US Food and Drug Administration has granted Hamilton Medical a 510(k) clearance to market the Hamilton-G5 ventilator. Designed expressly with patient safety in mind, the ICU ventilator features the unique Ventilation Cockpit. This intuitive user interface provides a graphic representation of the patient's lung mechanics and shows when the patient may be ready for separation from the ventilator. Like other Hamilton Medical ventilators, the Hamilton-G5 offers the proven closed-loop ventilation mode, ASV. ASV automatically applies lung-protective strategies, reducing the risk of operator error and promoting early weaning. The optional P/V Tool maneuver records a static/pressure curve at the bedside for safe determination of PEEP and tailored lung recruitment. The Hamilton-G5 is designed to provide positive pressure ventilatory support to adult, pediatric, and optionally, infant patients. It is intended for use in a hospital and institutional environment where healthcare professionals provide patient care, including use at the patient bedside for intra-facility transport. Contact hamiltonmedical.net.

LINKING UP

MediServe and Theronyx today announced a partnership in which MediServe becomes the exclusive marketing, sales, and support provider for the Theronyx suite of software solutions for respiratory care in the United States. MediServe will

continue to market its award-winning MediLinks solution and services to clients who require MediLinks industry-leading ability to adapt to a unique workflow and tightly integrate with hospital information systems. The company will market the Theronyx OPUS-RT solution to clients seeking a respiratory care solution that can be rapidly deployed with minimal integration. MediServe will also market the new Theronyx solution for ventilator management in critical-care settings, OPUS-CriticalCare, which targets efficient management of ventilator patients. Both companies will continue to enhance their current products and develop additional advanced products and services for the healthcare market.

HISTORY

Draeger recently celebrated its double centennial of medical safety and technology. The company arrived in the US in 1907, bringing the first mobile short-term respirator, the Pulmotor. Other highlights in the company's history: 1902: first anesthesia machine; 1904: first innovation in breathing developed by Bernhard Drager, the 1904/09 model respiratory protective device; 1907: first mobile short-term respirator, and the birth of the "Draegermen," who operated it; 1913 world altitude record of 6,120 m for airplanes set with Draeger high-altitude breathing apparatus; 1947: iron lung prototype developed; 1950: Draeger unveiled its Model G first integrated anesthesia and ventilator apparatus; 1952: Poliomat, the first long-term ventilator; 1959: Draeger intros its Assistor 640, the first pressure-controlled ventilator; 1989: Babylog debuts, the company's first neonatal ventilator; 2001: Savina is Draeger's first mobile ventilation system; 2006: SmartCare/PS, the first automated knowledge-based ventilation weaning system is launched in the US; 2007: Oxylog 3000 ICU-level performance emergency transport ventilator is launched. For more contact draegermed.com.

OVER THE RAINBOW

Masimo featured its Masimo Patient SafetyNet, a new remote monitoring and clinician notification system, along with its upgradeable Masimo Rainbow SET technology platform, at the AARC Congress. Patient SafetyNet combines the performance of Masimo Rainbow SET pulse oximetry with wireless clinician notification via a pager to provide safety to patients on general care floors where nurse-to-patient levels preclude the level of direct surveillance needed to preempt sentinel events. When a SafetyNet-monitored patient is in respiratory distress, meaningful and actionable alarms are generated by the Masimo bedside monitor and sent wirelessly to designated clinicians. The Masimo Patient SafetyNet instantly routes bedside-generated alarms through a server to a clinician's hand-held paging device in real time. The system also allows for escalation of the alarm to additional clinicians. The SafetyNet can support up to 40 bedside monitors and can be integrated into a hospital's IT infrastructure or operate as a standalone wireless network. Contact masimo.com.

INSPIRATION

Inspired Technologies, Inc announced it obtained FDA 510(k) clearance for its VIAspire Oxygen Portable, a component of its Personal Oxygen System. The lightweight, long duration and quick-to-fill portable provides a ready supply of liquid oxygen for patients requiring oxygen therapy. The VIAspire features the SmartDose technology, an algorithm that responds to a patient's breath rate. SmartDose delivers more oxygen when the patient needs it, supporting optimal oxygen saturation levels and thus promoting activity. Another part of VIAspire, the Liquefier,

received 501(k) clearance in September. The VIAspire Oxygen Portable fills faster and lasts longer than transfilled gas portables and is available in three sizes. The company also announced the closing of its latest financing round. Birchmere Ventures, Cardinal Partners, Draper Triangle Ventures and Innovation Ventures have joined in funding the company's next stage of growth. For more about Inspired (formerly COPD Partners), contact inspiredtechnologies.com.

INSURANCE

Due to the success of the recently launched BCI Capnocheck pocket-sized fully quantitative capnometer, Smiths Medical PM, Inc. has decided to enhance its service offering with the addition of a new optional insurance program that covers loss, damage, or theft for one year when purchased in conjunction with the unit. The BCI Capnocheck capnometer monitors carbon dioxide concentration and respiratory rate in one easy-to-use device. The Capnocheck capnometer uses miniaturized mainstream ET_{CO₂} technology, providing unmatched accuracy in a lightweight, cost effective capnometer. Unlike other capnometers, the Capnocheck capnometer does not need routine calibration. Its applications include intubation verification, an indicator for return of spontaneous circulation, routine airway management, ventilator transport and weaning. Smiths Medical PM, Inc. is a designer, manufacturer, and distributor of BCI patient monitors, diagnostic spirometers and PneuPac transport ventilators. Located in Waukesha, WI, Smiths Medical PM, Inc is part of Smiths Group, London. For more information, please contact (800) 558-2345, smiths-medical.com.

PRODUCT Q&A

Transcutaneous Monitoring of tcpO₂/tcpCO₂/SpO₂: An Increasingly Useful Tool in Conscious Sedation

An interview with Philip Lazzara, RRT, RCP, Product Manager, Transcutaneous Monitors, Radiometer America Inc.

Give us an example of where CO₂ can be used as an early warning of respiratory depression.

Historically, transcutaneous monitoring has been an extremely useful tool in the NICU for trending neonatal ventilation. Used for procedural sedation (bronchoscopy, endoscopy, colonoscopy), transcutaneous monitoring delivers similar benefits for monitoring ventilatory status. When tcpCO₂ measurement is combined with pulse oximetry, the clinician is able to monitor oxygenation and heart rate along with ventilation, allowing them to detect respiratory depression before other monitoring parameters indicate physiologic compromise.

With the growing adoption of HFOV (high-frequency oscillatory ventilation), in the adult arena, do you see transcutaneous monitoring as a growing trend?

Absolutely. As in the neonatal arena, transcutaneous monitoring can be used to trend CO₂ changes and allow the early detection of hypercapnia during HFOV.

What does Radiometer offer in the way of transcutaneous monitoring solutions for conscious sedation applications?

Radiometer's TOSCA 500 monitor is well-suited for use in procedural sedation. The monitor comprises the elements of a

transcutaneous pCO₂ sensor and an optical Masimo SET pulse oximetry sensor in one convenient ear clip, providing optimum comfort to the patient during monitoring. (If needed, the sensor can be adapted for placement on the chest.) The sensor can be heated to a constant temperature of 42°C, allowing the monitoring period to be continued when the patient is moved to the step-down unit.

What are some of the other applications in which Radiometer's TOSCA sensor can be utilized?

The ready-to-use TOSCA system ensures reliable measurements in many clinical situations, including emergency medicine, intensive care (post-extubation), pediatric sleep medicine, and non-invasive ventilation. It is also appropriate for monitoring patient-controlled analgesia, where self-administration has the potential to result in undetected respiratory depression.

SPOTLIGHT ON CAPNOGRAPHY

CHECKMATE

Smiths Medical PM, Inc offers the BCI Capnocheck capnometer. This pocket-sized, fully quantitative capnometer monitors carbon dioxide concentrations and respiratory rate in one easy-to-use device. The Capnocheck capnometer uses miniaturized mainstream ETCO₂ technology, providing unmatched accuracy in a lightweight, cost effective capnometer. It does not need routine calibration, and is powered by two AAA batteries. Applications include intubation verification, an indicator for return of spontaneous circulation, routine airway management, ventilator transport and weaning. It provides a fully quantitative numeric value that is now recommended in the American Heart Association 2005 guidelines. Contact (800) 558-2345, smiths-medical.com.

SPOTLIGHT ON AEROSOL DELIVERY

NOT NEBULOUS

Aerogen is a specialty medical device company dedicated to improving patients lives through the use of its nebulizer range for pulmonary drug delivery to both acute care and homecare patients. The Aeroneb Pro nebulizer offers caregivers the opportunity for improving drug delivery efficiency while reducing the drug and personnel costs associated with respiratory care in the hospital setting. Incorporating Aerogen's OnQ micropump technology, the Aeroneb Pro nebulizer adds no pressure or volume to ventilator circuits and minimizes drug waste by nebulizing virtually all medication. The Aeroneb Pro produces a fine particle, low velocity aerosol optimised for deep lung deposition. Being autoclavable, it enables multi-patient use with infants through adults. The Aeroneb Solo nebulizer is the latest addition to Aerogen's nebulizer range. Designed for use with ventilated patients from infants through adults, the Aeroneb Solo features all the advantages of the Aeroneb Pro but with the increased convenience of being a single patient use device. The Aeroneb Solo represents a new dimension in acute care nebulization and is the first single patient use, high efficiency nebulizer available to care givers. It provides the additional functionality of continuous nebulization when powered by the Aeroneb Pro-X controller. No other nebulizer offers such flexibility, and, when coupled with the high

efficiency that our customers have become accustomed to from the Aeroneb Pro, the Aeroneb Solo nebulizer creates a new standard of care for nebulization of mechanically ventilated patients. Contact aerogen.nektar.com.

LIGHTER THAN AIR

The LiteAire collapsible, disposable, dual-valved holding chamber delivers pop-up convenience and effective drug output by meeting, and often exceeding, the performance of other plastic chambers at a fraction of the cost. The 160cc paperboard LiteAire is lightweight, stores flat and may be used by a patient over multiple pMDI doses for one week. For more information, contact Thayer Medical Corporation, Tucson, AZ (800) 250-3330, thayermedical.com.

VENTILATION ROUNDTABLE

VersaMed Medical Inc.

Wayne Wrolstad, Director of Marketing

What recent advances in technology have you introduced over the past year?

Over the past year, VersaMed has added significant enhancements to its flagship product, the iVent201. These include an optional 4 hr internal battery, integral SpO₂ monitoring, an integrated programmable nebulizer, and extended patient range with tidal volume reduced from 100ml to 50ml.

How have your company's R&D efforts affected user satisfaction?

Each year VersaMed invests heavily and above industry standard in research, new product development and existing product improvements. The decisions made are driven to a large degree from customer input. During the spring of 2007, a customer satisfaction survey polling iVent201 users of one year or more was conducted throughout the US. This survey demonstrated the preponderance of our customers is highly satisfied. At the same time, constructive input provided was passed back to R&D, resulting in additional projects to further improve our products. We strongly believe that R&D efforts do indeed improve customer satisfaction but require close and continuous communication with our customers to ensure they provide the value needed to our end users.

Where do you believe ventilation technology will be five years from now?

The trend towards automated and simple or sophisticated closed-loop ventilation and monitoring techniques will become common in the marketplace. This trend will serve to enhance patient safety, reduce necessary caregiver interaction with the ventilator, add consistency to ventilator management practices and perhaps improve outcomes. Interconnectivity between the ventilator and Hospital Information Systems (HIS) for billing and record keeping, and not only clinical purposes, will be demanded in the US marketplace.

What are your product's users' biggest concerns that you hear as a manufacturer, and how are you addressing them?

Cost pressures and more time for direct patient-caregiver

interaction rate amongst the highest of our customers' concerns. Providing value which addresses those concerns and others means we must continue to do the following: enhance our current product feature set without adding cost, add new products to address unmet needs, offer continuous educational and product training opportunities, and assure that the service and technical support provided by VersaMed and our partners is second to none. In 2007, VersaMed entered into an exclusive partnership with TriAnim to provide sales, service and support of the iVent201 Ventilator throughout the USA. This partnership with TriAnim has vastly enhanced our ability to provide timely, top-notch support to our end users. The new features to our current upgradeable ventilator platform (described above) deliver additional capabilities and utility with no increase in price.

Draeger Medical Inc.

Ed Coombs, MA RRT, Sr. Marketing Manager, Ventilation, Draeger Medical, Inc.

What recent advances in technology have you introduced over the past year?

Draeger has been introducing the SmartCare option, which is exclusive to the EvitaXL ventilator. SmartCare is a knowledge-based ventilation system developed to improve the efficiency and effectiveness of the weaning protocols. SmartCare automates the weaning process, based on the user's input, and uses continuously measured parameters and patient respiratory profiles. As the level of ventilator support is adjusted automatically, the patient's response and ability to adapt to each change in support is evaluated.

Automating weaning protocol can lead to reductions in the cost of care and improved resource utilization.

How have your company's R&D efforts affected user satisfaction?

Draeger is constantly investing R&D efforts, with a goal of improving patient outcomes and facilitating efficiencies for health care professionals. The development of the lung protection package option for the Evita XL, which provides two methods of lung recruitment, is an example. Now caregivers have the option of using a slow volume inflation curve or an incremental/decremental EIP/PEEP procedure to safely and effectively recruit the lung. Through customer feedback, Draeger has provided a customizable interface that can match the monitoring needs of the most critical patients as well as those requiring less diagnostic bedside care.

Where do you believe ventilation technology will be five years from now?

Ventilation systems will continue to incorporate closed-loop feedback systems that are focused on minimizing the length of stay for patients requiring mechanical ventilation. Technologies or protocols that reduce the incidence of ventilator-induced lung injury, ventilator-associated pneumonia and associated complications from mechanical ventilation will continue to be developed. Additionally, efforts to reduce the chances of operator error will be undertaken to minimize the possibility of sentinel events. Draeger sees this as a tremendous opportunity to work with the respiratory care and medical communities to

increase awareness of current trends in mechanical ventilation and the needs of our customers.

What are your products' users' biggest concerns that you hear as a manufacturer, and how are you addressing them?

All customers want to know that a best-in-class manufacturer backs its products through clinical and biomedical support and exceptional customer service. As a corporate partner of the AARC, Draeger actively participates in promoting the respiratory care profession. Draeger has a team of product specialists and clinical applications specialists that provide product training on a wide array of its ventilation products, such as the Evita Ventilator series, Babylog 8000 ventilator, Oxylog transport ventilator and other various ventilator accessories. Draeger also maintains a strong relationship with "Intensive Care On-Line Network" (ICON), which can provide consultation services 24 hours a day, 7 days a week.

Cardinal Health

Terry Blansfield, RRT, Director of Marketing, Advanced Product Development, Respiratory Care

What recent advances in technology have you introduced over the past year?

Cardinal Health is committed to an aggressive product development program which is intended to address key clinical problems facing medical practitioners today. In December 2007 at the 53rd AARC Congress in Orlando FL, the first of these new products debuted. The Revel and Enve Ventilators represent a quantum leap in the development of critical care and mid acuity ventilators. Both ventilators feature the patented ActivCore gas delivery system and weigh in at less than 10 pounds. ActivCore provides all of the performance required for all ventilator applications, including up to 180 lpm of sustained flow, while delivering an impressive 4 hours of operation on an internal battery which can be hot swapped to extend time indefinitely. These revolutionary ventilators incorporate an active exhalation valve, comprehensive selection of modes, an integrated spontaneous breathing trial and even pulse oximetry.

How have your company's R&D efforts affected user satisfaction?

User satisfaction is at the foundation of everything we do at Cardinal Health. We constantly obtain feedback from customers on our existing products as well as current information on key research and challenges facing medical practitioners and their patients. This information drives our R&D and sustaining efforts and the subsequent feedback provides confirmation that we are indeed moving the practice of medicine and quality of care forward. Our customer satisfaction experience is also enhanced by developing quality educational and service / support products.

Where do you believe ventilation technology will be five years from now?

The next several years will see a major leap for ventilators in two key areas. First, will be information handling and expert systems. This will allow continuous monitoring and correlation of patient information providing direct feedback to clinicians alerting them of any change in patient condition far in advance of current systems. Secondly, we will see a major evolution of

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SAFETY SIMPLICITY QUALITY

HAMILTON The New Standard!

Intelligent Ventilation® makes virtually every other mechanical ventilator obsolete. Hamilton Medical has set new standards in patient safety, error reduction, and risk reduction while improving healthcare quality.

Safe Mechanical Ventilation means:

- Ventilators must be simple to operate!
- Ventilators should help hospitals comply with their own protocols and "best clinical practices"!
- Ventilators must offer protection that is automated and integrated!
- Patients deserve the opportunity for comfort and quality care!

Intelligent Ventilation® consists of FOUR UNIQUE ELEMENTS that are distinctly different from anything offered in other ventilators. Each of these four elements has clinical documentation that supports it.

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2. PV Tools - for lung protection protocols.
3. Human Factors Training - utilizing aviation methodology standards.
4. The first and only "Ventilation Cockpit" - one picture is worth a thousand numbers.

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MEDICAL

user interfaces. This new focus on human factors will target enhanced safety and reduce “information overload” of the clinician allowing them to focus on the patient and not the medical devices.

What are your product’s users’ biggest concerns that you hear as a manufacturer, and how are you addressing them?

Cost of ownership is a major concern in the current climate of limited reimbursement in medicine. Providing quality products, designing for long service life and ease of maintenance is something we incorporate into our product design to help ease this burden. Additionally, our customers are faced with budgetary cutbacks which may limit educational opportunities for their staff. We have staffed, developed and fielded a large number of Clinical Educators to address this need. Our Clinical Educators and Clinical Support Specialists provide a comprehensive array of educational programs, even offering Continuing Education Credits to our customers. There is also a large interest in integration of ventilators to hospital information systems. To ease the development cycle, our current generation ventilators use a standardized open serial interface. This unique approach simplifies implementation for host developers. Additionally, we provide all specifications and development tools free of charge to host developers, thereby allowing them direct control over development cycles to speed implementation.

Respironics

What recent advances in technology have you introduced over the past year?

In September, we released a technological breakthrough for the Esprit Critical Care Ventilator: the Speaking Mode Option. The Esprit ventilator is now the first and only positive pressure ventilator to enable speech function without the use of an external one-way valve. The clinician simply deflates the patient’s trach tube cuff and turns on the software option. The Esprit ventilator controls the exhalation valve to force the exhaled gas up through the vocal cords and permit normal speech. It also responds to occlusions by returning to the patient’s normal settings.

How have your company’s R&D efforts affected user satisfaction?

Respironics invented the leading edge technology in noninvasive ventilation, digital Auto-Trak sensitivity, which automatically adjusts to changes in leaks and patient breathing patterns. The Auto-Trak technology was originally introduced in our BiPAP Vision ventilator and is one of the reasons our customers have been so satisfied with the BiPAP Vision ventilator’s performance and ease of use. More recently, we have added Speaking Mode to the Esprit ventilator, which has satisfied our customers’ needs in several ways. First, it eliminates the need to break the patient’s breathing circuit before and after speaking trials, which reduces opportunities for infection and greatly simplifies the process. Second, the safety net provided by the Esprit software gives the user a higher level of confidence over the past practice of using external one-way valves to permit speech.

Where do you believe ventilation technology will be five years from now?

Future ventilation systems will provide better integrated patient

monitoring and increased patient comfort. They will also have more intuitive user interfaces that enable caregivers to manage treatment. We also expect to see great improvements in decision support technology, which will build on the monitoring and interface advancements to help avoid complications during mechanical ventilation treatment.

What are your product users’ biggest concerns that you hear as a manufacturer, and how are you addressing them?

Our customers’ biggest concerns have to do with how to provide quality healthcare with reduced reimbursement. Many are also concerned with the constant barrage of new modes and new acronyms from ventilator manufacturers. At Respironics, we are committed to providing quality, cost-effective solutions to healthcare challenges. We strive to provide superior technology, along with training and education, to help our customers handle the challenges that lie ahead.

Hamilton Medical

What recent advances in technology have you introduced over the past year?

Hamilton Medical is committed to a new paradigm that we call “Intelligent Ventilation.” The goal of Intelligent Ventilation is to eliminate patient harm due to mechanical ventilation. Intelligent Ventilation is about patient safety, clinical quality improvement and error reduction. Intelligent Ventilation consists of four key elements:

1. ASV – the only “ventilation autopilot”
2. PV Tool – automated, hassle-free determination of best PEEP and Lung Recruitment
3. Human Factors Training – error reduction using techniques proved effective in commercial aviation.
4. The Ventilation Cockpit – one picture is worth a thousand numbers. Ventilation “situational awareness.”

How have your company’s R&D efforts affected user satisfaction?

Hamilton Medical is continually involved in R&D to improve user satisfaction, patient/ventilator and clinician/ventilator outcomes. We bring together expert clinicians to attend Intelligent Ventilation “group think” sessions. These are a combination of users and non-users who provide us with feedback as to what their needs are for future development. The message we received from clinicians was that they did not want to see new “modes” or “features” added to ventilators. They want ventilators to evolve into “physiologic” monitors that provide them with succinct and easily discerned information that will help them manage patients. Clinicians are subject to increasing demands (implementing ARDS protocols, “ventilator bundles”....), dwindling resources, and information overload. They want “Intelligence” from medical devices to cut through the noise and give them the key clinical data to assess patient status and make decisions regarding clinical management. They want reduced complexity of operation and features that reduce their task load so they can focus on patient care.

We have developed a new graphic user interface which is set up much like an airline cockpit with “pictures” of the lung and overall ventilatory status (a graphical display of lung compliance, resistance, spontaneous activity, lung volume). A picture is worth a thousand words and research demonstrates

this helps clinicians to identify conditions much more quickly than before. We call this “Situational Awareness.” We are also doing R & D on Human Factors Training. This will help the user by promoting better understanding and usage of medical equipment while providing a safe and effective learning environment.

Where do you believe ventilation technology will be five years from now?

In five years, ventilation technology will be completely automated. The airline industry ‘error’ rates utilizing technology such as autopilot have a proven superior safety record. Automation of routine tasks and accepted clinical practice guidelines are safer for the patient as human errors are reduced. There is less ventilator induced lung injury and patients can be weaned from ventilators at a faster rate using closed-loop control systems.

What are your product’s users’ biggest concerns that you hear as a manufacturer, and how are you addressing them?

Once a user has adopted our philosophy of Intelligent Ventilation, their biggest concern is how to get their coworkers and other clinicians on board. Some express a fear that technology is “replacing” them. With experience, they realize that technology only serves as an extension of their clinical armament, it frees them to spend more time focused on complex patients and clinical assessment of the big picture. Hamilton has a team of clinical specialists who are available to educate clinicians on the benefits of Intelligent Ventilation. Workshops are provided in different locations throughout the country several times a year to give clinicians the opportunity to keep abreast on the latest technology and research.

Breas Medical

What recent advances in technology have you introduced over the past year?

Breas introduced the Vivo 30 and Vivo 40: a new series of bilevel ventilators. Vivo is a flexible, advanced, and clinically safe respiratory solution, which enables patients to safely make the transition from hospital to home. The Vivo 30 and Vivo 40 provide non-invasive respiratory support with the choice of PSV, PCV, or CPAP modes. Enhanced Pressure Support modes give clinical flexibility when needed and a maximum pressure of 40mbar offers the ability to treat difficult restrictive conditions. The standard internal battery on the Vivo 40 assures a 2 hours battery operation beyond the external DC supply. Its intuitive user-interface with home and clinical modes allows both the patient and clinician to adjust the desired settings easily and safely. Clinical mode provides full and precise control over all settings and parameters. The home mode gives the patient easy access to user features which assist in finding just the right level of comfort. An optional integrated heated humidifier comfortably humidifies the patient air. The attractive appealing design together with the logical user interface makes the Vivo an integrated part of any home environment. Please visit our website, breas.com, to look at our product.

How have your company’s R&D efforts affected user satisfaction?

Thanks to the development of eSync—our highly responsive trigger technology—our Vivo bilevel ventilators synchronize smoothly and efficiently with the patient’s breathing pattern. eSync provides individual and comfortable treatment for each patient. Improving upon ordinary flow based triggering systems; eSync intelligently measures not only the flow but also the patient’s initial effort when triggering a breath. Thanks to these exact measurements the VIVO responds immediately when the patient demands a new breath and delivers the right pressure at the precise moment needed.

High-Frequency Chest Compression: A Practical Therapy for Patients with Bronchiectasis

Jane Braverman, PhD; Heather Miller, BA

Retained airway secretions, chronic infection and mucus impaction are the main factors leading to respiratory failure in bronchiectasis. Uncleared mucus is strongly correlated to episodes of acute illness and progressive, often sharp declines in FEV1. Assistive airway clearance therapy (ACT) is an intuitive intervention for patients with impaired clearance mechanisms and is recognized as standard of care for the management of bronchiectasis. Although a variety of ACT modalities are available, many are unsuitable for patients with certain functional or comorbid conditions or with severely diminished lung capacity. High-frequency chest compression (HFCC) is the only therapy able to provide consistent effective clearance for bronchiectasis patients regardless of individual limitations and treatment obstacles. HFCC is recommended in the medical literature for patients with bronchiectasis of all etiologies.

Bronchiectasis is a serious and growing public health concern.^{1,2} Prevalence is high in developing countries, owing largely to lower rates of childhood immunization, inadequately treated respiratory infections and other factors associated with poverty.^{3,5} In contrast, bronchiectasis in industrialized countries has long been regarded as a relatively rare condition.⁶ That impression is changing rapidly. Improved imaging techniques, especially high-resolution computed tomography (HRCT), are yielding a growing number of positive diagnoses.^{7,8} It is now possible to detect bronchiectasis early, to recognize clinical manifestations and to correlate clinical features with structural abnormalities in the airways.⁹

PATHOPHYSIOLOGY

Bronchiectasis may be induced by an infectious insult in any patient with defective host defense mechanisms, diminished mucociliary clearance function and obstructed airways.⁵

Bronchiectasis is not a disease per se. It is best described as a syndrome characterized by irreversible airway dilation and thickening of the bronchial wall arising as a consequence of chronic bacterial/mycobacterial colonization, viral or fungal infection and severe inflammation.¹⁰⁻¹³ Symptoms include chronic cough, daily production of large volumes of viscid,

purulent sputum, declining pulmonary function with commensurate dyspnea and general debility. Progression is marked by increasingly frequent, severe respiratory exacerbations, gross lung tissue damage, mucus plugging and respiratory failure. Regardless of the underlying cause, the common denominator in bronchiectasis is the breakdown of the lung defense system - especially airway clearance mechanisms.

Final common pathway

Bronchiectasis is the final common pathway of a diverse array of respiratory and systemic diseases.^{10-13, 14-16} The condition is nearly universal among adult cystic fibrosis (CF) patients.^{17,18} As survival into early middle age is now common, the absolute number of such patients has risen significantly. Increased use of high resolution computed tomography (HRCT) has led to identification of CF in patients previously missed; adults now make up nearly seven percent of new CF diagnoses.¹⁹ Other disorders associated with bronchiectasis include congenital diseases, most notably dyskinetic ciliary syndromes, primary and acquired immunodeficiency states, inhalation/aspiration injuries, and numerous rheumatic and inflammatory conditions.^{10-14,20} Increasingly, bronchiectasis is emerging as a complication of solid organ and bone marrow transplantation.²¹

PREVALENCE

The actual prevalence of bronchiectasis in the United States is difficult to estimate. Because bronchiectasis is a complication of an antecedent condition, it is rarely cited as a primary diagnosis.⁶⁻⁷ As an example, although bronchiectasis is clinically demonstrable in about 90% of adults with CF, that information is not easily retrieved from medical records.⁷

Non-CF bronchiectasis (NCFB)

The most recent assessment of the prevalence and economic burden of non-cystic fibrosis bronchiectasis (NCFB) was published in 2005 by Weycker et al.⁸ In a retrospective cohort study, data were extracted from a health care claims database incorporating more than 30 U.S. insurance plans encompassing 5.6 million covered lives. Author's found:

- Diagnoses of NCFB: 1,424
- Overall prevalence : 52.3 per 100,000 adults
- Mean age at diagnosis: 61 years
- Gender: 68% female; prevalence higher among women

Jane Braverman is Director of Clinical Programs; Heather Miller is Business Development Specialist, RespirTech. This article is provided by RespirTech.

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at all ages

- Prevalence increased with age
 - Age 18-34: 4.2/100,000
 - Age > 75: 271.8/100,000

Extrapolating from the current U.S. population, an estimated 110,000 Americans over the age of 18 yr may be assumed to have NCFB. To some extent, this number is corroborated by the rank of bronchiectasis as a leading indication for surgical lobectomy or lung transplantation.²²⁻²⁴

Economic burden

*Costs related to severe respiratory illnesses consume a major and rapidly growing proportion of health care resources and expenditures.*²⁵

The overall economic burden of advanced lung disease is rising rapidly. Where data exist, it is apparent that costs related to the morbidity and mortality of these illnesses are substantial. As aging populations with significant chronic lung disease grow, their healthcare expenses rise disproportionately. When matched for age, sex, geographic region, and several selected comorbidities, patients with NCFB used significantly more medical resources than their cohorts. Treatment costs for NCFB are currently estimated at \$630 million annually in the United States alone.⁸

Data from a 2005 study show that persons with NCFB, compared with non NCFB cohorts, averaged...

- 2.0 additional days in hospital (1.7-2.3)
- 6.1 additional outpatient encounters
- 27.2 (25.0-29.1) more days of antibiotic therapy
- Total excess medical care expenditures: \$5681 (\$4862-\$6593)

Contemporaneous United Kingdom statistics for bronchiectasis-related hospitalizations are consistent with US figures:²⁶

- 7,605 Emergency room visits [0.06% of total for all causes] for 2002-2003
 - 78% required admission
 - 54% required emergency admission
 - 61% of admission were for women; 39% for men
 - Mean length of stay (LOS) per episode: 10.5 days
 - Median LOS: 8 days
 - Mean age of patients hospitalized for bronchiectasis: 60 years
 - Bronchiectasis hospitalizations for 15-59 year olds: 37%
 - Bronchiectasis hospitalizations for people > 75 years: 22%
 - Single day hospitalizations: 16%
 - Hospital bed days for bronchiectasis: 0.09% (48, 984).

Mortality rates after first ICU admission for bronchiectasis are high. In the first study of its kind, a retrospective analysis (1990-2000) of patient outcomes for first admissions to the ICU for respiratory failure secondary to bilateral bronchiectasis showed in-hospital deaths at 19% and one-year mortality rates of 40%.²⁷

TREATMENT

Surgery

Diffuse bronchiectatic lung disease develops rapidly in patients with recurrent infection and ineffective secretion clearance mechanisms. Although a complete surgical cure is rarely possible, some patients may be helped by removal of the most

septic lung regions.²⁸⁻³⁰ The goal is to reduce acute infective episodes, to diminish production of purulent, tenacious secretions and to remove airways prone to uncontrolled hemorrhage. Post-surgical lifetime therapy is necessary to maintain the health of less involved lung regions. Follow-up studies of surgically treated bronchiectasis patients show mixed outcomes: Mortality reported in case series papers range from 0% to more than 8%; complication rates vary between 9.4 % and 23%.³⁰ Complications include empyema, hemorrhage, prolonged air leak. As a consequence of persistent obstructive atelectasis or suppurative expansion in remaining lung tissue may be poor.²⁹ For appropriate patients, surgery for bronchiectasis may be a good choice. In follow-up studies, the majority showed marked improvement of symptoms; fewer than 10% were unimproved or worsened.³⁰ However, most bronchiectasis patients are not suitable candidates for surgery and must rely upon medical treatment.

Medical treatment

*“With its tenacious sputum and defects in clearance of mucous, good bronchial hygiene is paramount in the treatment of bronchiectasis...”*¹⁶

Medical treatment for bronchiectasis is focused upon controlling infection and inflammation and managing secretions.^{10,11,31-33} Besides cystic fibrosis and dyskinetic ciliary disorders, bronchiectasis is the prototypical indication for interventions to enhance mobilization and removal of secretions.^{10,34,35} With disease progression, radiological studies show the presence of large volumes of viscid mucus and multiple mucus plugs.^{9,12} Significant quantities of mucus are also seen in diseased distal pulmonary passages.^{9,12} Retained secretions are both necessary and sufficient to drive the bronchiectatic process. Accordingly, standard care includes combination therapy with mucolytic and mucokinetic agents, bronchodilators and antiinflammatory therapy and, most critically, some form of physical/mechanical airway clearance therapy (ACT).^{10, 11, 13, 31, 34-36}

Airway Clearance Therapy

*“Airway clearance techniques are indicated for specific diseases that have known clearance abnormalities...including cystic fibrosis, dyskinetic cilia syndromes, and bronchiectasis from any cause.”*³⁷

The goal of ACT is to avoid retention of pathogen-laden mucus and thus control the cycle of recurrent infection leading to progressive pulmonary deterioration.^{35,37-39} Efficient removal of pooled respiratory secretions, combined with antibiotics and other drugs, can moderate episodes of acute illness and delay progressive deterioration. Pulmonologists that treat NCFB patients routinely prescribe ACT as an essential component of the care plan.^{10,11,13,31} Mobilization of secretions can be accomplished by a variety of techniques and devices. However, finding a suitable ACT for bronchiectasis patients is often a challenge because physical and disease-related factors can diminish or negate therapeutic benefits.

Chest physiotherapy

Chest physiotherapy (CPT) aka percussion and postural drainage (P& PD), can be used effectively in some patients with bronchiectasis. Although studies in patients with NCFB are sparse, available data show enhanced mucus mobilization when CPT is used compliantly three to four times daily.^{40,41}

Although, under ideal conditions, CPT can work well, the method is not suitable for most patients with NCFB. For CPT to be useful in the management of bronchiectasis, a competent, reliable, physically able caregiver must administer manual or mechanical percussion of the chest wall for 3-5 minutes on each of 9-12 thoracic regions, pausing to strategically position the patient to permit mucus drainage, coughing and breathing techniques. CPT is *unrealistic* for patients without a dedicated caregiver. It is *inappropriate* for those physically unable to assume and tolerate required postures or with contraindications such as gastroesophageal reflux. And CPT is ineffective for those with cognitive or emotional barriers that preclude daily therapy. For the majority of patients living with NCFB in the twenty-first century, CPT is neither a practical nor wise choice for secretion management.

Alternatives to CPT

Some bronchiectasis patients have been shown to benefit from ACTs including choreographed breathing maneuvers (active cycle of breathing exercises) and a variety of devices that require active effort, mastery of technique and/or physical agility. Examples include oral high-frequency (OHF) devices and positive end-expiratory pressure (PEP) masks.⁴² Other patients with advanced disease and/or a variety of comorbidities may not have the physical stamina or lung capacity to benefit from techniques that depend on forced expiration. For patients unable to use such ACTs effectively, high-frequency chest compression (HFCC) therapy offers an ideal solution.

High-frequency chest compression

HFCC therapy is an FDA- approved airway clearance technology used widely for nearly two decades. 43 Basic research studies demonstrate several synergistic physiological effects that enhance mucus mobilization and clearance.^{43,44} Dozens of clinical trials demonstrate the safety and efficacy of HFCC in a broad range of patient populations.^{43,44} The therapy has been used successfully by more than 70,000 patients with impaired airway clearance arising from an array of acute and chronic conditions that compromise mucociliary clearance. In numerous published studies, investigational endpoints include the comparative volume of expectorated secretions, changes in pulmonary function scores, quality of life gains and reductions in healthcare utilization. HFCC is the only ACT shown to sustain or improve pulmonary function.⁴⁵

HFCC therapy is administered by means of an air pulse generator attached by two lengths of tubing to an adjustable, inflatable jacket/vest garment fitted over the users' 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.⁴³

Tolerance barriers and risk for gastroesophageal reflux are eliminated because, unlike CPT, the therapy does not require Trendelenberg positioning. 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.⁴³ Because HFCC is automated, treatments are consistent and reliable. Adherence to daily airway clearance therapy has been shown to modify the progression of pulmonary deterioration in patients with impaired secretion clearance function.^{44,45} In bronchiectasis, long-term use of HFCC

may prove to be the most cost-effective component of care. The human and economic benefits are even greater if mechanical ventilation, lung reductions surgery and lung transplantation can be avoided.⁴⁶⁻⁴⁹

SUMMARY

Bronchiectasis patients with uncontrolled disease require frequent hospitalization for treatment of severe respiratory exacerbations. They experience accelerating declines in lung function, progressive lung damage and eventual respiratory failure. Extended survival and improved general health for patients with severe septic respiratory disease is predicated upon daily clearance of airway mucus. HFCC is an evidence-based therapy that meets or exceeds standard of care criteria. Physicians' preference for HFCC is clear; they prescribe it for the majority of their CF patients as well as thousands of patients with non-CF bronchiectasis. Patient acceptance and satisfaction is demonstrated by superior adherence to therapy. Improved patient outcomes support cost-effectiveness. HFCC may be relied upon to meet the intensive lifetime therapy needs of patients NCFB.

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Adaptive Dual Control Breaths – VTPC & VTPS

Cyndy Miller, RRT

Introduction

Recently, ventilator manufacturers have introduced new choices for breath delivery that allow the ventilator to control pressure and volume based on a feedback loop. This is often referred to as adaptive control or dual control. Adaptive-dual control combines the advantages of both pressure and volume control breath delivery. The following paper explores the strengths and weaknesses of volume and pressure ventilation and explains how combining the two can benefit the patient.

Strengths and Weaknesses of Volume Control

On modern ventilators, volume controlled ventilation is flow controlled ventilation. The ventilator delivers mandatory breath flow to the patient at a precise flow rate and flow pattern for a pre-determined amount of inspiratory time. The patient receives a specific tidal volume each breath while airway and alveolar pressures vary as a result of patient effort and patient lung mechanics. During volume control, flow rate, flow pattern and inspiratory time don't change even if there are changes in the patient's effort or the patient's lung conditions. Instead, airway and alveolar pressures change (fig 1).

Volume control remains a very popular choice for ventilating adult patients. For some, it provides good synchrony, for others it does not. Volume control's fixed flow patterns sometimes fail to match the flow needs of actively breathing patients and this can cause the patient to experience air hunger and/or dys-synchrony. If flow is set low enough to allow for an appropriate duration of inspiratory time, patient peak flow needs may exceed ventilator flow delivery and the ventilator may impose work of breathing rather than relieving it. If flow is set high enough to quench the patient's initial flow need, the resulting inspiratory time may be too short, truncating before the patient finishes inhaling.

Some ventilators address this link between flow and inspiratory time by allowing flow, inspiratory time and tidal volume to be adjusted during volume control. But this technique may give the clinician a false impression. They may believe that flow is

The author is Director of Clinical Education, Newport Medical Instruments, Inc. This paper is a report on the Newport e360, provided by Newport Medical Instruments, Inc.

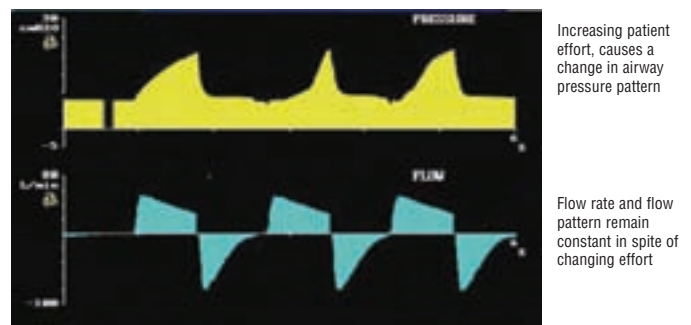


Figure 1: Examples of Volume Control Breaths with Changing Patient Effort

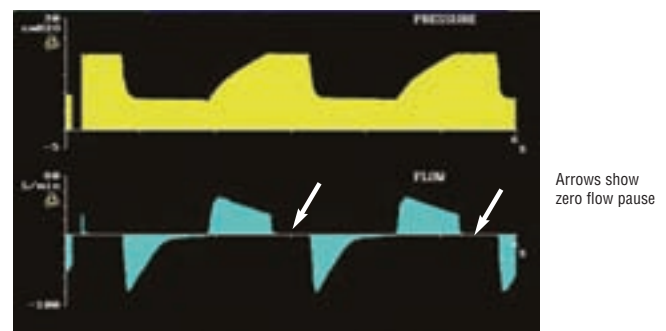


Figure 2: Examples of Volume Control Breaths with End-inspiratory Pause

delivered for the entire inspiratory time but it is not. Flow stops as soon as the tidal volume is delivered, thereby creating a zero-flow pause for the duration of the inspiratory time at the end of each breath (fig 2).

Beyond the issue of dys-synchrony, fixed flow patterns can also result in critically high end-inspiratory pressures on patients with poor lung mechanics. This can worsen their clinical outcome (fig 3).

Finally, when the fixed flow patterns are used for ventilating pediatric patients with uncuffed (leak-prone) endotracheal tubes, actual volume delivery and therefore gas exchange may swing widely with waking and sleeping states (fig 4).

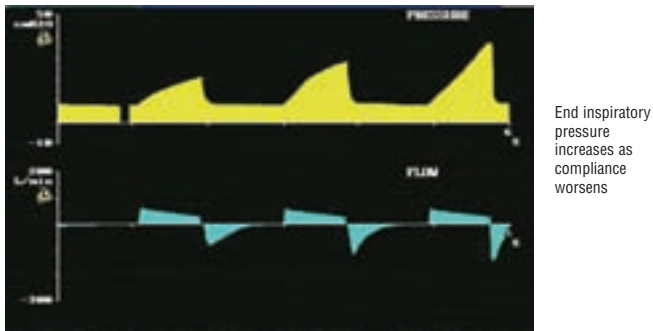


Figure 3: Example of Volume Control Breaths with Changing Lung Conditions

Strengths and Weaknesses of Pressure Control

Pressure controlled ventilation has been available as an alternative to volume controlled ventilation for many years. Rather than controlling flow (and volume) and allowing pressure to vary, this breath type controls airway pressure and allows flow (and volume) to vary. Pressure control's variable flow patterns can match the flow needs of actively breathing patients with an increase in flow at the time of need, so actively breathing patients need not experience air hunger. Since flow is managed independently of inspiratory time an increased flow will not necessitate a shortened duration of flow (inspiratory) time and increased potential for dys-synchrony (fig 5).

The fact that airway pressure and inspiratory time don't change with changes in the patient's effort, flow needs or lung conditions makes pressure control well suited to lung protective strategies.

Finally, when pressure control with variable flow is used for ventilating patients with uncuffed (leak-prone) endotracheal tubes, actual volume delivery and therefore gas exchange remain fairly consistent during both waking and sleeping states (fig 4).

In summary, this method of ventilatory support can provide more comfortable, synchronous ventilation for actively breathing patients, may play a part in lung protective strategy for patients with stiff lungs and may provide more consistent gas exchange when airway leaks are present.

One concern with the use of pressure control is that when airway and lung conditions worsen, tidal volume may decrease (rather than airway pressure increasing) and gas exchange may be inadequate. Improved lung conditions may result in an inappropriate increase in tidal volume. With volume monitoring and volume alarms this comfortable form of ventilation can be a safe choice for ventilating all patients (fig 6).

In spite of the volume monitoring and alarms, pressure controlled ventilation has failed to provide the same caregiver confidence in consistent ventilation and gas exchange as volume ventilation. For this reason, its use has mostly been limited to pediatrics or extended inspiratory time application for adults with acute lung injury.

Combining Pressure and Volume Ventilation: Adaptive Dual Control

Recently, ventilator manufacturers have introduced new choices for breath delivery that allow the ventilator to control pressure and volume based on a feedback loop. This is often referred to as dual control or adaptive dual control (table 1).

Dual control ventilation can offer the benefits of both volume and pressure control style of breath delivery. Delivered tidal volume and gas exchange are reasonably predictable. At the same time, flow is variable and distending pressures are controlled so ventilatory support can be more comfortable and synchronous for actively breathing patients, can be safer for patients with stiff lungs and can provide more consistent gas exchange when airway leaks are present.

Adaptive dual control breath management is available for mandatory and for spontaneous breath-styles.

Even though this breath type is sometimes thought of as volume control breath type, each mandatory breath is delivered in a manner consistent with the pressure control breath type. Unlike traditional pressure control breaths, the pressure control level of these breaths is automatically adjusted in small increments up and down, as needed, within a user-set range with the goal of delivering the user-set tidal volume.

Each spontaneous breath is a pressure support breath. Unlike traditional pressure support breaths, the pressure support level

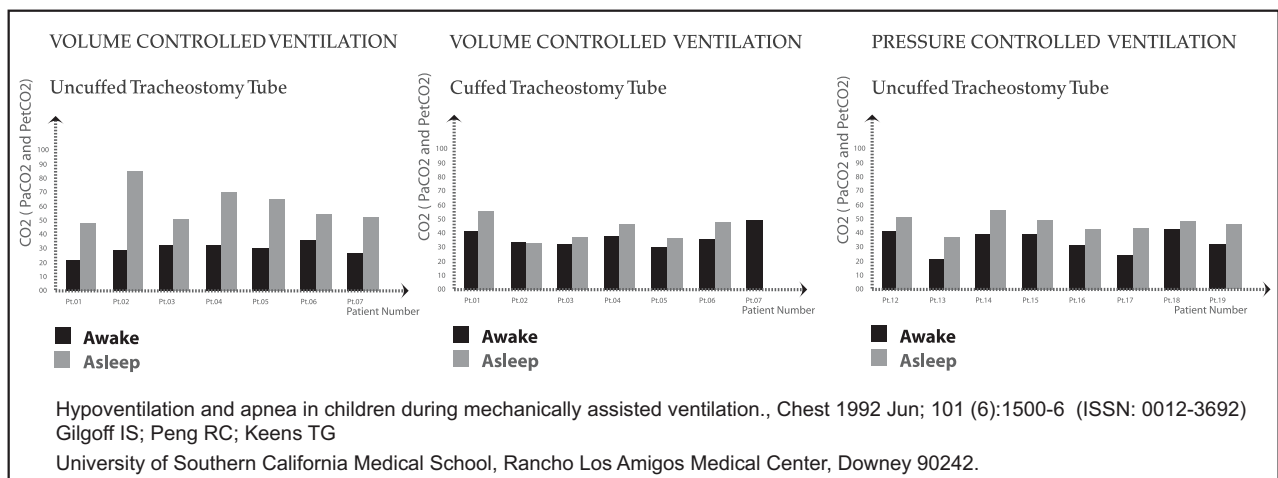
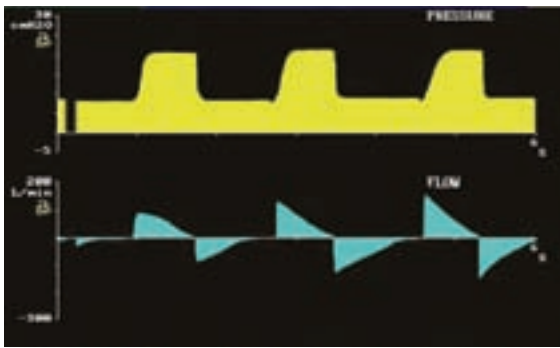
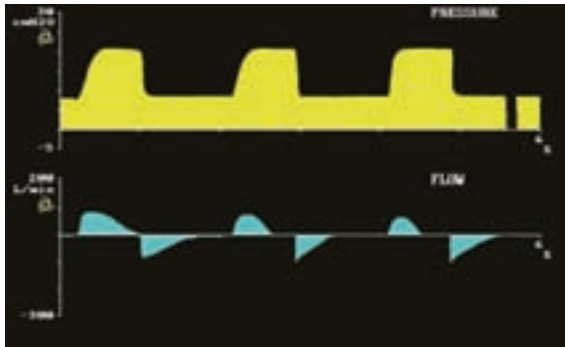


Figure 4: Study shows that when ventilating patients with uncuffed tracheostomy tubes, CO2 levels may increase significantly during sleep with Volume Controlled Ventilation but not with Pressure Controlled Ventilation.



Flow is automatically adjusted to meet patient effort.

Figure 5: Example of Pressure Control Breaths with Changing Patient Effort



Tidal volume decreases as lung conditions worsen.

Figure 6: Example of Pressure Control Breath with Changing Lung Conditions

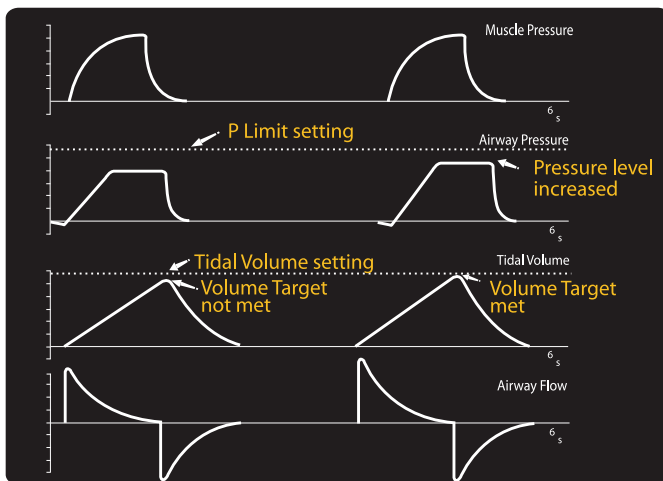


Figure 7: Example of Adaptive Dual Control Mandatory Breaths

of these breaths is automatically adjusted in small increments up and down, as needed, within a user-set range with the goal of delivering the user-set tidal volume.

This adaptive dual control design is available on the Newport e360 Ventilator as Volume Target Pressure Control (mandatory) breaths and Volume Target Pressure Support (spontaneous) breaths (fig 7).

Adaptive dual control combines the ability to limit distending pressure with relatively confident volume delivery. The user set volume is not guaranteed for each breath (hence the name Volume Target Pressure Control); it is targeted for each breath. Pressure control/pressure support adjustment continues in safe increments until volume delivery matches set tidal volume.

Dys-synchrony and its complications may result if the slope rise

of the breath is not managed properly or if there is a mismatch of the mandatory breath inspiratory time or pressure support breath flow cycling off threshold (expiratory threshold) and the patient's neural inspiratory time. Care should be taken to manage these parameters properly to make best use of the new breath type.

Adaptive Dual Control: Volume Target Pressure Control (VTPC) and Volume Target Pressure Support (VTPS) Breath Types

When using VTPC and VTPS breath types on the e360 Ventilator, the user first selects a Pressure or Volume Control mode: A/CMV, SIMV, or SPONT. Turning ON Volume Target in the Advanced data set on the Graphical User Interface changes the breath type from Pressure Control or Volume Control to Volume Target Pressure Control (fig 8).

VTPC - A/CMV: All breaths are Volume Target Pressure Control mandatory breaths (VTPC). The user-set breathing frequency is the minimum number of breaths the patient receives. Any additional patient efforts that result in a trigger will be supported by additional VTPC mandatory breaths. Breath by breath, the e360 adjusts the pressure control level, up and down by 0 to 3 cmH₂O per breath, in order to deliver the user-set tidal volume at the lowest possible pressure control level. The maximum pressure control level the e360 will select is equal to the Pressure Limit setting and the minimum level is PEEP plus 5 cmH₂O.

This mode is nearly identical to Pressure Control A/CMV except that rather than the Pressure Limit setting being the pressure control level for every breath, it is the maximum pressure control level for every breath. (See Figure 9).

VTPC – SIMV (VTPC mandatory breaths + VTPS spontaneous breaths): The patient receives a fixed number of Volume Target Pressure Control mandatory breaths (VTPC) at the user-set breathing frequency. Any additional patient triggers are supported by Volume Target Pressure Support breaths (VTPS). Breath by breath, the e360 adjusts the pressure control and pressure support levels, up and down by 0 to 3 cmH₂O per breath, in order to deliver the user-set tidal volume at the lowest possible pressure control and pressure support levels. The maximum pressure control level the e360 will select is equal to the Pressure Limit setting and the minimum level is PEEP plus 5 cmH₂O. The maximum pressure support the e360 will select is equal to the Pressure Limit setting minus PEEP and the minimum level is PEEP plus 5 cmH₂O. The same user-set tidal volume applies to both the VTPC and the VTPS breaths.

This mode is nearly identical to Pressure Control SIMV with Pressure Support except that rather than the Pressure Limit setting being the pressure control level for every mandatory breath, it is the maximum pressure control level for these breaths. And rather than setting a Pressure Support level, the Pressure Limit also serves as the maximum pressure target for pressure support breaths.

VTPC-SPONT (VTPS): All breaths are Volume Target Pressure Support breaths. Breath by breath, the e360 manages the pressure support level up and down by 0 to 3 cmH₂O per breath, in order to deliver the user-set tidal volume at the lowest possible pressure support level. The maximum pressure support the e360 will select is equal to the Pressure Limit setting minus

Adaptive-Dual Control
Full and Partial Support
Newport e360 & e500: VTPC & VTPS Volume Target Pressure Control & Volume Target Pressure Support
Maquet Servo 300, Servo i & Viasys Avea: PRVC & VS Pressure Regulated Volume Control & Volume Support
Puritan Bennett 840: Volume Ventilation Plus
Drager Evita 4: Auto Flow
Hamilton Galileo: Adaptive Support Ventilation

Table 1: Adaptive Dual Control Breath-types

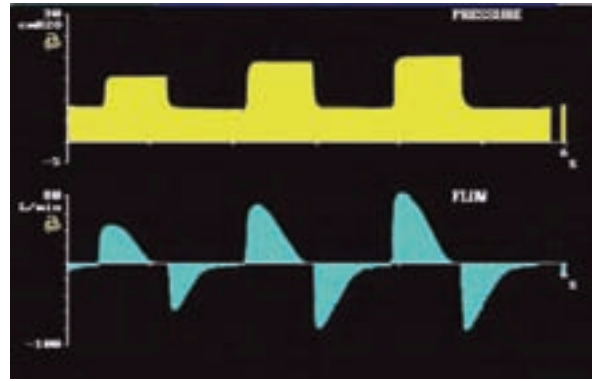


Figure 9: Example of VTPC / ACMV

PEEP and the minimum level is PEEP plus 5 cmH₂O. This mode is nearly identical to SPONT with Pressure Support except that rather than using the Pressure Support setting to determine the pressure support level for every breath, the Pressure Limit determines the maximum target pressure support level.

In every VTPC mode; A/CMV, SIMV and SPONT, the user sets a target tidal volume just like they do in volume control. This volume setting is the target volume for every breath. The user also sets a pressure limit like they do in pressure control. This pressure limit is the maximum amount of pressure that will be targeted for mandatory and spontaneous breaths. The actual target pressure will change when needed to bring the delivered inspiratory volume up to or down to the user-set volume. The e360 will deliver breaths at the lowest pressure possible using pressures at or below the user set pressure limit. Like pressure control, VTPC mandatory breaths (in A/CMV and SIMV) are cycled off by a user-set inspiratory time, and like pressure support, VTPS spontaneous breaths (in SIMV and SPONT) are flow cycled off at the Expiratory Threshold setting.

The user selects a mode in the same way they normally do. A sicker, less stable patient is ventilated in A/CMV while more stable patients are ventilated in SIMV or SPONT. In A/CMV and SIMV, the same care must be taken to set breathing frequency and inspiratory time in a way that maximizes tidal volume delivery while allowing the patient time for complete exhalation in order to avoid auto-PEEP, ineffective triggering, and dys-synchrony. And the usual rules apply for weaning breathing frequency.

Indications and Contraindications for VTPC/VTPS: The goal of VTPC and VTPS breath delivery is to use the least amount of support that will attain the prescribed volume delivery. Since this is generally the goal for most patients, VTPC and VTPS are appropriate choices for ventilating a wide range of patients. There are a few exceptions. Using this breath type on patients who exhibit erratic breathing patterns may result in erratic,

frequent fluctuations in target pressure. This could contribute to dys-synchrony. And using this breath type on patients with high metabolic demands and high minute volume demands could result in an increase in imposed work for the patient since the ventilator will automatically reduce support as the patient's high demand causes delivered volume to increase. As always, sound clinical observation and monitoring will help you to make the best choices in breath type.

Setting Slope/Rise for VTPC/ VTPS Breaths: The patient's flow demand and respiratory mechanics determine how fast pressure will rise at the airway and how fast volume will enter the lung in response to gas delivered from the ventilator. This will affect the amount of work of breathing that is imposed on an actively breathing patient and the amount of tidal volume that can be delivered within a set amount of time. If you set a slow Slope/Rise, it may impose more work on an actively breathing patient. A slow rise may also result in a lower volume delivery.

If the user set tidal volume is not reached by breath-end when the volume target breath type is selected, the Newport e360 will increase the pressure level for the breath that follows. This means that a slower Slope/Rise may result in a higher pressure control or pressure support level. In some cases, increasing the inspiratory time or decreasing expiratory threshold may extend the duration of flow delivery and therefore allow more volume to be delivered at a lower pressure level. But this practice may increase the risk of auto-PEEP and breath phase dys-synchrony. It is usually preferable to try increasing the Slope/Rise to a faster setting before lengthening the inspiratory time.

The e360 Graphic User Interface makes it very simple to manage the Slope/Rise setting for the lowest imposed work of breathing and the most efficient volume delivery. Adjust the Slope/Rise via the Advanced Data Set while observing the pressure waveform. Set Slope/Rise so that pressure rises very rapidly without significantly overshooting the target pressure. (See Figure 10).

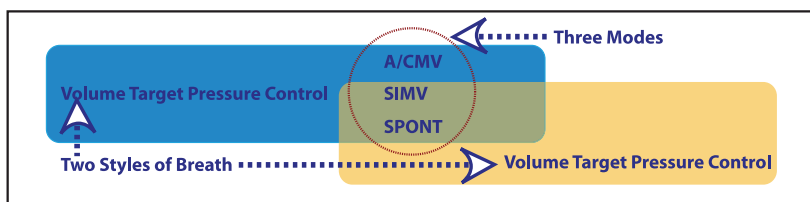


Figure 8: VTPC Breath Type and Mode Selections on Newport e360 Ventilator

Setting Inspiratory Time for VTPC Breaths: The inspiratory time setting is very important when ventilating with the VTPC breath type because, like the Slope/Rise setting, it influences how much volume will enter the lung at any given target pressure. The Graphic User Interface makes it easy to assess the appropriateness of the inspiratory time setting.

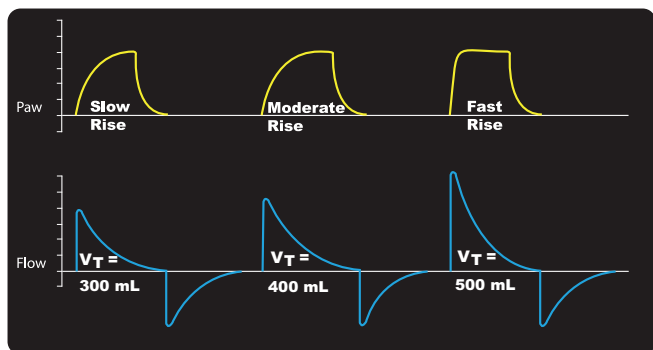


Figure 10: Example of how slope rise affects volume delivery

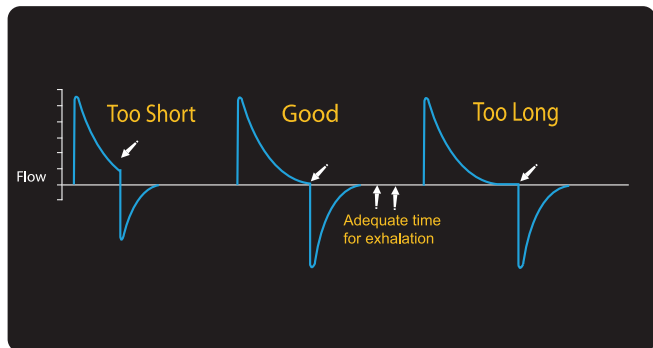


Figure 11: Example of how to set inspiratory time to optimize volume delivery for a patient who is not actively breathing

For patients who are not actively breathing, it may be suitable to lengthen inspiratory time until the flow waveform reaches zero before the ventilator switches to exhalation. This will help to optimize volume delivery as long as there is still enough time left between breaths for adequate exhalation (fig 11).

For patients who are actively breathing, the inspiratory time must coordinate with the patient's neural inspiratory time. A cycling-off mismatch between patient and ventilator may result in discomfort, agitation, expiratory resistance, auto-PEEP and missed triggers. Use the pressure waveform for assessing the appropriateness of when inspiration cycles off. Increase the Inspiratory Time until the pressure waveform slightly slopes up at the end of inspiration. (This upward slope indicates that the breath is too long and the patient is trying to exhale prior to when the ventilator switches to exhalation.) Then decrease the setting in small increments until the end inspiratory upward slope is gone (fig 12).

Use the flow waveform for assessing the appropriateness of exhalation time. Expiratory flow should return to the zero baseline prior to the onset of the next breath. Inadequate exhalation time will result in auto-PEEP which will decrease volume delivery for the next breath and decrease trigger reliability.



Figure 12: Example of how to set inspiratory time to optimize synchrony for an actively breathing patient

Setting Expiratory Threshold for VTPS Breaths: The Expiratory Threshold setting will determine the inspiratory time for VTPS breaths. It is the flow cycling off threshold. When flow delivered to the patient decreases to the Expiratory Threshold setting (a percent of peak inspiratory flow), the breath will cycle to exhalation (fig 13).

A cycling-off mismatch between patient and ventilator may result in discomfort, agitation, expiratory resistance, auto-PEEP and missed triggers.

Patients with long time constants, like those with COPD, need a high (high % of peak flow) Expiratory Threshold to provide good inspiratory to expiratory synchrony. Since their lung filling time is relatively long, a higher expiratory threshold will ensure that the breath ends at a suitable time. ARDS and pulmonary fibrosis patients have short time constants and therefore benefit from a low (low % of peak flow) Expiratory Threshold. Their lung filling time is more rapid and therefore they need a lower Expiratory Threshold in order to prolong the breath to a suitable length. To maintain good synchrony, the Expiratory Threshold needs to be re-evaluated when the patient's respiratory time constant (resistance or compliance) changes because this influences lung filling time and therefore it influences the inspiratory time resulting from any particular Expiratory Threshold setting (fig 14).

If the inspiratory flow ends before the patient finishes inhaling, inspiratory muscle work continues into and possibly through the ventilator's expiratory phase.

The patient's continued effort may cause re-triggering or "stuttering" of the ventilator support. Also, if the support is too short, the tidal volume is smaller and therefore the e360 may need to escalate target pressure in order to meet the target tidal volume.

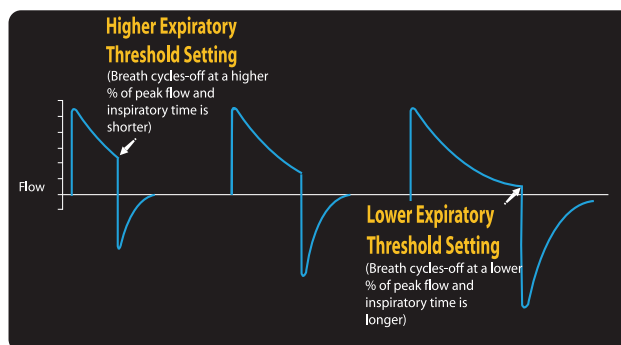


Figure 13: Example of how three different flow cycling-off thresholds affect inspiratory time in pressure support.

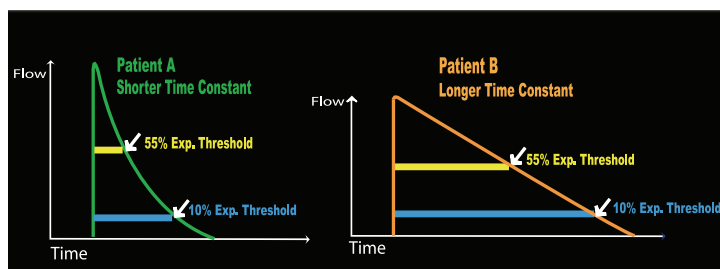


Figure 14: Relationship between time constant and Expiratory Threshold

If the inspiratory flow ends after the patient starts to exhale, tidal volume delivery may appear to be increased, but the cost for the extra volume is high on the expiratory side. These patients often recruit expiratory muscles to “fight” against the ventilator flow. This increases their expiratory workload. Even worse, the increased expiratory resistance caused by prolonged support may lengthen the amount of time it takes the patient to completely exhale, increasing the likelihood of dynamic hyperinflation/ auto-PEEP and triggering (expiratory to inspiratory) dys-synchrony. This expiratory dys-synchrony problem, which often leads to trigger dys-synchrony can be common for patients with COPD.³

Auto-PEEP caused by shortened expiratory time or increased expiratory resistance can result in missed triggers that may further contribute to breathing dys-synchrony.

The e360 Graphic User Interface makes it very easy to assess the appropriateness of the Expiratory Threshold setting and make changes as necessary. Ideally the patient will benefit from the lowest Expiratory Threshold that does not impede exhalation. From the Advanced Data Set, adjust the Expiratory Threshold down until the pressure waveform slightly slopes up at the end of inspiration. (This upward slope indicates that the breath is too long and the patient is trying to exhale prior to when the ventilator switches to exhalation.) Then increase the setting in small increments until the end inspiratory upward slope is gone. Remember that increasing the setting will shorten the breath.

Summary

Adaptive dual control ventilation can offer the benefits of both volume and pressure control style of breath delivery. With adaptive dual control, delivered tidal volume and gas exchange are reasonably predictable. At the same time, flow delivery is variable and distending pressures are controlled so ventilatory support can be more comfortable and synchronous for actively breathing patients, can be safer for patients with stiff lungs and can provide more consistent gas exchange when airway leaks are present.

The e360 VTPC and VTPS breaths provide breath to breath adaptive dual control of ventilation for better patient ventilator synchrony. The added advantages of adjustable Slope-Rise and adjustable Expiratory Threshold makes it easier to customize breath delivery based on patient needs.

Adaptive Dual Control Benefits: 1) Maintain adequate alveolar ventilation within safe distending pressures; 2) Automated escalation or withdrawal of support; 3) Safer for weaning patients – prevents rapid shallow breathing because the support is adjusted to keep tidal volume delivery at a user-selected value; 4) Minimize imposed work for the patient during spontaneous assisted breathing; 5) Improve patient comfort; 6) Minimize patient need for sedation; 7) Potential for reducing patient ventilator days.

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VORTRAN VAR Technical Report 07-02

Summary

On November 30, 2007, ECRI Institute issued a Medical Device Hazard Report (H0009 – Critical Priority Medical Device Alert) on their website (www.ecri.org) titled: “VORTRAN VAR/SureVent Gas-Powered Resuscitators May Spontaneously Stop Delivering Breaths.” The ECRI recommendations for clinical applications of the VAR are consistent with VORTRAN’s product instructions **not to leave patients unattended during resuscitation**. However, we were concerned about the testing conditions and ventilation parameters that ECRI selected for evaluating the VAR because we were not able to duplicate the results. The published ECRI Medical Device Hazard Report was reviewed by our clinical specialists and they found that: “Overall, the Alert is not appropriately worded and seems to be based on data collected from clinical scenarios that are outside of clinical reality/device performance parameters.”¹

Background

ECRI requested samples of the VAR from VORTRAN on April 29, 2005 for evaluation and conducted in-house testing in June 2005. ECRI called and requested additional technical support on June 15, 2005 and on August 19, 2005 called and stated that “VAR will stop cycling at times” without any further elaboration. Two years later, VORTRAN received an e-mailed draft report from ECRI dated September 6, 2007 requesting SUPPLIER’S REVIEW: HEALTH DEVICES PROBLEM REPORTING SYSTEM REPORT. The e-mail stated that the attached draft report would be published in an upcoming issue of Health Devices. ECRI requested that VORTRAN review the attached draft, note our suggestions for additions or corrections, and telephone or email our comments to ECRI.

VORTRAN requested a review of the ECRI testing protocol. VORTRAN received a document containing a total of six (6) sets of testing parameters. VORTRAN attempted to duplicate the testing conditions and submitted our findings and concerns to the ECRI on September 13, 2007 and followed up with a visit to ECRI facility on October 24, 2007 to confirm that the operational characteristics and performance of the VAR were understood by ECRI. The revised report was made available to VORTRAN on November 16, 2007 for review and again VORTRAN offered comments on November 21, 2007. We again objected to the testing conditions and their conclusions. ECRI called on November 30, 2007 and informed VORTRAN that the report would be posted on their website the same day.

ECRI Testing Conditions

Following is VORTRAN’s response to the ECRI Testing Data received Sep-12-2007:

VORTRAN has endeavored to reproduce the testing on our Michigan TTL single lung (Model 3600i) and dual adult lungs (Model 5600i) with the PnueView data acquisition package (version 1.216.94). The results of the initial set-up evaluation and the duplication of the testing are presented below.

ECRI Test Condition 1

TEST CONDITIONS: MTTL C= 20, R=20 Flow @40 LPM, desired TV=600 mL, RR=10-12 bpm.

VAR pressure level set at 25-35 cmH₂O range.

VAR delivered: RR 33 bpm, TV 423 mL. I increased pressure setting TV=450, RR =30 bpm. I changed the rate setting to midrange. The unit delivered a RR of 20 bpm then stopped functioning; I disconnected the unit from the test lung it delivered a breath then stopped. It spontaneously started again then stopped. It repeatedly stopped functioning when it started again the breaths delivered were at the same levels.

- Repeated testing RR set at slow delivered RR 46bpm then stopped disconnected and reconnected delivered RR=11 bpm
 - Repeated another day delivered RR 30 bpm then stopped
- For these cases the VAR delivered (approx). Ti =1 sec, I:E =1:2 or 1:1, PEEP=8 cm H₂O, PIP=32 H₂O

VORTRAN:

1. The desired test condition of TV= 600 mL at flow of 40 LPM (=666 mL/sec) for a RR of 12 bpm (5 sec breath) is only achievable if the Ti = 0.9 sec and Te = 4.1 seconds. Using MTTL dual lung model, setting the left and right lung compliance to 0.02 cm-H₂O, (this yields a system compliance of 0.02+0.02=0.04 for a dual lung), using resistors of Rp 20 at the left, right lung feed and airway tube, the slowest respiratory rate achievable is 14 bpm. The delivered parameters were a Ti of 1.04 sec, I:E=1:3.2, delivering TV of 628 mL. When the rate dial is adjusted inward from this setting, to further slow down the rate, the VAR will go into the spontaneous breathing mode, similar to the pressure support mode of other ventilators. Mandatory breathing will stop (pressure controlled mode) and patient triggering effort is required for a supported breath.
2. The ASTM F920-93² minimum performance requirement is delivering TV>600 mL, at RR=20 bpm, I:E=1:2, C=0.2 L/cm H₂O for patient body mass of >40 kg. The VAR meets and/or exceeds this performance requirement easily at these settings.
3. For the reported results of RR 33 bpm delivering TV of 423 mL at a flow of 40 LPM, the calculated Ti+Te=1.8 sec, with Ti=0.63 sec yields a Te=1.17 sec and a resultant I:E of 1:1.9 is expected. Again when the rate dial is adjusted inward to slow down the rate, the VAR enters into spontaneous mode and stops mandatory cycling. It is easily corrected by adjusting the rate dial outward so that the VAR will resume mandatory controlled breathing.

4. A PEEP of 8 cm is also highly unusual since the Michigan Test and Training Lung and its associated software PnuView is not designed to capture accurate intrinsic PEEP value. Using an external Magnehelic pressure gauge (0-50 cm-H₂O), in addition to the front panel pressure gauge on the MTTL, we recorded PIP/PEEP of 18/3 cm-H₂O. The calculated TV, using delta P times compliance for the left and right lung, of 600 mL = (18-3)X0.02Left+(18-3)X0.02Right.

ECRI Test Condition 2

TEST CONDITIONS: MTTL C= .1 L/cm H₂O, R=20 Flow @40 LPM, desired TV=650 mL, RR=20 bpm.
VAR pressure level set to 25-35 H₂O range, med fast range, the rate spontaneously changing then stopped functioning
For this case VAR delivered TV=1.393 L, Ti 2.97 sec, PIP 33 cm H₂O, PEEP=8 cm H₂O, I:E 1:1.5

VORTRAN:

5. Using MTTL dual lung model, setting compliance, left lung to 0.1 and right lung to 0.1 L/cm-H₂O, using Rp 20 at left, right and airway, the slowest rate achieved is 9 bpm with PIP/PEEP of 20/4 cm-H₂O.

Desired test condition of TV= 650 mL and RR=20 bpm at 40 LPM (=666 mL/sec) at C=0.1 L/cm-H₂O.

a. If the compliance is set at 0.1 for left and right lungs, system compliance is 0.1+0.1=0.2 L/cmH₂O.

The delta P with a TV=1.393 L (TV/C, 1.393/0.2) is 6.96 cm-H₂O.

b. If the compliance is set at 0.05 left and right lungs, system compliance is 0.05+0.05=0.1 L/cm-H₂O.

The delta P with a TV=1.393 L (TV/C, 1.393/.1) is 13.9 cm H₂O.

The recorded PIP=33 and PEEP=8 yield a delta P of 25 cm H₂O. Compliance is calculated by TV/P. Thus 1.393/25=.056, approximately a 0.06 L/cm-H₂O system compliance. This yields a .03 left and right compliance setting. We were not able to duplicate your finding with these parameters.

ECRI Test Condition 3

Spoke with Jim Lee verified no leaks. As per his suggestion turned flow down to 30LPM.

Repeated: TEST CONDITIONS: MTTL C= 20, R=20 Flow @40 LPM, desired TV=600 mL, RR=10-12 bpm.

Stopped functioning restarted after 5 minutes delivered 2 breaths stopped, restarted, stopped, restarted.

Flow set to 20LPM

VAR delivered: RR 24 bpm, TV 398 mL, RR 18 bpm, TV 398 mL, RR 16 bpm, TV 395 unit stopped functioning

VORTRAN:

6. As explained in Note 1, RR of 10-12 bpm is not achievable at 40 LPM.

7. The setting of 20 LPM (333 mL/sec), TV of 398mL indicated a Ti of 1.2 sec. This yields:

RR 24 bpm (Te=1.3 sec) and I:E=1:1

RR 18 bpm (Te=2.1 sec) and I:E=1:1.8

RR 16 bpm (Te= 2.6 sec) and I:E=1:2.2

The VAR should cycle as expected with estimated PIP of approx 23 cm and PEEP of 3 cm (Delta-P of 20 X Compliance of 20 = TV =400 mL)

ECRI Test Condition 4

TEST performance with changing compliance 0.020 to 0.1, R=20
TV 1.744 L unit stopped functioning

VORTRAN:

8. Compliance of 0.1 L/cmH₂O (changed from 0.02 L/cmH₂O) is a 500% change.

The VAR may need an adjustment anytime compliance changes.

Small changes will result in a changed RR which results in a stable minute ventilation to the patient.

ECRI Test Condition 5

TEST CONDITIONS: MTTL C= 20, R=5, Flow @26 LPM, desired TV=650 mL, RR=20 bpm.

VAR delivered: TV 606 mL, PIP 39 cmH₂O, Ti 1.8sec, PEEP 7cm H₂O, I:E 1:1.1, RR 16 unit stopped functioning.

VORTRAN:

9. This is a typical setting for the VAR and the device should begin cycling. Further investigation on the stoppage of the device will be needed.

ECRI Test Condition 6

Pediatric TEST CONDITIONS: 0.03 L/cm H₂O, R=20 Flow @20LPM, desired TV=100 mL, RR=20 bpm

VAR delivered: RR 43 bpm, TV 74mL, PEEP 7 H₂O, PIP 38 H₂O, Ti 1.41 sec unit stopped functioning

- Retested same conditions RR 70 bpm adjust 1 turn rate dial stops increased 1 turn RR71bpm
- Retested same conditions RR 70 bpm stopped

VORTRAN:

10. The VAR-Plus recommended setting is from 150 mL TV (10 kg of body mass) and up. The resultant setting of TV 74 mL at RR of 43 bpm, suggested Ti+Te = 1.4 sec. At a Flow of 20 LPM (333 mL/sec) and TV of 74 mL, Ti = 0.22 sec, with resulting Te = 1.18 sec. The resultant ratio of I:E=1:5.4 is outside of the VAR-Plus operating range. A compliance of 0.03 L/cm-H₂O setting with a Delta-P of 31 (PIP 38 – PEEP 7) should have resulted in a TV of 930 mL. Again, the results do not match testing parameters as indicated.

Discussion

From the preliminary review of the ECRI Testing Data received September-12-2007, we summarized our observations below:

First, it appeared that each time the VAR was adjusted from mandatory breathing mode to spontaneous breathing mode, it was reported as “spontaneously stopped.” It was not unexpected for the VAR to stop cycling when it is set at spontaneous breathing mode.

In fact, this is the normal function of the VAR as a pressure limited flow controlled pneumatic resuscitator. It is not a time-cycled device like most automatic resuscitators, so it will not turn on or off at set time intervals.

The VAR's modulator functions as a pressure pop-off valve. When the modulator is “closed,” gas is delivered to the patient; until the pressure reaches the set PIP, then it “opens.” When the modulator is “opened,” the patient exhales until the intrinsic PEEP (lower pressure limit), is reached and the valve closes again. VAR users and trained clinicians are keenly aware of the operational characteristics of the VAR and the nature of the disease state of each patient using the VAR. A small rate dial adjustment to lower RR, without a compensating change in supply flow, can cause the VAR to enter the spontaneous mode

and stop cycling. Simply adjusting the rate dial outward will set VAR back into mandatory breathing mode.

Secondly, the VAR is not a full feature ventilator and will never be marketed as such. The range of ventilation parameters for the VAR will always be more limited than other ventilators intended for the ICU. The biggest variable for the VAR, as with any pressure cycled type of ventilator, is actually the patient's compliance. There are only 3 adjustments that are available to VAR users: [1] flow, [2] PIP and [3] the rate dial.

[1] The flow is adjusted using an associated flow meter or regulator. Most users tend to max out the flow which limits their ability to further fine tune the settings. This is because the inspiratory time may be too short at a maximum flow rate of 40 LPM.

[2] The PIP adjustment is common to respiratory therapies and we typically recommend a factory preset 25 cm-H₂O, as the starting point. [NOTE: The VAR products are 100% inspected and tested at PIP setting of 25 cm-H₂O at the VORTRAN manufacturing site.]

[3] The most challenging setting is the rate dial. It functions as an adjustable exhalation needle valve for controlling the patient's exhalation flow rate. When adjusting the rate dial inward, more resistance causes a slower patient exhalation. A longer exhalation time equals a slower rate and eventually the VAR will enter into spontaneous mode and stop cycling. In the spontaneous mode, the slightest patient inhalation effort will trigger an inhalation cycle to begin and pressurize the patient to the set PIP. Stoppage in spontaneous mode is simply a function of the VAR.

Conclusion

The VAR has received FDA 510(k) clearance and has been in successful commercial usage since 1997. During the entire 10 years the VAR has been used, there have been no known adverse effects or any recorded Medical Device Reporting (MDR) events. The VAR is marketed as a "gas-powered automatic resuscitator" and was never intended to be a full feature ventilator. As a "*Simple automatic (hand-off) resuscitator delivering positive pressure breaths*" the VAR is pneumatically driven and therefore does not have the diverse settings available as on a full feature ventilator. Attempting to set the VAR to settings outside its' operating range is inappropriate.

ECRI's recommendation is premised on an artificial extrapolation of potential device risks, specifically, those arising from a clinician's failure to follow common sense and clear product instructions to simply monitor a patient's breathing.

For example: ECRI stated in the report that "*VORTRAN recommends—and specifies in the VAR user's guide—that the VAR units be used only by trained personnel who continuously monitor the patient. While we agree with this statement, we consider it unreasonable to expect that such a recommendation will always be followed; continuous monitoring should not be a substitute for proper device design. A clinician could be briefly called away or distracted, and the intermittent performance of the device could go unnoticed, potentially resulting in patient injury or death.*"

It is unreasonable to assume that clinicians WILL NOT follow the manufacturer's labeling and instructions. The conclusion should amplify those instructions and remind all users that the VAR be monitored continuously to avoid any

episode of spontaneous mode if the patient is apneic.

Because VAR is a pressure cycled device, a leak may cause the device not to cycle when it can not reach the set pressure (PIP). An airway occlusion may also cause the device to cycle rapidly. This is inherent to the design of a pressure cycled device.

The VAR is a pressure limited, flow controlled device. When a user disconnects the VAR from a patient (or test lung), it will automatically start in the inhalation phase of the cycle. The cycle will inflate to the set PIP and then enter the exhalation phase. Because the settings (flow and correlated exhalation resistance) are outside the operating range of the automatic mode, the device will not re-enter the inhalation phase. Rather, it will stay in the spontaneous breathing mode, waiting for the patient to initiate a breath.

The VAR is a mechanical/pneumatic device. The biggest UNCONTROLLED variables in setting up the VAR are the patient's lung compliance (C) and airway resistance (R). The settings that can be controlled are gas flow (Q), peak inspiratory pressure (PIP) and exhalation resistance (RATE). There are no default settings that can be created on the VAR to set the breathing rate. This is because the exhalation phase can vary with C and R through the Rate Dial (which functions like a variable resistance). Patient compliance and airway resistance cannot be controlled on the VAR and have a very wide range of values. A pneumatically controlled device should not be expected to match the settings achievable by a full feature microprocessor controlled ventilator.

Furthermore, VORTRAN's VAR-Monitor, a VAR non-cycling alarm is pending 510(k) review and will effectively address the concerns that the VAR "May Spontaneously Stop."

In conclusion, we agree with ECRI's recommendation to focus more on amplifying VORTRAN's product training and education to closely and constantly monitor all patients using the VAR. We thank ECRI for their evaluation and confirming the need for such monitoring vigilance.

References

1. Review written by Dave Swift, RRT, Campus Coordinator – Professional Practice (Ed), Charge Respiratory Therapist – Maternal Newborn Ottawa Hospital – Civic Campus, Canada [refer to Attachment II].
2. ASTM Designation: F 920 – 93, Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans (Re-approved 1999)

Attachment I – Comments from John Moltzner, RCP

Thank you for the opportunity to contribute my experience regarding the VAR device as it pertains to the ECRI report. I would like to briefly summarize my thoughts relating to specific statements within ECRI's review from a clinician's perspective. Just to note, I have worked at Mercy General Hospital (340 beds/34 ICU beds acute care cardiac referral center) as an RCP Clinical Specialist responsible for clinical design and implementation for 15 years, and have been an active RCP for 24 years.

The history of the ECRI draft report includes direct dialogue with the design team at VORTRAN Medical, so I'll proceed from the basis that the underlying pneumatic principles of the VAR are recognized by ECRI, namely that if the rate control is dialed "down" into the "spontaneous" position, it is possible that small changes in patient resistance or compliance may prolong the expiratory time and therefore move the set rate from a minimal

back up rate (prolonged expiratory time) to a zero rate. Additionally, I was not provided with the test conditions used in the report, e.g. PSI, flow rates, lung analog design etc. to evaluate test design that may or may not accurately represent true clinical conditions.

From "Background and Discussion": *"Although we do not know of any reports of these units stopping on patients, we are concerned because they are used as life supporting devices to deliver positive pressure breaths to non-breathing critically ill patients."* And *"The manufacturer and VAR Users Guide recommend that the unit only be used by trained personnel who continuously monitor the patient. While we agree with this recommendation, it is unreasonable to expect that these recommendations will always be followed. Continuous monitoring should not be a substitute for proper device design."*

- With close to ten years of clinical use, there are no known reports of any patient harm during use of the VAR devices. Our institution has been using the VAR as an MRI ventilator and transport support during this ten year interval, and we have never had an adverse event related to the VAR. When properly set by trained staff, the likelihood of an inadvertent loss of patient breath support appears to be minimal.

- The VAR is clearly not a replacement for a full functioning ventilator—it should be considered as an alternative to a manual resuscitation bag. FDA approval is based on this premise, and any reasonable clinician trained in life supportive measures would never leave a patient alone while bagging them. Our facility's expectation is that the RCP stays with the patient whenever the VAR is used. From a clinician's perspective of responsibility, it is reasonable to expect the bedside practitioner to stay in attendance with the patient under the conditions of use described by VORTRAN Medical and the FDA, and this is stated clearly in the device instructions.

- At our facility the backup rate is always set to a minimum of 8-10, making the likelihood of accidental loss of the VAR support rate due to entry into the spontaneous position highly unlikely. I would not recommend setting the backup rate below 8 breaths per minute.

- It may be a greater risk to make an assumption that device design can be relied upon as a substitute for licensed and trained professional care.

From *"All three units stopped spontaneously functioning at some time during our testing, one unit stopped numerous times. In all cases the unit would restart, sometimes requiring user intervention and other times a unit would spontaneously start cycling again without any intervention. For those units that required user intervention, sometimes just tapping the unit restarted it, but other times the unit remained in an inactive state of not cycling until it was disconnected from the test lung and then reconnected."*

Since I was not provided with the test conditions, I will say that the only time I have seen the intermittent cycling described above is when the VAR rate control is set very close to the spontaneous setting. Clinically, if you see that the breath rate is lower than you desired, you simply turn the rate controller counterclockwise 1/4 - 1/2 a turn to increase the breath rate from the VAR.

Please submit any discussion to: Johnmoltzner@comcast.net, John Moltzner, RRT, RCP, Clinical Specialist, Mercy General Hospital, Sacramento, CA, Clinical Consultant, VORTRAN Medical Technology 1, Inc.

Attachment II – Comments from Dave Swift, RRT

I have attempted to reproduce all of the ECRI test results and cannot. Some of the parameters used are outside of the normal physiology expected in a living patient and are definitely outside of the range put forward for the VAR or VAR-Plus.

From your documentation, I cannot determine how long the test was running before the units stopped or paused.

From the document provided (re: alert) I have some comments:

1. You cannot legislate or demand that the manufacturer design a product that would prevent the end user/clinician from ignoring common sense and doing something inappropriate or dangerous with the device.
2. Critical care ventilator manufacturers recommend that the ventilators be monitored by trained clinicians. As with the VAR, if someone is not around to hear the alarms (ventilator) or monitor the device (VAR) you have the potential for injury or death. However, the ventilator manufacturers have not had ECRI recommend a recall. The manufacturers repeatedly stress the importance of the units being monitored by trained personnel and identify the risks associated with it - the same as Vortran has done.
3. Vortran should put a label on each of the units that states something along the lines "the device should be continuously monitored by a trained clinician while the device is in use".
4. A recommendation will be made to Vortran that the units be equipped with a FAIL TO CYCLE audio alarm.
5. It needs to be made clear that in the spontaneous mode there is no form of backup rate or alarm capability -the labeling should repeatedly reflect this.

Remember, the VAR is not a ventilator and is just a step above a manual resuscitator bag. Other similar units (ex. AMBUmatic) do not carry any alarms and have been in clinical use for many, many years. There have been no report incidents for the VAR or similar devices for a very good reason - the clinicians know and respect the clinical limitations of the device.

Overall, the Alert is not appropriately worded and seems to be based on data collected from clinical scenarios that are outside of clinical reality/device performance parameters.

I agree that the pause/spontaneous stopping issue needs to be addressed but that is a clinical reality. It is no different from the characteristics of some adult vents (ex. BP 7200) that will go safety valve open if there is any interruption in A/C power. Depending on how critically ill a patient is, this carries the potential for serious harm - but all the clinicians know this is a characteristic and monitor for it.

Dave Swift RRT, Campus Coordinator – Professional Practice (Ed). Charge Respiratory Therapist - Maternal Newborn, Ottawa Hospital -Civic Campus, Ontario, Canada, dswift@ottawahospital.on.ca.

Enhancing the Safety of Medical Suction

Patricia Carroll, RN, BC, CEN, RRT, MS

Abstract

Medical suctioning is essential for patient care. However, few clinicians receive training on the principles of physics that govern the safe use of medical suction. While all eight manufacturers of vacuum regulators sold in North America require occlusion of the tube before setting or changing vacuum levels, anecdotal evidence reveals that clinicians are not aware of this requirement or skip this step when pressed for time. This white paper summarizes the physics relating to medical suction, the consequences of damaged mucosa, the risks to patient safety when suction levels are not properly set and regulated, and technology advances that enhance patient safety.

Medical suction is an essential part of clinical practice. Since the 1920s, it has been used to empty the stomach, and in the 1950s, airway suction levels were first regulated for safety. Today, medical suction is used for newly born babies and seniors, and in patients weighing between 500 grams and 500 pounds. Medical suction clears the airway, empties the stomach, decompresses the chest, and keeps the operative field clear. It is essential that clinicians have reliable equipment that is accurate and easy to use.

Why a safety mindset is important

The current focus on patient safety extends to suction procedures and routines. When suction pressures are too high, mucosal damage occurs, both in the airway¹ and in the stomach. If too much negative pressure is applied through a chest tube, lung tissue can be drawn into the eyelets of a thoracic catheter.² Researchers are examining the connection between airway mucosal damage and ventilator-associated pneumonia. In pediatrics, airway suction catheters are inserted to a pre-measured length that avoids letting the suction catheter come in contact with the tracheal mucosa distal to the endotracheal tube.³ Mucosal damage can also be mitigated with appropriate suction techniques, and every effort should be made to reduce this insult to the immune system of patients who are already compromised. Damaged airway mucosa releases nutrients that support bacterial growth,⁴ and *P. aeruginosa* and other organisms are drawn to damaged epithelium.^{5,6} Mucosal damage

in the stomach can result in bleeding and anemia as well as formation of scar tissue.

Physics of suction

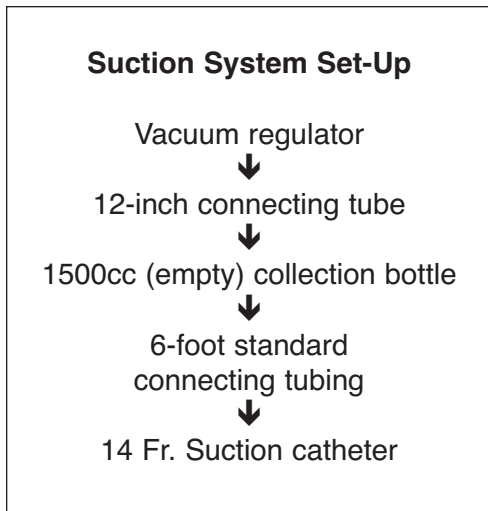
Flow rate is the term used to describe how fast air, fluid, or secretions are removed from the patient. Ideally, clinicians need the best flow rate out of a vacuum system at the lowest negative pressure. Three main factors affect the flow rate of a suction system:

- The amount of negative pressure (vacuum)
- The resistance of the suction system
- The viscosity of the matter being removed

The negative pressure used establishes the pressure gradient that will move air, fluid, or secretions. Materials will move from an area of higher pressure in the patient to an area of lower pressure in the suction apparatus. The resistance of the system is determined primarily by the most narrow part of the system—typically, a tubing connector—but the length of tubing in the system can increase resistance as well. Watery fluid such as blood will move through the suction system much more quickly than thick substances such as sputum. At one time, it was thought that instilling normal saline into an artificial airway would thin secretions, enhancing the flow of secretions out of the airway. However, research shows no thinning occurs and the patients' oxygenation drops with saline installation. Thus, the practice should be abandoned.^{7,8}

Increasing the internal diameter of suction tubing or catheters will increase flow better than increasing the negative pressure or shortening the length of the tube. However, in most clinical applications the size of the patient will be the key factor determining the size of the catheter that can be safely used. Researchers at the Madigan Army Medical Center explored factors affecting evacuation of the oral pharynx for emergency airway management. They tested three substances—90 mL of water, activated charcoal, and Progresso vegetable soup—with the three different suction systems, progressing from a standard 0.25-inch internal diameter to a 0.625-inch internal diameter at its most restrictive point. All systems evacuated water in three seconds. The larger diameter tubing removed the soup 10 seconds faster and the charcoal mixture 40 seconds faster than the traditional systems. The researchers note that this

This article was provided by Ohio Medical.



Box 1. Suction System Set-up.

A nurse passing the bedside of an infant in the ICU saw blood inside the tube used for airway suction. After checking the child's condition, it was evident that bleeding was not expected. Further investigation determined the maximum level of negative pressure set on the wall regulator was -200mmHg; far more than recommended suction levels for infants. The nurse performing the suctioning did not occlude the tubing to set a safe maximum level of negative pressure. *(personal communication to Ohio Medical Corporation)*

Box 2. Case study.

advantage in removing particulate material can speed airway management and reduce the risk or minimize the complications from aspiration.^{9,10,11}

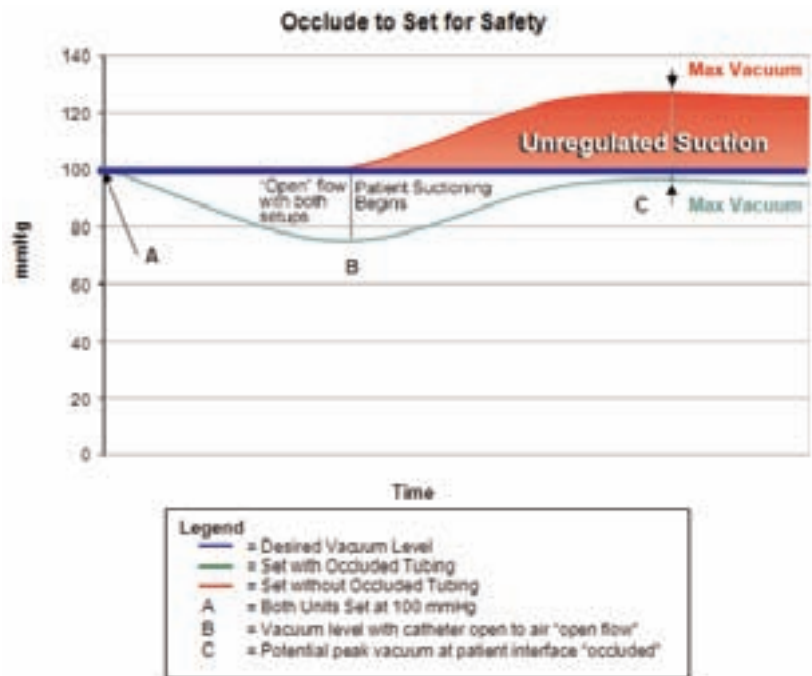
Occlude to set for safety

Vacuum regulators are ever-present in the hospital setting. Clinicians use them daily and may not be as attentive to this equipment with the demands of monitors and devices alarming and competing for the clinician's attention and time. Few clinicians learn the finer points of setting up suction systems. A nursing fundamentals text published in 2007¹² does not specify critical elements except to tell the nurse to follow manufacturers' instructions. The text leaves out the critical, universal "occlude to set" step that is recommended by all eight manufacturers of vacuum regulators used in North America.

While a number of organizations have published guidelines, ultimately the clinicians must determine the maximum allowable level of negative pressure that can be applied to the

patient. This is determined by a number of factors: where the suction pressure is applied (airway, stomach, oral pharynx, pleural space, operative field), the age and size of the patient, the susceptibility for mucosal or other tissue damage, and the risks associated with removing air during the suction procedure.

Once the maximum level has been determined, the vacuum regulator must be adjusted so that the maximum pressure is locked in; that is, the regulator must be set correctly so it will not permit a higher pressure to be transmitted to the patient. With traditional technology, the clinicians must actively occlude the system by either pinching the suction tubing closed, or occluding the nipple adaptor (where the tubing is attached) with the finger. Once the system is occluded, the regulator is set to the maximum desired pressure; then the occlusion is released. If the system is not occluded during set-up, the maximum pressure is then unregulated and can spike to harmful levels (see Figure 1 and Box 2).



Suctioning is a dynamic process. As catheters are used to remove substances from the body, the degree of open flow continually changes based on the fill of the catheter and the viscosity of the substance being removed. Under these dynamic conditions, the regulator continually compensates by adjusting flow rate within the device and the tubing to maintain the desired negative pressure. Periodically, mucus plugs or particulate matter will occlude the patient tube. If the system was not occluded to establish the maximum safe pressure at set-up, pressure will spike to clear the occlusion, and once the occlusion passes, the patient will be subjected to potentially dangerous, unregulated vacuum pressures (see Figure 1).

Figure 1 illustrates results of a bench test of two suction systems. The systems were set-up identically as noted in Box 1. The desired maximum level of suction is 100 mmHg (A). One system was set at 100 mmHg with the system open to flow (red line); the other was set by occluding the system to set 100 mmHg (green line). During open flow, the “occlude to set” system will have a lower pressure than the desired maximum pressure because there are no occlusions in the system (B). Once suctioning begins, a dynamic flow condition occurs with varying levels of obstruction, and pressure rises within both systems. The point of maximum suction is key. In the “occlude to set” system, the pressure never rises above the desired maximum pressure of 100 mmHg. In the other system, pressure in this bench test spiked to 125 mmHg of unregulated suction. Without “occlude to set,” the pressure can rise to 25% higher than the desired maximum level or more, exposing the patient to a safety hazard when regulated suction is needed.

Higher negative pressure is a particular hazard for patients with friable mucosa in the airway or stomach, making it more susceptible to traumatic tears. It is also a hazard for infants who have small lung volumes. When all other variables are stable, a 25% increase in negative pressure will increase the amount of air pulled through the system by 25%. That increase could result in a significant loss of lung volume in intubated neonates and infants.¹³

Breakthrough technologies enhance safety

An ideal patient safety device removes clinician variables as much as possible by providing the added safety passively while the clinician carries out the procedure. Traditionally, the optimal safety of regulated vacuum pressure has depended on the clinicians’ action to occlude the system to set maximum pressure. Now a breakthrough technology from Ohio Medical Corporation in its new Intermittent Suction Unit (ISU), occludes the system automatically when the clinician adjusts the pressure level. This creates a highly effective, passive safety system that removes the clinician variable and protects the patient from unintended, unregulated pressure spikes during suction procedures. The “push to set” innovation assures the clinician that the patient will not be subjected to pressure higher than that set on the regulator.

Another key safety aspect of any vacuum regulator is the ability to quickly adjust to full vacuum mode when emergency strikes and rapid evacuation is essential. An additionally unique concept introduced by Ohio Medical is the dual-spring design of the regulating module contained within the vacuum regulator. This feature provides the clinician with the ability to control vacuum levels more precisely in the clinical range of 0-200 mmHg as well as the ability to achieve full vacuum when

needed with only 2 turns of the knob on the regulator. In other regulators, six or more knob turns are needed to achieve “full vacuum,” and “full vacuum” capability may be limited to the clinical range, not the full system vacuum provided by the Ohio Medical ISU. Since full vacuum is needed in emergency conditions, this enhanced responsiveness saves time when seconds are critical.

While vacuum regulators are often considered basic equipment in the hospital, research and innovation from Ohio Medical Corporation has shown vacuum regulators do have a role in enhancing patient safety in clinical settings. Clinicians should advocate for technology that provides passive safety protection, enhanced control of vacuum pressures, rapid response and ease of use – all of which contribute to a culture of safety around the patient.

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Fleet Standardization

Fleet Standardization offers opportunity for health systems to stay on cutting-edge of respiratory care, facilitate training, reduce costs

With budgetary constraints, it is typical for healthcare systems to replace their ventilators on an as-needed basis. However, this strategy results in a number of different ventilators in use throughout their systems—even in their individual hospitals.

Recently, two healthcare systems with multiple hospitals, one in the Mid-Atlantic region and one in the South, were given approvals to replace their entire ventilator fleets with a common supplier. They saw fleet standardization as an opportunity that would lead not only to the highest quality of care for their critically ill patients, but also ideal working conditions for their staff.

“Safety and competency were the driving forces behind our decision to standardize our fleet,” said the director of respiratory care in the Mid-Atlantic healthcare system that is comprised of five acute-care hospitals, the largest of which is 362 beds.

“Fleet standardization provides an extra measure of safety because the respiratory therapists know no matter where they are working, they are always going to reach for the tidal volumes in the same way and know that the alarms are always the same,” said the director of respiratory care for the Southern system, which is comprised of three hospitals with nearly 1,000 beds. Standardization also results in cost savings and less downtime as the ventilators and their parts are interchangeable.

After much research and evaluation, both healthcare systems chose the SERVO-i from MAQUET, finding that it is not only state-of-the-art in acute-care ventilation, but that it also offers all the functionalities they require in one machine and is easily upgradeable.

The Mid-Atlantic healthcare system purchased 67 SERVO-i ventilators while the Southern healthcare system purchased 70. Here is how and why the two very different health systems made the choice they did.

Selection of ventilators a rigorous, objective and lengthy process

From the start, the healthcare systems realized that choosing a ventilator manufacturer for its fleet would not be a simple matter. They would need to approach it with a process that was rigorous and objective. Their overriding concern was to find a manufacturer that could provide one platform to address the very different requirements of all their patient populations.

“One of our big goals was to standardize to one machine that we could use for both medical and surgical needs,” said the clinical education coordinator for the Mid-Atlantic system, which serves a mostly adult population.

The Southern hospital system serves adult, pediatric and neonatal populations. So it was critical to choose a ventilator that could serve the tiniest of neonates to the most severe, adult trauma patients.

Both healthcare systems also wanted a fleet of ventilators that would be easily adaptable to changing clinical situations and that could be upgraded to allow them to stay on the cutting-edge of respiratory care. The Southern system has one of the largest cardiology programs and one of the busiest Level I trauma centers in the country.

Choosing the best machine includes matrix, visits and on-site trials

Once they received the administrative approvals, the first step for both sites was to assemble teams to help choose the ventilator that would best meet their needs. The teams included representatives of all those involved in the delivery of respiratory care—not only respiratory care staff but also administrators, physicians and biomedical engineering.

With the teams in place, they devised spreadsheets listing the factors and functionalities members believed to be the most important in the ventilator they eventually would acquire.

The spreadsheets went through a number of versions. At the Mid-Atlantic hospital, the final round had 32 features ranging from the ability to easily monitor plateau pressure as per lung protective strategies to the ability to reset automatically from standby mode.



The SERVO-i, here in the medical intensive care unit, also serves the hospital's surgical patients.

The Southern hospital team found that making a matrix of critical criteria was most helpful because it clarified which ventilator was the best for its situation. "We could see the SERVO-i was the one ventilator that would allow us to do everything we wanted," said its director of respiratory care. "The other ventilators would, too—but only if you were able to put them all together."

Site visits corroborated their research findings. "When we

went on site visits, and after we spoke with a lot of hospitals about what they liked and didn't like about the ventilator systems they were using, it only reinforced our decision," said the respiratory care director for the Southern hospitals.

Likewise, said the director of respiratory care at the Mid-Atlantic hospital system: "When we went on SERVO site visits, it reaffirmed what we had been talking about in our selection discussions."

Evaluators emphasize ease of use, modes, OLT, trending and ability to upgrade

On the clinical side, the evaluation teams compared ventilators for ease of use, monitoring and graphics packages, modes and maneuvers, tidal volume, triggering, trending, battery backup, and staff training and support. The teams also compared the ease of moving the ventilators and the ability to upgrade the equipment.



SERVO-i's Nasal CPAP feature in use in the neonatal intensive care unit.

The evaluation team at the Southern system particularly liked the SERVO-i's range of user interface tools that allow clinicians to tailor the ventilator to changing patient conditions, and ensure a high degree of accuracy in pressure and flow. The system supports controlled mechanical ventilation, assisted ventilation, non-invasive ventilation and Nasal CPAP. Additionally, the transport capability of the SERVO-i ensures that patients can be moved without

interruption of ventilation. For example, patients requiring non-invasive ventilation in the emergency room can be transferred to the ICU while maintaining NIV.

The range of modes is, of course, an important feature for adults, but the Southern system also was interested in neonatal applications. "The big push right now in NICUs across the country is to decrease chronic lung injury by reducing ventilation. We are very interested in the SERVO-i's neonatal noninvasive CPAP applications, and are excited about having them available," said its director of respiratory care.

The SERVO consists of four configurations—SERVO-i Infant, SERVO-i Adult, and SERVO Universal in Basic and Extended editions. The configurations mean "we can use the same ventilators for our youngest as well as our adult patients, and that is a tremendous advantage," he added.

The SERVO-i ventilator platform's Open Lung Tool (OLT), which provides a graphical display for effectively determining the pressure needed to successfully recruit the lung, proved another attractive feature. With the Open Lung Tool, it is easy to identify patients who are likely to benefit from a recruitment maneuver at a point in time or position. Also, its dynamic compliance and carbon-dioxide excretion monitoring provide a quality assessment of the effect any intervention has on the patient's lung.

Both teams also appreciated the SERVO's trending package, which was not available on all ventilators they evaluated. "We've used the 24-hour trend data display to determine how well the patient is responding to the oxygen therapy," said the clinical education coordinator for the Mid-Atlantic system. "If a patient's blood gas is abnormal, you can go back and look to see what was going on. By checking the trending, it can confirm a problem and reinforce the physician's decision on whether a change is necessary to correct it."

Finally, the teams for both centers valued the SERVO's easily upgradeability, ensuring it would meet their future needs. The respiratory care directors agreed that having upgradeable equipment means the hospitals in the system can easily remain on the cutting-edge in mechanical ventilation as technology advances.

Team finds service, support as important as functionality of machines

On the business side, the members of the evaluation teams looked at a number of factors, including the longevity and market share of the vendor in the United States. They also looked at purchase price, cost of operation, maintenance and repair, and warranty.

Based on the company history and positive reactions that were received from other respiratory departments at other hospitals, they knew MAQUET would be available long-term for parts and service. The purchase would represent a sizable investment for the systems, and they needed to be sure the manufacturer it chose had longevity.

The director of clinical engineering for the Southern system also saw benefits in the SERVO-i's components—batteries, CO₂ modules, etc.—being interchangeable. "Not only would interchangeability help increase uptime, but it also would result in savings from not having to inventory as much product," he said.

"Each SERVO-i ventilator comes with two expiratory cassettes, which is a real advantage," he continued. "This allows for much faster turnaround between patients than we could with our previous ventilators."

Service was another major criterion for the evaluation teams at the two sites.

"Part of the selection process was the clinical support we had during the evaluation," said the chief pulmonologist for the Mid-Atlantic system.

Availability of Maquet staff made training, transition problem-free

Both sites report that their transition to new ventilators went extremely well.

Three weeks before the conversion for the Southern system, an implementation and clinical training crew of six MAQUET employees was on site every day—two at each hospital—to teach and demonstrate the use of the new ventilators to all 101 therapists, nurses and other staff members who had to be trained. It made the transition of switching from the existing units to the new ventilators all in one day incredibly smooth. “We didn’t have any problems—Zero! It shows you the ventilators did what they were supposed to. The very fact that the whole process was uneventful speaks volumes,” said the respiratory care director.

It took about a week for the Mid-Atlantic hospitals to convert their fleet of ventilators to the SERVO-i. Several training sessions were held at various times during the day so that all the 83 respiratory care staff would be comfortable with the machine. “When we went live, each facility had two clinical specialists from MAQUET here to assist as necessary,” said its director of respiratory care services.

“We basically didn’t have any problems,” added the clinical education coordinator for the Mid-Atlantic hospital system. “That right there shows you that the ventilators did what they were supposed to do.”

SERVO helps systems reach ultimate goal of reducing ventilator stays

A key goal of standardizing their fleets was to reduce ventilator stays because the longer a patient is on a ventilator, the greater the chances of complications, including pneumonia.

“Our surgical patients’ recovery stays on our ventilators have decreased since the introduction of the SERVOS,” the chief of pulmonary care for the Mid-Atlantic system said. “How much of that is because of the ventilators and how much of it is other factors and procedures, I can’t say, but I believe it is really the entire care of the patient including the SERVO-i.”

A pulmonary specialist practicing in the area served by the Southern hospital system appreciates the respiratory monitoring and display capabilities of the SERVO-i, and believes it is helping him provide quality care.

“It’s very easy for me to determine what has transpired with the patient over the last 24 hours. All I have to do is make different entries on the screen and a graph will pop up showing what has occurred,” he said.

The graphic information allows him to make necessary adjustments in the respiratory care of his patients. “It gives me more information so I can care for the patient better and hopefully reduce his or her ventilator stay.”

Prototype—Selection Criteria Spreadsheet

#	Features	MAQUET SERVO-i	Ventilator 2	Ventilator 3	Ventilator 4	Ventilator 5
1	Current Modes of Ventilation					
2	Variable flow for patient synchrony in the VCV mode to prevent flow starvation					
3	Ability to provide lung protective strategy					
4	Flow termination during disconnect					
5	Variable triggering (p vs. f) internal or external triggerable; if external, what manufacturers are compatible					
6	Measure/trend lung mechanics					
7	Measure/trend auto-PEEP					
8	Measure/trend spontaneous parameters					
9	Trending					
10	How is trending accomplished; how is data stored					
11	Graphics					
12	Apnea parameters					
13	Fail-safe valve					
14	Connectivity with hospital informatics system					
15	Use with adults, pedis, neonates					
16	Appropriate alarm settings					
17	Alarm volume is adjustable					
18	All alarms are caregiver silenceable					
19	Ease of use					
20	Backup power supply battery specs					
21	Backup battery time					
22	How are batteries charged; internal or external, how often are they replaced					
23	Heavy-duty compressor (min 180LPM @ 50psi)					
24	Blower or turbine instead of a heavy-duty compressor					
25	Ability to tie into nurse call system					
26	Compact size					
27	Durability					
28	Few add-on parts					
29	PM interval					
30	PM parts/cost					
31	Ability to provide nebulizer					
32	Added cost for nebulizer					
33	Non-invasive capabilities					
34	Transport cable					

#	Features	MAQUET SERVO-i	Ventilator 2	Ventilator 3	Ventilator 4	Ventilator 5
35	Company support for continuing education					
36	External wall air water trap					
37	Length of warranty					
38	Integral heated expiratory filter; how often is it changed; does it break the circuit for changes; is it disposable or sterilizable					
39	Agreement for filters and consumables					
40	Tube compensation					
41	Adjustable disconnect sensitivity (to 95%)					
42	“PEEP shower prevention”					
43	Patient-Cancelable Backup Apnea Ventilation					
44	Screen: size, single or dual, degree of rotation, view ability					
45	Previous setting button for quickly alternating modes of ventilation					
46	Dedicated Biomed screen with vent hours, error codes, alert history					
47	Repair/service history with vendor: positive or negative					
48	Vendor history with similar hospitals					
49	Number of service technicians in area dedicated solely to ventilator repair					
50	Do the vendors offer Biomedical Engineering training					
51	How old is the product line; when will it be phased out by vendor for a replacement model					
52	What is the operating system: Windows-based, Linux-based, or embedded software					
53	How much does it cost for service contracts; what types are offered for Biomedical Engineering, if needed					
54	Footprint off cart					
55	Footprint on cart					
56	Can vent be wall mounted					
57	Closed-loop ventilation mode					
58	Specs of blower/turbine to meet negative flow demands from patient and wall suction					
59	Capable of providing independent lung ventilation					
60	Connectivity with patient information systems					
61	Number of FDA alerts on vent					
62	Number of FDA recalls on vent					
63	Equipment weight off cart					
64	Equipment weight on cart					

“My Ventilator Load is Too Much”

Melissa Turner, BA, RRT

Today it seems that fully staffed respiratory therapy departments are more of a luxury than the standard. The aging of the population will only exacerbate staffing issues as the capacity of RT programs cannot meet the increasing demand for therapists. Along with the stress to RT's caused by short staffing comes challenges to ensuring patients receive the best care possible. It is no surprise that an increase in errors is a possibility when staff members are overworked due to a lack of qualified staff.

A question we've been asked that's difficult to answer: Is there a “safe” maximum number of ventilators that should be assigned to an RT?

To date, there is no literature that points to a magic number of ventilated patients per therapist as being unsafe. We cannot define a “safe” ventilator-to-therapist ratio as there are many factors involved such as :

- Are the RT's dedicated to the ICU or are they required to take ‘floor’ patients?
- What respiratory tasks are shared with nursing (eg suctioning, airway care, etc)?
- Are protocols in place to reduce unnecessary treatments, ABGs, etc?
- Is there a patient driven weaning protocol to facilitate reduced LOS or is the ventilator bundle in place? (Noting that these higher level assessments may require more RT assessment time.)
- Are you implementing ARDSnet or other lung protective strategies?
- Are you required to attend unit rounds?

An article in *Critical Care Medicine, Respiratory Care Manpower Issues*, Vol 34, No 3, supplement, reported that the average number of ICU beds assigned to an RT was 10.2. They did not report the RT to ventilator ratios. The Society of Critical Care Medicine has published the following recommendations:¹

- “At least one respiratory therapist should be assigned to the unit.” The presence of full-time respiratory care practitioners/ therapists dedicated to the ICU can reduce length of stay, shorten ventilator days and reduce overall

ICU costs.”

- “The number of therapists assigned to the unit is based on some index of acuity” (eg using the AARC benchmarking data or a system of ‘relative value units’ to justify staffing levels)
- “All health care professionals who provide these high risk, high volume, problem prone procedures should be included in the institutional credentialing program.”

The California Code of Regulations sets forth, for the first time nationally, the following requirements for ICU staffing: sufficient respiratory therapists and /or respiratory therapy technicians to provide support for resuscitation and maintenance of the mechanical ventilators in a ratio of 1:4 or fewer on each shift.

The JCAHCO 2002 Sentinel Event Alert on Preventing Ventilator-related Deaths and Injuries reported that inadequate staffing contributed to over 1/3 of patient incidents. The commission recommended “Review staffing process to ensure effective staffing for ventilator patients at all times”.

So with above context, our combined 30-plus years experience and an informal consensus of some users, we would give an answer of 4-8 ventilators per RT (the lower range if protocols, bundles, etc are required).

An approach one might take to justifying staffing levels would be to identify the key evidence based recommendations that should be done for all ventilator patients. These include, but are not limited to, implementing a protective low Vt strategy or open lung protocol for ALI/ARDS patients, daily assessments of readiness to wean criteria and subsequent spontaneous breathing trials, head of bed elevation. These and other guidelines are now standard of care and have been documented to reduce morbidity and mortality. Additionally, one should create units of service or relative value units to capture the time for implementing protocols etc, even if these are ‘no charge’ procedures.

If staffing is insufficient to accomplish these, one could take the position that patient safety is compromised and risk management is adversely affected.

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Melissa Turner is with Hamilton Medical.

“RELENTLESS” – SmartCare/PS knowledge based weaning systems

An interview with Phillip Thaut, RRT-NPS, RPFT, Adult Respiratory Clinical Specialist, Utah Valley Regional Medical Center. Information provided by Draeger Medical.

What are the challenges associated with weaning long-term patients from mechanical ventilation?

I would say that crating enough time for therapists to spend with each of their long-term patients is one of the major challenges in a busy ICU. The demands placed upon them severely limit their ability to make the frequent adjustments that a marginal patient can require. As a result, I have witnessed several scenarios where a therapist would prematurely discontinue a weaning trial based on a written protocol, for example if the patient became tachypneic.

What do you see as being the main advantages of a closed-loop knowledge based weaning system?

One of the most important benefits of a closed-loop knowledge based weaning approach is its ability to frequently make the necessary adjustments in ventilatory support without the interruptions, fatigue and the inherent tedium associated with weaning a poorly conditioned, marginal ventilator patient.

What are the principal advantages of using SmartCare instead of relying solely on clinical practice?

I have spent hours at the bedside monitoring patients who were being maintained on the SmartCare/PS system and have been amazed with some of the results. It is interesting to observe how SmartCare/PS works in a methodical, consistent, efficient—and in some respects—relentless manner while carefully titrating pressure support for patients that are either severely deconditioned or have near end-stage chronic lung disease.

“Relentless” is an unusual term; can you elaborate on this?

When I say that SmartCare/PS is relentless, I am referring to its ability to titrate the level of pressure support on a continual basis. SmartCare/PS constantly monitors patients’ respiratory frequency, tidal volume, and metabolics (EtCO₂), testing their capability for small decreases in pressure support while maintaining them in a “zone of comfort.” In other words, maintaining their spontaneous workload at the maximum level the patients can tolerate comfortably. Every few minutes, SmartCare/PS’s knowledge base evaluates the patient’s potential for a small decrease or, if necessary, an increase in pressure support, minimizing the risk for overwhelming fatigue and respiratory failure. As I mentioned earlier, such frequent and minor adjustments in pressure support would be unrealistic if



Phillip Thaut, RRT-NPS, RPFT,
Adult Respiratory Clinical Specialist
Utah Valley Regional Medical Center

attempted by a bedside practitioner due to the time required and the tedium involved.

Can you cite a typical example of this “relentless” approach to weaning?

I have personally been involved with several difficult weaning scenarios that have failed our written weaning protocols but where patients were successfully weaned within 48 hours after initiating SmartCare/PS. I have been very impressed with the consistency and effectiveness of the knowledge based approach in helping us wean very difficult patients. However, rather than being replaced by the automation of this closed-loop protocol, the practitioner is provided with more time to supervise and monitor the process. The most significant realization comes from the fact that the weaning process is continuous and does not necessarily rely on the availability or constant presence of the practitioner at the bedside throughout the weaning session.

How has the use of SmartCare impacted on your quality indicators?

Our Draeger EvitaXL ventilators have been in service since June of 2006. Our observed patient-ventilator interaction and patient comfort have both improved, especially with patients who have previously been described as “difficult to wean” from mechanical ventilation. As a result, SmartCare/PS has become an essential adjunct to our current ventilator management strategy. As our experience with SmartCare/PS operation increases, we see the opportunity to advance care continuing to evolve.



Utah Valley Regional Medical Center, Provo, Utah.

Case Study

- 83 year old female
- probable myocarditis
- possible aspiration
- severe esophagitis
- severe COPD with chronic CO₂ retention
- total invasive mechanical ventilation: 8 days

After initial intubation and stabilization, cardiac catheterization demonstrated relatively clean coronary arteries with an ejection fraction of approximately 22%, probably due to acute myocarditis. After stabilization of hemodynamics and improved ejection fraction with inotropic support, weaning mechanics were obtained and spontaneous CPAP-pressure support trials were initiated via written protocols.

After six days of mechanical ventilation with limited tolerance for spontaneous CPAP-pressure support trials the patient was unable to be weaned. Additionally, it was not possible to sustain a pressure support level of < 18 cmH₂O without significant tachypnea or weaning trial failure. The overwhelming ventilatory fatigue required an A/C mode for recovery for more than 24 hours. Concerns regarding the risks for ventilator dependency and continued weaning failures prompted placing the patient on the Draeger EvitaXL equipped with SmartCarePS.

Settings:

- body weight: 58 kg
- type of intubation: endotracheal
- humidification: heated humidifier with heated wire circuit
- COPD: Yes
- neurologic disorder: no
- night rest: yes
- pressure support goal: 10 cmH₂O

With SmartCare/PS the patient was able to sustain extended spontaneous CPAP-pressure support trials with pressure support titrated from 18 to 10 cmH₂O and was liberated from invasive mechanical ventilation in less than 48 hours. The patient was thereafter supported with intermittent noninvasive mask ventilation until discharge.

...Continued from page 43

The problem of overworked therapists and understaffed departments is not one that will be resolved anytime soon. In the meantime we are challenged with finding innovative ways to continue to serve and care for our ventilated patients the best and safest way possible. Technology may provide some answers:

Riding on the heels of automation in other fields such as the airline industry, mechanical ventilation technology is advancing. One answer in particular is 'Intelligent' Ventilators which include Closed Loop Ventilation systems such as Adaptive Support Ventilation (ASV), "SmartCare" and others in development stages. ASV is classified as an Optimal Closed Loop System. Once placed on ASV, a ventilation autopilot, the ventilator adapts to an optimal rate and tidal volume for a particular minute ventilation based on the patients pulmonary mechanics to provide the least work of breathing for the patient. In ASV the ventilator adapts to the patients lung mechanics and drive. ASV will adapt to the patient breath by breath while ensuring that the patient does not have over distention, autoPEEP, or deadspace ventilation. If the patient is able to wean, it will allow them to wean automatically. ASV automatically makes the changes a clinician would make if they stayed bedside with the patient 24 hours a day, 7 days a week. Other modes of ventilation require an input of static settings that do not adapt to changes in the patient condition. This may adversely affect patients when clinicians are not readily available to make necessary changes to prevent over distention, dead space ventilation, auto-PEEP, high airway pressures, etc. SmartCare is an automated rules based weaning system in which 'protocol' developed by clinicians are programmed into the ventilator and based on variables such as RR, CO₂, pressure support is automatically weaned. With SmartCare, the ventilator adapts settings to the programmed rules.

As stated by James Conway, IHI Senior Fellow and former executive VP and CEO Dana-Farber Cancer Institute, "Our systems are too complex to expect merely extraordinary people to perform 100% of the time."

Closed Loop Systems move the RT from a task orientation to an enabler, assessor, and critical thinking orientation. Intelligent Ventilators can do rote work for us, thus freeing us up to accommodate patients requiring more intense clinical focus.

Efficacy of Confrontational Counseling For Smoking Cessation In Smokers With Previously Undiagnosed Mild To Moderate Airflow Limitation: Study Protocol Of A Randomized Controlled Trial

Daniel Kotz, Geertjan Wesseling, Marcus J.H. Huibers, Onno C.P. van Schayck

Abstract

Background: The use of spirometry for early detection of chronic obstructive pulmonary disease (COPD) is still an issue of debate, particularly because of a lack of convincing evidence that spirometry has an added positive effect on smoking cessation. We hypothesise that early detection of COPD and confrontation with spirometry for smoking cessation may be effective when applying an approach we have termed “confrontational counseling,” a patient-centered approach which involves specific communication skills and elements of cognitive therapy. An important aspect is to confront the smoker with his/her airflow limitation during the counseling sessions. The primary objective of this study is to test the efficacy of confrontational counseling in comparison to regular health education and promotion for smoking cessation delivered by specialized respiratory nurses in current smokers with previously undiagnosed mild to moderate airflow limitation.

Methods/Design: The study design is a randomized controlled trial comparing confrontational counseling delivered by a respiratory nurse combined with nortriptyline for smoking cessation (experimental group), health education and promotion delivered by a respiratory nurse combined with nortriptyline for smoking cessation (control group 1), and “care as usual” delivered by the GP (control group 2). Early detection of smokers with mild to moderate airflow limitation is achieved by means of a telephone interview in combination with spirometry. Due to a comparable baseline risk of airflow limitation and motivation to quit smoking, and because of the standardization of number, duration, and scheduling of counseling sessions between the experimental group and control group 1, the study enables to assess the “net” effect of

confrontational counseling. The study has been ethically approved and registered.

Discussion: Ethical as well as methodological considerations of the study are discussed in this protocol. A significant and relevant effect of confrontational counseling would provide an argument in favour of early detection of current smokers with airflow limitation. Successful treatment of tobacco dependence in respiratory patients requires repeated intensive interventions. The results of this study may also show that respiratory nurses are able to deliver this treatment and that intensive smoking cessation counseling is more feasible for respiratory nurses than for physicians who often lack time.

Background

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease which is characterized by airflow limitation that is not fully reversible.¹ Spirometry is the gold standard for the diagnosis and assessment of the disease.¹ COPD is currently the fifth leading cause of death worldwide,² and projections for 2020 indicate further increase in global mortality, placing COPD on the third position of lethal diseases.³ Cigarette smoking is by far the most important risk factor for COPD, and smoking cessation is the single most effective way to reduce the risk of developing COPD and to affect the outcome in patients at all stages of the disease.^{4,5} Underdiagnosis of COPD is a worldwide problem.⁶ Most patients present to their doctor for various other reasons but often have respiratory symptoms, and in those who do present with respiratory symptoms, COPD is not always suspected nor diagnosed.⁷ Because of the irreversible and progressive nature of the disease, early intervention is important. However, the use of spirometry for early detection of COPD is still an issue of debate.⁸⁻¹⁰ The most important counterargument is that there is no convincing evidence that spirometry has an added positive effect on smoking cessation.¹¹⁻¹³

Why use spirometry for smoking cessation? In theory, spirometry might be useful as a motivational tool for smoking cessation in smokers who are at risk of developing (or have) COPD. While most smokers acknowledge that smoking is dangerous, many trivialize their own perceived risk of the disease, or deny or avoid information about the dangers of

Daniel Kotz and Onno C.P. van Schayck are with the Department of General Practice, School for Public Health and Primary Care (CAPHRI); Geertjan Wesseling is with the Department of Respiratory Medicine, Maastricht University Hospital; Marcu J.H. Huibers is with the Department of Clinical Psychological Science, Maastricht University, Maastricht, the Netherlands. This study is funded by grants from the Dutch Asthma Foundation, PICASSO for COPD, and Maastricht University Hospital. Reprinted from BMC Public Health, BioMed Central, © 2007 Kotz et al, licensee BioMed Central Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License.

smoking in order to reduce cognitive dissonance.¹⁴⁻¹⁸ One might therefore expect that confronting smokers with an objectively (by spirometry) identified negative consequence of smoking (airflow limitation) positively affects the outcome of their quit attempt. This idea was already proposed in the 1960s by Peters and Ferris who argued that assessing the negative effects of smoking on lung function “might serve as a lever to influence the young adult to reduce his smoking habits”.¹⁹ Since then, various studies have been performed to study the efficacy of spirometry for smoking cessation. The results, however, are inconclusive as shown in a systematic review by Wilt et al on spirometry as a motivational tool for smoking cessation.^{11,12} Also, previous studies have one or more important methodological limitations such as unstandardized counseling intensity, incomparable or uncontrolled use of pharmacological aids for smoking cessation between experimental and control group, and different (or unclear) baseline levels of lung function and motivation to quit smoking. More well- designed research is needed to assess the efficacy of spirometry for smoking cessation.

Hypothesis and research questions: We hypothesize that early detection of COPD and confrontation with spirometry for smoking cessation may be effective if the following approach we have termed “confrontational counseling” is applied.²⁰ Confronting patients with COPD is not an isolated approach but should be integrated into state-of-the-art smoking cessation treatment. Confrontational counseling should consist of several counseling sessions on an individual, face-to-face level, under supervision of a trained smoking cessation specialist, and in combination with evidence-based pharmacological treatment for smoking cessation.

Our primary research question is: what is the efficacy of confrontational counseling in comparison to regular health education and promotion for smoking cessation delivered by specialized respiratory nurses in current smokers with previously undiagnosed mild to moderate airflow limitation (ie GOLD¹ stage 1 and 2 COPD) with regard to prolonged abstinence from smoking during a period of 12 months?

In this group of smokers with previously undiagnosed mild to moderate airflow limitation we want to address the following secondary research questions:

1. Which baseline characteristics are predictors of outcome (ie 12-month prolonged abstinence from smoking)?
2. What are the effects of early detection of airflow limitation and smoking cessation on lung function, perceived specific health-related complaints, quality of life, and mental health after 12 months follow-up?
3. What is the cost-effectiveness and cost-utility of early detection in combination with confrontational counseling delivered by respiratory nurses?
4. What are the effects of labeling of disease (COPD) on self-efficacy, perceived health status, quality of life and mental health?
5. What are the ethical considerations of early detection of airflow limitation and subsequent confrontational counseling for smoking cessation?

Methods/Design

Study design: In short, the design of this study is a randomized controlled trial comparing confrontational counseling delivered

by a respiratory nurse (RN) combined with nortriptyline for smoking cessation (experimental group), health education and promotion delivered by a RN combined with nortriptyline for smoking cessation (control group 1), and “care as usual” delivered by the GP (control group 2). Early detection of smokers with mild to moderate airflow limitation is achieved by means of a telephone interview in combination with spirometry. For an overview of the study design see figure 1.

The efficacy of smoking cessation interventions in clinical studies depends on the characteristics of the study population, the intensity of behavioural support, and the use of pharmacological aids for smoking cessation.²¹ In order to isolate the effect of confrontational counseling on smoking cessation, other factors that are associated with the outcome must be standardized between the comparison groups. All participants of this trial have previously undetected mild to moderate airflow limitation. Participants from both the experimental group and control group 1 receive an equally intensive counseling (in terms of number, duration, and scheduling of counseling visits) and dosage of nortriptyline for smoking cessation. Another reason for using an active control is that it would not be ethically sound to withhold smokers with airflow limitation from smoking cessation treatment.

Sample size calculation: The primary research question aims at a contrast in efficacy between the experimental group (confrontational counseling) and control group 1 (health education and promotion). Therefore, the calculation of the sample size is based on the identification of a difference in proportion of prolonged abstinence after 12 months between these two groups. We estimated the relevant difference in proportion to be 15%: 35% quitters in the experimental group versus 20% quitters in control group 1. When putting the risk of a type I-error at 5% and the risk of a type II error at 20%, 136 participants per group are needed at onset to detect a difference in proportions of 15%. Considering 10% lost to follow-up, 150 participants per group are needed in the experimental group and control group 1 (136 x 0.9-1). We expect a larger difference between the experimental group (35%) and control group 2 (8%).²² Therefore, fewer participants are needed in control group 2. We used a formula for the calculation of sample sizes of unequal groups and set the ratio between the experimental group and control group 2 at 3:1. This resulted in a minimum of 32 participants in control group 2 (taking into account 10% lost to followup).

Preparation of the trial: In preparation of the trial, all GPs in Dutch and Belgian Limburg (the area surrounding the city of Maastricht) have been informed about the study. We have prepared an office for the screening, counseling, and follow-up visits of participants at Medical Centre Annadal, Maastricht. We have built a relational database for the control of all study events and the collection of data. This is very important because of the complexity of the study.

Recruitment of participants: Subjects are recruited in the general population (through advertisements in local newspaper, flyers, posters, and mailings to households) and in primary care practices (during consultations and through posters and personalized mailings) in Dutch and Belgian Limburg. The text in the advertisements, on flyers, and on posters explains that Maastricht University is performing a study on smoking cessation treatment in which individual counseling is combined

with medication for smoking cessation. Current smokers aged 35 to 70 years, who are motivated to quit smoking, are asked to contact us by telephone or by e-mail. We also refer to a website with information about this study. No information about the target condition we are looking for (airflow limitation) is given to participants during recruitment.

In- and exclusion criteria and process of eligibility

screening: Eligibility is screened in two steps; during an initial telephone interview followed by spirometry. The following inclusion criteria are checked during the telephone interview: smoking history of 10 or more pack years; being motivated to stop smoking; being competent to read and speak Dutch; and reporting a respiratory symptom, defined as an affirmative answer to at least one of the following three questions: 1. "Do you cough regularly?" 2. "Do you cough up phlegm (sputum) when you don't have a cold?" or 3. "Have you been shorter of breath lately?" Exclusion criteria are: evidence of a prior respiratory diagnosis, defined by an affirmative answer to the question, "Do you have COPD, chronic bronchitis, asthma or asthmatic bronchitis?" Participants are also not allowed to have undergone a lung function test (spirometry) during the preceding 12 months. One or more contraindications for using the smoking cessation medication (nortriptyline) are also reasons for exclusion, among others the current use of antidepressants. Nortriptyline is a tricyclic anti depressant which should not be used for smoking cessation in conjunction with another antidepressant. After the end of the telephone interview, an appointment for spirometry at Medical Centre Annadal is scheduled. Subjects are eligible for participation who have airflow limitation defined as post-bd. $FEV_1/FVC < 70\%$ in combination with postbd. $FEV_1 \geq 50\%$ of predicted value; ie mild (GOLD 1) or moderate (GOLD 2) airflow limitation, according to the international GOLD guidelines.¹ The results of spirometry are not discussed during or directly after spirometry.

Subjects with severe airflow limitation are excluded from participation and advised to contact their GP or a lung physician for further evaluation. Subjects without airflow obstruction (post-bd. $FEV_1/FVC \geq 70\%$) are also excluded. These smokers are told that despite their normal lung function, they still are at risk of getting other smoking related diseases which are not measured by spirometry, such as cancer or cardiovascular disease. They are strongly recommended to give up smoking. Both groups of excluded smokers get the advice to stop smoking and receive a box with information material about all existing therapies for smoking cessation from the Dutch foundation for a smoke free future (STIVORO).

Spirometry: Spirometry is performed by two qualified research assistants under permanent supervision of a pulmonologist (GW) according to the criteria of the American Thoracic Society (ATS) / European Respiratory Society (ERS) task force for standardization of lung function testing^{23,24} using a Vitalograph 2120 (Vitalograph Ltd, Buckingham, England). After a minimum of three acceptable and reproducible FVC maneuvers, a bronchodilator (500 mg terbutaline) is administered to the subject in preparation for the reversibility test. After 15 minutes, another series of three FVC maneuvers is performed. All spirometric test results are independently validated by a pulmonologist (GW) and by a specialised lung function laboratory assistant who was not involved in the trial. In case of initial disagreement, consensus is obtained during re-examination.

Informed consent procedure: Written information about the study is sent to the candidate participant after the telephone interview, along with the informed consent form. The candidate has at least one week time for reflection before spirometry and can contact the researcher or the research assistant (RA) for further information at any time. The informed consent form is signed by the participant in presence of the RA during the visit for baseline spirometry.

The participant information letter gives information about the existence of two intervention groups only. It says that in one group participants receive "care as usual" by their own GP (this is control group 2) and in the other group participants receive treatment from a trained RN. The latter group is in fact a combination of the experimental group (confrontational counseling by RN + nortriptyline) and control group 1 (health education and promotion by RN + nortriptyline). These two groups are identical with regard to the number and duration of counseling sessions and the use of nortriptyline, but differ only concerning the content and style of the behavioural support: confrontational counseling versus health education and promotion. Just this difference in content must not explicitly be mentioned in the participant information letter in order to safeguard the internal validity of the study. We would jeopardize the idea behind early detection of patients with airflow obstruction by means of spirometry if we would speak about "confrontational counseling" or mention the target condition (airflow limitation). Participants must not know that we use results from spirometry as part of one intervention. The design we use is adapted from Zelen's design^{25,26} which may be particularly useful when evaluating the full unbiased impact of screening interventions.²⁷

At the end of the study, after the 12-month follow-up visit, all participants will indeed be fully informed about the real nature of the study. All participants and their corresponding GPs will be informed about the result of the spirometry. If a GP needs the results of spirometry for the regular care of his/her patient before the end of the study, the required information will be provided. This procedure is approved by the medical ethics committee of Maastricht University and Maastricht University Hospital.

Randomization and planning procedure: All eligible subjects with previously undetected mild to moderate airflow limitation are contacted by telephone a few days after baseline spirometry to be randomised to one of the three intervention groups (apart from those candidates who changed their mind and who are no longer willing to participate in the study). Also at this moment, the results of spirometry are not discussed. The database of the trial incorporates a randomization system of seven participants per block, allowing an unequal group allocation of 3 : 3 : 1; experimental group : control group 1 : control group 2. When eligible subjects are contacted by telephone, the RA randomises the subject by pressing a button on the computer screen. The database then randomly allocates the subject. Neither the primary researcher nor any other person involved in the study can predict or influence which treatment group the next participant will be allocated to. After randomization, all treatment and follow-up visits are planned for the whole study period. A schedule with all visits is sent to the participant. At the same time, the GP of each participant is sent a letter informing the GP that the participant is taking part in the study.

Table 1: Overview of measurements per visit.

Measurement	Baseline visit	Follow-up visit 1 (day 50)	Follow-up visit 2 (day 197)	Follow-up visit 3 (day 379)
Demographic characteristics	•			
Smoking:				
Tobacco use and quit attempts[41]	•	•	•	•
Fagerström Test for Nicotine Dependence (FTND)[42]	•			
Health perception: (self-constructed questions)				
health concerns	•	•	•	•
risk perception	•	•	•	•
self-exempting beliefs	•	•	•	•
Respiratory health complaints:				
COPD diagnostic questionnaire[43, 44]	•			
Medical Research Council (MRC) dyspnoea scale[45, 46]	•		•	•
Clinical COPD Questionnaire (CCQ)[47, 48]	•	•	•	•
Health-related quality of life:				
EuroQol (EQ-5D)[39, 40]	•	•	•	•
Short-form 36-item questionnaire (SF-36)[49, 50]	•	•	•	•
Chronic Respiratory Questionnaire self-reported (CRQ-SR)[51, 52]	•	•	•	•
Mental health:				
Beck Depression Inventory (BDI)[53]	•	•	•	•
Hospital Anxiety and Depression Scale (HADS)[54-56]	•	•	•	•
Cost diary: measurement of direct and indirect medical and non-medical costs[38]		•	•	•
Physical measurements:				
Physical height and weight	•	•	•	•
Post-bronchodilator spirometry	•			•
Urine cotinine (only in self-reported quitters)		•	•	•

Experimental group and control group 1: L-MIS as the common basis of counseling: Participants from both the experimental group and control group 1 receive counseling delivered by a RN combined with nortriptyline for smoking cessation. The common basis for the counseling is the so-called “L-MIS” protocol for the treatment of nicotine and tobacco addiction which has been implemented among all respiratory nurses in the Netherlands in recent years.²⁸ The number of counseling sessions, their duration and scheduling is fixed in both the experimental group and control group 1 (see also figure 1). The first face-to-face counseling session (FC1; day 1, duration 40 minutes) starts with getting acquainted with each other. The RN tries to build up a relationship with the participant which is based on trust. The participant’s smoking characteristics are defined by asking about smoking status, cigarettes smoked per day, and readiness to quit. Nicotine addiction is assessed by number of cigarettes per day and moment of smoking the first cigarette after waking up in the morning. The motivation for quitting smoking is assessed and increased by asking the readiness for quitting and reasons for smoking and quitting. Also, the health risks of smoking are discussed and the pros of quitting. The use of nortriptyline for smoking cessation is discussed, including mechanism, dosage,

administration, and possible side effects (for more information about the study medication see paragraph “use of nortriptyline for smoking cessation”). The participant starts with the intake of the study medication the same day.

At the beginning of the second face-to-face counseling session (FC2; day 8, duration 40 minutes), the use of the study medication is evaluated and possible side effects are discussed. Barriers of quitting and the most important problems with previous quit attempts are discussed. The RN tries to increase the participant’s self-efficacy towards smoking cessation. The focus of the second session is to prepare the participant for the TQD. The RN discusses with the participant how to deal with the most important barriers of quitting smoking. The RN anticipates problems with withdrawal, difficult moments, and craving. The RN provides pointers for the TQD and schedules the telephone counseling on that day.

On the TQD (day 14), the participant is counselled on the telephone (TC; duration 5 – 15 minutes). The RN evaluates the quit attempt, discusses difficult moments, and gives advice for quitting and abstaining from smoking.

The third face-to-face counseling session is scheduled directly after the TQD (FC3; day 15, duration 40 minutes) and starts with an evaluation of the quit attempt and the use of the study medication (including possible side effects). The RN discusses with the participants what is going well and what is problematic with this quit attempt. The RN identifies difficult moments and strategies to deal with these situations in the future. Participants who did not quit smoking yet or who already relapsed are asked about their reasons and are

encouraged to try again.

The fourth face-to-face counseling session (FC4; day 22, duration 40 minutes) basically resembles the third session; the RN evaluates the quit attempt and the use of the study medication. As this is the last counseling session, the focus lies on preparing the participant for continuation of the quit attempt during the follow up period. The participant is asked to continue with the intake of nortriptyline according to the protocol. At the end of the session, the RN asks the participant’s feedback on the perceived effectiveness of the behavioral support and the study medication.

All RNs have had initial training in the use of the L-MIS method and are experienced in the treatment of nicotine addiction. All RNs are trained to use a tailored version of the L-MIS protocol which is specifically designed for this trial. The compliance of RNs with the treatment of participants is stimulated by the use of a protocolized treatment manual, including intervention registration forms providing information per session about all the aspects of smoking cessation counseling to be addressed. The RNs are trained to fill out these intervention forms during each counseling session.

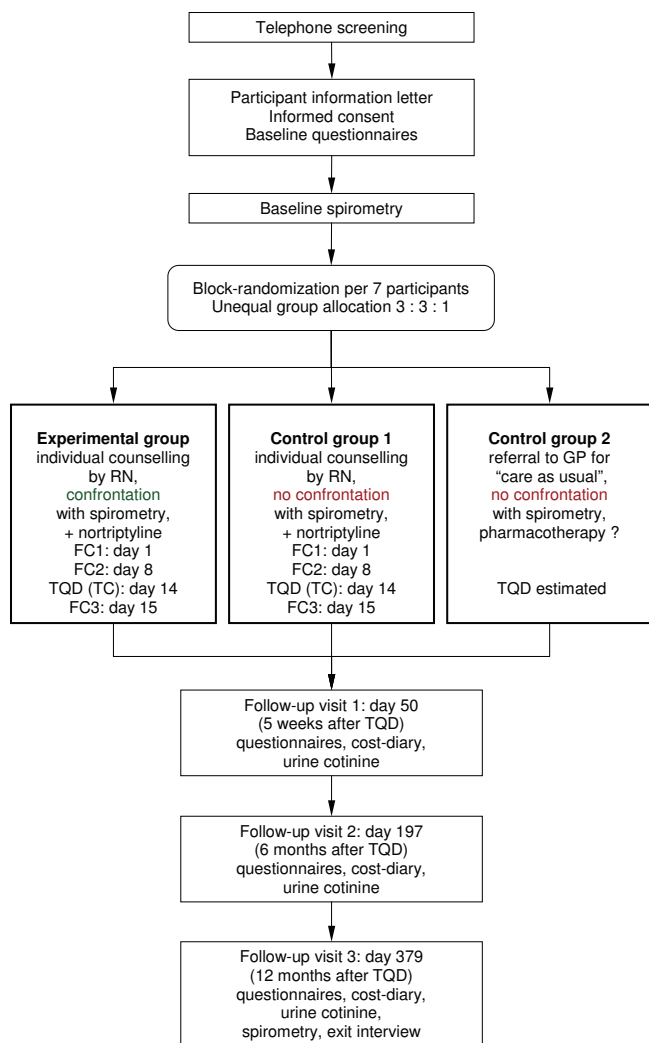


Figure 1. Design. FC=face-to-face counselling session; TC=telephone counselling session; TQD=target quit date; RN=respiratory nurse; GP=general practitioner.

Discriminative component in the experimental group:

confrontational counseling: The number of counseling sessions, the duration, and the scheduling are identical between the experimental group and control group 1. However, specific aspects of “confrontational counseling” are added to the L-MIS in the experimental group which discriminate the treatment from the treatment in control group 1. These aspects derive from the principles of “confrontational counseling” which we have described in more detail elsewhere.²⁹ Confronting patients with COPD is not an isolated approach but should be integrated into state-of-the-art smoking cessation treatment. Confrontational counseling should consist of several counseling sessions on an individual, face-to-face level, under supervision of a trained smoking cessation specialist, and in combination with evidence-based pharmacological treatment for smoking cessation.

A key element of confrontational counseling is to confront the participant with his/her airflow limitation during the first counseling session (FC1). The RN discusses the results of the participant’s individual baseline spirometry and explains the manifestations of COPD; COPD is a slowly progressive, irreversible but treatable disease. Most importantly in this respect is to make the participant understand that his/her cigarette smoking is the primary cause of the disease. The

negative effect of smoking on the lungs is illustrated by showing and comparing images of a normal lung and a “smoker’s lung”. The participant is asked to recognize common symptoms, functional limitations, and participation problems associated with COPD. The natural history of COPD is discussed and illustrated using the so-called “Fletcher curve” (see also figure 2).³⁰ Confronting patients with a serious disease that has a bad prognosis arouses fear. Fear arousal is not a goal in itself and it is not likely to automatically lead to the desired action (smoking cessation). Therefore, when discussing the results of spirometry, the RN tries to make the participant understand that there is an effective and feasible therapy for the disease: smoking cessation. Because airflow limitation has been detected early in the participant, early treatment is possible to avoid further damage. Smoking cessation is the only therapy to reduce the progression of the disease resulting in prolonged life expectancy and improved quality of life. The motivation of the participant to stop smoking in combination with the behavioural counseling offered by the RN and the smoking cessation medication (nortriptyline) increases the chance of the participant to quit smoking and to subsequently improve health. At the end of the session, the participant receives a folder with background information on COPD which is developed by the Dutch College of General Practitioners (NHG). In contrast to the experimental group, participants from control group 1 are not being confronted with the detected airflow limitation. The RN from control group 1 is instructed not to discuss the result of spirometry at any time, but to treat the participant as a “healthy smoker”.

The information about airflow limitation and COPD during the first counseling session probably has impact on the participant. At the beginning of the second counseling session (FC2), the RN asks the participant to reflect on this information. The RN assesses whether the participant has processed the information correctly and provides feedback on the thoughts, feelings, and beliefs the participant reports. Again, the positive effect of smoking cessation on the history of lung function is stressed and illustrated using the Fletcher curve. This is repeated during later counseling sessions if necessary.

Confrontational counseling comprises more than merely confronting the participant with his/her results from spirometry. It is a patient-centred approach which involves specific communication skills and elements of cognitive therapy. An important condition is a relationship (also known as alliance) between RN and participant in which both roles are equivalent (rather than an expert-recipient relationship). The RN respects the participant’s freedom of choice regarding his/her own smoking behaviour. The RN stimulates the participant to reflect on his/her smoking behaviour by carefully listening to the participant’s story, using open ended questions, paraphrases, and reflections. Confrontational counseling aims to identify certain cognitions about smoking such as health concerns, risk perception and self-exempting beliefs. The RN tries to challenge irrational beliefs about smoking by raising the smokers’ consciousness about these beliefs, testing their reality, and by exploring the relationship between beliefs and behaviour. An example for a typical self-exempting belief of a smoker would be: “Smoking is possibly not very harmful because many smokers live long. My grandfather is 85 and he smoked all his life”. The RN will try to challenge this belief for instance by conducting an objective risk assessment, or by exploring biases in the belief itself.

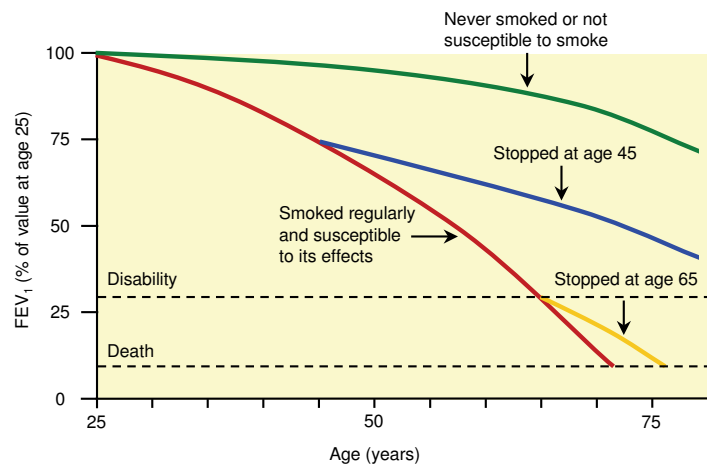


Figure 2. "Fletcher curve". Adapted from Fletcher & Peto (1977): The natural history of chronic airflow obstruction[30].

At the end of the first, second, and third counseling session, the RN hands out a smoking cessation diary to the participant. Homework is an essential element in cognitive therapy, and self-monitoring diaries are used as extra input for the counseling sessions. In the first diary (evaluated during FC2), participants have to record their smoking behaviour; they have to count the number of cigarettes smoked and have to describe one situation in which they experience great desire to smoke. In the second diary, participants have to record their thoughts when smoking. Again they have to count the number of cigarettes and have to describe one situation, but also what was on their mind directly before and after lighting up. In the third diary (evaluated during FC3), participants have to describe both behaviour and thoughts in situation when they have great desire to smoke.

To ensure the building of an alliance between RN and participant, it is important the participant is counselled by one and the same pulmonary nurse during the whole intervention period to prevent contamination between the groups. Consequently, each treatment group has its own RNs. All RNs have had initial training in the use of the L-MIS method and are experienced in the treatment of nicotine addiction. Additionally, RNs from the intervention group will receive a four-hour group training in confrontational counseling. The group training is lead by a cognitive therapist (MJH) who acts as supervisor throughout the study, and incorporates practical training with a simulation patient. Supervision meetings between RNs and the supervisor will be planned every 6 weeks during the whole intervention period of the trial.

RNs from control group 1 do not receive an introductory group training but receive feedback during regular evaluation meetings between the RN and the principal investigator.

Control group 2: care as usual by GP: Participants from control group 2 are referred to their own GP for smoking cessation treatment. They are asked to make an appointment with their GP within the next ten days. They are provided with a referral letter explaining to the GP that the person is participating in a study on smoking cessation. This letter does not give any information about the results from spirometry and the fact that the participant has airflow limitation. The GP is asked to provide the care he/she usually provides to patients who want to quit smoking. In the Netherlands, primary "care as usual" for smoking cessation involves the use of a protocol for low

intensity health education and promotion, the so-called "H-MIS."²² According to the protocol of the H-MIS, the GP and/or the assistant takes the following steps to assist the smoker during a quit attempt: determine the smoking profile of the smoker, determine the motivation to stop smoking (and increase the motivation if necessary), talk about the barriers of quitting smoking, set a target quit date, discuss the use of smoking cessation aids, and arrange follow-up. A semi-structured interview will be used among participants from control group 2 during the first follow-up visit (day 50) in order to assess whether participants have consulted their GP and which treatment for smoking cessation the GP has delivered.

Neither participants from control group 2 nor their GP will be informed about the results from spirometry and the detected airflow limitation. However, if a GP explicitly requests the results from spirometry they will be provided (see further paragraph "ethical considerations").

Use of nortriptyline for smoking cessation: Previous research has shown that the combination of counseling and pharmacotherapy is more effective than either alone³¹⁻³³ and international guidelines recommend the use of pharmacotherapy in all patients trying to make a quit attempt.^{21,34} Participants from both the experimental group and control group 1 receive an equal dosage of nortriptyline (Nortrilen) for smoking cessation. Nortriptyline is a tricyclic anti-depressant which has been shown to be a cheap and effective alternative for the anti-depressant bupropion (ZybanTM).^{31,35} Participants start taking nortriptyline on the day of the first counseling visit (FC1, day 1) in which they receive instructions about the use of nortriptyline by the RN. A run-in period of 10 days until the TQD is needed to achieve steady-state blood levels of nortriptyline. From day 1 through day 3, participants take one pill of 25mg nortriptyline once a day (preferably after dinner). From day 4 through day 7, participants take 50mg a day (given as two pills of 25mg). As from day 8 through the end of the treatment period (day 49), participants take 75mg a day (given as three pills of 25mg). The RN monitors the correct use of the medication and the occurrence of side-effects during the intervention period. In case of unpleasant or severe side-effects, the dosage will be reduced or the use of the medication will be stopped. At the first follow-up visit (day 50) the RA collects and counts the remaining pills.

Follow-up visits: Three follow-up visits for all participants are scheduled at day 50 (approximately five weeks after the TQD), day 197 (approximately six months after the TQD), and day 379 (approximately twelve months after the TQD; see also figure 1). The TQD in participants from control group 2 is set at 8 weeks after the day participants were randomized and informed about group allocation. We estimated that this would be sufficient time to schedule a consultation with the GP and to prepare stopping smoking, and that the time lag between day of randomization and TQD would be about the same compared to the experimental group and control group 1 (in the latter groups, we account for a delay between day of randomization and start of treatment). Participants receive a reminder letter including a follow-up questionnaire and a cost diary seven weeks prior to all three visits. The RA calls every participant one week prior to the visit to confirm the appointment. Minor deviations from the scheduling of follow-up visits will be allowed in order to retain as many participants in the study as possible.

At every follow-up visit, participants hand in their questionnaire and cost-diary. The RA briefly discusses the quit attempt. Urine is collected from every self-reported nonsmoker for the analysis of cotinine levels.

During the final follow-up visit, spirometry is repeated in all participants. All spirometric outputs are carefully evaluated by a pulmonologist (GW) and reported to the participant's GP by letter. All participants are asked to consult their GP for information about their lung function and further treatment.

Data collection: An overview of all measurements per visit is given in table 1. The paper-and-pencil questionnaires are filled out at home by the participants and are handed in during the visits. Completion of the questionnaires takes about 30 minutes. Data from the questionnaires will be double-entered and checked by blinded assistants from the centre for data and information management of Maastricht University (MEMIC).

Urine is collected from every self-reported non-smoker during each follow-up visit to validate non-smoking. The urine is kept in a 100mL plastic cup with a screw cap and temporarily stored in a refrigerator for a maximum of seven days before delivery to the laboratory of the Department of Health Risk Analysis and Toxicology (GRAT) of Maastricht University. The concentration of cotinine in urine is measured by a highly specific radioimmunoassay using monoclonal antibodies.³⁶ The reagents for the assay are obtained from the Department of Biochemistry, Brandeis University, Massachusetts, USA.

The analysts assessing the urine cotinine levels and all assistants entering data from questionnaires are kept blind to the group allocation of participants.

Data analysis: The primary outcome measure is prolonged abstinence from smoking during a period of 12 months after the TQD. Prolonged abstinence is defined as follows: abstinent from smoking at all three follow-up visits; at day 50 (approximately 5 weeks after the TQD), day 197 (after six months), and day 379 (after 12 months). Participants are allowed to miss the second follow-up visit (day 197) if they have been abstinent from smoking at the first (day 50) and the last follow-up visit (day 379; interpolation). A participant is defined as abstinent from smoking at a follow-up visit if both of the following two conditions are met:

1. urine cotinine level <50ng/mL³⁷ and
2. self-reported quitter, not having smoked a single cigarette since stopped smoking.

All randomized subjects will be included in the analysis and subjects not showing up at the follow-up visit or with a missing value on one of the two above measures are regarded as smokers (intention-to-treat analysis). Statistical difference in primary outcome will be analysed using Chi-square tests.

The secondary research questions will be analysed as follows (see the last paragraph of the introduction for an overview of all secondary research questions).

1. Baseline predictors of outcome will be analysed by regressing the primary outcome measure (12-month prolonged abstinence) on candidate predictors measured at baseline (such as age, sex, airflow limitation, previous quit attempts, or nicotine dependence) in a multivariate logistic regression model, controlling for treatment group.
2. The health effects of smoking cessation will be analyzed by regressing measures of lung function, perceived specific health-related complaints, quality of life, and mental health on abstinence at each follow-up visit using linear regression models.
3. The cost-effectiveness and cost-utility of early detection of airflow limitation in combination with smoking cessation will be analysed using data from the cost diaries.³⁸ Participants fill out these diaries during three periods of six weeks each: during the intervention until the first follow-up visit (day 50), during the period until the second follow-up visit (day 197), and during the period until the last follow-up visit (day 379). The economic evaluation is based on direct medical costs (e.g. treatment costs, spirometry), direct non-medical costs (e.g. reimbursement of travelling expenses), and on indirect costs (e.g. sickness absence), which are related to respiratory complaints. Effects are measured in physical units (such as number of successful quit attempts, FEV1) and Quality Adjusted Life Years (QALY'S) are measured with the EuroQol (EQ-5D).^{39,40}
4. The effects of labelling of disease (COPD) will be analysed by mediation and moderation analyses using linear and logistic regression models. The outcome variable in these analyses is abstinence from smoking at the first follow-up visit. Only data from the experimental group and control group 1 will be used.
5. The ethical considerations of early detection of airflow limitation will be analysed in a qualitative analysis using data from the ethical exit interviews which are performed in participants attending the last follow-up visit.

Ethical approval, review, and registration of the trial:

Participants of this study are not fully informed about the real purpose of the study at the beginning, which is to detect and confront smokers with airflow limitation. Participants from control group 1 and control group 2 are not informed about their results of spirometry during the intervention and follow-up period. This approach is necessary to assess the additional effect of early detection of and confrontation with airflow limitation above the effects of individual counseling and medication use. As already explained in the paragraph "informed consent", all participants as well as their GPs will be fully informed about the purpose of the study and the results of spirometry after the last follow-up visit.

This procedure is approved by the medical ethics committee of Maastricht University and Maastricht University Hospital. We believe that it is ethical to withhold information about the results from spirometry to participants of this study for at least two reasons. The first reason is that the smokers participating in this trial would probably not have been diagnosed with airflow limitation outside the trial setting early due to the problem of underdiagnosis of COPD in primary care. The second reason is that all smokers from this trial receive the most effective therapy for airflow limitation from either the RN or their own GP, which is smoking cessation treatment. Data from the ethical analysis, which is based on the interviews with participants during the last follow-up visit, should provide information about the participants' view on the ethical aspects of this trial.

Time frame. The follow-up of participants is planned until this year. All data will be continuously collected, entered, and cleaned. The analysis of data regarding the primary research question will not be initiated before the completion of follow-up and data collection in the last participants (during the course of the year 2008).

Discussion

We presented the protocol of a study assessing the efficacy of confrontational counseling for smoking cessation in current smokers with not earlier diagnosed mild to moderate airflow limitation (i.e. GOLD stage 1 and 2 COPD). The design of this study is a randomized controlled trial comparing confrontational counseling delivered by a respiratory nurse (RN) combined with nortriptyline for smoking cessation (experimental group), health education and promotion delivered by a RN combined with nortriptyline for smoking cessation (control group 1), and "care as usual" delivered by the GP (control group 2). We hypothesise that early detection of COPD and confrontation with spirometry for smoking cessation is more effective than regular health education and promotion and primary care as usual for smoking cessation.

In the design of this randomized controlled trial, the baseline risk of all participants is the same; they all have previously undetected airflow limitation. Only participants from the experimental group are confronted with their disease. Participants from the two control groups are not informed before the end of the trial. All other factors which are known to be associated with abstinence from smoking are standardized in both the experimental group and control group 1: type of counsellor (RN), type of counseling (face-to-face and by telephone), number and duration of counseling sessions, and type (nortriptyline) and dosage of smoking cessation medication. Therefore, we are able to assess the "net" effect of confronting and counseling smokers with COPD.

There are several critical success factors to be mentioned. A large number of smokers will have to be screened in order to obtain enough eligible participants. No smokers with known airflow limitation are allowed to enter the trial. Also, during the whole recruitment period, candidate participants must not be informed about the real purpose of the study at the beginning; to detect and confront smokers with airflow limitation. This means that a large number of smokers generally interested in quitting must be recruited in order to filter out eligible smokers with airflow limitation.

We expect eligible smokers to have a strong preference to be

placed in one of the groups receiving counseling by an RN in combination with smoking cessation medication, because they may find this intervention more effective than care as usual by their own GP. Therefore, we expect a lower compliance in participants from control group 2 and differential lost to follow-up in this group. It should be noted here that the intervention in control group 2 is probably not care as usual for smoking cessation as it appears in primary care. This is because smokers are more or less "referred" from the study team to their GP and are likely to ask for the same smoking cessation medication as participants randomized to the other two groups (nortriptyline).

Blinding of neither participants nor RNs is possible, because we want to assess behavioural interventions. All participants know what kind of counseling they receive, as do the respiratory nurses who provide the counseling. However, analysts assessing the cotinine levels and assistants entering data from questionnaires are blinded for the group allocation of participants.

The primary outcome, 12-month prolonged abstinence from smoking, is estimated from abstinence measures at three time points. This outcome is therefore no perfect measure of continuous outcome, but it is a feasible estimation, which is very usual in this field of research. Abstinence from smoking is the primary endpoint of this study, but can be regarded as a surrogate for the expected long-term positive effects of smoking cessation on health.

Conclusions

Early intervention in COPD is of paramount importance because of the irreversible and progressive nature of the disease. The use of spirometry for early detection of COPD still is an issue of debate because of a lack of convincing evidence that spirometry has an added positive effect on smoking cessation. A significant and relevant effect of confrontational counseling compared to regular health education and promotion for smoking cessation would provide an argument in favour of early detection of current smokers with airflow limitation. Successful treatment of tobacco dependence in respiratory patients requires repeated intensive interventions. The results of this study may show that RNs are able to deliver this treatment and that intensive smoking cessation counseling is more feasible for RNs than for physicians who often lack time.

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The Costs of Preventing the Spread of Respiratory Infection In Family Physician Offices: A Threshold Analysis

William Hogg, David Gray, Patricia Huston, Wei Zhang

Abstract

Background: Influenza poses concerns about epidemic respiratory infection. Interventions designed to prevent the spread of respiratory infection within family physician (FP) offices could potentially have a significant positive influence on the health of Canadians. The main purpose of this paper is to estimate the explicit costs of such an intervention.

Methods: A cost analysis of a respiratory infection control was conducted. The costs were estimated from the perspective of provincial government. In addition, a threshold analysis was conducted to estimate a threshold value of the intervention's effectiveness that could generate potential savings in terms of averted health-care costs by the intervention that exceed the explicit costs. The informational requirements for these implicit costs savings are high, however. Some of these elements, such as the cost of hospitalization in the event of contacting influenza, and the number of patients passing through the physicians' office, were readily available. Other pertinent points of information, such as the proportion of infected people who require hospitalization, could be imported from the existing literature. We take an indirect approach to calculate a threshold value for the most uncertain piece of information, namely the reduction in the probability of the infection spreading as a direct result of the intervention, at which the intervention becomes worthwhile.

Results: The 5-week intervention costs amounted to a total of \$52,810.71, or \$131,094.73 prorated according to the length of the flu season, or \$512,729.30 prorated for the entire calendar year.

William Hogg is with the Department of Family Medicine, University of Ottawa; Hogg and Zhang are with The CT Lamont Primary Health Care Research Center, the Élisabeth Bruyère Research Institute; Gray is with the Department of Economics, the University of Ottawa;; Huston is with the department of Surveillance, Emerging Issues, Education and Research Division, Ottawa Public Health, Ottawa, Canada. The authors are very thankful to Dr Carmel Martin, who contributed in the design and implementation of the facilitation study. We also thank three referees for their efforts and their constructive comments. Funding for this research was provided by the Ontario Ministry of Health and Long Term Care Primary Health Care Transition Fund. The views expressed in this report are the views of the authors and do not necessarily reflect those of the Ontario Ministry of Health and Long Term Care. Reprinted from BMC Health Services Research, BioMed Central, © 2007 Hogg et al, licensee BioMed Central Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License.

The variable costs that were incurred for this 5-week project amounted to approximately \$923.16 per participating medical practice. The (fixed) training costs per practice were equivalent to \$73.27 for the 5 week intervention, or \$28.14 for 13-week flu season, or \$7.05 for an entire one-year period.

Conclusions: Based on our conservative estimates for the direct cost savings, there are indications that the outreach facilitation intervention program would be cost effective if it can achieve a reduction in the probability of infection on the order of 0.83 (0.77, 1.05) percentage points. A facilitation intervention initiative tailored to the environment and needs of the family medical practice and walk-in clinics is of promise for improving respiratory infection control in the physicians' offices.

Background

There is a paucity of empirical evidence in the literature about actual intervention strategies to improve respiratory infection control practices and analyze the efficiency implications for health policy. Prevention, especially within health care settings, has assumed paramount importance in the fight against respiratory infection. Since influenza is typically transmitted by droplets and contact routes, there are precautions that can be taken to reduce its transmission.¹⁻³ Interventions designed to prevent the spread of respiratory infection within family physician (FP) offices could potentially have a significant positive influence on the health of Canadians. While there are costs associated with the implementation of any intervention, the benefits stemming from the outcomes of such interventions have the potential to outweigh them.

However, there are few evaluations of outreach facilitation that have studied the net costs of delivering interventions of this nature that exist in the literature. An exception is a study authored by Hogg, Baskerville, and Lemelin,⁴ which consisted of a randomized, controlled, field trial of an intervention aimed at improving preventative care tailored to the needs of participating family practices. It demonstrated the effectiveness of a multifaceted outreach facilitation in improving overall preventative care performance. It is the first analysis of cost consequences of an outreach facilitation intervention of which we are aware, and it indicated that the cost savings attributable to the reduction in inappropriate testing on the one hand, and increases in appropriate testing on the other hand, may outweigh all of the intervention costs. Those authors argued that a costly intervention that achieves success may be preferred on a cost-benefit basis to a cheaper one that demonstrates very little or has

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Planning & consensus building	5 (0.6)	10 (1.1)	11 (1.3)	6 (0.7)	12 (1.4)	44 (5.0)
Waiting time	3 (0.3)	4 (0.5)	4 (0.5)	3 (0.3)	3 (0.3)	17 (1.9)
Travel and administration						
Travel	199 (2.2)	24 (2.7)	23 (2.6)	22 (2.5)	29 (3.3)	117 (13.4)
Administrative duties relating to PH/FM	57 (6.5)	55 (6.3)	82 (9.4)	119 (13.6)	91 (10.4)	403 (46.1)
Other: vacation, sick time	89 (10.2)	59 (6.7)	53 (6.1)	21 (2.4)	37 (4.2)	258 (29.5)
Total	175 (20)	175 (20)	175 (20)	175 (20)	175 (20)	875 (100)

For 53 practices by the 5 outreach facilitators

Notes: Total hours = 875 (25 days x 5 facilitators x 7 hours/day). **PF** refers to Practice Facilitator. All figures have been rounded to the nearest hour. The total for each row (in the right-most column) indicates the number of raw hours worked by all five facilitators for each activity. The figure listed beside it in parentheses indicates the share of the 875 hours that is accounted for by that activity. The total for each column (in the bottom row) indicates the number of raw hours worked by each facilitator on all activities combined. The figure listed beside it in parentheses indicates the share of the 875 hours that is accounted for by each facilitator.

Table 1: Number of hours of intervention work activity and the distribution of total hours*

no lasting effect.

While based on an original and a very different application, this current study employs a similar approach to investigating the resource allocation implications of another type of outreach facilitation intervention that was designed to prevent the spread of respiratory infection within FPs' offices. Evidence from a systematic review has shown that influenza transmission occurs primarily by the droplet and short-distance contact routes.¹ The best practices promoted by the intervention are the droplet and contact precautions, which are described presently. From a clinical perspective, improvement in adoptions of best practices prevents the respiratory virus transmission and therefore, is likely to reduce transmission rates.

Methods

Intervention program: Our particular case consists of an outreach facilitation intervention designed to improve respiratory infection control practices in community-based FP offices. It was conducted in the City of Ottawa and delivered by five public health nurses. To our knowledge, it was the first facilitator-based intervention to promote respiratory infection control guidelines. Although the intervention has been documented in detail elsewhere,^{2,5} we provide a summary of the intervention and its outcomes in this paper.

A total of 53 family medicine practices participated in this pre-post intervention observational study, and all 53 completed the study intervention. Of the 143 participating physicians, 110, or 77% of them, completed all or part of the pre-intervention questionnaire. The objective was to determine the effectiveness (in terms of compliance) of a short-term intervention to facilitate the incorporation of best practices in respiratory infection control in primary care offices. A mnemonic was developed for both the nurses and physicians to summarize the best practices by the acronym "MASKS" (Mask for the patient with cough and

fever, Alcohol gel hand sanitization, Seating of potentially infectious patient apart from others, "Kleen"- Disinfection of hard surfaces and Signage). The intervention commenced with the public health nurse facilitators providing the baseline audit feedback on the respiratory infection control practices in the participating family physicians' practice to physicians and to other practice staff. Physicians were presented directly (and other staff either directly or indirectly through the physicians) with evidence-based best practices and a facilitative tool kit. This tool kit contained colorful signage outlining best practices for respiratory infection control, signage demonstrating proper hand-washing techniques and use of alcohol-based gel, a reference list of major guidelines sources and web sites, four infection control articles, a box of procedural masks, wall-mounted alcohol gel dispensers with refills, alcohol gel pumps, and hospital-grade disinfectant wipes. During the five-week intervention with their assigned recruited practices, the facilitators worked independently. Throughout the intervention the facilitators corresponded with the project team daily and attended scheduled weekly meetings to share information and strategies.

In order to measure outcomes, four respiratory control activities for an ambulatory office were viewed as the primary indicators of effective respiratory infection control: 1) Signage posted in or about the waiting room; 2) The receptionist giving masks to patients having a cough and/or fever; 3) Instructing patients having a cough and/or fever to use alcohol gel to clean their hands; and 4) Requesting patients having a cough and/or fever to sit at least one meter away from others. Professional nurse auditors were deployed once to obtain data before the intervention and once six weeks after the intervention. The auditor sat for an hour in the waiting room of the physicians' offices and noted the presence or absence of the four respiratory control activities listed just above. They also inquired as to how often potentially contaminated areas were cleaned with disinfectants, and if alcohol-based hand gels were used in examining rooms. The auditors were blinded to the outcome measures and aware only of data gathering requirements. In order to separate the intervention from the data collection, the physicians, office staff and facilitators were blinded from the outcomes and were not informed of the presence of the auditors.

Statistically significant differences between before and after the intervention were observed for all four of the primary outcome measures: 67.3% (95% CI: 54.1%-80.5%), 48.1% (34.0%-62.1%), 54.7% (38.9%-70.5%) and 34.6% (20.1%-49.0%), respectively. Overall, the number of practices that applied all of the four audited primary prevention measures was 3.8% (0%-9.1%) prior to the intervention and 52.8% (38.9%-66.7%) following the intervention (p<.001), demonstrating a 49 (35.1-63.0) percentage point increase in the adoption rate of best practices. This study demonstrated that facilitation of a multi-faceted intervention by public health nurses successfully promoted best practices in respiratory infection control in primary care practices. However, it did not consider health-related outcomes before or after the intervention.

Cost analysis: We conducted a cost analysis of the respiratory infection control intervention. A standard cost-benefit analysis or cost-effectiveness analysis could not be conducted in this case due to the absence of information on health-related outcomes. As supportive information, we also attempted to evaluate a threshold value for the intervention's effectiveness that could

justify the costs incurred by the intervention in terms of the potential cost savings. Standard methodological approaches can be found in Drummond et al.⁶ and Muennig.⁷ We determined the explicit costs of the intervention from the perspective of the provincial government, which is responsible for financing health care in Ontario. The potential cost savings for this intervention referred to the costs of medical care averted due to the improved respiratory infection control practices that reduce the probability of infection in the physicians' offices. These implicit cost savings can include the cost of healthcare provider visits by patients experiencing illness symptoms, the cost of medical tests and procedures, and the cost of hospitalizations that were avoided.

Intervention costs: The actual explicit costs of the intervention over 5 weeks were gathered from the Public Health Budget Rationale (2004) for the inputs of labor, auditing services, supplies, facilitator travel, and honoraria that compensated the practices for the time diverted from normal activities. Labor costs referred to the salaries and benefits of the five nurse facilitators and of the 0.5 full-time-equivalent project manager. The audit costs included the costs of the audit itself, involving feedback both before and after the intervention provided to the practices, as well as the traveling costs of the auditor. Supply costs referred to the costs of the tool kits provided by the facilitators for each practice. An honorarium was paid to each FP practice site for the time it spent participating in the project.

In addition to those variable costs, which vary directly with the number of practices that participate, it is important to include the fixed costs of the intervention, which consisted primarily of training the nurse facilitators. The investment in training generated returns extending well beyond the 5-week period of execution of the intervention. The amortization period for recovering the cost of training is much longer than this time frame for the initial intervention, as the skills obtained from training can be utilized again in subsequent years. The initial training cost should therefore be distributed across the estimated useful life of the investment item, taking into account the discount factor. We selected a discount factor of 5 percent as recommended by other papers containing cost analyses.^{4,6,7} In addition to the discount rate, we have to select the length of the time period over which to amortize the training cost, which should be related to the life span of the training. As Desai⁸ pointed out in his application to obstetrics, often the analyst must assume a length for the useful life span, but this is often initially unclear. Existing research from the field of organizational behaviour indicates that the payoffs stemming from a one-time, up-front investment in employer-paid training for human resources intervention tend to decline after four years.^{9,10} Due to the fact that the facilitators received their

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training over a two-week period, we adopted a somewhat shorter amortization period for the cost of their training by assuming that it is valid for 3 years.

The cost of the training of the five nurse facilitators was amortized over a 3-year life span at a discount rate of 5% based on the training expenses that were initially incurred at the beginning of the intervention. In another scenario, we included the entire training cost into cost analysis instead of amortizing it, which would imply that the training has no value after the current season. Results were also presented at discount rates of 0% and 8% in the mathematical summary which details the discounting process.

The other costs listed in the public health budget rationale, such as recruiting participating practices, office assistance, and projection management were not included because these were costs incurred for this particular research pilot project rather than those of the intervention. Those costs would not arise in the facilitation intervention implementation if it were to be adopted on a widespread basis.

All of the direct costs were presented in micro detail for the 5-week period over which the intervention was executed, both in terms of total levels and on the basis of costs per practice. As such, the cost estimates that we generated should generalize to similar projects in other geographic areas that are on either larger or smaller scales. We have made some assumptions regarding how a facilitation program might be organized in order to deal with evaluating the costs of training the facilitators. Our outreach facilitation program is most likely to be effective if

Cost item	Rationale	Amounts (2004) (Five weeks) ¹	Amounts (2004) (3 months) ²	Amounts (2004) (per year) ³	Amounts (2004) (Five weeks) ⁴
Salaries and benefits	Five Nurse Facilitators	\$15,147.35	\$39,383.11	\$157,532.44	\$15,147.35
	0.5 full-time equivalent project manager	\$4,831.54	\$12,562.00	\$50,248.02	\$4,831.54
Total training	Course, experts, test practices	\$3,883.20*	\$3,883.20*	\$3,883.20*	\$10,562.30
Audit	Auditors and travel	\$11,100.00	\$28,860.00	\$115,440.00	\$11,100.00
Supplies	Tool kits	\$7,472.18	\$19,427.67	\$77,710.67	\$7,472.18
Facilitator travel		\$2,426.44	\$6,308.74	\$25,234.98	\$2,426.44
Honorarium	Each practice site was compensated for time lost	\$7,950.00	\$20,670.00	\$82,680.00	\$7,950.00
Intervention costs		\$52,810.71	\$131,094.73	\$512,729.30	\$59,489.81

*The training cost was amortized over 3 years using 5% discount rate, and therefore the training cost for each calendar year was \$3,883.20, as shown in the additional file 1. This training cost for five facilitators would be totally fixed for a 3-year period. Even if these 5 facilitators were to conduct this activity for the entire flu season, and thus serve more than 53 practices, this cost would not change.

¹ Costs for the 5-week intervention based on the actual 5-week length of the project.

² Assume that intervention lasts 3 months (13 weeks) during flu season. All figures except the training cost were obtained by converting the 5-week totals (that apply to our particular intervention) listed in third column to weekly rates and then multiplying by 13.

³ Assume that intervention lasts one year (52 weeks). All figures except the training cost were obtained by converting the 5-week totals (that apply to our particular intervention) listed in third column to weekly rates and then multiplying by 52.

⁴ Costs for the 5-week intervention based on the actual 5-week length of the project and the training cost was not amortized.

Table 2: Total costs for the intervention

delivered during or just before the peak season for respiratory infections (ie, September, October, and November). Hence our training activities would ideally be applied for 3 months per year over 3 years, generating a cumulative total of 9 months of utilization. While the program would aim to introduce proper respiratory infection control practices to be followed all year round, the medical practitioners might be more interested just prior to the influenza season. Therefore, although the training remains valid for years into the future, we envisaged that the program would be delivered during that 3-month period every year. We nevertheless also produced estimates based on the scenario for which the intervention is executed year-round.

Cost savings: While the explicit costs of implementing this intervention can be assessed with accuracy, it is much more difficult to estimate the implicit cost savings because of the lack of information regarding a key event, namely the reduction in the probability of spread as a direct result of the intervention. We assume without solid evidence that improved infection control reduces the respiratory infection rate at physicians' offices, but we certainly do not know how by much the probability of infection changed after the intervention. In order to generate an accurate estimate of the total healthcare costs averted by this intervention, one would require the following pieces of information: i) the incidence or frequencies of transmission at

Variable	Value	Value (sensitivity analysis)*
Cost per hospitalization	CN \$4,931.89	CN \$4,931.89
Cost per outpatient visit	CN \$84	CN \$84
Probability of infected people who were hospitalized	0.472% (0.344%, 0.478%)	0.472% (0.344%, 0.478%)
Probability of infected people who had any outpatient visit	45.45% (37.5%, 50%)	45.45% (37.5%, 50%)
Number of patients visiting physician offices in 5 weeks	104,033	104,033
Total intervention costs for 5 weeks	CN \$52,810.71	CN \$59,489.81
Efficacy of Intervention	0.83% (0.77%, 1.05%)	0.93% (0.87%, 1.18%)

*Total intervention costs included the training cost without amortization.

Table 3: Threshold calculations

physicians' office, ii) the effect of the intervention in reducing those rates, iii) the probabilities of the various potential health outcomes that could arise given infection, and iv) the cost of the treatments associated with those outcomes. With the exception of item iv), these pieces of information were not available. Drawing from several data sources in the literature, we therefore adopted an indirect approach to estimate the potential health-care costs that might be averted as a result of the intervention, and we attempted to make a case that the potential benefits were large relative to the explicit intervention costs.

There are a range of treatments for different influenza patients according to the seriousness of the infections. The patient who is infected with influenza may rest at home, visit an emergency room, or be hospitalized. If the patient only needs care at home, he or she may request sick leave from his or her job. In such a case, cost arises from the patient's perspective or the societal perspective (from the lost output) but not from the Ministry of Health's perspective. Another

possibility is that a few patients die from influenza, but it is impossible to attach a precise value for the cost of death. Therefore, we only took the intermediate events of outpatient visits and hospitalizations into account in estimating the avoided costs.

The costs denominated in US dollars (as they were presented in some studies that we cited) were converted into Canadian dollars by the current exchange rate,¹¹ and costs from data in prior years were adjusted for inflation and denominated in 2004 constant dollars using appropriate component of the Consumer Price Index¹² where necessary.

Threshold analysis: The underlying approach for the cost analysis of the intervention involves an efficacy rate, which is defined as the decrease in the probability of transmission that is attributable to the intervention. We could not evaluate this quantity, but we could evaluate the threshold value that would render the intervention beneficial, which was judged to be worthwhile if: Cost savings – intervention cost > 0.

The cost savings attributable to the intervention were expressed as follows: (Cost of hospitalization for a flu patient × number of flu cases avoided due to the intervention in the physician's office × proportion of the infected people who were hospitalized) + (Cost of outpatient visit for a flu patient × number of flu cases avoided due to the intervention in the physician's office × proportion of the infected people who had an outpatient visit). Note that infected individuals who were hospitalized or who had an out patient visit may or may not have passed through the FPs' practices; there are other modes of infection besides transmission in these clinics.

The second element in each of the terms in parentheses, which is a counterfactual, can be expressed as: the number of flu cases avoided in the physician's office due to the intervention = number of patients visiting the physician's office × (probability of contracting influenza in that office without the intervention - probability of contracting influenza in that office with the intervention). Substituting that expression into the primary

equation yields the following expression after a slight algebraic manipulation: (probability of contracting influenza in the office without the intervention – probability of contracting influenza in the office with the intervention) = intervention cost / [number of patients visiting the physician’s office × (cost of hospitalization × proportion of infected people who were hospitalized + cost of outpatient visit × proportion of infected people with an outpatient visit)].

A critical element for this calculation is transmission rates for influenza in settings such as physicians’ offices. While there are articles in the literature dealing with the incidence of transmission of certain viruses within the general population, we were unable to find research pertaining to the incidence of transmission within physician offices or similar locations involving close contact with the public, such as waiting rooms, emergency rooms, and school busses. We searched for papers on Medline, CINAHL and EMBASE by the key words “Influenza or flu, and Transmission or infection, and Bus or waiting room or emergency room or emergency department or physician office,” and we also asked for help from several experts in this area to search for the requisite information. We did locate some information regarding the incidence of transmission of influenza during airline flights. In our judgment, however, these figures are not reliable estimates of the rate of infection with and without the intervention that would occur in a FP’s office.

In light of that source of uncertainty, our approach was to calculate an estimated value for the left side of the above expression (i.e the reduction in the likelihood of infection) that represents a threshold value for the minimum efficacy of the intervention such that the potential cost savings of the intervention outweigh its costs. We solve that expression for the lowest possible value at which the net costs of the intervention would be negative. If the efficacy of the intervention is any lower than that value, its net costs would be greater than 0.

Results

Intervention costs: Table 1 presents the number of hours of intervention work activity and the percentage of total hours spent at the 53 medical practices by the facilitators. The total number of hours worked was 875 (25 days x 5 facilitators x 7 hours/day). In Table 1, it should be noted that the time spent on “other” needs to be removed from the analysis, as that labor time was not allocated to the project. Therefore, the total hours for the five public health nurse facilitators spent on the intervention should be the figures listed under the “Total” label minus those listed under the “Other” label, which worked out to a total of 617 hours. On average, they spent approximately 11 ½ hours at each practice for which they were responsible. Given a yearly salary of one nurse facilitator of \$47,876 (in the Ottawa area) and an annual total of 1,950 hours worked in one year, the hourly wage

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1. AHA Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Part 6, p. 1-87.



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rate of one nurse facilitator was \$24.55. This generated a labor cost per practice of \$285.80. In the 5-week intervention period, the labour costs (for time actually worked) for all five nurse facilitators combined amounted to \$15,147.35 (\$24.55 x 617 hrs).

The total costs for the intervention are presented in Table 2. The third column provides the data on the costs of the outreach facilitator intervention denominated in 2004 dollars on the basis of the 5-week period during which they actually worked. The fourth column contains similar data, except that all of the costs were estimated on the basis of a 13-week (or 3-month) time period that corresponds to the peak flu season. These figures were calculated based on the assumption that the 5 facilitators would work at the same pace for 13 weeks instead of 5 weeks, and would thus visit approximately 138 practices. Similarly, the figures in the fourth column of Table 2 were based on the assumption that the 5 facilitators would work at the same pace for an entire year, and would thus visit approximately 551 practices. The difference between these three scenarios consists of a pro-rating of all of the variable costs while holding the training costs fixed. The figures in the last column were exactly same as those in the third column except for the training cost. The training cost presented in the last column was not amortized over 3 years, which accounts for the approximately threefold increase in the training costs coupled with no change in the other costs. The intervention costs amounted to a total of \$52,810.71 that was actually incurred over the 5-week intervention, \$131,094.73 per flu season, or \$512,729.30 per calendar year.

In order to extrapolate these cost figures to other geographical areas, the distinction between the variable costs and the fixed

costs plays an important role. The variable costs that were incurred for this 5-week project amount to \$48,927.51, which is the sum of all of the costs listed in the third column of Table 2 with the exception of the training costs. This corresponds to approximately \$923.16 per participating practice. In order to estimate the corresponding variable cost for a similar project elsewhere, one can extrapolate that estimate by multiplying by the number of practices involved. This estimate is premised on salaries in effect in the Ottawa area, as well as travel distances for a fairly large urban area.

The (fixed) training costs must be calculated in a different fashion, however. As explained in the mathematical summary (see Additional file 1), we calculated an annual value of \$3,883.20 for the training costs. This figure is equivalent to \$73.27 for each participating practice. Had these five facilitators worked for the entire 13-week flu season, the total training costs would still be \$3,883.20, but many more practices could have been involved, thus lowering the per-practice training cost to \$28.14 (\$3,883.20/138 practices). If these same facilitators were to be assigned to this project on a year-round basis, the per-practice training costs would become one quarter of the prior figure, or \$7.05, because the nurses work 4 times longer during the year.

Cost savings: The first element that we obtained for the expression for averted costs was the number of patients that passed through the offices of the participating physicians, and were therefore at risk of becoming infected. In pre-intervention questionnaire, physicians were asked how many patients they typically see per half-day, from which we may estimate the number of patients visiting the physician offices during a 5-week period. 103 physicians responded to the question, and the mean value was 14.55. Imputing this value to all of the physicians that were covered in our intervention, approximately 104,033 patients visited the 143 participating physicians over 5 weeks.

The figures for the costs of treating influenza patients were drawn from several sources. Hogg, Baskerville and Lemelin⁴ performed a cost savings analysis associated with administering influenza vaccine in the elderly. They obtained the estimated cost of an emergency room visit due to influenza from Jacobs and Hall, which was approximately CN \$76.00 in 1999 or CN \$84.00 in 2004.^{4,13} This cost was virtually identical to the costs for an outpatient visit reported in other studies.^{14,15} Thus, for the value of the out-patient component of health care that includes visits to the physician's office and to the emergency room, we used the figure of \$84.00. The Ontario Case Costing project provided the total cost of hospitalization for the following treatments: pneumonia (CN \$4,462 in 1999 or CN \$4,931.89 in 2004), chronic respiratory conditions (CN \$4,445 in 1999 or CN \$4,913.10 in 2004), and congestive heart failure (CN \$5,417 in 1999 or CN \$5,987.46 in 2004) for patients 65 years of age and older.⁴

We turn next to the proportion of people infected with influenza that ended up being hospitalized. An estimate of this proportion can be obtained by dividing the hospitalization rate among all subjects with influenza (regardless of where it was contracted) by the proportion of all subjects who become infected (regardless of where it was contracted). The latter quantity can be thought of as the illness or transmission rate of the influenza. In an analogous fashion, an estimate of this proportion of infected people who had an out patient visit can be obtained by dividing the out-patient rate among all subjects with influenza by the proportion of all subjects who become infected.

Unfortunately, we could find no paper in the literature that provided values for the hospitalization rate or the outpatient visit rate given that a patient has influenza. In order to obtain rough estimates of these quantities, we borrowed heavily from the paper by Nichol¹⁶ that dealt with vaccination against influenza. By a systematic literature review, the author obtained estimates of "the hospitalization rate due to influenza and its complications," "outpatient visit rate due to influenza and its complications," and "the influenza (and its complications) illness rate" among healthy working adults aged between 18 and 64 years. Nichol also derived from the Monte Carlo simulation the difference of the hospitalization rate (as well as the outpatient visit rate and the illness rate) for influenza and its complications between unvaccinated and vaccinated subjects. However, the influenza's complications were widely defined in Nichol's paper. In our analyses, we focused on only influenza and pneumonia associated with influenza. Therefore, by assuming that vaccination is 100% effective in preventing episodes of influenza (and pneumonia associated with influenza), we used the number of vaccinated individuals as a proxy for the number of non-infected subjects. In this respect, the three difference rates reported by Nichol can be interpreted as each of these three incidence rates due to influenza only (and pneumonia associated only with influenza). Therefore, we used these differences, 0.026% (95% probability interval (PI): 0.011%, 0.043%), 2.5% (1.2%, 4.5%), and 5.5% (3.2%, 9.0%), as our estimates for the hospitalization rate due to influenza only, outpatient visit rate due to influenza only, and the influenza illness rate, respectively.

When we inserted these values into the expression for the proportion of infected patients who ended up hospitalized, we obtained a value of 0.00472 (PI: 0.00344, 0.00478), and the value for the proportion of infected patients who had an outpatient visit was 0.4545 (PI: 0.375, 0.5). Inserting all of the figures that we obtained above back to the primary expression for the cost savings, and combining that information with the value for the explicit costs of intervention, the efficacy of the intervention (probability of contracting influenza in the office without the intervention - probability of contracting influenza in the office with the intervention) was equal to 0.83% (PI: 0.77%, 1.05%). The implication is that the threshold value for the efficacy at which the cost savings of the intervention barely outweigh the costs was 0.83%. The goal would thus be to reduce the probability of infection occurring in FPs' offices by at least 0.83%. In addition, if we included the nonamortized training cost into analysis, the threshold value rose slightly to 0.93%. The figures that entered into the calculations are presented in Table 3.

Discussion

This paper has provided detailed information on the costs of an outreach facilitation initiative designed to prevent the spread of infectious diseases by promoting best practices in respiratory infection control in primary care practices. We have generated accurate estimates of the explicit costs of implementing such a program on a per-practice basis, which permits the extrapolation of these unit costs to other geographical domains. We have also provided some preliminary estimates of the potential cost savings to the health-care system. Due to the lack of knowledge about the frequency of respiratory infection occurring at physicians' offices, particularly an estimate of the reduction in the probability of infection attributable to the intervention, we did not have enough evidence to evaluate precisely the benefits of the intervention. As an alternative approach, we undertook a threshold analysis to estimate a threshold value of the efficacy

that could render the intervention cost saving. Based on our conservative estimates referring to direct savings in the form of health-care costs averted, there are indications that the outreach facilitation intervention program would result in cost savings if it could achieve a reduction in the probability of infection at the physician offices on the order of 0.83 percentage points. This implies that if we assume that there was a 1.00% chance of contracting influenza in FP offices without intervention, to achieve the efficacy rate of 0.83%, the probability of contracting influenza in FP offices with intervention would be 0.17%, representing a large relative risk reduction in influenza transmission in FP offices. On the other hand, if we assume a higher probability of contracting influenza in FP offices without intervention, such as 5%, to achieve the targeted efficacy rate of 0.83%, the probability of contracting influenza would be approximately 4.2%, representing a smaller relative risk reduction in influenza transmission in FP offices. Moreover, in addition to the direct cost savings to the health care system that may be realized, there are potential indirect cost savings associated with our intervention as well, such as the potential to avoid disastrous human loss and suffering caused by viruses such as the Severe Acute Respiratory Syndrome (SARS). The scope of the influences of the infectious diseases such as SARS and influenza extend far beyond the costs that were mentioned above, especially in the health-care and tourism sectors. The total costs in terms of lost production of the SARS epidemic to Toronto's economy had been estimated to be \$1 billion, and the estimate for the economic cost for all of Canada was around \$1.5 billion.¹⁷ Within the health care sector, the indirect costs borne by non-SARS patients were enormous. SARS affected all health-care workers – especially those on the front line – and delayed non-emergency surgeries such as organ transplants and cancer radiation.¹⁸ According to Ontario Health Minister Tony Clement, as of June 27, 2003, SARS had cost Ontario's healthcare system \$945 million, which was spent mostly on special supplies and added health-care workers needed to protect healthcare workers, as well as on constructing specialized SARS clinics and isolation rooms.¹⁷ This in turn had a huge impact on non-SARS related health care system utilization, both due to diversion of resources as well as severe stress amongst the health care providers. For instance, a study comparing the periods before and during the SARS outbreak in the GTA and non-GTA areas by Woodward et al found the greatest impact of SARS on reduction in the utilization of inpatient and outpatient hospitalization, diagnostic testing, physician and emergency department visits, use of prescription drugs, intensive care bed availability, and cardiac care during April 2003 to May 2003.¹⁹ Avoiding such negative consequences implies that our intervention may also generate implicit or indirect cost savings.

Conclusions

The 5-week intervention costs amounted to a total of \$52,810.71. The results of the cost analysis suggest that the intervention can be cost saving because the 0.83% point reduction of the probability of influenza at the physicians' offices appears to be a feasible target for the effectiveness of the studied intervention. A facilitation intervention tailored to the environment and needs of the family practice and walk-in clinics is of great promise for improving respiratory infection control in the physicians' offices. Future research to conduct further economic evaluations of such an intervention based on adequate data—particularly in relation to infection incidence rates and the ability to lower them—would aid in important public health policies and administrative decision-making on implementing preventive care guidelines.

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To Use Pressure Support Or Not To Use Pressure Support

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

Airway pressure release ventilation (APRV) was first described in 1987 by Stock and Downs. Since that time it has become commercially available on several different ventilators. Some indications for use of APRV are to help oxygenation and augment ventilation for ALI or low-compliance lung disease patients, although it has also been used successfully in patients with airway disease. Many centers convert ARDS patients to APRV if oxygenation, plateau pressure or pH goals cannot be met within the ARDS network protocol. APRV is available under names such as DuoPAP+, BiLevel, BiPAP, and APRV, depending on which manufacturer makes the ventilator. Most manufacturers today include the ability to use pressure support (PS) within the APRV mode.

APRV uses different strategies than conventional ventilation. Conventional ventilation requires an elevation in airway pressure above baseline to generate a tidal volume. This potentially increases the risk of over distension if excess tidal volume and/or plateau pressure is applied. APRV uses a release from a set pressure down to a lower pressure to generate the mandatory tidal volume. One sets a High Level of CPAP (P_{high}) and then periodically drops very briefly to a Low level of CPAP (P_{low}).

Since ventilation in APRV is a result of releasing from a set pressure, the risk of barotrauma/volutrauma/overdistension is reduced. APRV could be viewed as a mode in which one applies high PEEP to keep the lung recruited and rather than apply a tidal volume above PEEP, the PEEP is briefly released to a lower level. The re-establishment of the PEEP following the brief drop to the lower PEEP/CPAP level generates the periodic tidal volume. However, since the goal is to maintain the recruitment pressure or high PEEP/CPAP level (P_{high}), only a limited number of releases or mandatory tidal volumes can be achieved. In order to achieve adequate minute volume, APRV typically requires spontaneous breathing between the mandatory 'release' breaths. Some ventilator manufacturers allow the clinician to apply pressure support to the spontaneous breaths during APRV. More commonly, automatic tube compensation is applied. The potential problem with applying PS during APRV is that it may generate higher spontaneous volumes above the P_{high} which could lead to a significant increase in transpulmonary pressures.

APRV allows patients to breathe anytime during the ventilatory cycle. It is through spontaneous breathing that patients realize many benefits of APRV. The negative intrathoracic pressures generated with spontaneous breathing help increase venous return to the heart and therefore increases cardiac output which

also in turn improves organ perfusion and function. With the addition of PS, the effects of spontaneous breathing might be mitigated.

Another benefit of spontaneous breathing is the distribution of ventilation. Spontaneous breathing favors a distribution of ventilation to the dependent, well-perfused areas of the lungs and atelectasis is discouraged since diaphragmatic contraction opposes alveolar compression. On the other hand, if PS is utilized improvements in distribution of ventilation and V/Q matching may be defeated. With significant PS levels, the areas of the lungs that are ventilated may become primarily the areas away from those receiving maximal blood flow, or the non-dependent areas.

Although PS is available for use with APRV application, clinicians should carefully consider employing it during this mode. Clinicians must evaluate the reasons for utilizing APRV. If among those reasons are improving ventilation-perfusion matching, decreasing shunt, limiting peak airway pressures, preventing over distension, improving cardiac output and delivery of oxygen, then it is wise not to utilize PS during APRV. If the patient appears to be working too hard with spontaneous breaths, the recommendation is to alter the P_{high} setting to achieve a better 'recruited' lung with better compliance which should reduce WOB.

None of the pioneering APRV centers publications refer to utilizing pressure support during APRV. They used unassisted spontaneous breathing or automatic tube resistance compensation.

On some ventilators tube compensation and TRC are mutually exclusive, whereas on others they can be independently set. In more conventional modes, one could rationalize using both tube compensation and pressure support as the tube compensation only offsets resistive work due to the artificial airway and does not offset patient airway resistance or elastic work (work due to reduced compliance).

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The authors are with Hamilton Medical.



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