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News

Fall 2017

Save the Date For These Fall 2017 Bubble CPAP Conferences

These unique programs will share successful bubble nasal CPAP experience, discuss rationale, plus practical aspects and strategies for replicating success with bubble CPAP use. The conferences are intended for the entire neonatal critical care team and other allied health professionals in the neonatal intensive care arena. The 27th Annual Course Respiratory Care of the Newborn—A Practical Approach is on October 7-8, 2017 in New York, NY. Learn more at www.ColumbiaCME.org. And the 7th Annual Bubble CPAP and Non-Invasive Respiratory Management of the Newborn Conference runs December 9-10, 2017 in Washington, DC. Learn more at www.bubblecpap.org.

Tech Leader Joins Respiratory Therapy Advisory Board

Alex Stenzler, Founder and President of Novoteris and President of 12th Man Technolgoies in Greater Los Angeles, has joined the Editorial Advisory Board of Respiratory Therapy. Stenzler has been described as a "genius in science and engineering - an inventor and innovator through and through." His certifications included Registered Pulmonary Technologist-NBRC, and Certified Respiratory Therapy Technician-NBRC. Through research grants, Stenzler was: Principal Investigator, Passive measurement system for respiratory mechanics in newborns, National Institute of Health 1985-1986; Principal Investigator, Passive measurement system for respiratory mechanics in ventilated newborns, National Institute of Health 1986-1987; Principal Investigator, Nitric Oxide for Prevention and Treatment of Pandemic Flu, Defense Advanced Research Projects Agency (DARPA), 2010-2011. Stenzler was honored in 2001 by the March of Dimes as Orange County Technology Leader; and in 2008, he was honored with the Cardinal Health Founder's Award. Stenzler has also served as an executive with such companies as CareFusion 207, Cardinal Health, and SensorMedics.

New Patient Monitoring Unveiled

Medtronic plc has announced the US launch of the Vital Sync monitoring and clinical decision support (CDS) solution. The system is designed to simplify time-intensive patient care processes and help clinicians prevent or mitigate harmful and costly adverse events. The Vital Sync CDS solution combines remote monitoring software with wireless monitoring devices and a series of customizable CDS mobile applications to improve clinical protocol implementation and management of patients on medical-surgical floors and in the ICU. The Vital Sync CDS solution gathers patient physiological data directly from a variety of wireless and bedside devices, manufactured by Medtronic and third-parties. Analytics are continuously and automatically calculated, with customized alerts and notifications to help clinicians know as soon as possible if a patient is deteriorating. Respiratory therapy and nursing teams can remotely access patient data to make insightful assessments

for more effective and earlier interventions. Patient data is accessed through the Vital Sync virtual patient monitoring platform. The solution also offers customizable tools, such as the Vital Sync Physiological Patch, a lightweight wireless device applied to the chest area that continuously collects and transmits physiological data, including heart rate, respiration rate, single-lead ECG and body position, to monitor vitals, facilitate pressure ulcer prevention protocols and help identify patient deterioration. The Vital Sync Weaning Readiness and SBT Monitoring App allows clinicians to continuously monitor and receive alerts indicating when a mechanically ventilated patient is ready to begin a weaning trial based on established clinical protocols. It also remotely tracks a patient's breathing pattern and other vitals through a spontaneous breathing trial so that clinicians can intervene if a patient falls outside predefined thresholds. The Vital Sync Early Warning Score App applies automated calculations based on published evidence for an early warning score to help give clinicians an earlier indication of patient deterioration. The app can detect subtle changes in patient deterioration using multiple parameters-enabling clinical intervention before a single parameter device would recognize a problem. Many common hospital-based patient safety issues are preventable. According to a recent report by the ECRI Institute, the top three patient safety concerns for healthcare organizations in 2017 are: insufficient management of electronic health record data, unrecognized patient deterioration and ineffective use of clinical decision support tools. The Vital Sync CDS solution was designed based on clinician input and clinical evidence to help hospitals avoid these and other patient safety challenges.

Novoteris, LLC Receives FDA and Health Canada Clearance

Novoteris, LLC, a clinical stage medical device and pharmaceutical developer focused on innovative nitric oxide gas applications, announced that both the US Food and Drug Administration and the Therapeutic Products Directorate of Health Canada have cleared its Phase 2 clinical trial application. Novoteris will now begin recruiting subjects into its Phase 2 trial that will be using inhaled nitric oxide for the treatment of Cystic Fibrosis (CF). This multi-center trial will randomize sixty subjects recruited from five cystic fibrosis research centers (Seattle, Los Angeles, Milwaukee, Charleston and Vancouver) to either Thiolanox nitric oxide product or a placebo treatment, delivered with its unique computerized trace-gas mixing system. The Novoteris investigators' Phase 1 pilot trial in Europe reported encouraging microbiological and significant lung function changes following two weeks of the same treatment in patients with CF. The broad-spectrum anti-microbial property of nitric oxide widens the enrollment eligibility of subjects in this Phase 2 trial with the only exclusion being for Non-Tuberculosis Mycobacterium (NTM), which will be studied in separately planned trials. Gaseous nitric oxide's potent antimicrobial properties, lack of bacterial resistance, and small molecule penetration capabilities could provide a promising alternative, non-antibiotic approach to treating infections in people living with the disease. "The clearances by the FDA and Health Canada will enable us to advance our work with this novel therapy and represents an important step for Novoteris" stated Alex Stenzler, President of Novoteris. Cystic fibrosis (CF) is an autosomal recessive genetic disorder that affects the lungs most critically. Difficulty breathing is the most serious symptom, which results from frequent lung infections that are most often treated with lifelong inhaled antibiotics. Development of drug resistance to



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available antibiotics is a major concern for patients with CF.

Accriva Diagnostics Acquired by Instrumentation Laboratory

The Accriva organization announced that it has been acquired by Werfen Life Group, SA, (Werfen), and its subsidiary, Instrumentation Laboratory (IL). Accriva's globally recognized portfolio of POC diagnostic products for coagulation and anti-platelet therapy response will allow IL to establish a market-leading position in hospital-based POC Hemostasis testing, expand its position in POC Critical Care testing and complement its leadership of the Hemostasis Laboratory market. IL will continue to maintain Accriva's operations in San Diego, CA. "The acquisition of Accriva strengthens our leadership in Hemostasis, Critical Care and Patient Blood Management testing," said Ramon Benet, CEO at IL. "We see great synergy between our organizations and look forward to further impacting positive clinical outcomes and reducing healthcare costs in point-of-care testing with the breadth of this comprehensive portfolio." Accriva is a leading diagnostic company focused on creating best in class products that provide more timely, precise information, leading to improved treatment outcomes. With over 40 years as a leader in the fields of hemostasis management and point-ofcare testing, globally recognized Accriva product brands include: Hemochron POC coagulation systems; VerifyNow anti-platelet therapy response systems; AVOXimeter CO-Oximetry systems; and Tenderfoot, Tenderlett and Surgicutt incision products. With commercial and manufacturing operations located in San Diego, CA, Accriva diagnostic products are distributed to hospitals and critical care settings in over 90 countries.

High Frequency Ventilator Unveiled

Bunnell Incorporated has announced the upcoming release of the new LifePulse High Frequency Ventilator-Model 204! Since 1988, the Life Pulse HFJV has been used for treating premature babies in acute respiratory failure in hospitals in the US and Canada. Bunnell continues a tradition of providing proven, unique High-Frequency Jet Ventilation technology in the new Model 204 LifePulse for the treatment of critically ill infants with ventilator-induced lung injuries. The new LifePulse, also known as the "Jet" ventilator, features many upgrades and benefits. More information can be found at www.bunl.com. The Model 204

LifePulse will be available for distribution beginning in September. Health Canada approval is pending. As a committed partner in effective and quality healthcare, Bunnell offers free trials, training and education, and industry-leading customer support including 24/7-hotline support at 800-800-4358.

FDA Clears First Full Home-Use Spirometer with Wireless Connection

Monitored Therapeutics, Inc. (MTI), an emerging best-in-class remote patient management company, has received FDA 510(k) clearance for its GoSpiro Home Spirometer. This is the first spirometer that was specifically developed as a homeuse wireless connected spirometer that works with a wide range of smartphones, tablets or PCs. Michael Taylor, Chief Development Officer, pointed out that "The GoSpiro is the only spirometer currently on the market that has met the latest and more stringent ISO and FDA device requirements for home use." The GoSpiro collects diagnostic quality forced spirometry (FVC) and slow spirometry (SVC) with the same accuracy as hospital laboratory systems and provides immediate feedback to patients on the quality of their test performance. The GoSpiro seamlessly integrates with MTI's GoHome[™] Patient Health Monitor, which collects and transmits data from patients and delivers physician's instructions to them, and with a suite of remote patient monitoring tools already integrated to monitor diseases such as Asthma, COPD, heart disease, hypertension and diabetes. Monitored Therapeutics, Inc. continues to strengthen its focus on respiratory disease management with the addition of the GoSpiro. "The GoSpiro's 510(k) marks a critical milestone towards completing our system to manage patients with pulmonary disease in their homes." said Monitored Therapeutics, Inc. Co-founder and CEO William Zimlich. "This is one more step towards our goal of improving patients' lives and reducing healthcare costs." MTI products include GoHome, GoSpiro, and the MTI CarePortal. Monitored Therapeutics, Inc. is based in Dublin, OH with technology development offices in Garden Grove, CA. For additional information, visit: www. monitoredrx.com

Automatic Resuscitator a Go

Vortran Medical announced that it has been granted FDA 510K and CE certification approval for the new and improved automatic resuscitator called the GO₂VENT (Gas Operated Ventilator).

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The latest addition to their product line offers an option for ventilation of patients during an MRI or CT scan. The GO_2VENT has been tested per FDA regulations by Dr Frank Shellock to meet the MRI compatibility testing and has been approved as a MR Conditional device and is perfect for use during a scan. The new model uses Copper springs to remove the chance of artifacts in the MRI picture. The GO_2VENT can be used on a wide patient population from 10kg and above and is a great option for post-operative transport, isolation areas, emergency use and of course disaster management. The new GO_2VENT offers the user an ability to save on oxygen consumption now with an easily CEO of Circadiance. "SleepWeaver 3D promotes sleep health for Obstructive Sleep Apnea (OSA) and other CPAP and BiLevel users" continued Groll. Circadiance's newest most flexible elastic interface creates a great seal on many face types. "The beauty of SleepWeaver 3D is the new interface design that allows a loose fit while providing a comfortable, reliable seal to the OSA patient" stated Tom Lucas, Director of Global Sales at Circadiance. "The SleepWeaver 3D features include a new wing-shaped stay that routes the headgear under the ears, ensuring comfort and a great fit" continued Lucas. The SleepWeaver 3D Soft Cloth Nasal CPAP Mask is intended to provide an interface for continuous

changeable FiO₂ controller which allows the clinician to easily change from 100% O2 down to 50% to save gas especially when using a tank during a transportation. The New and improved GO₂VENT has changed colors to a more attractive blue and offers clinicians a simple 3 step set up guide right on the device to easily and rapidly set up the resuscitator on a patient especially during an emergency type situation when time is of the essence. For more details, visit the VORTRAN Medical website www.vortran.com

Circadiance Launches the SleepWeaver 3D Soft Cloth CPAP Mask

Circadiance announced that it has launched the SleepWeaver 3D Soft Cloth CPAP Mask in the US. This launch follows the recent FDA 510(k) clearance to market for this mask. The



airway pressure (CPAP), AutoCPAP or Bi-Level therapy. It is intended for single-patient reuse in the home and singlepatient reuse in the hospital/ institutional environment. It is indicated for use in patients greater than 66lbs (30kg).

Oscillating Positive Expiratory **Pressure Device** Launched D R Burton Healthcare Products LLC announced the launch of the iPEP Oscillating Positive Expiratory Pressure (OPEP) device, which uniquely combines **OPEP** and Incentive Spirometer therapies to address all-three respiratory needs: lung expansion, treatment of atelectasis, and secretion clearance. "The iPEP system represents a breakthrough in airway secretion clearance therapy by providing patented volumetric-

SleepWeaver 3D mask addresses the need in the market for a mask that creates a comfortable seal on many face types while providing the features that promote user compliance to CPAP therapy. SleepWeaver 3D is soft, light, quiet and does not cause facial irritation from plastic. "The SleepWeaver 3D Mask provides a soft, loose fitting, light weight, and great sealing alternative to the tight fitting, hard plastic masks. The mask is easy to fit, and unlike hard plastic masks you don't have to over-tighten the straps of the mask to get a great seal", stated David Groll,

based OPEP therapy. The iPEP takes the mystery out of OPEP therapy by providing patients and healthcare providers with biofeedback that measures the patient's inspiratory capacity during therapy," according to Dennis Cook, BSRT, RRT, CEO of D R Burton. Along with a slow-coached inhalation, the iPEP provides superior Expiratory Flow Bias, a key driver of secretion clearance outlined in a recently published study. The iPEP system includes a palm-sized PocketPEP, a compact OPEP device for active patients for use at home to help prevent

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pulmonary-related readmissions. Cook explains, "There is a need to prevent pneumonia in high risk patients, such as postoperative and patients with increased mucous production. The D R Burton family of OPEP products are designed to reduce the risk of not only hospital acquired pneumonia, but also reduce risk of pneumonia at home after discharge." D R Burton met with clinicians to discuss these products both at the American Thoracic Society International Conference on May 19-24 in Washington, DC and at the National Teaching Institute & Critical Care Exposition on May 22-25 in Houston, TX. (Reference: Pursley, DM, Analysis of three Oscillating Positive Expiratory Pressure Devices During Simulated Breathing, Respiratory Therapy 2017; Volume 12, No. 1, 52-56.)

Sleep Apnea Increases Health Risks

Central sleep apnea (CSA) may double or triple the risk of atrial fibrillation (AF), researchers say. Previous studies have shown a high prevalence of AF in patients with obstructive sleep apnea (OSA). CSA has been linked with AF in patients with heart failure, but whether the association exists in the general population hasn't been clear. Dr Susan Redline of Brigham and Women's Hospital in Boston and colleagues investigated the link between OSA, CSA and incident atrial fibrillation in close to 3,000 adults over age 40 (mean age 63, 55% women, 86% white). Close to half the participants had at least mild OSA; about onefifth had moderate or greater OSA (apnea-hypopnea index of 15 or higher). Seventy-four participants (2.5%) had CSA, defined as a central apnea index of 5 or higher; 84 (3%) had Cheyne-Stokes respiration, and 135 (4.6%) had CSA or Cheyne-Stokes respiration. Over a median follow-up of 5.3 years, 338 people were diagnosed with AF at a median of 1817 days after the baseline assessment, as reported online July 3 in the Journal of the American Heart Association. Patients who developed AF were older, more likely to have high blood pressure and/ or diabetes, take heart medicines, and have a previous history of heart disease, heart failure or stroke compared to those who didn't develop AF.

Childhood Asthma Risks

An analysis from the Bogalusa Heart Study suggests childhood asthma is independently associated with increased left ventricular (LV) mass in adulthood, a well-established predictor of major CV events and death. "The most important implication of this finding is that prevention and treatment of asthma in the early stages of life is very important to reduce the risk of heart disease in adulthood; that is the take-home message," senior author Dr Lu Qi (Tulane University, New Orleans, LA and Harvard University School of Public Health, Boston, MA) said. Dr John Gottdiener (University of Maryland Medical Center, Baltimore) observed that the difference in LV mass index between adults with a history of childhood asthma and nonasthmatics was only about 8%. "Although this difference would by itself confer a relatively small incremental risk of incident CVD (about 1.08-fold increase) based on Framingham Heart Study data, in large populations with major comorbidities, the public-health implications could be substantial," he said. The incidence of asthma in children has nearly doubled since 1980, and its prevalence is estimated at nearly one in 10 children and 7% in adults, Gottdiener noted. Despite this, the investigators point out that the number of studies specifically examining the relationship between asthma and LV hypertrophy or heart failure (HF) can be counted on one hand. The team was interested in examining HF but because of too few cases in the Bogalusa Heart Study, LV mass was used as a surrogate marker, Qi said.

Respiratory Therapy Welcomes Industry Leader to Advisory Board

Dan Van Hise, Vice-President of Marketing with Chart Industries' BioMedical Division based in Ball Ground, GA, has joined the Editorial Advisory Board of Respiratory Therapy. The BioMedical division includes CAIRE Inc., a globally-recognized brand in oxygen therapy and manufacturer of portable and stationary oxygen concentrators, and liquid oxygen therapy systems. Dan has been an RRT since 1981, beginning his career as a staff therapist at Beth Israel Hospital in Boston and then quickly moving up the ladder to the position of Shift Supervisor and Clinical Educator. He then moved to several other hospitals in the New England Area in management roles, including the Emerson Hospital and the Elliott Hospital. During this time, he also became more involved in Neonatal and Pediatric Respiratory Care and early on became one of the first Neonatal-Pediatric Specialists. Following this achievement, Dan then moved to Colorado to serve as the first Neonatal Respiratory Supervisor at CU Medical Center (University of Colorado). It was during this time that he became an expert in neonatal lung function and was a key contributor in the design of a product called VenTrak that was sold to Novametrix Medical Systems. Since 1992, Dan has been highly involved in the marketing and design of Respiratory Products including mechanical ventilators, oxygen therapy devices, CPAP devices, non-invasive ventilators, and several respiratory diagnostic devices. He is also very active with the AARC International Committee and strongly supports the growth of the Respiratory Care profession and industry.

Connections Found Between Migraines and Sleep Apnea

New data suggest that patients with migraine, especially chronic migraine, are at increased risk for sleep disturbances, including sleep apnea (SA). About 37% of patients with migraine responding to a survey were deemed to be at high risk for SA, which is much higher than estimates in the general population. And because over 75% of migraine respondents with SA were diagnosed by a physician, "it may be worthwhile to start asking our patients about this," said Dawn C Buse, PhD, a licensed clinical psychologist and associate professor, Department of Neurology, Albert Einstein College of Medicine of Yeshiva University, New York City. "We haven't tested this yet, but the hope is that if sleep apnea is associated with more frequent headaches, treating sleep apnea might benefit headache." Dr Buse, who is also director of behavioral medicine for the Montefiore Headache Center in New York City, presented the new results from the Chronic Migraine Epidemiology and Outcomes (CaMEO) study at the Congress of the European Academy of Neurology (EAN) 2017. Both depression and anxiety have a bidirectional relationship with migraine, Dr Buse told delegates. Such a relationship also exists in sleep disorders; sleep disorders can aggravate migraine and migraines can worsen sleep disorders. Researchers recruited participants from an online panel by using quota sampling. Survey invitations were sent to 16,763 CaMEO study respondents, of whom 12,810 provided valid data. Researchers divided participants into those with episodic migraine (EM) and those with chronic migraine (CM) on the basis of headache frequency; headache on 15 or more days a month was considered CM. The analysis included 11,699 participants with EM and 1111 with CM. Participants were typical of online survey populations, said Dr Buse. For example, their average age was about 42 years. But there were some differences between the EM and CM groups. For example, the CM group contained more women, and, not surprisingly, said Dr Buse, those with EM were significantly more likely to

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be employed. "Also not surprising was that our CM folks are more likely to have a high BMI [body mass index]," she said. Participants completed baseline and 3-month follow-up surveys now to over 1.5 years. Risk for SA was assessed as high or low by using the Berlin Scale for Sleep Apnea. On the basis of this scale, 37.0% of respondents were at high risk for SA (EM, 35.6%; CM, 51.8%; P < .001). This risk for SA "is quite high compared population estimates," which can be as low as 9%, commented Dr Buse.

Teen Depression and Poor Breathing Linked

Sleep-disordered breathing (SDB) may play a role in persistent depressive symptoms and poor response to standard pharmacologic treatments in adolescents, new research suggests. Screening adolescents with treatment-resistant depression (TRD) for SBD "may be clinically valuable, since SDB is readily treatable," said Teena Chase, MD, PhD, Department of Psychiatry, University of Ottawa, Ontario, Canada, during her oral presentation here at SLEEP 2017: 31st Annual Meeting of the Associated Professional Sleep Societies. Diagnosing and treating SDB may improve clinical outcomes early in the course of mood disorders in adolescents and lead to better long-term prognosis, she said. The prevalence of SDB in the adolescents is estimated to range from 1% to 7%, but data are inconsistent. Major depressive disorder affects 5% to 8% of adolescents, and 40% may be treatment resistant. A recent meta-analysis found a significant relationship between depressive symptoms and obstructive sleep apnea (OSA) in children. To investigate further, Dr Chase and colleagues did a retrospective chart review, exploring breathing disturbances during sleep assessed with polysomnography in adolescents with TRD and their relation to depressive symptom severity. Participants were 20 outpatient adolescents with TRD (no response to two 6-week trials of antidepressants) and 20 healthy controls matched for sex and age. The severity of depressive symptoms was rated on the Beck Depression Inventory (BDI-II). They found that rates of SDB (respiratory disturbance index > 10) were significantly higher in the TRD group than the control group (50% vs 15%; P =.018). In the TRD group, respiratory disturbances correlated with depressive symptoms (controlling for body mass index, r =0.59; P = .007). Interventional studies are required to determine whether SDB treatment could improve clinical outcomes early in mood disorders, Dr Chase said.

Big Data Yields Big Insights for Treatment of Central Sleep Apnea

According to a new ResMed-sponsored (NYSE:RMD) study, people with treatment-emergent central sleep apnea (CSA) have a significantly greater risk of terminating positive airway pressure (PAP) treatment. Researchers found that 3.5 percent of patients had CSA during the first 90 days of PAP therapy. The study, Trajectories of Central Sleep Apnea during Continuous Positive Airway Pressure and Association with Therapy Termination: A Big Data Analysis, was presented today at the 2017 American Thoracic Society International Conference. This analysis highlights the importance of: Untreated sleep apnea increases the risk of other chronic diseases known for being prevalent with sleep apnea, including drug-resistant hypertension (83 percent), morbid obesity (77 percent), type 2 diabetes (72 percent) and stroke (62 percent). Findings from the largestever study of patients with treatment-emergent CSA, presented at the April 2017 European Respiratory Society and European Society of Sleep Research conference showed that switching treatment from continuous positive airway pressure (CPAP)

to adaptive servo-ventilation (ASV) therapy significantly improved the patient's adherence to therapy. It also showed that those with treatment-emergent CSA who switched from CPAP to ASV used their therapy longer and had significantly fewer apneas (breathing stoppages or reductions) during sleep. "This study provides the most robust view available on the prevalence of CSA in patients on PAP therapy," said Dr Carlos Nunez, ResMed's chief medical officer. "The findings in this new research, combined with the research presented in April 2017, underscore the importance of keeping patients on therapy through regular monitoring, and rethinking the conventional wisdom on therapeutic options based on each patient's disease severity." The new analysis defined three groups among patients with CSA - emergent, persistent and transient - based on whether the condition was present at the start of therapy or emerged during the first 12 weeks. All three groups showed a significantly higher risk of terminating their therapy than those without CSA. The risk was highest among the emergent group, whose CSA only became apparent during treatment, and were 1.7 times more likely to terminate their therapy than those without the condition. The study authors included: Atul Malhotra, University of California San Diego, United States; Peter Cistulli, University of Sydney, Australia; and Jean-Louis Pépin, Grenoble Alpes University, France. A retrospective analysis used anonymous, aggregated telemonitoring data from a US positive airway pressure therapy database, (ResMed AirView[™]) and analyzed it for the presence or absence of CSA during CPAP therapy at baseline (week 1) and after 12 weeks. Session data included weekly values by averaging within each week for each patient. Defined patient groups were: OSA, emergent CSA, persistent CSA and transient CSA. Groups were compared to identify risk factors for different forms of CSA, and adherence and therapy termination rates were determined. Patients with any form of CSA during CPAP were at higher risk of terminating therapy in the first 90 days versus those who did not develop CSA (hazard ratio 1.7 for emergent CSA, 1.4 for persistent CSA and 1.3 for transient CSA; all p<0.001). Obstructive sleep apnea (OSA) and central sleep apnea (CSA) are the two most common types of sleep apnea, a condition that results in repetitive pauses in breathing during sleep. OSA is a sleep disorder in which the throat muscles relax, block the airways and stop the flow of breath during sleep. CSA is a sleep disorder in which the brain does not transmit the "breathe" signal to the muscles that control breathing during sleep. In either situation, the lack of oxygen causes the person to wake up to catch their breath and start breathing again, interrupting continuous sleep. This may occur multiple times in an hour. In some patients with OSA, CSA may emerge and only become apparent during CPAP therapy. This was recognized in the third edition of the International Classification of Sleep Disorders and called "treatment-emergent CSA".

VP Joins ARCF Board

Drive DeVilbiss Healthcare's Vice President of Global Respiratory and Sleep, Joe Lewarski, was recently elected to the American Respiratory Care Foundation Board of Trustees. The American Respiratory Care Foundation (ARCF) is dedicated to promoting respiratory health through the support of research, education, and patient-focused philanthropic activities in respiratory care. ARCF trustees are appointed by the AARC President upon ratification of the AARC Board of Directors. Lewarski, a registered respiratory therapist and Fellow of the American Association for Respiratory Care (AARC), has served multiple terms on the American Association for Homecare (AHH) board

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1 Dunne R et al. Aerosol dose matters in the Emergency Department: A comparison of impact of bronchodilator administration with two nebulizer systems. Poster at the American Association for Respiratory Care. 2016



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Women With SDB Less Likely to Have SA Diagnosis

Women with sleep-disordered breathing (SDB) symptoms are less likely than men to be diagnosed with sleep apnea, or to receive treatment for it, new findings show. "Snoring females with daytime sleepiness may be underdiagnosed and undertreated for sleep apnea compared with males, despite running a similar risk of developing hypertension and diabetes," Dr Eva Lindberg of Uppsala University in Sweden, the lead author of the new study, said. While SDB occurs roughly twice as often in men than in women, women account for only about 20% of patients at sleep clinics, Dr Lindberg and her team note in their report. There has been little study of the health effects of SDB in women, the researchers add, but they may be similar to those in men and possibly worse. The researchers looked at data from the Respiratory Health in Northern Europe (RHINE) study on 10,854 men and women born between 1945 and 1973 who completed questionnaires in 1999-2001 and again in 2010-2012. People with a sleep apnea diagnosis at baseline were excluded from the study. During the study period, 25% of men and 14% of women with SDB symptoms were diagnosed with sleep apnea, and 17% of men and 11% of women with SDB received treatment. At follow-up, 6% of men and 3% of women with SDB received CPAP. Factors associated with receiving treatment included age, body mass index, SDB symptoms at baseline and weight gain. However, female gender was linked to a lower likelihood of treatment (adjusted odds ratio 0.3). SDB symptoms were associated with an increased risk of hypertension and diabetes (aOR 1.5 for each) in both men and women, regardless of age, body mass index, smoking and weight gain. "We recommended physicians to be aware of sleep-disordered breathing also in females and ask females about symptoms of snoring and daytime sleepiness, and refer those with positive answers for sleep apnea recordings," Dr Lindberg said. She noted that data in the current study was from self-report. "We have continued by performing full-night polysomnography on female and male cohorts, matched for age and BMI, to be able to compare men and women with verified sleep apnea for symptom profiles and health consequences."

Optical Coherence Tomography Tested on Respiratory System

Research conducted by Yuye Ling, MS; Xinwen Yao, MS; Ute A. Gamm, PhD; Emilio Arteaga-Solis, MD; Charles W. Emala, MD; Michael A. Choma, MD, PhD; and Christine P. Hendon, PhD was selected as Editor's Choice in the March 2017 issue of Lasers in Surgery and Medicine (LSM). The manuscript titled, "Ex vivo visualization of human ciliated epithelium and quantitative analysis of induced flow dynamics by using

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optical coherence tomography" was published in LSM, the official journal of the American Society for Laser Medicine and Surgery, Inc. (ASLMS). Ciliated epithelium plays a crucial role in removing pathogens from the pulmonary tract. In this paper, a 3D optical imaging technology termed optical coherence tomography (OCT) was used to analyze ciliary functions, which showed a great potential to help understand and diagnose various pulmonary diseases. "Motile cilia are microscale protrusions from ciliated epithelium and are found on the linings of various human organs such as the respiratory tract, fallopian tubes, epididymis, and middle ear, and are essential for organizing mucous or water flow across the epithelial surface. The process of mucociliary clearance is an important self-defense mechanism of the respiratory system. Failure of mucociliary clearance, which is found in patients that suffer from primary ciliary dyskinesia, cystic fibrosis, and chronic obstructive pulmonary disease, often leads to chronic infections and impaired lung function," stated Dr Hendon. "This manuscript presents the first demonstration of using optical coherence tomography (OCT) to visualize and quantify ciliary motion and mucociliary flow on human tissue. OCT provides high resolution imaging of biological tissues at high speed and with high sensitivity. We demonstrate quantitative data for ciliary functions such as cilia beat frequency and flow rate measurements from OCT image sets of ex vivo human trachea samples. The results also provided insights on the ciliary functions within healthy human trachea samples, encouraging follow-on studies of ciliary functional analysis by OCT." Dr Christine Hendon is an Assistant Professor of Electrical Engineering at Columbia University in the City of New York. For over 10 years, Dr Hendon's research has focused on optical coherence tomography system and image processing development with applications in cardiology, cardiac electrophysiology, and women's health.

Oxygen Device Developer for Battlefield Care

CAIRE Inc. has formally announced the launch of the new SAROS 15 oxygen concentrator for combat casualty care. The SAROS 15 is designed to replace oxygen cylinders and large oxygen generation equipment used in field hospitals, casualty evacuation, en route care, and on the battlefield. Standing at 33 inches tall and weighing 46 pounds, the device was developed for the US Air Force to generate up to 15 LPM oxygen, and operate via wall outlet (AC) power or by rechargeable battery power. The company says the unit can endure extreme temperatures and harsh conditions and sand, dust, salt fog, vehicle and aircraft vibration, all commonly found in modern military environments.

Connectivity Solution Announced

Instrumentation Laboratory announced the launch of its Customized Connectivity solution, GEMweb Plus 500, to hospitals and hospital networks around the world. From a single dashboard, GEMweb Plus 500 offers complete control of GEM Premier Critical Care testing systems, including new GEM Premier 5000 with Intelligent Quality Management 2 (iQMâ2), as well as connectivity to non-IL-manufactured devices at the point-of-care. Expanding upon the original GEMweb Plus platform, GEMweb Plus 500 offers enhanced mobility with accessibility from tablet devices, in addition to any networked analyzer or PC. Seamlessly integrating control of analyzers, test results and operators into one easy-to-use system, GEMweb Plus 500 simplifies and centralizes point-ofcare testing management. To ensure quality management, users can monitor iQM2 and iQM, including detection, correction and documentation of corrective actions in real-time. Facilitating accreditation, GEMweb Plus 500 automates multi-level operator authorization and full traceability of users, actions and competency certification. "GEMweb Plus 500 Custom Connectivity addresses the challenge of managing point-ofcare testing in hospitals today. Combining test results, analyzer and operator data, it offers Lab Managers and Point-of-Care Coordinators real-time control from anywhere, anytime, as well as seamless accreditation support," said Giovanni Russi, VP of Worldwide Marketing at IL. "Together with our new GEM Premier 5000 system, GEMweb Plus 500 Custom Connectivity delivers a complete Critical Care testing solution for improved patient care and efficiency." GEMweb Plus 500 supports integration with Hospital Information Systems, Laboratory Information Systems and Electronic Medical Records. Users can access data from any networked GEM Premier analyzer, including GEM Premier 5000, 4000 and 3500 systems, and non-IL devices in real-time. Connectivity to ROTEM, Hemochron and other IL systems is currently in development.

AARC EXECUTIVE PREVIEWS

Aerogen

Booth 637

What products will you be presenting at AARC?

Aerogen will be presenting our high performance aerosol drug delivery system, featuring vibrating mesh technology. These products include the Aerogen Solo and the Aerogen Ultra.

Are there any new products you wish to emphasize?

Aerogen is transforming patient care throughout the hospital. Aerogen's high performance aerosol drug delivery system can be used in multiple modalities for infants to adults. This year Aerogen is celebrating 20 years of high performance technology.

Why should AARC participants visit your display?

AARC participants should visit the Aerogen display to view a demo of our groundbreaking technology and to say hello to the AARC's long-time industry friend. Also at the Aerogen booth, information on a special event to celebrate 20 years of Aerogen technology.

Alere

Booth 101

What products will you be presenting at AARC? The epoc[®] Blood Analysis System.

Discuss educational/training materials you'll be offering We will have a dinner program with guest speakers again for 2017.

What speakers or papers will you be featuring?

- Patti DeJuilio, MS, RRT-ACCS, RRT-NPS, Clinical Director, Respiratory Care Services, Sleep Centers Northwestern Medicine Central DuPage Hospital
- Russelle A Cazares, MHA, RRT-NPS, Clinical Service Manager, Respiratory Care Services, Children's Hospital Los Angeles
- Clarke Woods, BS, RRT FABC, Director, Thoracic Surgery and Pulmonary Services, Pinnacle Health System

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Spend less time on your process and more time with your patients.

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To get an up close understanding of how bedside ABG testing can positively impact patient outcomes and improve clinician satisfaction.

DR Burton

Booth 244

What products will you be presenting at AARC?

D R Burton Healthcare, innovators in respiratory products, are showing our family of Oscillating Positive Expiratory Pressure devices:

- \bullet the $i PEP^{``}$ System including the PocketPEP
- the vPEP®

Are there any new products you wish to emphasize?

D R Burton Healthcare is introducing the iPEP[™], the only volume based Oscillating Positive Expiratory Pressure (OPEP) that provides patient feedback for more efficacious therapy. The iPEP includes the PocketPEP[™], ideal for patient OPEP therapy at home. All D R Burton OPEPS offers superior OPEP secretion clearance even for patients with low breath volumes.

What speakers or papers will you be featuring?

D R Burton Healthcare is showcasing the following papers:

- The Importance of Expiratory Flow Bias in Secretion Clearance - Pursley, DM, Analysis of Three Oscillating Positive Expiratory Pressure Devices During Simulated Breathing. Respiratory Therapy 2017; Volume 12, No. 1, 52-56
- The Importance of Volume Pursley, D Analysis of Tidal Volume and Expiratory Pressure during Oscillatory PEP Therapy in Healthy Subjects. Respiratory Therapy Vol. 11 No. 2 Spring 2016

Discuss educational/training materials you'll be offering

D R Burton Healthcare provides the following educational materials to support OPEP therapy with our devices:

- Quick Start Instructional Tear Sheets, ideal for patient education
- Posters featuring OPEP instructions for use
- Instructional videos

Why should AARC participants visit your display?

Visit D R Burton Healthcare at booth #244 to sign up for your free sample of the iPEP and vPEP systems for superior OPEP therapy.

Electromed

Booth 359

What products will you be presenting at AARC?

Electromed will present the SmartVest® SQL® Airway Clearance System at AARC congress 2017. The SmartVest system uses high frequency chest wall oscillation (HFCWO), a proven therapy prescribed for people with impaired airway clearance, that helps clear the lungs of excess mucus, reducing the risk of respiratory infections and hospitalizations.

The SmartVest system consists of an inflatable garment connected to a programmable air pulse generator. During

therapy, the SmartVest garment delivers a rapidly repeating pulse of air, alternately squeezing and releasing the upper body. Each squeeze simulates a "mini cough," which acts to loosen, thin and propel mucus toward major airways, where it can be more readily expectorated or suctioned away.

Are there any new products you wish to emphasize?

Electromed recently announced the late June launch of the SmartVest SQL with SmartVest Connect[™] wireless technology, a personalized HFCWO therapy management portal for patients with impaired airway clearance. The SmartVest SQL with wireless technology features built-in cellular connectivity, offering healthcare teams and patients access to treatment information to better collaborate in making patient-centered care decisions. SmartVest Connect is available online at https:// connect.smartvest.com to pediatric and cystic fibrosis patients using a wirelessly enabled SmartVest SQL system.

SmartVest Connect enables patients to track progress of their therapy plan and includes a real-time SmartVest Score and easy-to-read goal reports that provide an in-depth look at performance. Created to encourage patient engagement, SmartVest Connect provides feedback for patients to take an active role in their HFCWO therapy, fostering improved therapy adherence. Additionally, SmartVest SQL with SmartVest Connect is simple, intuitive, and designed to automatically update following completion of a therapy session: just plug it in.

What speakers or papers will you be featuring?

In two recently published case review outcome-based studies, the clinical effectiveness of SmartVest was proven by comparing a year of exacerbation-related healthcare utilization, medication, and respective costs for non-cystic fibrosis bronchiectasis patients to a standard of care control. These outcome-based studies demonstrated a significant reduction in healthcare utilization and its associated costs when bronchiectasis patients were treated with SmartVest for one year: 57% reduction in antibiotic prescriptions, 59% decrease in hospitalizations, and 60% fewer emergency department visits. And although it was not a part of the protocol, 68% of the patient population unreservedly reported a significant improvement in their quality of life after a year of using SmartVest, representing a potentially appreciable impact on overall patient well-being.

Why should AARC participants visit your display?

Participants will learn firsthand what makes the SmartVest system a preferred choice for HFCWO therapy through hands-on demonstration of the SmartVest SQL. Managing symptoms like chronic cough, shortness of breath and stopping the cycle of recurrent respiratory infections with the SmartVest system can significantly reduce healthcare utilization and associated costs.

FloSure Technologies, LLC

Booth 815

What products will you be presenting at AARC?

The Simex Subglottic Secretion Aspiration System is available as cuff S and cuff M. The system is the only fully automated, intermittent device cleared by the FDA specifically for the aspiration of subglottic secretions which pool above the ballooned cuff in mechanically ventilated patients and can enter the lower airways, causing pneumonia, and a greatly increased risk of mortality.



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Are there any new products you wish to emphasize?

A recently completed randomized, controlled trial of the Simex automated subglottic aspiration system, demonstrates the combined potential of using the device along with tracheal tubes with integrated suction ports. The volume of secretions removed with the system are up to 10-fold those previously removed via traditional suction methods. The Simex Subglottic Secretion Aspiration System has been used for over 6 years and in over 1500 patients in both ICU and long-term care settings.

Discuss educational/training materials you'll be offering.

Booth attendees can meet Jerry Gentile, BSRT, BSHA, MBA, MPH, EdD(c), RT, RRT, to ask questions and learn more about his clinical experience with the Simex system and the results of his RCT. Demonstrations of the product and copies of published articles will be available.

Why should AARC participants visit your display?

The benefits of subglottic secretion drainage (SSD) are well documented, but until recently, SSD has proved impractical to implement adequately. Booth attendees will gain a clear understanding of how use of the automated system can make SSD a practical protocol and standard of care. The Simex system reduces patient risk, improves patient comfort, allows for more rapid weaning from mechanical ventilation, and for faster restoration of the ability to swallow, and to speak. It effectively reduces staff burden and provides overall cost benefits to the institution.

Hamilton

Booth 601

What products will you be presenting at AARC?

- HAMILTON-G5
- HAMILTON-C3
- HAMILTON-C1
- HAMILTON-T1
- HAMILTON-MR1
- HAMILTON-H900
- IntelliCuff

Are there any new products you wish to emphasize? • HAMILTON-H900

Discuss educational/training materials you'll be offering.

- Hamilton eCollege- free and open e-learning website for online education on mechanical ventilation and ventilators. Everyone is eligible for registration.
- Transpulmonary pressure measurement demonstration

Why should AARC participants visit your display?

Learn about the new exciting new features available on the Hamilton platform. Live demonstration of transpulmonary pressure measurement. We will be serving waffles and coffee at the booth!

Hill Rom

Booth 235

What products will you be presenting at AARC?

• Monarch[™] Airway Clearance System – Revolutionary new mobile technology for airway clearance

- The Vest[®] Airway Clearance System
- MetaNeb[®] System
- Others?

Are there any new products you wish to emphasize?

The Monarch[™] Airway Clearance System. Began launch in May, 2017.

Discuss educational/training materials you'll be offering

- Hands-on demonstration of the Monarch System at the booth.
- Video animation of the Monarch System mechanism of action at the booth.
- Video testimonials of people using the Monarch System as a revolutionary new mobile technology for airway clearance.
- Educational and marketing materials available to electronically send to customers (clinician brochure, characterization study data, fitting guides, etc.).

What speakers or papers will you be featuring?

- Video testimonials shown at the booth: People using the Monarch System as a revolutionary new mobile technology for airway clearance and how it has impacted their daily lives.
- No plans for a live speaker at this time.

Why should AARC participants visit your display?

 Introducing the Monarch Airway Clearance System — Revolutionary new mobile technology that works. This Monarch System is a high frequency chest wall oscillation (HFCWO) therapeutic device. The therapy combines mobility with targeted kinetic energy and airflow to thin and mobilize secretions from the airways. By allowing patients to move about freely during therapy, it empowers them to take control of their therapy — and lives. Connected in care to you, their health care team, via the VisiView[™] Health Portal patients can collaborate in their treatment planning. A game-changer in HFCWO.

Instrumentation Laboratory

Booth 213

What products will you be presenting at AARC?

- GEM[®]Premier[™] 5000 system
- GEMweb®Plus 500 Custom Connectivity
- Avoximeter[®]
- Hemochron Elite[®]

Are there any new products you wish to emphasize?

GEM Premier 5000 with Intelligent Quality Management 2 (iQM®2)

Discuss educational /training materials you'll be offering:

Pre-Analytical Training Kit for optimizing results in Critical Care testing.

Why should AARC participants visit your display

To learn about our entire Critical Care product portfolio, including the recently FDA-approved GEM Premier 5000 system with iQM2.

What speakers or papers will you be featuring?

Paper: "Measurement of Total Hemoglobin Reduces Red Cell Transfusion in Hospitalized Patients Undergoing Cardiac Surgery: A Retrospective Database Study" published in Perfusion.

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References: 1. Burudpakdee C, et al. Pulmonary Therapy 2017; 3(1): 163–171. and Svenningsen S. et al. COPD 2016;13(1):66 – 74. Words or phrases accompanied by [™] and [®] are trademarks and registered trademarks of Monaghan Medical Corporation or an affiliate of Monaghan Medical Corporation © 2017 Monaghan Medical Corporation. Booth 460

What products will you be presenting at AARC?

We are featuring the AffloVest, our fully mobile HFCWO airway clearance device. The AffloVest pioneered mechanical oscillation airway clearance therapy for patients with severe respiratory diseases such as bronchiectasis, cystic fibrosis and other neuromuscular diseases.

The AffloVest is battery operated and uses Direct Dynamic Oscillation technology that closely mimics hand CPT to help mobilize and clear secretions, allowing for full freedom of mobility during treatment. The AffloVest features 8 built-in oscillating modules that, for the full range of sizes offered, are anatomically placed to target the lobes of the lung and allow for targeted customized treatment plans using the digital controller.

Are there any new products you wish to emphasize?

We are introducing now our next generation AffloVest which is much lighter, quieter, more efficient yet smaller profile battery, long life — state of the art motors, and improved patient ease of use. This new AffloVest is on average 2 pounds lighter (over 20% weight reduction) than the previous version which was already by far the lightest mobile, mechanical oscillation vest on the market. This next generation AffloVest is also sleeker, more slim fit, utilizing streamlined components and tailored styling.

Discuss educational/training materials you'll be offering.

Conference attendees can stop by the booth to learn more about several new educational initiatives we have recently introduced. This includes accredited training for RTs and case managers, and peer to peer physician modules on the symptoms and treatment of bronchiectasis.

What speakers or papers will you be featuring?

Visitors who come see us can obtain copies of 3 independent clinician papers that show lung function score improvement and this improvement being maintained over a large time period with 2 separate groups of cystic fibrosis patients that switched to the AffloVest after using air bladder technology. We are in the process of publishing even more data including data from an IRB approved study.

Why should AARC participants visit your display?

Hands on demos of the AffloVest technology are a great way to see and feel firsthand the effectiveness of this treatment. Participants will see why AffloVest is becoming the state of the art oscillation treatment method. Visitors to our booth will also have access to supporting clinician papers, product information, resources for prescription and reimbursement, and information on new programs we offer for patients and clinicians.

Instrumentation Industries

Booth 221

What products will you be presenting at AARC?

We will be presenting our complete line of Inline MDI Adapters, as well as Silicone Connectors, Christmas Tree Connectors, our Instant Flow Valves, Pilot Tube Repair Kit, Cuff Pressure Monitors, Vacuum/Pressure Gauges and NIF Meters to name some of the items at our Booth.

Are there any new products you wish to emphasize?

We have just received FDA approval for our latest Inline Adapter. This adapter now allows users of the Combivent[®] Respimat[®] Inhaler to be administered in line through a ventilator circuit.

Discuss educational/training materials you'll be offering.

We will have product information sheets as well as the actual products at our booth for participants to have a hands on experience.

Why should AARC participants visit your display?

We have everything needed to make Respiratory Therapy work for you. With our selection of Connectors and Adapters, accessories and ventilator products, you will be able to make any connection easily. We have many difficult to find parts that are essential to do your job.

Medtronic

Booth 413

What products will you be presenting at AARC?

Certainty in uncertain situations is something you need wherever you are. And it's why Medtronic is excited to showcase a suite of airway monitoring and management solutions. Medtronic capnography and pulse oximetry monitors offer early insights into your patient's ventilatory status, so you can act faster and intervene sooner. And if your patient can't breathe sufficiently, Medtronic airway access and ventilation technology is there to help. To help simplify time-intensive patient care processes and help mitigate harmful and costly adverse events, Medtronic clinical monitoring and clinical decision support (CDS) solutions are available.

Clinician time and resources may be limited, but a patient's needs are not. Microstream[¬]-enabled capnography monitoring provides an early warning of opioid-related respiratory depression¹, and may offer clinicians the opportunity to provide care sooner and quickly determine how to intervene, reducing risk and potentially saving time, money and lives. Enhance capnography monitoring with Omnistream[¬] etCO₂ sampling lines with Uni-junction[¬] technology to capture quality etCO₂ samples from either the nares or the mouth, while delivering oxygen.

The Nellcor[®] pulse oximetry system with OxiMax[®] technology takes a dramatic departure from standard pulse oximetry technology by moving signal calibration data out of the monitor and into the sensor. The Nellcor[®] pulse oximetry system is designed to offer accurate, reliable readings even during low perfusion and other forms of signal interference. It is engineered to be intuitive, easy-to-read, and offer easy access to critical measurements needed to help keep patients safe.

The Puritan Bennett[™] 980 ventilator is designed to promote more natural breathing^{*} and may help improve patient comfort.² This system is engineered to deliver sensitive, precise breaths to help meet the needs of both the patient and the clinician.

You do your best to avoid airway complications. You know they can be associated with significant patient morbidity and unnecessary expense.³⁵ But sometimes they can occur when you least expect.^{6,7} With the McGRATH[™] MAC video laryngoscope, you can be better prepared for the unexpected.

Allegiance Bird Datex EME VIOSYS BEAR Pulmonetic AirLife VOICE VOICE VUNTUS Isothermal Micro Jaeger Sensormedics Vital Signs Engstrom

WE ARE BREATHING NEW LIFE INTO RESPIRATORY CARE.

Allow us to introduce you to our company, Vyaire Medical. While our name may be new to you, our products have been used in and around your medical center for decades for the diagnosis, treatment, rehabilitation and monitoring of respiratory conditions in every stage of life. / Learn more about us by visiting vyaire.com.

Combine confidence with simplicity and convenience—so your first attempt is your best.

During AARC 2017, please stop by the Medtronic booth to learn more about our family of Shiley[™] airway products, including our newest tracheostomy solution, Shiley[™] Flexible adult tracheostomy tubes. They now feature a softer, clear flange that promotes airflow around the stoma, as well as other enhancements including our patented TaperGuard[™] cuff technology.

Also, learn about how our TaperGuard^T cuff technology provides a significant reduction in microaspiration⁸ and see the difference for yourself during a product demo.

Medtronic is committed to providing respiratory monitoring and airway and ventilation management solutions across the continuum of care in a variety of settings. From acute to longterm care, to home care and emergency medical services, Medtronic is dedicated to partnering with clinicians to improve clinical outcomes and positively impact patient quality of life beyond the hospital.

Are there any new products you wish to emphasize?

Launched in early 2017, the Capnostream[™] 35 portable respiratory monitor offers comprehensive respiratory monitoring to help you respond earlier and intervene sooner if your patient is showing signs of respiratory compromise. The monitor provides information to help support clinical decisions and may improve workflow.

Medtronic launched the Vital Sync[™] 2.6 monitoring and clinical decision support (CDS) solution this summer, and will demonstrate this innovative system live at AARC 2017. This innovative solution is designed to simplify time-intensive patient care processes and help clinicians mitigate harmful and costly adverse events. Integrated and customizable, the Vital Sync[™] CDS solution 2.6 combines remote monitoring software with monitoring devices and a series of CDS mobile applications to help improve clinical protocol implementation and management of patients on medical-surgical floors and in the ICU. You will have the opportunity to experience the new weaning readiness and spontaneous breathing trial apps that are part of the clinical decision support tools included in Vital Sync[™] CDS solution 2.6 — both in the booth and at the tech suite.

Puritan Bennett[™] 980 ventilators enable patients to breathe more naturally^{*} through some of the most innovative breath delivery technology available.

Discuss educational/training materials you'll be offering.

Medtronic will offer educational opportunities, so be sure to stop by booth 413 for the latest information designed to help support your clinical decisions, enhance patient safety and improve workflow. Medtronic also offers both accredited and nonaccredited online training designed to help clinicians provide innovative solutions and improve patient care. Get started now at www.Medtronic.com/Covidien/Education.

Medtronic has been a proud sponsor of the AARC National Sputum Bowl Competition for more than 30 years and counting. The Sputum Bowl is a contest in which challengers can test their respiratory care knowledge and compete for the most points under the double-elimination bracket system. We look forward to supporting another exuberant competition this year starting on October 4, 2017.

What speakers or papers will you feature?

Meet guest speakers at Medtronic booth 413 and learn from the experts in your field. Also, join us for a breakfast symposia on early mobility for ventilated patients on Friday, October 6. Stop by our booth for more information on the symposia.

Why should AARC participants visit your display?

No matter how many (or few) clinicians may be on the floor, hospital staff must strive to minimize events that can lead to longer hospital stays or transfers to the ICU. In every circumstance, clinicians must act quickly, safely, effectively and efficiently to meet the needs of a wide variety of patients. Experience firsthand and learn how Medtronic can be your trusted partner with solutions designed to optimize clinical efficiency and outcomes.

*Compared to conventional mechanical ventilation (VC,VC+,PC,PS).

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- 7 Huitink JM, Lie PP, Heideman I, et al. A prospective, cohort evaluation of major and minor airway management complications during routine anaesthetic care at an academic medical centre. Anaesthesia. 2017;72(1):42–48.
 8. FDA 510(k) clearance.

MGC

Booth 429

What products will you be presenting at AARC? MGC Diagnostics[®] will display recent product developments and technology advancements, including systems for pulmonary function testing and gas exchange testing. Pulmonary Function Testing systems include: The Platinum

Karisma Got Her Groove Back



Not only can Karisma dance to her favorite song, but now thanks to her Passy Muir® Valve, she can sing along too.

To find out how the Passy Muir® Valve can help restore your patient's voice, enhance swallowing, reduce aspiration, expedite weaning and decannulation, and significantly enhance quality of life, visit www.passymuir.com







(Aqua Color™)

Elite[™] body plethysmograph and the Ultima Series[™] cardiorespiratory diagnostic systems. Both have RTD[™] real time diffusion technology which delivers clinically significant graphic data and immediate results. Gas Exchange Testing systems include: The Ultima CPX[™] metabolic stress testing system, CCM Express[®] indirect calorimeter and the Ultima[™] CardiO2[®] gas exchange analysis system with integrated 12-Lead ECG. Our latest version of BreezeSuite[™] cardiorespiratory diagnostic software incorporates HIPAA — HITECH Security Safeguards to protect your patient's Identifiable Health Information. We will also be showcasing the CPFS/D[™] USB spirometer — a full function, portable spirometer and Resmon[™] PRO FULL FOT (Forced Oscillation Technique) device.

Are there any new products you wish to emphasize?

MGC Diagnostics will be highlighting the Resmon[¬] PRO FULL FOT which received FDA 510K clearance to market last year. The FOT is designed to provide medical professionals the ability to measure the mechanical properties of the respiratory system during normal tidal breathing, which provides a simple, effort-independent assessment for patients age 4 and up. The FOT helps to determine the degree of obstruction, the delta in inspiratory and expiratory reactance, heterogeneity, and bronchial reversibility with no forced maneuvers.

Discuss educational/training materials you'll be offering.

Managing the MGC Diagnostics[®] exhibit will be our best in class clinical, sales and support staff available to answer not only your product questions, but provide expert consultation for your clinical application and cardiorespiratory business needs.

Why should AARC participants visit your display?

MGC Diagnostics[®] delivers diagnostic solutions for detection, classification and management of cardiorespiratory patients worldwide. This singular focus guides our strategy and defines our commitment to customers, employees and shareholders. These attributes make us uniquely qualified to solve today's challenges and uncover solutions for tomorrow's opportunities.

Neotech

Booth 523

What products will you be presenting at AARC?

Neotech will be exhibiting some exciting new products this year, along with our core product line including the NeoBar[®] ET Tube Holder, Little Sucker[®] Oral and Nasal Suction Devices, Neotech RAM Cannula[®], EZCare[™] Softtouch Tracheostomy Tube Holder, and NeoGrip[®] Tubing and Cable Holder.

Are there new products that you wish to emphasize?

Neotech is excited to announce two new products! The Curved Sucker XL is the ideal suction device for pediatric care. The Curved Sucker XL offers a soft, flexible tip similar to a bulb syringe that is anatomically curved for better application to larger patients. We will also be featuring our exciting new NeoGlo[™] Transilluminator.

Discuss educational/training materials that you will be offering.

We will have Neotech catalogs, product sell sheets, and our team of Neotech clinical consultants that are available at our booth for hands on training on a variety of products.

Why should AARC participants visit your display?

Neotech loves our RTs and AARC is always one of the highlights of our year. We're excited to show off our new products and share some fun surprises, and we're proud to be celebrating our 30-year anniversary. Don't forget to stop by and grab your free product sample bag, some of our fun giveaways and learn about our exciting promotions! Be sure to get your discount promo code for a purchase of a NeoGlo and be the first to see our NeoHug product launching early 2018!

Nonin

Booth 608

What products will you be presenting at AARC?

We will be showing a variety of pulse oximetry and capnography products at AARC. Specifically, we will be showing the Onyx Vantage 9590, Go2 9570 and Nonin Connect Elite 3230 fingertip oximeters; the WristOx2 wrist worn oximeter; the PalmSAT 2500 handheld oximeter; the Model 7500 tabletop oximeter; the new RespSense II and LifeSense II capnographs; and all of our SpO2 sensors.

Are there any new products you wish to emphasize?

We are excited to share our new capnography solutions, the RespSense II and LifeSense II. We encourage attendees to come see the improvements we have made to these products!

Discuss educational/training materials you'll be offering.

Among the variety of materials we will have at our booth, we think attendees will be especially interested to read the Clinimark Study White Paper and learn how not all pulse oximeters perform alike.

Why should AARC participants visit your display?

We are excited to show attendees how Nonin pulse oximetry provides superior accuracy, durability and reliability in the widest range of patients; how our sensor durability can contribute to lower overall SpO2 costs; and to learn about our COPD STEP program.

Passy Muir

Booth 653

What products will you be presenting at AARC?

NEW Anatomical Demonstration and Teaching Model - Passy-Muir, Inc. (Irvine, CA) announces the release of its new tracheostomy pediatric airway model. The Tracheostomy Pediatric Airway Model (P.A.M.[™]) features pediatric appropriate anatomy and is designed for use by healthcare practitioners (HCP) to teach other HCP, students, families and patients about the young child airway and application of the Passy Muir® Valve. Accessories, including a PMV[®] 2001 (Purple Color[™]) Valve, syringe, pilot balloon label, cuffed tracheostomy tube and PMV[®] Secure-It[®] strap are provided to show a variety of tasks related to tracheostomy and use of speaking valves. A nasogastric tube is provided to show proper placement, and the tracheoesophageal wall is designed to demonstrate how overinflation of the tracheostomy tube cuff can cause undue pressure and other possible complications. Lightweight and conveniently sized, the new model is ideal for patient and family education, physician and staff competencies, hand-off communication and classroom instruction. Available November



Mercury Medical[®]

Focuses on developing innovative airway technology that provides real-world solutions and improved patient outcomes. Contact us today about these three proven lifelines from one trusted brand name.

FLOW-SAFE[®] II for PACU

The only totally disposable CPAP system with built-in pressure gauge to verify delivered pressure and pressure relief valve.

Fast, easy set-up.



AG Cuffill

Disposable Digital Cuff Pressure Gauge

The compact AG CUFFILL device digitally measures cuff pressure for assisting in controlling the volume of airway cuffs.

AG CUFFILL

naso-flo°

Only our unique nasopharyngeal airway device provides a built-in oxygen port for direct O₂ connection and higher FiO₂ delivery. Also available with Oxygen Port & EtCO₂ Connector with Filter.

Visit Mercury Medical at Booth #719 AARC Congress 2017 Indianapolis, Indiana October 4-7, 2017

FAILURE TO ADAPT

TO CHANGE CAN

CONSEQUENCES.

HAVE SERIOUS

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2017, visit www.passymuir.com for more information or to order.

Adapters from Passy Muir – Passy Muir, the manufacturer of the no-leak speaking valve offers two color-coded adapters to provide clinicians with an easy way to connect the Passy Muir[®] Valve in-line for mechanically ventilated patients. The PMV-AD1522[™] is a step-down adapter designed to connect the PMV[®] 007 (Aqua ColorTM) to a ventilator circuit containing an in-line suction catheter. The flexible, PMV-AD22[™] adapter is designed for use with the PMV[®] 2001 (Purple Color[™]). Both are latex free, and like all Passy Muir products, proudly made in the USA.

TRACHTOOLS[™] Communication App – This user-friendly app for iPhone, iPad, and Android is designed to facilitate patient communication and education, provide valuable information regarding tracheostomy, and foster patient participation in their care. For communication, the app features a speech board, which includes prerecorded phrases enabling patient communication at a touch of a button in user-defined male, female, or child voices. The communication features include an attractive and intuitive menu, and a custom phrase record option. For education, the app includes patient videos, a cleaning and care guide, and easy access to patient and clinician resources. Passy Muir provides the app to patients and clinicians free of charge from the App Store or Google Play.

New addition to the Toby Tracheasaurus[™] Pediatric Program – Passy Muir will be revealing a new addition to its popular Toby Tracheasaurus[™] Pediatric program. Featuring a pediatric tracheostomy tube and Passy Muir[®] Valve, the new Toby TracheasaurusTM plush puppet provides therapists with a lighthearted method to introduce children to tracheostomy and the Passy Muir Valve, while facilitating vocalization and enhancing therapeutic activities.

Are there any new products you wish to emphasize?

The PMV-AD1522[™] and PMV-AD22[™] Adapters, conveniently available at the same place as our valves: Available wherever you purchase other Passy Muir products, these adapters are designed to provide a secure connection between the Passy Muir Valve[®] and a tracheostomy tube, ventilator tubing, closed suction systems, or other adapters. Each adapter is latex free, color coded for easy identification, and provided in re-sealable, multiple unit packaging. The PMV-AD1522 is a step-down adapter designed to connect the PMV[®] 007 (Aqua Color[™]) to a T-piece type closed suction system. The flexible PMV-AD22 adapter is designed for use with the PMV[®] 2001 (Purple Color[™]). All Passy Muir products are proudly made in the USA.

Discuss education/training materials you'll be offering:

- New icon-based reference bibliography with citations of up-to-date research specific to tracheostomy. Colorful icons make it easy to quickly find a reference by category and application.
- Passy Muir Pocket Guide. Handy pocket-sized Assessment & Placement, Accessories & Connections guide featuring useful information pertaining to patient selection, airway assessment and Passy Muir[®] Valve placement. Includes information regarding ventilator connections, clinical benefits, care and cleaning, and therapeutic techniques.

• Journal of Aerodigestive Health. Written by clinical professionals for clinical professionals, the journal features papers and research by respiratory therapists, speech-language pathologists, and physicians on the latest clinical information for working with patients with tracheostomy and the Passy Muir[®] Valve.

If interested in contributing an article, or to learn more about how you can be involved in the journal, please email aerodigest@passymuir.com

Passy-Muir, Inc. is committed to improving the quality of life for tracheostomized and ventilator-dependent patients. To meet this mission, we provide free education through on-line self-study webinars and onsite inservices tailored to meet the needs of your facility. These educational opportunities are free and provide CEUs for respiratory therapy, speech pathology, and nursing. Visit www.passy-muir.com/education for more information.

We also offer a national seminar at a nominal cost which provides 8 CEUs, delivers state-of-the-art education from both an RRT and SLP through didactic lecture, with patient videos, hands-on instruction, specialized training in ventilator application and dysphagia management, and case studies to synthesize all the information. Don't miss out on the 2017 opportunity that is still available: October 21st (Adult) in New Orleans, LA; Stay tuned for a 2018 seminar near you — with dates and places to be announced soon. Visit www.passymuir.com for more information.

Why should AARC participants visit your display?

Visiting our display gives you an opportunity to participate in interesting hands-on activities, check out our adapters and the new P.A.M.[™] tracheostomy pediatric airway model, explore the TRACHTOOLS[™] app, and learn about our exciting new seminars and educational offerings.

SoClean

Booth 456

What products will you be presenting at AARC? We will be presenting the SoClean 2, SoClean 2 Go, and the SoClean ProLab.

Are there any new products you wish to emphasize?

The SoClean ProLab is a new product we've been working on. While the SoClean 2 is a home unit, the ProLab is commercial unit for use in sleep labs or other medical settings. The ProLab uses UV-C germicidal ultraviolet light as well as ozone to kill 99.9% of CPAP pathogens. It is a class 1 medical device that achieves log 3 or greater disinfection and makes it easy for technicians, RTs, and doctors to quickly and safely disinfect patients' equipment on-site without the need for any special equipment or safety precautions.

Discuss educational/training materials you will be offering.

We will provide product spec sheets that highlight features and benefits of the SoClean system. Tutorial videos explaining the setup and operation of the SoClean will also be made available.

What speakers or papers will you be featuring?

SoClean white paper, brochures, rack cards.

Why should AARC participants visit your booth?

To discover a modern, more effective way of daily disinfecting CPAP equipment. Our goal is to improve CPAP compliance through convenience. SoClean makes it easy to clean your CPAP equipment, which encourages customers to clean their equipment regularly and often.

SouthMedic

Booth 313

What products will you be presenting at the AARC?

Vyaire will be presenting Southmedics' OxyMask at the 2017 AARC. OxyMask is the better oxygen mask for patient safety. One mask that can deliver 1 to 15+ litres per minute, 24 to 90% oxygen concentration. The open design reduces the risk of CO2 rebreathing and aspiration of emesis. With one mask there is less contaminated clutter at the bedside providing significant safety benefits and cost savings to the hospital.

Are there any new products you wish to emphasize?

OxyMulti-Mask provides FiO2 up to 83% with a universal adapter that connects to most aerosol nebulizers. OxyMulti-Mask is well suited for the ambulance or emergency department allowing effective delivery of aerosol therapy without compromising O2 delivery.

Discuss educational / training materials you'll be offering

OxyMasks' website, www.thebetteroxygenmask.com provides full details on the OxyMask technology, clinical research and product training.

What speakers or papers will you be featuring?

All of OxyMasks' clinical evidence is posted at http://thebetteroxygenmask.com/research-papers/.

Why should AARC participants visit your display?

We welcome clinicians to learn how an open concept mask such as OxyMask can increase their patient's safety, comfort and oxygen therapy compliance...all while positively impacting their budget.

TRACOE

Booth 252

What products will you be presenting at AARC?

TRACOE will be showing Innovative Tracheostomy tubes and accessories for tracheostomy and laryngectomy. At our booth we will also display speaking valves and cuff pressure management devices.

Are there any new products you wish to emphasize

With the TRACOE twist plus we offer a tracheostomy tube with the largest inner diameter lumen available today. It comes in many different versions as we offer all standard features such as cuff, fenestration and subglottic suctioning.

Since the correct pressure in cuffs is such an important factor we have developed our smart cuff manager. This device will keep the pressure of a high volume low pressure cuff between 20-30 cm $\rm H_2O.$ You can see the TRACOE smart cuff manager at our booth.

We will also be showing our new range of cuffed silicon cannulas for pediatric and neonatal patients. Visit our booth to find out more.

Discuss educational/training materials you'll be offering

Our campaign 'A look through the tube: It's the inner values that count!' explains how our TRACOE twist plus line offers the biggest lumen to the patients. We also have brochures on our very successful and patented speaking valve with unique features. The paper 'Step by step to decannulation using a speaking valve' by Dr. phil. Maria-Dorothea Heidler shows how a speaking valve can support this process.

The paper 'Tracheostomy tube management: Therapeutic criteria for the specific selection of adequate sizes' by Norbert Niers explains the importance of choosing the correct size of tube for the patients.

Why should AARC participants visit your display?

TRACOE has over 50 years of experience in manufacturing innovative tracheostomy products and we are the experts for airway management solutions. We are open to any questions and discussion visitors might offer.

Ventec

Booth 249

What products will you be presenting at AARC?

VOCSN integrates five separate medical devices, including a critical care Ventilator, 6 L/min equivalent Oxygen concentrator, Touch Button Cough[™] assist, hospital grade Suction, and high performance Nebulizer, into one unified respiratory system. The VOCSN unified respiratory system is the only portable life support device to combine five respiratory therapies into a single, 18-pound device.

Discuss the educational/training materials you'll be offering.

Discussions on the benefits of integrated care and demonstrations of how VOCSN combines five therapies in one device.

What speaker or papers will you be featuring?

The Ventec Life Systems Clinical Board will be present throughout AARC.

Why should AARC participants visit your display?

Experience VOCSN first hand. See how easy it is to run a cough therapy with VOCSN and Touch Button Cough. Learn about the Oxygen Direct system that delivers the equivalent of up to 6 L/min with the on board oxygen concentrator and the integrated Ventec One-Circuit.

VORTRAN

Booth 210

What Products will you be presenting at the AARC? We will be presenting our newest product the GO2VENT Gas Operated Ventilator. This is the latest version in the line of automatic resuscitators offered by VORTRAN Medical. We will also be showing our PercussiveNEB and our soon to be released low flow PercussiveNEB due out before the end of the year.

Are there any new products you wish to emphasize? Yes, the new GO2VENT.

Discuss educational/training materials you'll offer.

We always have training videos and studies at our booth for anyone who needs them!

Why Should AARC participants visit your display?

VORTRAN Medical is the inventor of the world's only fully disposable ventilator. VORTRAN also offers a unique way to combat secretion clearance using the PercussiveNEB.

EXECUTIVE PROFILE

Ventec Life Systems

Describe your product(s) and its unique features.

VOCSN integrates five separate medical devices, including a critical care Ventilator, 6 L/min equivalent Oxygen concentrator, Touch Button Cough[™] assist, hospital grade Suction, and high performance Nebulizer, into one unified respiratory system. The VOCSN unified respiratory system is the only portable life support device to combine five respiratory therapies into a single, 18-pound device.

VOCSN works across the continuum of care, from the hospital to home, and for pediatric patients weighing more than 5 kg to adults. VOCSN is designed to improve care for patients with neuromuscular disease (eg, Muscular Dystrophies, ALS), impaired lung function (eg, COPD, Cystic Fibrosis, Lung Cancers, Emphysema), spinal cord injury, and pediatric development complication (eg, premature births, Chronic Lung Disease). Patients can get all five therapies or just the mix of therapies needed.

Tell us about the latest advances in the area your product serves.

Ventilator patients often need more than just a ventilator. Patients typically need multiple devices, power cords, patient circuits, and accessories which significantly impede mobility. VOCSN is more than 70% lighter and smaller than existing machines, features a nine-hour on-board battery, and is controlled through an intuitive touchscreen interface and userfriendly operating system.

Integration not only reduces size and weight, it makes care easier. Switching between five devices to provide therapies is time consuming and uncomfortable. The VOCSN Touch Button Cough is activated with the touch of a button to make airway clearance easy. By unifying ventilation, cough, and suction into one system, it now takes seconds instead of minutes to administer cough therapy with Touch Button Cough. Patients remain connected to the ventilator at all times, and there is no need to disconnect circuits between uses. The system is designed to reduce the gaps in ventilation, decrease the risk of patient misconnection, and minimize exposure to the patient's airway.

Discuss your R&D process, including clinical user input.

VOCSN is inspired by ideas from patients, caregivers, medical professionals, and a team of more than 30 leading engineers. Doug DeVries, founder and CEO of Ventec Life Systems, is a pioneer in mechanical ventilation with nearly four decades of experience and numerous successful devices including the LTV series of ventilators.

The experienced Ventec team is motivated by the belief that people are more than their medical conditions and that technology should evolve to make life easier. We conducted hundreds of user tests and received input from our leading clinical board to develop a device and operating system that operates more like a smart phone than a medical device. VOCSN was designed for everyday mobility and ease of use so that patients can focus on their relationships with loved ones and live their life.

Discuss the educational services you offer for use of your product.

The Ventec team will continue collaborating with respiratory thought leaders to introduce VOCSN across the continuum of care through demonstrations, training videos, and interactive online training.

Currently we are working with select partners on a controlled rollout to maintain a close connection between patients, caregivers, and the team that created VOCSN. We will work directly with each patient to monitor the VOCSN experience from the hospital to the home. Feedback from this period will help our team to develop further training resources to continue to redefine respiratory care.

What new technology do you see as having the greatest impact on your area of expertise?

Improved respiratory technology will facilitate everyday mobility for patients and enahnce patient compliance and tracking.

Patients need more than just a portable ventilator. The integration of five devices with VOCSN is the beginning of integration, but the opportunity exists to further integrate additional monitoring and therapy accessories. Integrating respiratory equipment and data with other nonmedical equipment and devices — such as smart wheelchairs—will produce comprehensive solutions that empower patients to take control of their care.

The proliferation of connected devices is expanding the possibilities for remote monitoring and telemedicine. VOCSN is equipped with Wi-Fi and Bluetooth technology not currently enabled. As remote monitoring technology matures and the regulatory environment evolves, VOCSN will support secure remote patient and device monitoring. Seamlessly connecting patients, caregivers, and devices will provide greater access to care and increased patient engagement.

Spend Less On Mechanical Ventilation For Better Patient Outcomes

Ronald Shiffman, RRT

I have been watching our healthcare system slow-motion train wreck for 3 decades. Congress is struggling with a healthcare bill which everyone hopes will insure more people and relieve the threat of exploding costs. Experts on economics and healthcare say 'no one knows how to lower healthcare costs.' Actually, that's not true. No one knows how to listen to new ideas on how to lower healthcare costs. Who says they have to come from the medical and nursing professions? We've been waiting in vain to hear some answers from these professional organizations for years. I am a respiratory therapist and I have a hypothesis about how to save tens of millions of dollars nation-wide on mechanical ventilation and with 10% better outcomes. Is anyone listening?

Good news on the horizon

Within a few years (approximately 5-10) artificial intelligence and powerful super-computers will accomplish in healthcare what the medical profession has never been able to do — control and ultimately reduce costs.

Research shows a 30-40% mortality rate for patients on mechanical ventilation longer than 12 hours. Sixty percent of these patients will not survive beyond one year, even if they are weaned off of mechanical ventilation — 790,257 hospitalizations occurred involving mechanical ventilation in 2005, estimated national costs were \$27 billion representing 12% of all hospital costs — (The American Association of the Surgery for Trauma).

If we could save one in 10 patients, one day in the hospital, we could save a lot of money and patient discomfort. I have worked directly with ventilator patients for 35 years and I know that magnitude of savings is possible.

We don't know what we don't know. A brief survey of the literature indicates that caregivers for ventilator patients do not agree on best practices for many common procedures. Should we instill normal saline prior to suctioning a tracheal tube? Should we break the circuit in order to give the patient a few deep breaths with a resuscitation bag prior to suctioning? These are not unimportant questions. They are vital. If you were to refer to the many studies in the literature to find the answers to these questions, you would be disappointed. Unambiguous

Ronald Shiffman received his diploma from the NYU-Bellevue School of Respiratory Therapy in 1976. He has 35 years experience in direct patient care mostly in adult ICUs. He began his career at Duke Medical Center in Durham, NC and is recently retired from UNC Medical Center in Chapel Hill, NC. solutions are not to be found. In practice, the only way to be sure of how to wean patients off of mechanical ventilation is to have learned from extensive experience.

Just because a patient caregiver knows how to bag and suction a patient from his training and experience, doesn't mean he knows when to do it, and it certainly doesn't mean he knows why it is critically important. How many respiratory caregivers are aware that in the 1950s Henrik Bendixon showed that peri-op/post-op atelectasis could be reversed with 3 or 4 deep breaths. This simple procedure not only opens collapsed alveoli, it increases lung compliance which makes it easier to breathe for patients newly extubated.

A post-op cardiac patient has been on mechanical ventilation over night for about 16 hours. During morning rounds, the question arises: Should we wean to extubation or continue full vent support for another 24 hours? Despite divergent opinions, the decision is made to increase PEEP to 10 and continue ventilation. Why? Does the medical community have a scientific basis for making the right decision in this case? Not really. This is where artificial intelligence (AI) will revolutionize healthcare. The supercomputer will have a database of thousands of patients in the exact same stage of their weaning process and will calculate the statistical likelihood of success if PEEP is increased to 10. Ventilator decisions like this one occur all of the time and can be critical to the patient's outcome. Pre-AI, I offer two rules of thumb that have worked for me over the years. 1) If the patient's numbers and appearance look good, continue weaning. The longer the patient is on the ventilator, the more that can go wrong, and the less likely the patient will ever get off. 2) PEEP is not harmless. It reduces cardiac output and is associated with retention of fluid in the body. PEEP is a tool which can greatly assist in the management of ventilator patients with large A-aO2 gradients. It splints open collapsed alveoli thereby reducing pulmonary capillary shunt and raising PaO2. Like every essential tool, PEEP is invaluable, but it should be applied thoughtfully - not excessively.

Inspiratory Capacity: The Key to Home Monitoring Patients with COPD

Alex Stenzler

The focus of this editorial may seem counter-intuitive to many. Chronic Obstructive Pulmonary Disease (COPD) is by definition a disease that obstructs the airways, which seems best monitored by frequent measurements of airflow obstruction. The tool that has been the mainstay of monitoring COPD patients at home is a spirometer and its measurements of Peak Expiratory Flow (PEFR), Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity (FVC). Yet the scientific data suggests that the volume measurements collected during slow vital capacity maneuvers such as Inspiratory Capacity (IC) and Slow Vital Capacity (SVC) inform the most as to COPD patients' response to treatment, forecasting exacerbations, and predicting mortality.

Periodic exacerbations of symptoms are the major cause of morbidity, mortality and health care costs in patients with COPD and one-third of patients with an exacerbation are re-hospitalized at 90 days. Effective treatment of COPD exacerbations, which reduce rehospitalizations, results in significant increases in Forced Expiratory Volume in 1 second (FEV1), Mid-Expiratory Flow (FEF25-75), Peak Expiratory Flow (PEF) and IC with associated reductions in the Borg Dyspnea Score. Yetkin, et al, found that the increase in IC was more significantly correlated with the improvement in the Borg Score than the FEV1.¹

Tantucci, et al, recruited 222 patients with mild-to-moderate COPD with an average follow-up for 5 years.² They studied the stable condition relationships of respiratory mortality and morbidity with measurements of FEV1, FEV1/FVC, IC, PaO2, PaCO2 and Body Mass Index (BMI). All these variables were associated with mortality at the univariate analysis. However, in a multivariate regression analysis for mortality, IC and PaO2 remained the only significant, independent predictors. Inspiratory Capacity, FEV1/FVC, and PaO2 were also significantly related to morbidity, as independent predictors of hospital admissions because of exacerbations. They concluded

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Cassanova, et al, followed 689 COPD outpatients with a wide range of airflow obstruction every six months with measurements of lung function, exercise capacity and dyspnea indices up to 5 years with a median period of 34 months.⁴ They reported that IC/TLC may better reflect the overall impact of disease severity, and could have a great potential impact on the multidimensional evaluation of COPD. They concluded that resting hyperinflation measured as IC/TLC is an independent predictor of respiratory and all-causes mortality in COPD with a significant threshold IC/TLC value of <25%. Similar results were reported by French et al, with a statistical association of an IC/TLC ratio or inspiratory fraction should be considered in addition to other lung function parameters in the proper assessment of patients with COPD.

The volume of air that can be inhaled from the resting endtidal expiratory level (FRC) to total lung capacity (TLC) is the inspiratory capacity and any structural change that increases FRC will encroach upon and reduce the IC. In COPD, these changes are primarily the result of either air trapping that results from airway closure during exhalation that precludes emptying of the alveolar, or from losses in elastic recoil of the lung parenchyma that shifts the end-tidal mechanical zero point to a higher lung volume. In either case, a reduction in IC has significant negative physiologic implications for ventilatory capacity with increased respiratory muscle load and increased respiratory neural drive. These changes clearly explain the findings of reduced exercise capacity and its associated findings of reduced muscle mass in COPD patients and evidence of treatment failure, exacerbation and hospitalization. What we now know is that the progression of hyperinflation that is associated with frequent exacerbations and a faster decline in FEV1 requires better monitoring of changes in Inspiratory Capacity, and that IC monitoring of exacerbation recovery enables tracking of the improvements in symptoms and physical activity that are associated with reductions in lung hyperinflation.

Knowing what to monitor in patients with COPD is only one critical element of effective monitoring, with the other being patient adherence to performing the test. If patients don't perform the test, just the availability of monitoring will have no



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impact on outcomes. In a study by Cushen et al of COPD patients at home, they found that adequate forced spirometry testing was only completed by 70% of their subjects, while 90% were able to adequately perform the slow spirometry measurement.³ There is a message in these results that should not be lost on us. Not only do we need to monitor the right parameters, but that we need to pick ones that patients are best able to perform.

While the medical community has to some extent been appropriately monitoring the airway function of patients with COPD with forced spirometry, it has now been shown that it has been perhaps missing the as important or more important home monitoring of IC in these patients. We should not miss the use of such a simple monitoring test to follow our patients' status. As respiratory care practitioners, it is critical that we use our influence to introduce this concept into the home monitoring programs we participate in or manage if we are to improve the outcomes in the COPD patients in our care.

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The MetaNeb[®] System: An Airway Clearance Solution Helping Patients Breathe Easier Across Care Settings

Carlos A. Urrea, MD, MPH

The issue of pulmonary complications in the post-operative setting continues to impact clinicians, patients, and as a result, hospital executives. Such complications, which may include pulmonary atelectasis and pneumonia, are widespread and often can be quite serious. However, key advancements have been made in the treatment and prevention of such issues, which are already making a difference with patients.

One product in particular is making a difference: The MetaNeb[®] System, manufactured by Hill-Rom. This product review examines the benefits of this system. The MetaNeb System is indicated for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with compressed oxygen.

MetaNeb can treat (and in some cases prevent) complications through consistent lung expansion, working in tandem with continuous high frequency oscillation and aerosol delivery. It also has the ability to provide supplemental oxygen when used with compressed oxygen. Implementation of MetaNeb carries an upfront investment that may give healthcare administrators pause. But data show that such an investment may be offset by lower costs for respiratory therapist time per patient, which may result in comparable or even lowered expenditures for both therapies.

A study¹ published in Expert Review Respiratory Medicine found that as many as 40% of all post-surgical patients in the United States experience pulmonary complications, which result in greater lengths of hospital stay, readmissions to the hospital in particular the ICU, mortality, and overall healthcare costs.

The patients that are most commonly associated with pulmonary complications are those undergoing cardiothoracic, open heart, upper abdominal or chest surgery. Other patients include those who have undergone trauma, spinal cord injuries or chronic pulmonary conditions such as COPD, cystic fibrosis or bronchiectasis.

Of all these patient groups, cardiothoracic and open heart surgery are the critical areas where complications such as atelectasis are most often observed. According to the National Institutes of Health, the medicine used during surgery to

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temporarily put a patient to sleep can decrease or stop normal efforts to breathe and cough.

Pulmonary atelectasis develop when the tiny air sacs (alveoli) within the lung get deflated. The amount of lung tissue involved is variable but they may take the form of a complete or partial collapse of a lung, or lobe of a lung. Therefore; atelectasis can make breathing difficult and lower overall oxygen.

Lung expansion techniques have proven to be effective therapies. Evidence shows that such techniques (as practiced by MetaNeb and other systems) may hold the key to the reduction of post-surgical pulmonary complications, in some cases by as much as 50%. The prevention of these types of complications may reduce associated costs per patient by up to 92%. For respiratory therapists, surgeons or pulmonologists, this is welcome news. Such therapies can take place immediately following surgery. Factors such as the site of the surgery (upper abdominal or cardiothoracic), the length of the procedure, or the type of anesthesia used are common preoperative risk factors, and play a role in whether to adapt such protocols once the surgery is finished.

MetaNeb expands the lungs by alternating cycles of continuous positive expiratory pressure (CPEP) and continuous high frequency oscillation (CHFO) combined with aerosol delivery. First, CPEP works to expand the lungs. Ideally, CHFO therapy should be introduced immediately after the lungs have been expanded in order to thoroughly mobilize retained secretions in the patient. Aerosol is delivered quickly and efficiently in both lung expansion and secretion clearance. The cycles are alternated, and repeated twice over a period of ten minutes.

Finally, MetaNeb has been shown to integrate with concomitant therapies, including ventilation and nebulizers. The system was tested with two common ventilators to show how additional flow into a ventilator circuit will affect commonly used ventilation modes.

Additionally, a study² presented at a recent American Thoracic Society Conference compared MetaNeb to a standard Nebulizer Tee Configuration with two breathing conditions. The data showed that aerosol dosage is not affected when delivered with MetaNeb therapy when compared to a Nebulizer Tee configuration. *Continued on page 37...*

TPE Enables Permanent Cuff Pressure Management For Ventilated Patients

U Bahner, A Hahn

A commercial "toy" balloon has a permanent pressure level of 80 mbar. How should a small buffer balloon be configured so that a pressure level of only 25 mbar can be achieved? Is it possible to produce such balloon in a reliable injection molding process with a latex-free material?

This challenge was solved by a team of experts from three companies, each of them a leader in their respective markets:

- Tracoe medical GmbH, Nieder-Olm, Germany, a developer and manufacturer in the highly specialized field of tracheostomy and laryngectomy
- Wittenburg BV, Zeewolde, The Netherlands, a supplier of thermoplastic elastomers for high risk markets like medical, food or potable water
- Spang & Brands GmbH, Friedrichsdorf, Germany, a partner for the medical market in developing custom engineered solutions (mold design and injection molding)

Requirements

Tracheostomized patients must be ventilated with a special tracheal cannula. The cannula is caulked against the inner wall of the trachea by using an inflatable cuff. This will ensure, that the ventilation air flows into the lungs and will not be lost upwards through the pharyngeal zone.

Incorrect cuff pressure causes many complications and secondary problems for the patients. A low cuff pressure is a potential risk for a Ventilator Associated Pneumonia (VAP), because secretion and thus bacteria can flow past the cuff into the lungs. For severely debilitated patients it means danger to life. If the cuff pressure is too high, the arterial vasculature of the trachea could be compressed and leads to necrotic tissues.

VAP prevention is given great attention meanwhile around the globe. Numerous publications report of high morbidity and mortality rates, especially with regards to the enormous consequential costs to the health system. In the US recently the onus of proof is reversed in case of the costs caused by complications preserved in hospitals, like eg pneumonia.

The stand point of the funding agencies in the US is that the hospitals are liable for the pneumonia because of incorrect treatment (eg wrong cuff pressure). Due to this the hospitals have to bear the additional treatment cost themselves if they

Udo Bahner is with Wittenburg BV, Zeewolde, The Netherlands. Andreas Hahn is with Tracoe medical GmbH, Nieder-Olm, Germany.



Figure 1. The Tracoe smart Cuffmanager system (inflated and not inflated)

are unable to prove that the treatment was done according to gold standards. Independently to the costs, much more serious is the fact that between 20% to 60% of the patients will suffer ventilation pneumonia (VAP), eventually dying of it.

Perfect pressure

The perfect cuff pressure is approximately 25 mbar. Unfortunately there are different factors during normal treatment that may cause fluctuation of cuff pressure. Depending on movement, tonus or relaxation of the patients, the trachea offers more or less space to the inflated cuff. Unsteady cuff pressure is well known and due to the serious consequences it has become more and more the focus of the medics. In hospitals the cuff pressure is usually measured every eight hours and manually regulated if necessary. In Great Britain the intervals are reduced to four hours due to the VAP problem. But this is only a "snap-reading method". Corresponding there are many possible movements of the pressure between these intervals. Only a permanently regulated cuff pressure provides maximum safety.

When selecting the material for this type of buffer balloon, it turned out that a soft SEBS-based thermoplastic elastomer was the ideal material for this kind of application. But there was no functional standard material available on the market. Wittenburg received the order to develop an appropriate material. At the same time, the company Spang & Brands started to engineer an approriate injection molding tool.

Requirements for the material and mold:

• Good flowability to achieve very thin wall thicknesses
- Low air permeability
- Sterilizable with ethylene oxide
- · Material should not be too sticky in the mold
- Good aging resistance for a sterile life of 3 years
- Production in an automated injection molding process
- Clear geometric defined part must be realized (100 % technical reproducibility and constant functionality)
- Good balance of the material between inflatability and resilience



Figure 2. Filling of the balloon of the cuff manager

In autumn 2013 the Tracoe smart Cuffmanager has been introduced into the market. Its permanently increasing sales volume shows the good market acceptance. This single patient product could be used for 29 days and can be easily attached to the existing valve of the cannula's filling hose. The cuff of the cannula is thus filled and controlled by the blue balloon buffer.



Figure 3. Inflation of a cuff and inflatet cuff in human saggital model

The Tracoe smart significantly relieves the nursing staff, as the cuff pressure is permanently managed and all fluctuations automatically set into the safe pressure range. Even with significant pressure changes the cuff system remains stable, for example in extreme weather changes, repositioning of the patient or during transport of the patient via airplane (pressurized cabin).

Thanks to the close cooperation of the R+D departments of Tracoe medical, Spang & Brands and Wittenburg, all necessary requirements regarding material, production process and final product could be fullfilled and an innovative product with two pending patents successfully brought to the medical market.

MetaNeb System...continued from page 35

The impact MetaNeb has on clinical practice is significant. Volume expansion protocols have been shown to eliminate incremental days in the ICU and on a ventilator. They can be used as a first-line therapy approach for trauma, and increase protocol compliance while reducing the use of bronchodilators. This is one way patients get discharged earlier from the hospital and experience fewer readmissions. Chest X-rays can be clearer, showing results as quickly as four hours after the beginning of therapy. Such improvement can work to avoid re-intubation and extended stays. Vital capacity also may be improved, with no incremental costs. Lengths of stay in the hospital are reduced.

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Selecting Spirometers for Home Testing

Kevin McCarthy

Monitoring Spirometry at Home

The last several years have seen a large increase in the interest in telehealthcare. Some of this interest is driven by the lower costs of managing patients in their homes; some by the recent implementation of penalties for rehospitalization of patients after hospital discharge; and some driven by a mobile-centric population and the development of technology that makes this possible.

Spirometry has been used for decades for monitoring patients with pulmonary disease at home with varying success.¹ The intention for the monitoring has been mostly focused on following the progression of the disease, the effectiveness of patient treatment and most hopefully, for forecasting acute exacerbation.

Unfortunately, the promise of home monitoring of lung function has not fully lived up to its expectations. The data from home monitoring studies have been mixed, as to the quality of the measurement, the clinical outcomes and the economic impact.² Without the guidance and coaching of trained pulmonary technologist, the ability of patients to perform to ATS/ERS standards is questionable.⁴ In a recent manuscript, spirometry reports from 17 private physician offices were collected and analyzed for acceptability to ATS/ERS standards.³ Of those studies, 40 percent did not meet the acceptability requirements even though these tests were performed with supervision. If there is low quality of tests performed in physician offices, the likelihood of good quality data from self-administered tests would be anticipated to be even less.

The second aspect that affects the value of testing is the accuracy of the measurement devices themselves. Again, in that same publication of tests performed in physician offices, 94% of the spirometers failed to meet the ATS definition of acceptable performance when they were taken to a validation laboratory and tested on a certified waveform generator running the ATS waveform series. If the accuracy of devices is

Kevin McCarthy is a Registered Pulmonary Function Technologist and has been working in the field of pulmonary function testing since 1973. Most of career was spent at the Cleveland Clinic where he was manager of the pulmonary function laboratory. He has co-authored nearly 40 peerreviewed papers in the field of pulmonary function testing. He managed pulmonary function quality control in several NIH-funded registries and has extensive research experience. He currently is working in the field of pulmonary function quality in clinical trials. poor in the physician's office, the likelihood of accurate data coming from patient's home is not promising. The accuracy is not only affected by the spirometer's technology and its calibration process, but can be affected by where the calibration is performed if it is different than where the spirometer is used. If home spirometry is to be successful, then it is important to consider the different technologies used for home spirometric measurements in the decision making process for instrumentation selection.

Spirometers

There are several measurement technologies that are typically used for spirometers provided to patients for self-testing at home. These include:

Differential Pressure Pneumotachs

Figure 1 is a representative illustration of a differential pressure (DP) pneumotach. These flow sensors consist of a low resistance element that creates a pressure drop across the element (typically a screen, a plastic post or flap, or a Fleisch design with a set of laminar flow capillary tubes) with a differential pressure transducer that measures that pressure drop. As flow increases, there is a predictable, but not necessarily linear, change in pressure as it relates to the change in flow. The integration of the instantaneous flows in finite time periods enables the spirometer to calculate the volume passing through the spirometer in that period.

While there are usually no moving parts in DP pneumotachs, there are potential performance limitations related to changes to the resistor element (contaminants on the screen or in the



capillary tubes) that will change the pressureflow relationship. They are also sensitive to changes in temperature, humidity and altitude. Any of these changes would cause errors in flow measurements and the resultant volume calculations. In addition, pressure transducers are known to drift over time. For these reasons, frequent or even daily calibration of a DP

Figure 1. Differential Pressure Pneumotach



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TRACOE	twist plus REF 312	9	11.8	9	1.4
TRACOE	twist plus REF 312	10	12.8	10	1.4
Medtronic	Shiley XLT	8	13.1	8	2.55
Medtronic	Shiley DCT	8	12.9	7.3	2.8
Medtronic	Shiley Flexible Adult (neu)	9	12.4	8	2.2
smiths medical	Portex Blue Line Ultra	10	13.5	8.3	2.6

* OD measured using digital 0.150 mm callipers

* ID measured using Bohrkern Dormer A190 No 203 set

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pneumotach is required in order to meet ATS/ERS standards for diagnostic spirometry.

measurement of extremely low flows so as to meet the ATS/ ERS requirement down to 0.025 L/sec.

Ultrasonic Flow Meters

Figure 2 is a representative illustration of an ultrasonic flow meter. Ultrasonic flow meters work by locating two ultrasonic transducers on either side of the breathing path. The transducers emit and receive sound in alternating directions. When air is flowing in the tube, sound pulses that travel against the flow are slowed down and take a longer time to reach the opposite transducer. When a pulse is traveling with the flow it travels faster and takes a shorter time to reach the opposite transducer. The transit-time of each sound pulse is precisely measured with a digital clock. The air flow through the breathing path is calculated from the upstream and downstream transit-times and integrated into volume.

Because there are no moving parts, no mechanical components to catch sputum and no flow-resistive elements that can change with use, ultrasonic flowmeters have demonstrated longterm calibration stability. The ultrasonic flow measurement is independent of gas composition, pressure, temperature, and humidity thus eliminating errors due to these variables. This technology eliminates most problems associated with traditional methods of flow measurement making ultrasonic flow meters extraordinarily fast, reliable, and accurate.



Figure 2. Ultrasonic Flow Meter

Turbine Flow Meters

Figure 3 is a representative illustration of a turbine flow meter. Turbine flow meters work by locating a low inertial vane behind a swirl plate (or between two if bidirectional flow is measured) with the post of the vane rotating in a jeweled, low-friction bearing. The swirl plates deflect the air entering the flow path and convert the linear airflow into a helical flow past the vane. This angular velocity therefore becomes proportional to the flow and is detected by the interruption of a pair of infrared beams by the vane twice per rotation. The frequency of these interrupted pulses is therefore proportional to the flow and the number of pulses proportional to the volume. This binary light/no-light measurement is the most reliable method of measuring flow as light doesn't drift.

Similar to ultrasonic flow meters, turbine flow meters measure exhaled air directly at B.T.P.S. (body temperature and pressure with saturated water vapor) and have no requirement for temperature correction on exhalation and are not affected by humidity, temperature or altitude. Bidirectional turbine flow meters have electronic temperature sensors to correct inspired volumes and flow. These characteristics also make the turbine spirometer extremely stable and obviate the need for frequent calibration. The main limitation of many turbine flow meters (horizontal operation) is the difficulty it has with the



Figure 3. Turbine Flow Meter

Differentiating spirometers, depending on the need for hospital accuracy at home.

If spirometric measurements are to be meaningful, assuming that all technology on the market has been reviewed by the FDA, then the following specific characteristics are important when considering for home use:

- The spirometer should not require daily calibration in a patient's home and still meet ATS/ERS performance requirements.
- The spirometer should be able to measure full flow volume loops (inspiratory and expiratory).
- The spirometer should be able to meet the ATS/ERS standard for low flows
- The spirometer should be able to inform the patient if they performed the test according to ATS/ERS requirements.

Calibration

As discussed in the previous section, calibration requirements for diagnostic measurements are heavily dependent on the basic technology in the spirometer. These requirements can be significantly loosened for screening devices that do not measure Forced Vital Capacity and whose results are confirmed by an institutional diagnostic measurement. Long term calibration stability has been explored for both ultrasonic and turbine spirometers following long term use and they appear to remain within 1-2 percent over periods exceeding 2 years of use.^{6,7}

Full Flow Volume Loops

Many of the spirometers placed in home settings are exhalation only measurement systems and therefore require patients to take a deep inspiration, raise the spirometer to their mouth, get a good seal and then forcefully exhale. This coordination requirement, particularly difficult for older patients, can potentially take several seconds. As reported by D'Angelo, a pause at end inspiration can reduce flows by as much as 20-40%, and FEV1 by 8%.8 The importance of this is emphasized in the ATS/ERS Standardization of Spirometry statement that "the FVC manoeuvre should be begun with minimal hesitation. Reductions in PEF and FEV1 have been shown when inspiration is slow and/or there is a 4-6 s pause at total lung capacity (TLC) before beginning exhalation. It is, therefore, important that the preceding inspiration is fast and any pause at full inspiration be minimal (ie, only for 1-2 s)." Therefore the importance of the ability to transition from a deep inspiration to an immediate forced exhalation is not minimal, as it would improve the

Common Spirometers Used for Telehealthcare Applications

Manufacturer	Model	Measurement Technology	Screening or Diagnostic ¹	Full FV Loop	Approved for Home Use	Meets ATS/ ERS Low Flow Requirement	Test Quality Feedback (see Quality discussion below)
ERT	AM-1	Horizontal Turbine	Screening	No	Yes*	No	No
ERT	AM-3	Horizontal Turbine	Screening	No	Yes*	No	No
CareFusion	Micro 1	Horizontal Turbine	Diagnostic	No	Yes*	No	Yes
CoHero	SpiroThor	Ultrasonic	Diagnostic	Yes	No	NA	No
Ganshorn	SpiroScout	Ultrasonic	Diagnostic	Yes	No	Yes	No
MedChip	SpiroConnect	Vertical Turbine	Diagnostic	Yes	No	Yes	Yes
MIR	Spirobank	Horizontal Turbine	Diagnostic	Yes	Yes*	No	Yes
MIR	Spirotel	Horizontal Turbine	Diagnostic	Yes	Yes*	No	Yes
Monitored Therapeutics	GoSpiro	Vertical Turbine	Diagnostic	Yes	Yes	Yes	Yes
NDD	EasyOne	Ultrasonic	Diagnostic	Yes	No	Yes	Yes
PMD Healthcare	SpiroPD	Horizontal Turbine	Diagnostic	No	Yes*	No	6 Sec Timer Only
SDI	Astra300	Horizontal Turbine	Diagnostic	Yes	Yes*	No	No
Vitalograph	6300 Micro	Fleisch DP	Diagnostic	No	Yes*	No	No
Vitalograph	Asma-1	Horizontal Turbine	Screening	No	Yes*	No	Cough, TPF (120 ms)

*Indicates the spirometer was approved without being tested to meet current Home-Use requirements.

likelihood of more accurate measurements recorded at home and therefor provide the interpreting physician with more relevant data.

Low Flow Requirements

The ATS/ERS Standard requires that spirometers record flows as low as 0.025 l/sec.⁵ This is important for accurate measurement of FVC. However, when spirometers are tested to the ATS waveforms, they don't specifically test at that low a flow. Therefore, many spirometers that pass the ATS waveform test and are FDA cleared for sale, don't really meet all of the ATS/ ERS standards. This is a particular problem with many turbine spirometers that fail to meet this requirement. While turbine flow meters rotate on a jeweled bearing, because they are usually used in a horizontal position, they don't rotate exclusively on the point of the vane spindle, but also on the side of the spindle (See Figures 4a, b, c). This horizontal position causes minimal drag on the vane rotation, but sufficiently enough to prevent rotation at low flows. Only two manufacturers produce vertical turbines (MedChip's SpiroConnect and MTI's GoSpiro) that allow the vane to rotate on the tip of the spindle, enabling measurements at these low flows to meet the ATS/ERS standard.

Video of the low flow performance of the turbines tested can be seen at http://respiratorytherapy.ca/videos/spirometers.

Quality Problems with Self-Measurements

In the same review of spirometry measurements in physician offices discussed earlier, they evaluated the quality of the measurements collected by "trained" office assistants, nurses or the physician themselves. Of the 153 tests reviewed, 40% did not meet the minimum ATS/ERS standards for spirometry. If trained individuals can't encourage a patient to perform a spirometry test correctly, how would a patient testing themselves at home know if they performed it right? According to the ATS/ERS standards, there are five important requirements for a good test. These include 1) that the patient exhaled for at least six seconds (3 seconds in children <10 years of age); 2) that the back extrapolated exhaled volume is less than the larger of 5%





Figure 4a.





of the FVC or 150 mL; 3) that the time to peak flow occurs is minimal (estimated at less than 300 milliseconds); 4) that the exhaled flow at the end of exhalation is less than 0.025 liters per second; and 5) that there is no cough during the first second that could affect the measured FEV1. While most spirometers provide feedback as to the difference between the measured values and either previous or predicted values, only a few provide feedback as to the actual quality of the test. The MIR series of spirometers as well as the MTI GoSpiro, MedChip SpiroConnect, and the CareFusion Micro 1 measure and report all five quality parameters to the patient so that they know whether they need to repeat the measurement due to the poor quality of the maneuver.

Home Use Specific

Between 2014 and 2016, new ISO standards and FDA requirements were developed for medical devices used in the

home.^{9,10} These standards were driven by the recognition that environmental exposure in the home could have a greater effect on medical devices than when used in the hospital setting. These new standards raise the safety margins for electromagnetic interference, radio frequency immunity and coexistence, environmental exposures (particularly water ingress) as well as electrical safety and usability (labeling and instructions). This means that among other requirements, that they meet the ISO 60601-1-11:2015 for electronic devices for use in patient's home and the FDA Guidance Document, Design Considerations for Devices Intended for Home Use. While there are many spirometers that have FDA clearance to be sold for use in a patient's home, only the MTI GoSpiro has been actually designed for patient use at home and has passed these more stringent test requirements.

Conclusions

There are many spirometers that are used to monitor patient lung function at home. The differences between some of these devices are considerable as to their characteristics and operational performance. If the purpose of monitoring these patients is to be more than just going through the motions and to obtain meaningful data that guides their care and prognosis, then careful thought should go into the selection of spirometers used to monitor them.

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Avoid a Costly Mistake – Nonin Medical's WristOx₂ Model 3150 Beats VirtuOx VPOD in Hypoxia Testing

Introduction

Overnight pulse oximetry studies are often used to qualify patients for long-term oxygen therapy or screen an individual for oxygen desaturations that may be associated with obstructive sleep apnea. Regardless of the specific application of continuous pulse oximetry monitoring, it is imperative to use a device that will not only be accurate when the patient is well-oxygenated, but will quickly and accurately respond to sudden and/or significant oxygen desaturations.

Nonin Medical introduced its first wrist-worn pulse oximeter (WristOx® Model 3100) in 2004. Since that time, Nonin has been an industry leader in this form factor and was the first to integrate Bluetooth® technology into its wrist-worn pulse oximeters. Due to convenience of size and comfort, the company saw rapid adoption of its wrist-worn pulse oximeter in the clinical environment, particularly for continuous monitoring of oxygen saturation and heart rate during overnight studies and ambulatory tests.



The High Cost Of Missed Events

In the last several years, other wrist-worn pulse oximeters have been introduced under private label by inexpensive import manufacturers. Many of these devices are low cost and available through distributors and Medicare-approved Independent Diagnostic Testing Facilities (IDTF) throughout the United States. If these devices are missing sudden and/or significant oxygen desaturations (see Graph 1), the cost to both the patient and the healthcare provider could be profound. Missed desaturation events could result in an incorrect diagnosis, delayed treatment, repeat studies, extended hospital stays or premature discharge, missed home oxygen prescriptions or repeat hospitalizations.

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Nonin Medical WristOx₂ Proves To Be Superior In Capturing Oxygen Desaturation Events

In an independent lab test, hypoxia testing was performed on wrist-worn pulse oximeters from Nonin Medical (Wrist Ox_2^{\circledast} Model 3150, Plymouth, MN) and VirtuOx (VPOD, private label, Beijing Choice, Shenzhen, China).

After obtaining Institutional Review Board (IRB) approval, Clinimark Laboratories (Boulder, CO)¹, an independent hypoxia laboratory, tested healthy volunteer participants by inducing hypoxia events down to the 70-85% SpO₂ range. These events included concurrent induced low perfusion (one arm cooled in chilled air) and labored breathing. Nellcor brand pulse oximeters (Model N600, Medtronic, Minneapolis, MN) were used as reference monitors on both the cooled (low perfusion) and warm (normal perfusion) hands.

A sample size of seven subjects was tested, obtaining a total of 21 hypoxic events with nadir value below 85% SpO₂. In 20 of 21 hypoxic events (95.2%), the VirtuOx VPOD pulse oximeter failed to accurately measure the oxygen desaturation, resulting in no reading (displayed value read zero), frozen reading (displayed value failed to track the desaturation) or no tracking (displayed values were >10% higher than the reference oximeters) when compared to the reference pulse oximeter. The Nonin Medical WristOx₂ Model 3150 accurately measured 20 out of 21 desaturation events (95.2%) when compared to the Nellcor reference pulse oximeters (see Table 1 on the next page).

Graph 1. Example of Missed Desaturation Event by VirtuOx VPOD Wrist-Worn Pulse Oximeter



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- -Warm Reference SpO₂
- Cold Reference SpO₂
- VirtuOx SpO₂

In 20 of 21 hypoxic events (95.2%), the VirtuOx VPOD pulse oximeter failed to accurately measure the oxygen desaturation. The Nonin Medical WristOx₂ Model 3150 accurately measured 20 out of 21 desaturation events (95.2%).

Table 1. Results by Device

Pulse Oximeter	Number of Subjects	Total Number of Hypoxic Events	Accurate Reading	No Reading	Frozen Reading	No Tracking
Nonin Medical WristOx ₂ Model 3150	7	21	20 (95.2%)	1 (4.8%)		
VirtuOx VPOD	7	21	1 (4.8%)	6 (28.6%)	11 (52.4%)	3 (14.3%)
Nellcor N600 – cold reference	7	21	18 (85.7%)			3 (14.3%)
Nellcor N600 – warm reference	7	21	21 (100%)			

Summary

This study indicates that low-quality or low-cost import pulse oximeters may not be reliable for capturing true and significant oxygen desaturations which could, in turn, lead to costly mistakes affecting both provider and patient. The low-quality or low-cost wrist oximeter tested in this study failed to track nearly all critical hypoxic events below 85% SpO₂.

The Nonin Medical PureSAT® Pulse Oximetry Technology Difference

Only Nonin Medical provides proven pulse oximetry performance in the widest range of patient conditions and settings. Nonin's clinically proven PureSAT® pulse oximetry technology uses intelligent pulse-by-pulse filtering to provide precise oximetry measurements—even in the presence of dark skin, motion, low perfusion, shortness of breath and other challenging conditions. PureSAT automatically adjusts to each patient's condition to provide fast and reliable readings clinicians can act on.

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Can We Safely Widen Alarms on a Medical-Surgical Unit?

Dennis Jensen RRT and Michelle Eichbrecht, MBA, BS, RRT

As hospitals look to control costs and manage patients in a safe and cost effective manner, patients that are on a medicalsurgical unit may be sicker requiring a higher level of pain management which can lead to respiratory compromise (the second leading avoidable patient safety issue in the US).¹ Thus, the need for continuous electronic monitoring has increased in these areas of the hospital, and with this may come an increased number of alarms. In 2013, Providence St Peter's in Olympia Washington began screening high risk patients preoperatively for Obstructive Sleep Apnea (OSA) and putting them on capnography and pulse oximetry continuous monitoring if they had a score of >5 on the STOP-BANG² scoring grid. Since the monitors were linked to the nurse call, any alarm sounded at the nurse call station and staff resistance to using the monitors mounted as the number of alarms increased.

ECRI lists alarm fatigue at or near the top of their top 10 technology hazards for the past several years and 2017 is no different with alarms mentioned in the number three spot.3 ECRI is just one of many organizations that have addressed alarms in recent years. In 2012, The Association for the Advancement of Medical Instrumentation (AAMI) published Recommendations for Alarm Signal Standardization and More Innovation from an alarm summit attended the previous year by ECRI Institute, the US Food and Drug Administration, the Joint Commission, and the American College of Clinical Engineering.⁴ The American Association of Critical-Care Nurses (AACN) offered updated alarm safety guidance in May 2013.5 Suggested strategies to reduce alarm fatigue include proper skin prep for electrocardiogram (ECG) electrode placement, changing leads daily, customizing parameters based on the individual patient and establishing an interdisciplinary alarm safety team. In 2013, the Joint Commission released both a Sentinel Event Alert and a National Patient Safety Goal (NPSG - effective January 2014) dealing with alarm safety issues pointing to alarm fatigue, inadequate staff levels and non-customized alarm settings to name a few.⁶ The American Association for Respiratory Care (AARC) was also involved in the AAMI project and the interest grew out of a survey conducted by the Healthcare Technology Foundation (HTF) in advance of the AAMI in 2011. Since respiratory therapists (RTs) made up 14% of respondents to an earlier survey conducted in 2005-2006, the HTF reached out to the AARC to garner an even more robust response in 2011. RTs

ended up comprising 63% of the respondents to that survey, solidifying the AARC's place at the table. A new survey in 2016 was also conducted comparing results to 2011 and the AARC Times spring edition was recently published with this data.⁷

So what could be done to prevent alarm fatigue at Providence St Peter's to help balance patient safety monitoring with alarm management? Recommendations for reducing alarm fatigue include managing default settings and customizing to individual patient's baseline, education of the patient and family and educating staff to the importance of the safety monitoring for their patients and loved ones.8 In addition, implementing a remote monitoring system, instead of a nurse call interface which will alarm for any condition, that can tailor caution alarms versus urgent alarms for degree of severity can help control non-urgent situations and only alert a clinician to respond when the patient has met certain criteria. Consider any other contributing factors that may affect how you set alarm defaults such as altitude which may alter the normal patient values. The technology's smart alarm algorithms may also help reduce nuisance alarms if implemented ensuring staff is aware and trained on how the technology works including averaging times for the different parameters. It is also important that the ideal patient interfaces for end-tidal CO_2 (et CO_2) and SpO_2 have been chosen and placed on the patient properly. For example, some small adults may be better suited for the pediatric size oral/nasal sampling interface on the etCO₂ monitoring. You should consider the alarms as a system and not as one alarm only. For example, if the respiratory rate is set lower this may be acceptable because there is an apnea back up alarm and a low and high etCO₂ alarm as well.

Dennis Jensen, the Director of Respiratory and the Sleep Center at St Peter Hospital, has collaborated with anesthesia to arrive at a low respiratory rate (RR) alarm of six for caution and three for urgent based on high risk OSA patients (low RR was one of the most common alarms). The caution alarms sound in the room at the bedside monitor (rate of 6 breaths per minute (bpm) or a 10 second apnea period) and are also stored in the software for future reference by respiratory therapists. The Respiratory Therapist logs into the web based software to view the patient's information every 2-4 hours, paying close attention to trends such as number of apneas per hour, or respiratory rate over the past 2-4 hours. An apnea of 10 seconds (RR rate of 6) is concerning when reviewed as a trend, but hardly actionable as a onetime event that most likely the patient has self-corrected. A 20 second period of apnea (RR of 3) may be indication of

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	UNITE	URGENT ALARM	ALARM	EtCO	2
Oz HIGH	mmHg	65	56		4
CO2 LOW	mmilig	16	18		
CO2 HIGH	mmHg	8	8		RR
RHIGH	bpm	46	26	FICOz	Hart
RLOW	bpm	3	6	0	
OBREATH	-	30		2-0-	
BpO2 HIGH	*	100	100	SpO ₂	
BPOR LOW	-	83	88		
PR HIGH	bpm	140	140		70
PRLOW	bpm	30	60		PR
BAT SEC		OFF			6
IPI LOW		3	6		
CAUTION		DEFAULT	USB		HOME

Figure 1. Caution and Urgent Default Settings.

respiratory failure and should be acted upon immediately. This alarm is sent in a message form to the caregiver's alert device (pager phone). Not only is it sent to the primary caregiver but in the absence of an acknowledgment back to the software, it will send out 2 back up pages to other caregivers assigned to this patient.

When explained in this manner, and considering these sleep apnea patients were probably breathing that slow at home with no monitoring, anesthesia was supportive of this caution and urgent setting for low respiratory rate. In addition, other alarms, such as low and high $etCO_2$ are set so respiratory rate was not the only alert to respiratory compromise (see figure 1 for the default settings used at Providence St Peter's Hospital).

In addition, other studies have been conducted showing alarm defaults chosen by care environment and settings appear to be wider on the medical-surgical unit.⁹ Another study out of Dartmouth Hitchcock states using a low SpO₂ setting of 80%, low and high heartrate of 50 and 140 respectively, and 15 second alarm notification delay with an additional 15 second pager notification delay.¹⁰ These may seem unsafe but this study found improved outcomes in this post-operative orthopedic ward setting. The alternative can be a monitor being turned off from a high number of alarms and jeopardizing patient safety even further.

Dennis also uses the trends from the Integrated Pulmonary Index algorithm (a single number index derived from SpO_2 , heart rate, etCO₂ and respiratory rate on a 1–10 scale) in his protocol to identify patients deteriorating and who may need attention (see figure 2 for the etCO₂ protocol). The IPI can confirm a single parameter event since many times the duration of the event is long enough that pulse rate, SpO_2 , and etCO₂ can be adversely affected, which would display a low IPI index number. Clinicians use these parameters and the graphs of the parameters in order to develop strategies with their colleagues to intervene, with appropriate changes to the patients care. They have had a reduction of code blues in these areas by > 60% and no patients monitored with capnography and pulse oximetry have coded which has led consideration of expansion to additional patient groups beyond just those with higher STOP-BANG scores.¹¹



In summary, the key to a successful patient monitoring plan for the medical-surgical unit should consider and incorporate multiple disciplines and factors related to patients and hospital workflow. Knowing the technology you are using and how it averages and calculates to post numbers on the monitor will help you tailor defaults that are protective but will not lead to alarm fatigue. Having a protocol that clearly defines default settings and any allowable variation from these settings is important.

- Does your technology allow two levels of alerts? Are you interfaced to a remote monitoring system to help control which alarms get through? Educating patients and their family is helpful for compliance issues. Choose the proper patient interfaces for SpO₂ and etCO₂ for best monitoring performance.
- What else should you consider? Perhaps your hospital is located at an altitude and normal values are lower and this should be considered for default settings.
- How is your staff educated to the protocol, the importance of this monitoring, and the results of what you are doing? Help them feel proud of their work by sharing results with hospital staff.
- How are new staff trained and competence maintained? Once monitoring is implemented, an assessment of the most common alarms from the remote monitoring system (excluding the outliers) may also help to tweak the default settings even further and develop the perfect balance for you and your patients.

Any improvement project is a lot of work but we are learning from others as we move to improve patient safety on the medical-surgical unit and putting our patients first with these efforts.

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Program Profile: Transdisciplinary Neurorespiratory Mobile Lab Improves Healthcare for Veterans with Amyotrophic Lateral Sclerosis

Charles J Gutierrez, PhD, RRT, CPFT, FAARC,¹ Cathy Stevens, BS, RRT,² and Carmen I Gutierrez, RN, BSN³

Introduction

Amyotrophic lateral sclerosis (ALS) is a neuromuscular disorder characterized by progressively worsening paralysis. In the United States, ALS affects approximately 30,000 individuals of all races and ethnic backgrounds.¹ Risk of developing this chronic, clinically complex disease increases through age 70 and is greater in males.² Even though the disease is progressive and usually fatal, its rate of progression varies from individual to individual. As a result of multiple studies³⁻⁷ suggesting an association between military service and subsequent development of ALS, Department of Veterans Affairs (VA) expanded delivery of comprehensive clinical services to veterans with ALS. The response of the Spinal Cord Injury Center at VA Hospital, Tampa, FL, was spearheaded by a Patient Aligned Care Team (PACT) that was part of a patient-centered medical home initiative which delivered patient care via an inter-professional team-based clinical practice format.8 The mission of the Amyotrophic Lateral Sclerosis Patent Aligned Care Team (ALS PACT) was to plan, organize, deliver and manage healthcare for veterans with ALS.

As a result of continuing efforts to coordinate and deliver optimal clinical services, ALS PACT underwent a four-year transition from non-transdisciplinary to transdisciplinary clinical practice with an emphasis on inter-professional role release. Adoption of inter-professional role release resulted in an expanded scope of practice for all disciplines on the team, including neurorespiratory care, a sub-specialization of respiratory care. The expanded scope of practice enabled neurorespiratory therapists to successfully participate in an innovative transdisciplinary process to improve access to out-patient healthcare for rurally-based veterans with ALS. The role that neurorespiratory therapists played on ALS PACT was congruent with the American Association for Respiratory Care (AARC) task force recommendation that participation of greater numbers of advanced respiratory care practitioners on collaborative healthcare teams is needed in order to improve national healthcare outcomes in the future.9 Neurorespiratory therapists in ALS PACT worked collaboratively to improve: 1) in-patient survival benefits, 2) out-patient diagnostic services and 3) out-patient caregiver continuing education. A recent VA

Charles J Gutierrez is an Instructor, Hillsborough Community College, Respiratory Therapy Program, Tampa, FL; Cathy Stevens is a Program Leader, Neurorespiratory Care, James A Haley Veterans Hospital, Tampa, FL; Carmen I Gutierrez is a Research Coordinator, Cardiothoracic Surgery, James A Haley Veterans Hospital, Tampa, FL. study concluded that the effect of PACTs on improving patient care outcomes was especially important for high-risk patients that require ongoing case management of chronic, clinically complex medical conditions such as ALS.⁹ The impact that various clinical practice models have on desired patient care outcomes has become a topic of intense, widespread interest,¹⁰⁻¹² therefore, it is hoped that this program profile of ALS PACT, an inter-professional team engaged in a transdisciplinary mode of practice, will add to the literature on the subject.

Parenthetically, the trend toward transdisciplinary healthcare is occurring within the context of the Precision Medicine Initiative (PMI), a national healthcare project launched in 2015 to improve precision of future healthcare. The main objective of PMI is to combine multiple, large data sets from genomics, patient chart data, social media usage patterns and other venues to design more precise, more effective and presumably more personalized therapeutic interventions. Successful implementation of PMI, will very likely require a continuing stream of scientific breakthroughs which may be best achieved by a synergistic relationship between transdisciplinary clinical practice and transdisciplinary research.

Evolution of Clinical Practice Models

Increased complexity of the current healthcare ecosystem requires coordinated clinical teams capable of managing an array of tipping points along the healthcare continuum.¹⁴ Although a team's mode of operation may be either non-transdisciplinary or transdisciplinary, some researchers maintain that interprofessional clinical teams that provide chronic, clinically complex care should adopt a transdisciplinary mode, often characterized as the most efficacious and efficient form of interprofessional clinical practice.¹⁴ One feature that distinguishes transdisciplinary clinical practice is the presence of continuing, collaborative, clinical role release training sessions between clinical disciplines that comprise the team.^{14,15} Such sessions enable inter-professional sharing of knowledge and skill sets that typically lead to expanded scope of practice for clinical disciplines and improved patient care outcomes.

Although Karol et al, originally proposed collaboration and role release as independent canonical concepts associated with transdisciplinary clinical practice,¹⁴ ALS PACT functionally merged both concepts. Hence, collaborative clinical role release (CCRR) became the preferred moniker for denoting the systematic, inter-professional continuing education process by which clinical disciplines share knowledge and skill sets for the expressed purpose of improving safety, efficacy and efficiency of patient care and the improved healthcare outcomes that arise therefrom. An additional distinguishing feature of teams that operate in transdisciplinary mode is that they not only include multiple clinical disciplines but also a physician who promotes interaction and coordination among all team participants including patient, family and caregivers.

In-Patient Healthcare Outcomes

ALS PACT monitored in-patient outcomes to determine how well patients' healthcare needs were being met and simultaneously kept patients, families and caregivers abreast of alternative treatment options. Cardiopulmonary issues were the main reason for admission of veterans with ALS.¹⁶ Emergence of pulmonary complications such as atelectasis, mucus plugging and pneumonia, as well as declines in pulmonary function leading to ventilatory insufficiency or ventilatory failure were common reasons for admission. Hence, neurorespiratory therapists played an integral role in delivering transdisciplinary in-patient care.

Mean Duration of Stay Per Chief Complaint During Study Period (2007-2014)





Figure 1. Mean Duration of Stay According to Chief Complaint

ALS PACT's transition toward transdisciplinary clinical practice was semi-quantified by a retrospective, observational study which compared admission, death and survival rates between a period of non-transdisciplinary practice from 2007 to 2010, and a period of transdisciplinary practice from 2011 to 2014. Results indicated that when compared with non-transdisciplinary practice, transdisciplinary practice was associated with significant (p = 0.01) survival benefits for patients with ALS.¹⁶



Mean Admission, Death & Survivor Rates





Out-Patient Healthcare Outcomes

Approximately 23% of veterans reside in rural settings¹⁷ and of these, 56% are aged 65 years or older.¹⁸ Therefore, ALS PACT monitored out-patient outcomes such as access to diagnostic testing and continuing education for elderly and/or underserved veterans who resided in rural regions. Monitoring identified multiple, logistical barriers faced by veterans with ALS, who lived in rural regions, and who required periodic pulmonary function testing (PFT). Such testing was available in an urban setting, which meant that patient, caregiver(s) and family member(s) had to undertake extended commutes to a distant appointment site in a motor vehicle filled with passengers, electronic wheelchair, portable suction device, cough assist device, and consumable items. Once at the laboratory, pulmonary function testing was a physically demanding process which required that a patient, often fatigued by the commute, perform a series of repetitive breathing maneuvers while sitting and another series while laying down.

Transdisciplinary collaboration between neurorespiratory therapists and other disciplines in ALS PACT resulted in an ambitious proposal aimed at improving healthcare delivery and patient care outcomes. To obviate the need for patients to commute to a distant, stationary laboratory in an urban setting, the team proposed that a mobile PFT laboratory travel to patients' residence to perform in-home testing and continuing education. Although the value of laboratory-based pulmonary function testing of ALS patents was widely accepted,¹⁹ the role of in-home testing was unknown. Therefore, this was an opportunity for transdisciplinary innovation to undertake a proof of concept project that could improve healthcare of a fragile, underserved patient cohort. Hence, funding was procured for a project that would explore the feasibility of developing and implementing a mobile laboratory.

In-Home Neurorespiratory Care

ALS PACT participated in a transdisciplinary research and development project, patterned after a convergence research model.²⁰ A year-long effort culminated in a mobile laboratory comprised of clinician, mini-van, portable pulmonary function testing equipment, support equipment, clinical consumables and primary and back-up laptop computers. In-home PFTs were performed by a neurorespiratory therapist who was also a certified pulmonary function technologist (CPFT). Test results were returned to VA hospital and downloaded onto a dedicated server that enabled pulmonologists to access and interpret test results. In preparation for delivering in-home transdisciplinary care, the neurorespiratory therapist participated in collaborative, clinical role-release training sessions which included the following:

- Pulmonary function equipment-vendor technologists provided advanced product training and educational certification. This enabled neurorespiratory therapist to perform in-home spirometry, maximum inspiratory pressure (PImax), maximum expiratory pressure (PEmax) and impulse oscillometry measurements on veterans with ALS.
- Biomedical engineers provided assistance in designing a stabilizing a tripod platform that supported spirometry and impulse oscillometry interfaces for testing patients in upright and supine positions. This enabled neurorespiratory therapist to safely and comfortably perform acceptable and reproducible in-home pulmonary function testing on veterans with ALS.



Figure 3. Prototype of Tripod Platform

- Speech pathologists provided training on recording pre-PFT samples of patients' speech. This enabled neurorespiratory therapist to collect multiple, in-home samples of speech patterns used to analyse alterations in speech as a possible, surrogate indicator of changes in pulmonary function of veterans with ALS.
- Nurse specialists provided training in use of a telemedicine portal to facilitate patients' communication with staff at neurorehabilitation center. This enabled neurorespiratory therapist to employ a telemedicine portal to digitally transmit vital signs and audiovisual data during in-home testing of veterans with ALS.
- Assistive technologists provided training in iPad-centered communication. This enabled neurorespiratory therapist and assistive technologist to collaborate on configuring a smart home capability that would remind veterans to administer scheduled respiratory medications or perform specific interventions.

In-home Diagnostic Testing

Compact, mobile PFT equipment was configured, calibrated and disinfected per protocol prior to a series of "trial runs" to confirm the mobile laboratory's readiness for service. Neurorespiratory therapist drove mobile lab to patients' home and conducted all on-site testing. Patients underwent pulmonary function testing in sitting and supine positions to ascertain how differences in body position changed diaphragmatic function. In addition to spirometry in sitting and supine position, patients performed PImax (maximum inspiratory pressure) and PEmax (maximum expiratory pressure) maneuvers in sitting position. Although impulse oscillometry was not part of the original in-hospital testing protocol for patients with ALS, it was added to the in-home protocol to evaluate its diagnostic relevance. The transdisciplinary mobile lab played a significant role in improving healthcare access by enabling veterans with ALS, to undergo periodic pulmonary function monitoring without having to leave their residence and traverse long distances.

A subsequent preliminary study revealed that when compared with mobile lab spirometry, mobile lab impulse oscillometry was more comfortable and less physically challenging for in-home veterans with ALS.²¹ In the near future, instead of repetitively performing exhausting spirometric maneuvers, veterans with ALS may instead undergo impulse oscillometry which requires only spontaneous ventilation for short periods.

In-home Continuing Education

Inclusion of family and caregivers in comprehensive pulmonary rehabilitation was an important part of transdisciplinary rural healthcare outreach. ALS PACT viewed on-site clinical continuing education as an essential element in maintaining veterans and their caregiver(s) healthy-at-home. PFT sessions were followed by in-home mentored, continuing education sessions. These sessions afforded patient, family and caregivers an opportunity to pose questions regarding patient care, address clinical concerns and review or practice in-home neurorespiratory clinical interventions. Neurorespiratory therapist re-certified competencies of patient, family members and/or caregivers in such areas as:

- Portable oropharyngeal/tracheal suctioning
- Optimal body positioning to facilitate drainage of secretions
- Administration of aerosolized medications
- Mechanical cough assistance techniques
- Manual cough assistance techniques
- Emergency re-cannulation procedures
- Manual ventilation techniques
- Non-invasive positive pressure ventilation
- Monitoring daily peak cough flow measurements
- · Monitoring daily incentive spirometry measurements

Training sessions were welcomed by patients, families and caregivers and anecdotally resulted in high levels of patient care satisfaction. Addition of training sessions typically increased the length of time that the neurorespiratory therapist spent on-site due to time required to present clinical demonstrations and then confirm and document adequate return demonstrations. Presence of neurorespiratory therapist, mobile lab and supplemental equipment, frequently facilitated resolution of equipment and clinical procedural challenges that would have necessitated multiple subsequent visits.

ALS PACT embraced the concept that transdisciplinary team support of family members and caregivers of a patient with a chronic, clinically complex disease like ALS, was an exceptionally important healthcare objective. A recent study revealed that inclusion of family caregivers in comprehensive pulmonary rehabilitation maximized their adaptive coping skills and appeared to prevent negative psychological outcomes.²² Compared with usual patient-centered rehabilitation, familycentered rehabilitation delivered by the transdisciplinary mobile laboratory, may have maximized caregivers' emotional state and reduced the overall burden of providing daily care. Reducing the burden of care for family and caregiver was a key component of the neurorespiratory therapist's mission to increase access to healthcare and improve out-patient outcomes.

Discussion

Demographic trends in the U.S. reveal an aging population that will likely exhibit increased chronic, clinically complex healthcare issues and will consume significant healthcare resources.²³ Delivering high-quality care at reduced cost is strongly dependent on the presence of transdisciplinary teams adept at expanding inter-professional clinical roles and responsibilities in order to improve patient care outcomes.⁹ The demonstrated value of coordinated, collaborative interprofessional care in nursing homes²⁴ and inpatient settings²⁵ has increased the use of transdisciplinary care in VA and elsewhere.²³ Mechanisms by which transdisciplinary case management improves safety, efficacy and efficiency of healthcare outcomes have not been well defined and require further study. This program profile exemplifies the assertion by Karol et al, that transitioning toward a transdisciplinary clinical practice model potentially improves chronic, clinically complex healthcare outcomes.¹⁴

Veterans with ALS who reside in rural settings may constitute a fragile, underserved cohort. Delivering care to such patients requires careful, long-term planning and comprehensive case management by a transdisciplinary team whose focus is delivery of the right care to the right patient at the right time. The current article posits that transdisciplinary teams such as ALS PACT are particularly adept at responding to emerging healthcare needs as evidenced by adroit implementation of a PFT mobile lab that enabled rurally-based veterans with ALS to access specialized clinical services and continuing education in-home.



Figure 4. Trans-disciplinary clinical practice model improved rural neurorespiratory care

Transdisciplinary Clinical Practice Parallels Transdisciplinary Research

The recently launched Precision Medicine Initiative (PMI)²⁶ has become a national effort to leverage large data sets to mechanistically determine how disease occurs at population and individual levels and to design effective interventions. Implementing PMI, will be a complex, expensive undertaking that will depend on scientific innovations made possible through the merger of transdisciplinary clinical practice and transdisciplinary research, also known as Convergence.²⁰ Transdisciplinary clinical practice in the clinical sciences and convergence in the biophysical sciences are conceptually similar constructs whose synthesis may catalyse the clinical and technological breakthroughs needed to make precision medicine a reality. Both concepts utilize inter-professional cross-fertilization of ideas to spur innovation that might not otherwise be possible.

Institutions of higher learning are taking steps to educate the next generation of clinician-scientists to work in amalgamated, transdisciplinary clinical and transdisciplinary research environments. Students in the Respiratory Care Program at Hillsborough Community College learn fundamental patient care skills in a transdisciplinary clinical simulation laboratory at the college and then apply those skills during clinical rotations at area hospitals. Importantly, these clinical rotations include a visit to basic science laboratories at a nearby medical school to begin to understand the role that convergence research plays in improving patient care. The experience enables students to realize that transdisciplinary collaboration extends beyond the walls of the clinical affiliate where they are completing their clinical rotations. The message imparted to our emerging clinician-scientists is that the synergism between transdisciplinary clinical practice and transdisciplinary research, will very likely improve the prospects for delivering precision healthcare.

Summary

This program profile provides a brief overview of the operation of ALS PACT, an inter-professional team whose transdisciplinary clinical practice led to an innovative mobile lab as a mechanism for improving healthcare access for rurally-based veterans with ALS. In order to accelerate clinical innovations, interprofessional teams with a focus on chronic, clinically complex case management, should consider transitioning toward transdisciplinary clinical practice, with its emphasis on clinical collaborative role release, in the same manner that biophysical sciences are transitioning toward convergence research as a mechanism for accelerating scientific innovations. Given the looming social, economic and demographic challenges, continued integration of transdisciplinary clinical practice with transdisciplinary research promises to improve our nation's ambitious objective of harnessing innovations in order to deliver precise and personalized healthcare.

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Managing Patients on Mechanical Ventilation: An Innovative Approach

Ronald Shiffman RRT

The medical profession has not figured out how to improve the outcomes for patients requiring mechanical ventilation in 30 years. That fact alone results in unnecessary pain to patients, heart-rending anxiety for families, and great expense for society. As professionals whose primary concern is ventilating the sick, we need better ideas for treating our patients and new insights.

Recent scientific studies suggest that tidal volumes should be set between 6-8 ccs/kg. ideal body weight. But there has never been a study which suggests that the size of the tidal volume delivered improves patient outcomes. The ARDSnet study proved that 12 ccs/kg is detrimental. That's all.

Every patient is different, so experienced practioners should have the freedom to adjust tidal volumes based on several factors other than ideal body weight, such as patient comfort, peak ventilator pressures, patient spontaneous tidal volume on 10 of pressure support, end tidal CO2 values, etc.

This is what I do. I give every new ventilator patient 2-4 slow, deep, breaths with a resuscitation bag. This is preceded most of the time with instillation of 2-3 ccs of normal saline. Then I suction out the sections. I always bag my patients in the manner described at least twice per shift. This procedure eliminates atelectasis and retained secretions. It reduces the amount of peep that needs to be used to maintain adequate paO2 and lowers paCO2. It improves lung compliance and patient comfort. Because patients are comfortable, they require less sedation.

I start new patients on full ventilatory support. ASV has proven to me its superiority, but I can make weaning work in any mode. I target a normal ABG - 7.35 38 70-80 on 5-8 peep and 60% or less. Then I adjust the vent as needed. I want to see a vent rate of about 20, no higher than 24-26, a CO2 of 40, and the lowest FiO2 that maintains the paO2 in the target range. I don't believe 'permissive hypercapnia' is a helpful strategy. If CO2 is > 42 on a rate 24, I consider increasing the tidal volume. If this does not reduce the CO2, the patient has a significant physiologic dead space impairment which bodes ill. As patients'

Ronald Shiffman RRT received his diploma from the NYU-Bellevue School of Respiratory Therapy in 1976. He has 35 years experience in direct patient care mostly in adult ICUs. He began his career at Duke Medical Center in Durham, NC and is recently retired from UNC Medical Center in Chapel Hill, NC. vital signs and ABGs stabilize in the first few hours, I look for ways to gradually decrease vent support and estimate a time frame for the wean.

In the lung-protective strategy we use at our hospital, I have seen peep levels that are too high and used for too long. Some of the physiological effects of peep are detrimental. Peep decreases venous return which may stress the heart. Peep stimulates the body to hold on to fluid by increasing the production of anti-diuretic hormone and reducing renal artery perfusion. I believe this detrimental effect of peep is often overlooked or completely misunderstood.

I use peep to maintain oxygenation levels in the target range at 60% O2 or less. If paO2 falls below 70, I increase fiO2 liberally and I increase peep gradually. By the time I reach 10 of peep, the patient will be on 100%. I will increase peep up to 15 cmm H2O if paO2 falls below 60, but this situation clearly demonstrates that the patient is very sick. On rare occasions, I have seen peep levels of 16 or 17 change the course of a patients hospitalization for the better, but not enough to have confidence in the use of peep levels that high.

The following is an innovation I have used successfully, which has not been reported in the literature. I wean peep below 5 cm/H2O to as low as 2. Reducing peep increases urine output if the kidneys are functioning. When weaning a patient with the intent of extubating within 3-5 hours, below 5 cm peep helps the kidneys to eliminate excess fluid out of the body, which can be the difference between successful and failed extubation. Below 5 of peep is effective for 8-10 hours at reducing body fluid, but by then extubation is in order. It is not true that higher levels of peep prevent atelectasis. I have seen many X-rays which read 'atelectasis present' at 8-10 cm H2O of peep. Atelectasis is prevented with 3-4 slow, deep breaths with a resuscitation bag.

I have described my thinking and actions when I initiate a patient on mechanical ventilation and begin to wean. Most of the time, I use about 8 ccs/kg ideal body weight for tidal volume, respiratory rates < 24, inspiratory times > 1.0 seconds, peep 5-8, but up to 15 cm H2O in severe cases of hypoxia. The often neglected, but decisive difference in my ventilator management is the 3-4 slow, deep breathes with normal saline followed by suctioning at least twice per 12 hr. shift. This always makes the patient feel more comfortable and reverses atelectasis.

New Insights Highlighted for High-flow Nasal Cannula Support Therapy

Chris Campbell

The management of patients with respiratory failure is changing rapidly thanks to the "innovative and powerful technique" of High-flow Nasal Cannula (HFNC) supportive therapy.

To assist clinicians with these changes, Hernández et al. from the Department of Critical Care Medicine, Virgen de la Salud University Hospital in Spain, published an article detailing "new insights" about HFNC based on their review of existing literature and the team's own research.¹

For one thing, Hernández et al. provided a very specific term for describing HFNC. The therapy is often referred to as nasal high flow and high flow oxygen therapy, "but we believe that the most appropriate term is heated and humidified HFNC supportive therapy. This term reflects the features that generate the technique's clinical effects (i.e., the delivery of warm and humidified air at high flows through a nasal cannula)."

Treating and preventing hypoxemic respiratory failure starts with oxygen therapy — traditionally delivered using nasal prongs or masks.

Those maximal flow rates delivered through these devices, however, are limited, according to Hernández et al. because of the "discomfort generated secondary to insufficient heat and humidity provided to the gas administered. Although high-flow oxygen therapy is currently defined as flows greater than 30 L/min, it is accepted that flows up to 15 L/min can be delivered using conventional nasal prongs or masks; this flow is far less than the peak inspiratory flow of a patient with dyspnea. In addition, flows exceeding 6 L/min can lead to insufficient humidification provided to the nasal mucosa, even when a cold bubble humidifier is used. Therefore, room air dilutes the supplemental oxygen, resulting in a significant decrease in the fraction of the inspired oxygen (FiO₂) that finally reaches the alveoli. In recent years, new devices that deliver totally conditioned gas (37°C containing 44 mg H₂O/L [100% relative humidity] using a heated humidifier and a heated inspiratory circuit) through a wide bore nasal cannula at very high flow (up to 60 L/min) at a predetermined constant oxygen concentration (21 to 100%) have emerged as a safe and useful supportive therapy in many clinical situations."

New Insights

The authors found some interesting insights into the issue of

Chris Campbell is the Editor of Respiratory Therapy.

upper airway dryness, which can lead to intolerance and impact mucociliary functions, such as secretion clearance and airway defense.

"Results of studies demonstrate that HFNC reduces patient discomfort and upper airway dryness, although a potentially protective effect on mucociliary function requires further investigation," the authors wrote. "Another way in which HFNC improves extubation outcome and weaning is by conditioning the inspired gas. Various studies have demonstrated that HFNC improves the management of respiratory secretions and reported fewer reintubations secondary to upper airway obstruction and accelerated weaning in tracheostomy patients. These findings support the idea that gas conditioning probably alleviates inflammation of the tracheal mucosa after transglottic intubation, and a protocol that includes the use of HFNC prior to extubation, thereby preventing the administration of dry and cold air in the native airway of the patients, reinforces this approach."¹

The article also provides insights into carbon dioxide clearance, saying that information is lacking about the role of HFNC in managing hypercapnia, except for the mechanism of dead-space washout.

"By providing a high flow of fresh air during expiration," the authors wrote, "HFNC may be able to more rapidly washout the carbon dioxide (CO_2) filling the nasopharyngeal cavity." Möller et al. constructed an airway model using a computed tomography (CT) scan, and analyzed the lavage of gas tracers under apneic conditions. The authors observed a linear positive correlation between tracer-gas clearance in the model and the flow rate of HFNC, approximately 1.8 ml/s increase in clearance for every 1.0 L/min increase in flow.²

"However, in recent years, new studies have highlighted some additional mechanisms affecting CO_2 clearance. Alveolar ventilation has been suggested by Patel et al., after obtaining a mean apnea time of 17 min in surgical patients.³ The authors reported further evidence that classical apneic oxygenation provided little clearance of CO_2 apart from that obtained from limiting rebreathing. Continuous insufflation of a high-flow gas mixture facilitates oxygenation and CO_2 clearance through gaseous mixing. Evidence for the existence of flow-dependent, non-rhythmic ventilatory exchange can be provided by comparing the increase in rise of CO_2 under different continuous insufflation apneic conditions.

The article details data from the authors⁵ supporting a possible role of HFNC in managing hypercapnia after extubation, comparing non-invasive ventilation (NIV) to HFNC in a fixed 24 h protocol after extubation in high-risk for reintubation patients, using a non-inferiority randomized trial.

"There was a trend towards a higher rate of postextubation respiratory failure due to hypercapnia in the NIV group than in the HFNC group, although this difference was not deemed to be related to levels of hypercapnia with regard to reintubation."

When it comes to positive pharyngeal pressure, the authors found that HFNC can induce it during expiration due to its constant ingoing flow, "with the effect mainly determined by the flow rate provided by HFNC and the expiratory flow exhaled by the patient, with lower pressures when the patient keeps the mouth open.

Parke and McGuinness⁶ reported that HFNC increased the mean pharyngeal pressure by about 1 cmH₂O per 10 L/min, within a range of 30-50 L/min, but more recently,⁷ the same group reported that the linear increase in the pharyngeal pressure was maintained when using extra high-flow with 100 L/min (combining two HFNC systems), obtaining pharyngeal pressures up to 11.9 cmH₂O. However, these values were obtained in healthy volunteers and extrapolation to the critical care arena may not be appropriate.

"Despite this uncertainty about how much positive endexpiratory pressure (PEEP) can really be offered by HFNC, studies⁸ have demonstrated that end-expiratory lung impedance increases with rising flow rate of HFNC, suggesting an increase in end-expiratory lung volume. In addition, hemodynamic changes similar to those obtained in patients under NIV with pressure levels close to 10 cmH₂O have been reported."⁹

According to the article, when examining clinical data, the authors found that studies on acute hypoxemic respiratory failure focused on the effects of HFNC therapy on physiological variables^{10,11,12} Moreover, HFNC appeared to be better tolerated and achieved a greater level of comfort than conventional oxygen devices.^{10,12} HFNC was also usually better tolerated than NIV, although NIV obtained greater improvements in oxygenation.^{13,14}

Predicting Success

The authors highlighted the importance of the existence of accurate, early predictors of HFNC success. "Indeed, a recent propensity-score analysis associated early intubation (within the first 48 h) with better ICU survival.¹⁵ In spite of its limitations, the study by Kang et al.¹⁶ raises an important issue — the fact that delayed intubation may worsen the prognosis of patients treated with HFNC. Therefore, the ability to describe accurate predictors of HFNC success that can allow timely endotracheal intubation in patients who are likely to fail is a point of special interest."

"Clinicians should counterbalance efficacy and safety. On the one hand, the longer the duration of HFNC application, the greater the clinical efficacy. On the other hand, the longer the duration of HFNC, the greater the probability of delaying escalation of respiratory support when HFNC fails. In fact, as suggested by Kang et al,¹⁵ applying HFNC in patients with respiratory failure according to clinical response could lead to delayed intubation. This could be associated with a worse outcome, as has been shown with NIV. This may be possible because HFNC increases comfort, oxygenation and may disguise respiratory distress."

Conclusion

The article by Hernández et al. concluded that the wide use of HFNC support therapy is a positive move forward for patients with respiratory failure. However, they added that treatment should be "individualized" depending on situations and institutions.

"Delivery of heated and humidified oxygen at high flow rates through nasal cannulas is now widely used in adult patients," the authors wrote. "Its mechanisms of action and potential clinical benefits can help to improve the management of patients with acute respiratory failure or during the weaning phase. With the currently available evidence, several questions still remain unanswered; there is strong evidence for some clinical indications, but for other situations without that evidence decisions on HFNC treatment should be individualized in each particular situation and institution, taking into account resources, and local and personal experience with all respiratory support therapies. However, HFNC therapy is an innovative and powerful technique that is currently changing the management of patients with respiratory failure."

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Improving Mechanical Ventilation Management Process Aided with an Analytics Informatics System in the Intensive Care Unit

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Abstract

Objective: The importance of evidence-based guidelines for mechanical ventilation (MV) management is well accepted. However, timely actionable data are costly to generate manually. As part of a structured clinical process improvement, we evaluated the utility of an analytic informatics system on MV process management in an intensive care unit (ICU).

Methods: We used a pre-, post-, observational study design. There were 138 and 140 patients admitted to the ICU requiring MV in the pre- versus post- phases. During the pre-period, a MV management analytics system was implemented for automatic data collection only. During the post-period, a structured process improvement project was implemented supported with computerized reports from the analytics informatics system.

Results: After implementing process changes based on data generated from the MV management analytics system, spontaneous breathing trials occurred earlier in the day (P<0.0001). There was a statistically non-significant trending of shorter duration in the post-period in the milestones leading to extubation as well as a shorter MV duration (median; 97.8 vs 72.4 hours for the pre- versus post- periods; P=0.20).

Conclusions: Computerized ventilation data analytics systems could aid focused clinical process improvement. Continued refinement and effort are needed to further improve ventilator management effectiveness.

Keywords: Quality Improvement, Process Improvement;

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Electronic Health Record (EHR), Mechanical Ventilation (MV), Intensive Care Unit (ICU), Medical Informatics

Introduction

The intensive care unit (ICU) is one of the most expensive venues in a hospital. Mechanical ventilation (MV) is a significant component of that cost.¹ Mechanically ventilated patients represent approximately 3% of all acute care hospitalizations and 30% of all ICU admissions,¹⁻³ incur longer ICU stay than non-ventilated patients (mean, 6.9 vs. 2.9 days) and have greater average costs (\$31,574 vs. \$12,931).¹ The mean hospital length of stay (LOS) for a ventilated patient was 14 days accounting for 7% of all hospital days and an estimated 12% of all U.S. hospital costs.³ Although ventilated patients are only a small fraction of hospitalized patients, they represent a disproportionately large share of hospital days and costs.

Despite its efficacy in the management of critically ill patients, MV has iatrogenic complications such as ventilator induced lung injury and ventilator associated pneumonia (VAP). As many as 28% of patients receiving MV may develop VAP,⁴ with risk increasing with longer MV duration.⁵ Hence, reducing MV duration has clinical impacts on patients' outcomes.

The use of protocols to improve the management of sedation and to implement consistent processes for MV weaning with spontaneous breathing trials (SBT) have demonstrated significantly shorter times to extubation when compared to non-standardized weaning.⁶⁸ However, without a process for protocol compliance monitoring and automated data feedback, improvements in weaning and extubation through manual data collection are prohibitively expensive and difficult to achieve.⁹

Scientific evidence supports the recommendation that weaning from MV and discontinuation protocols that incorporate non-physician healthcare professionals should be used in ICUs.^{8,10} Several weaning and ventilator management protocols have been published and evaluated for use in the ICU.^{11,12} Commonly used is the "Wake up and Breathe" protocol.¹³ This protocol requires at least one daily spontaneous awakening trial with an appropriate reduction in the administration of intravenous sedation that can facilitate a SBT and subsequent weaning and removal of MV.

Concurrent electronic monitoring and use of data analytics may improve the safety and efficacy of MV. However, most standard ICU monitoring equipment and alarm systems lack the ability to recognize physiologic syndromes associated with ventilatorinduced lung injury, and VAP.¹⁴ A Cochrane review¹⁵ of available studies through 2013 concluded that automated "closed-loop" systems may result in reduced duration of weaning, ventilation and ICU stay; however, there was substantial heterogeneity in trials with very small numbers of patients, most of which had sample size in the lower double digits or even a single digit. Therefore, no firm conclusions could be drawn based on the review.

We conducted a structured process improvement study designed to assure standardized MV weaning procedures were incorporated aided by the use of a computerized analytics system intended to assist ventilation management. The system provides data analytics only; it does not use "closed-loop" intervention. We hypothesized that the computerized MV analytics system would provide timely data and clinical feedback to the providers. Through structured process improvement aided by automated clinical data feedback, providers could identify variations, adopt evidence-based practice, and hence potentially change practice and shorten MV duration.

Methods Study Site

The study site is a medical/surgical ICU in a tertiary-care, regional, and community referral hospital. The ICU has 20 beds with approximately 1,200 adult admissions annually. Approximately six patients per day are mechanically ventilated. Typically, two of these patients receive postoperative care; the remainder is treated for medical conditions. Patients requiring MV are under the care of 13 pulmonologists (mostly intensivists), 39 critical care nurses, and 42 respiratory therapists (RTs). The ICU patient to nurse ratio is 2:1 and the ventilated patient to RT ratio is 5:1. Physicians practicing in the ICU are communitybased physicians and therefore do not staff the ICU continuously.

The study protocol was developed as a non-interventional, process improvement project and was reviewed and approved by the hospital Institutional Review Board.

Data Source

Ventilation parameters were captured electronically through an automated analytics informatics system (Vyaire Medical vs Becton Dickinson [BD] — formerly CareFusion Corporation, Yorba Linda, CA) which automatically records the starting and ending time periods of MV, spontaneous breathing trials (SBTs), first ready to wean status (RTW), and extubation candidate threshold (ECT). A total of 10 new ventilator systems were installed approximately eight months prior to the current study. Patients monitored with the RKP analytics system were included for the current analysis. We linked clinical ventilation data with the administrative data, which included the patient's demographics, admission source, principal diagnosis, secondary diagnoses, and discharge status. We used administrative data for the following purposes: 1) to identify the mortality status at discharge, 2) to determine the principal diagnosis and comorbidities through standardized codes of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9CM); and, 3) to determine the source of admission (e.g. transfer from another acute care hospital, nursing home, etc.).

We used the Clinical Classification Software (CCS) and Comorbidity Software (CS) downloaded from the Agency for Healthcare Research and Quality (AHRQ) for the classification of principal diagnosis group and comorbidities, similar as being used by other studies.^{16,17}

Study Design

We used a pre-, post-, open-cohort, observational study design incorporating the elements of quality observational design.¹⁸ During the pre-period (February 1, 2013 to August 31, 2013), the RKP automatically collected ventilation analytics parameter data, but the results were not revealed to the clinicians. During the post-period, (September 1, 2013 to March 31, 2014), structured process improvement steps were implemented. The computerized RKP system analytics reports were made available to the clinicians via the Respiratory Care Clinical Practice Committee (the Committee) composed of staff respiratory therapists, lead respiratory therapists and the manager of respiratory therapy with oversight by the medical director. The goal of the Committee was to develop and implement a process improvement plan based on data from the previously blinded pre-implementation period as well as on-going analytics feedback during the post-period. Communication regarding the use of the RKP analytics was shared with the clinical staff through educational sessions as well as oneon-one instruction. The related activities included active engagement of the staff caring for patients (intensivists, nurses, RTs) with assessment of individual patient RKP analytics data as well as periodic review of overall clinical trends. These activities were done in conjunction with changes in ventilator and weaning management practices.

Operational Definitions of Key RKP Parameters

The RKP system allows sites to configure rules and thresholds that are used to identify exceptions to the hospitals policies and protocols. The rules and thresholds were set by clinicians in the study site based on guidelines.¹⁰

Ready to Wean (RTW): A respiratory rate < 35 breaths per minute (bpm), positive end-expiratory pressure $\leq 5 \text{ cmH}_2\text{O}$, FiO₂ ≤ 0.5 , minute ventilation <14 liters per minute, and remained within these settings for at least 60 minutes.

Spontaneous Breathing Trial (SBT): Changing the mode setting on the ventilator from continuous MV to continuous positive airway pressure (CPAP) with pressure support.

Extubation Candidate Threshold (ECT): A rapid shallow breathing index \leq 105, respiratory rate < 40 bpm, and FiO2 \leq 0.5.

Ventilator Weaning Process

The software parameters used to identify possible ventilator weaning candidates included a FiO₂ < 50%, Ve < 14 L/min, PEEP <6 and total respiratory rate of < 35 breath/min. A minute ventilation value of < 14 L/min was used as an indication that a patient may be a candidate for weaning. Upon reaching the weaning candidate threshold, each patient was assessed by a RT using the following parameters consistent with the evidencebased guidelines for weaning and discontinuing ventilatory support:¹⁰ a) the patient was free of agitation; b) vital signs were within normal limits; c) SpO₂ ≥ 88%, FiO₂ ≤ 50%, PEEP ≤ 8 cm H₂O; d) the patient demonstrated adequate inspiratory effort; e) the patient was free of myocardial ischemia; f) the patient was free of vasopressor usage; and g) the underlying cause of MV has been resolved. The patient was moved to a SBT only after satisfactory completion of this evaluation by a RT. During the

Table 1. Patient characteristics*

Variable	Pre-Period	Post-Period	P value
Number of discharges	138 (100.0)	140 (100.0)	
Age			
Mean (standard deviation)	62.6 (16.0)	64.2 (15.4)	0.4060
Median (1st, 3rd quartiles)	63.5 (53,75)	65 (57, 74)	0.4089
Gender			
Female	66 (47.8)	76 (54.3)	0.2804
Male	72 (52.2)	64 (45.7)	0.2804
Admission Source			
Ambulatory setting	97 (70.3)	75 (53.6)	
From another acute care hospital	24 (17.4)	44 (31.4)	0.0104
From nursing home or other facility	17 (12.3)	21 (15.0)	
Medicare	67 (48.6)	69 (49.3)	0.9024
Principal Diagnosis-based Clinical Group (CCS)+			
Respiratory failure	33 (23.9)	39 (27.9)	0.4523
Septicemia	24 (17.4)	27 (19.3)	0.6831
Pneumonia	11 (8.0)	9 (6.4)	0.6188
Other	70 (50.7)	65 (46.4)	0.4732
Secondary Diagnosis-based Comorbidities (CS) , Sorted by Frequency			
Fluid and electrolyte disorders	88 (63.8)	79 (56.4)	0.2102
Weight loss	71 (51.4)	73 (52.1)	0.9078
Hypertension	62 (44.9)	64 (45.7)	0.8953
Chronic pulmonary disease	53 (38.4)	63 (45.0)	0.2638
Deficiency anemia	48 (34.8)	44 (31.4)	0.5522
Renal failure	40 (29.0)	34 (24.3)	0.3749
Congestive heart failure	36 (26.1)	35 (25.0)	0.8354
Hypothyroidism	19 (13.8)	31 (22.1)	0.0671
Coagulopathy	24 (17.4)	23 (16.4)	0.8306
Obesity	23 (16.7)	23 (16.4)	0.9574
Other neurological disorders	13 (9.4)	23 (16.4)	0.0796
Liver disease	8 (5.7)	5 (3.6)	0.4084

* Note: Data were presented as number (%), unless otherwise specified; +CCS: Clinical Classification System by the Agency for Healthcare Research and Quality (AHRQ); CS: Comorbidity Software by the AHRQ). Comorbidity categories with high frequencies were presented.

study, a SBT was defined as either placing the patient on 5 cm H_2O of Pressure Support and 5 cm H_2O of CPAP or a t-tube.

Staff Training

RT staff training included but was not limited to the following: defining RKP clinical markers for the identification of possible ventilator weaning candidates; identification of patients with ventilator settings outside of our protective lung limitation threshold values, adverse effects, and appropriate corrective actions.

Storyboard displays, demonstrations of the RKP, and sharing of electronic educational materials were used for nurse education in the post-period. Engagement of the nursing staff resulted in question-and-answer sessions with active exchange of ideas regarding the use of data obtained from monitoring the RKP. Activities for pulmonologists included one-on-one demonstrations of the RKP as well as informational sessions during meetings of the critical care, quality improvement advisory, and pulmonary leadership committees. Consequently, staff members would take ownership of the care process.

Outcome Measures

MV process parameters included the duration from the first RTW to the first SBT as well as from the first SBT to the first ECT and other parameters. The outcomes included changes in timing of SBTs and total MV duration. The study was powered for a 1.47 days detectable difference in MV duration, a 35% reduction. We analyzed the MV duration on patients discharged alive because mortality may affect the duration of MV and confound this outcome. We also analyzed the entire study cohort including those expired in the hospital as a comparison.

Statistical Analysis

We conducted univariate analysis on all outcomes using the χ^2 test for dichotomous variables and the t-test and Wilcoxon

Table 2. Pre-verus post-period ventilation management parameters comparison

		Unadjusted Des	Adjusted Estimate on Pre- vs Post			
	Pre-Period, hours		Post-Peri	od, hours	Period Differences	
Weaning Parameter Duration Variables (all values in hours)	Mean (standard deviation)	Median (1st, 3rd quartiles)	Mean (standard deviation)	Median (1st, 3rd quartiles)	Estimated reduction in duration, hours (95% CI)	P value
From 1st RTW* to 1st SBT ⁺	37.0 (42.9)	23.3 (11.8, 44.5)	30.0 (31.2)	17.8 (9.0, 45.1)	-8.2 (-19.9, 3.6)	0.174
From 1st SBT to 1st ECT [‡]	26.0 (104.1)	0.0 (0.0, 4.3)	17.7 (36.1)	0.0 (0.0, 20.2)	-10.9 (-38.2, 16.4)	0.435
From 1st RTW to 1st ECT	53.6 (103.5)	24.1 (7.9, 58.1)	36.8 (40.7)	22.1 (9.1,48.6)	-20.9 (-47.2, 5.4)	0.121
From MV initiation to 1st ECT	70.4 (123.0)	38.7 (17.7, 78.1)	56.2 (50.0)	36.1 (15.8, 88.7)	-17.2 (-47.1, 12.8)	0.262
From 1st ECT to discontinue MV	84.7 (105.3)	34.6 (15.8, 120.1)	82.0 (114.0)	30.4 (11.4, 115.0)	-11.2 (-45.4, 23.1)	0.523
From extubation to discharge	169.3 (205.6)	132.0 (21.9, 214.0)	128.6 (159.7)	78.7 (6.6, 172.4)	-33.9 (-81.3, 13.6)	0.163
Total duration of MV	138.1 (152.7)	97.8 (32.9, 192.2)	119.6 (129.3)	72.4 (21.5, 171.3)	-23.8 (-60.5, 13.0)	0.206

Note: *RTW (Ready to Wean): a respiratory rate < 35 breaths per minute (bpm), positive end-expiratory pressure ≤ 5 cm H₂O, FiO₂ ≤ 0.5 , minute ventilation <14 liters per minute, and remained within these settings for at least 60 minutes. \pm SBT (Spontaneous Breathing Trial): changing the mode setting on the ventilator from continuous mechanical ventilation to continuous positive airway pressure (with or without pressure support). \pm ECT (Extubation Candidate Threshold): a rapid shallow breathing index ≤ 105 , respiratory rate < 40 bpm, and FiO2 ≤ 0.5 . MV: mechanical ventilation.

non-parametric test for the continuous variables. We developed multivariable models to control for confounders, by first conducting univariable analysis of candidate variables: demographics, principal diagnosis, and comorbidity in relation to the mortality outcome. We then fit a logistic regression model, using variables significant at P<0.05 in the univariable analysis as covariates. Finally, we fit multivariable general linear models for MV duration. Given the frequently skewed distributions of time variables, we conducted a sensitivity analysis using logarithmic transformations for the MV duration and refit the model to compare the direction of the parameter estimate and the associated P-value. All data analyses were conducted using SAS (V9.1, SAS Institute Inc., Cary, NC). A two-tailed P value <0.05 was considered statistically significant.

Results

Patient Characteristics

A total of 138 (pre-period) versus 140 (post-period) patients were included in the analysis. Patients in the two periods were similar in age, gender, and the distribution of specific diagnoses (Table 1). There was a significant increase in the number of admissions from transfers in the post period, from 17.4% to 31.4% in transfers from other acute care hospitals and from 12.3% to 15.0% in transfers from nursing homes or other facilities (P=0.01). The top three principal diagnoses were respiratory failure, septicemia, and pneumonia.

Process Management Change Assisted by the RKP Analytics System

At the transition from the pre- to post-period, the Committee reviewed the RKP data collected during the pre-period. The data patterns from the RKP, suggested a lack of night shift staff involvement (1900-0700) in the weaning process. The Committee considered this as a quality improvement opportunity and suggested conducting SBTs at earlier times of the day to allow adequate time for the attending physicians to evaluate patients prior to morning rounds. This suggestion to move the weaning time was approved by the medical director.

As can be seen in Figure 1, during the pre-period, SBTs occurred between 0700 and 1300 hours, peaking at 0800. In the postperiod, SBTs expanded to a wider window between 0300 to 1600 hours, peaking at 0300 as intended. The shift of SBT time to earlier hours of the day was statistically significant at P<0.0001.

Duration of Key Ventilation Process Parameters

Descriptive statistics are in Table 2. For the pre-versus postperiods, the mean (standard deviation) of the duration from the first ready to wean to the first spontaneous breathing trial was 37.0 (42.9) versus 30.0 (31.2) hours, with an adjusted estimate of 8 hours reduction (-8.2, 95% confidence interval: -19.9, 3.6; P=0.17). The corresponding duration of MV was 138.1 (152.7) versus 119.6 (129.3) hours, with an adjusted estimate of 23.8 hours reduction (-23.8, 95% CI: -60.5, 13.0; P=0.20). The adjusted estimates of pre- versus post- changes and 95% CIs for all MV parameters are illustrated in Figure 2. All parameters showed a positive trend in MV management with shorter durations in the sequence of milestones leading to extubation in the post-period, albeit not statistically significant.

Outcomes

The unadjusted in-hospital mortality was 26.1% versus 37.1% (P=0.05) for the pre- versus post- period. After adjusting for age, transfer-in status, principal admission diagnosis of respiratory failure, pneumonia, or septicemia, (variables significantly associated with the outcome,) the mortality was not statistically different for the pre- versus post-period (P=0.11). For the patients discharged alive, the unadjusted mean (SD) of the total duration of MV was 8.99 (9.47) versus 7.95 (8.72) days (P=0.43) for the pre- versus post- period respectively. The risk adjusted duration of MV was 1.2 days shorter in the post-period, but the P-value did not reach



Figure 1. Chronological frequency distribution of spontaneous breathing trials (SBT).

During the pre-period, SBTs occurred between 0700 and 1300 hours, peaking at 0800. During the post- period, SBTs expanded to a wider window between 0300 to 1600 hours, peaking at 0300 hours. The shift of SBT time to earlier hours of the day was statistically significant at P<0.0001.

statistical significance (95% CI: -3.8, 1.4; P=0.38). The logtransformed MV data yielded the same direction (shorter MV duration in the post- versus pre-periods) and slightly better P-value (estimate: -0.24 [log-scale], 95% CI; -0.52, 0.05; P=0.10). For the entire study population, the MV duration was 1.5 days shorter in the post-periods (95% CI: -3.5, 0.6; P=0.16).

Limitations

This study was implemented in a single center. Its application to other types of ICUs needs to be further tested. We attempted to incorporate the STROBE guidelines¹⁸ into our study structure and reporting of results. Despite the sample size limitation, our study had a larger number of patients than any of the reported studies in the Cochrane review.¹⁵ For the very sick patients who need MV, the science and technology continuously evolve while new challenges and opportunities continuously present.

Our findings are ecological in nature, and not necessarily causal. Nevertheless, measuring the impact of change in clinical practice is a benchmark of process improvement. Without automated analytics, it is costly to gather data manually. Without data feedback, it is difficult to track practice variation and persuade clinicians to change their behavior. Data analytics per se will not automatically bring changes if practitioners do not buy-in and take ownership of the care process. Hence, staff training aided with data analytics feedback is an important aspect of the structured care process improvement.

Discussion

There is a wide variation among institutions in procedures used by clinicians to discontinue sedation and wean patients from MV. Physicians often have favorite weaning methods that may differ from each other. RTs may have variation in their performance of weaning patients. Nurses may have variations in the practice of controlling delirium and delivery of sedation. Variations can also be related to the timing at which events occur. These variations often create a practice of weaning that may not be optimal.



Figure 2. Improvement of ventilation parameter duration in the post-period.

The diamond represents the point estimate of the change in the post-period compared to the pre-period with zero indicating no change between the pre-versus post period. A negative number indicates a shorter duration of the parameters in the milestones leading to extubation. The whisker shows the 95% confidence interval for the estimate. The figure shows that the point estimates were generally in the favorable (shortened) direction and trending towards statistically significant improvement of MV management. MV: Mechanical ventilation; RTW: ready to wean; SBT: spontaneous breathing trial; ECT: extubation candidate threshold.

We evaluated the impact of a structured process improvement plan on MV management aided by the computerized MV management data analytics. We found that the RKP analytics systems aided many changes of the MV management process. However, the observed reductions in MV duration did not reach statistical significance, in part, due to the limited sample size and lack of power to detect the significance. We powered the study assuming a 35% reduction, based on literature, as the effect size and only a 25% reduction was observed. This sample size and statistical power issue was also observed in the Cochrane review¹⁵ in which results of only 3 out of 16 published studies reached statistical significance.

Girard, et al ¹³ demonstrated the value of a paired sedation and ventilator weaning protocol which produced better outcomes. Our study site implemented the "Wake-up and Breathe" protocol for patients receiving MV in our ICUs several years before the present study was conducted. However, not all processes associated with weaning patients were standardized. Others9 have demonstrated that protocols alone, without active compliance monitoring, are not likely to improve extubation processes. Our study demonstrates that the availability of patient-specific data on the MV process from a computerized MV analytics informatics system combined with focused process improvement helped standardization of weaning protocols. Our data demonstrates a significant shift of SBT times to earlier in the day and an expanded window for SBT. These changes were triggered by a review of pre-period RKP analytics data and highlighted the value of using a computerized analytics system in reviewing and implementing process improvements.

Our process improvement activities included the frequent sharing of detailed performance data in a group setting, which might enhance accountability, especially when this is done with the entire team of intensivists, RNs, and RTs. During the postperiod the respiratory therapy team leaders reviewed ventilator weaning data daily. The addition of early morning ventilator weaning by the night shift staff was reinforced through the feedback of the RKP analytics system. Failed early morning SBTs were easily identified. Variations were promptly communicated. We invested significant time in the education of intensivists, RNs, RTs, and team leaders. This training enhanced the understanding and utility of respiratory dynamics in patients requiring MV for all the clinical staff, as shown in the significantly improved coordination and timing of SBTs. Dasta et.al.¹ demonstrated the daily cost for ICU patients receiving MV is at least \$3,759/patient/ day. Continued efforts to reduce MV can have a positive effect on hospital financial outlays for clinical care.

Conclusions

A computerized, ventilation data analytics system can aid staff training and timely feedback aimed at improvement in MV process management in the ICU setting.

Implications

Structured process improvement plans are often difficult to implement and monitor in daily clinical practice without an automated tool. Although we observed process changes with an automated tool, continued concerted effort among clinicians and application of technology are needed to further achieve improvement in ventilator care.

List of Abbreviations

- MV: mechanical ventilation
- LOS: length of stay
- ICU: intensive care unit
- EHR: electronic health record
- VAP: ventilator associated pneumonia
- RKP: Respiratory Knowledge Portal
- SBT: spontaneous breathing trials
- SAT: spontaneous awakening trials
- RTW: ready to wean status
- ECT: extubation candidate threshold
- RT: respiratory therapist
- RN: registered nurse
- PEEP: Positive end-expiratory pressure
- FiO₂: Fraction of inspired oxygen
- Ve: Minute volume
- SpO₂: Peripheral capillary oxygen saturation
- $H_2O:$ Water
- CPAP: Continuous Positive Airway Pressure

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Simplifying Respiratory Monitoring Using the Integrated Pulmonary Index[™] Algorithm

Greg Spratt BS, RRT, CPFT and David Giarracco

Introduction

Respiratory Compromise (RC), defined as respiratory decompensation through insufficiency, failure and/or arrest (Figure 1), may be preventable through earlier identification and intervention.^{1,2,3} Respiratory conditions are the leading cause of ICU admissions,4 rescue calls,5 and 'code blues,6 and occurs in nearly 1 of 8 elective surgery patients and 1 in 14 of all Medicare patients.^{7,8} It is projected that RC costs will reach \$37 billion annually by 2019⁸ and it ranks among the AHRQ Top 5 Most Rapidly Increasing Hospital Costs.⁹ Patients that develop RC while on the General Care Floor (GCF) have a mortality rate 29 times that of GCF patients that do not develop RC.¹⁰ In light of these sobering statistics, the potential for prevention offers a ray of hope. In a review of primary respiratory arrests, 64% were classified as potentially avoidable and of these, all had inadequate treatment prior to the event, while 67% demonstrated clinicians failed to respond to abnormal laboratory findings (Figure 2).¹¹

Many disease processes may lead to RC including impaired control of breathing, impaired airway protection, parenchymal lung disease, increased airway resistance, hydrostatic pulmonary edema, and right-ventricular failure.¹² These processes account for some of the most prevalent and expensive conditions treated in the hospital including sepsis, heart failure, pneumonia, ARDS, exacerbations of COPD/asthma, postoperative respiratory failure, many others.

Currently, a standardized and validated method of RC risk assessment with subsequent monitoring of those at increased risk does not exist leading some to suggest risk stratification is not an acceptable alternative and that all patients should be monitored (aka, surveillance monitoring).^{13,14} A survey of physicians and nurses revealed that 92% believe that continuous monitoring of patients who are at high risk or in early stages of RC can lead to earlier interventions, preventing further deterioration and 84% agree that RC monitoring can save money by preventing the need for more complex, more costly levels of care (eg, ICU admissions, intubation, ventilation, etc).¹⁵ Evidence suggests that the costs of continuous electronic monitoring are more than offset by cost reductions from event prevention.^{16,17}

Greg Spratt is a respiratory therapist and pulmonary function technologist and David Giarracco is a biomedical engineer. Both are employees of Medtronic engaged in projects and activities to improve technology solutions for early recognition and intervention in Respiratory Compromise.

The Challenge

Nurses and other clinicians often face tremendous challenges in monitoring multiple patients simultaneously. Many hospitals continue to use intermittent, manual methods of monitoring, visually counting a respiratory rate (RR) and performing oximetry spot checks. Manual monitoring is labor intensive requiring more staff, which is a difficult proposition in today's healthcare environment. In reality, hospitals face increasing patient to nurse ratios and staff reductions due to declining reimbursement and budget cuts. The duties of health-care providers have steadily expanded, and the amount of time actually spent per patient has declined. A study of medicalsurgical nurses in 36 hospitals showed that on average, they spend only 7 percent of their time on patient assessment and reading vital signs.¹⁸

Even if staffing ratios were not an issue, simple observation may not be sensitive enough to detect early signs of respiratory decline. Using capnography and impedance monitoring, a study of patients undergoing monitored anesthesia care (MAC) found that 26% of subjects experienced apnea of at least 20 seconds that went unidentified by visual observation from the anesthesia providers.¹⁹ Lightdale found that endoscopy staff using observation only documented poor ventilation in 3% of all procedures and no apnea while simultaneous capnography (blinded to observing staff) indicated alveolar hypoventilation during 56% of these procedures and apnea during 24%.²⁰ This demonstrates that even in an ideal one-on-one care setting, with direct and constant visualization, experienced providers cannot reliably detect a significant respiratory event such as hypoventilation and apnea.



Figure 1. Respiratory Compromise Cascade.

Figure 2. Respiratory Compromise – Common, Costly, Deadly and Preventable.

Common	Costly	Deadly	Preventable
Leading cause of ICU admissions, rescue calls, and 'codes ^{74,5,6} 1 of 8 elective surgery patients ⁷	RC costs will reach \$37 billion annually by 2019 ^s AHRQ <i>Top 5 Most Rapidly</i>	Mortality rate 29 times that of GCF patients that do not develop RC^{10}	Nearly 2 of every 3 cases of respiratory arrest found to be potentially avoidable ¹¹
1 in 14 of all Medicare patients ⁸	Increasing Hospital Costs ⁹		. ,

Exploring Better Solutions

The Integrated Pulmonary Index[™] algorithm (IPI)^{21,22} is a proprietary algorithm available on a variety of manufacturers' monitoring platforms, developed to help clinicians more easily monitor a patient's complete respiratory status by incorporating four real-time respiratory measurements: end-tidal CO_2 , RR, SpO₂ and pulse rate (PR), into a single number (Figure 3). IPI uses mathematical modeling, mimicking a human's logical thinking pattern to derive a respiratory status on a scale from 1 to 10, with 10 being a normal status (Figure 4).²³ To further assist clinicians in monitoring patients with evolving respiratory compromise, IPI trending is displayed (Figure 5) providing early indication that may not be indicated by the current value of any of these four parameters individually.

More than 40 papers have explored IPI's validity and potential value across multiple hospital environments and even outside the hospital. IPI has consistently been found to correspond closely with the clinicians' evaluation of the patient's respiratory status. Hospitals have now begun to incorporate IPI into their protocols for providing an earlier alert to evolving respiratory compromise.^{26,54}

The validity of the index was demonstrated in a retrospective analysis of continuous SpO₂, RR, PR, and etCO₂ readings obtained from 523 patients in a variety of clinical settings. IPI correlated well with expert interpretation of the continuous respiratory data (R = 0.83, p < 0.001), with agreement of -0.5 ± 1.4 . Receiver operating curves analysis resulted in high levels of sensitivity (ranging from 0.83 to 1.00), and corresponding specificity (ranging from 0.96 to 0.74), based on IPI thresholds 3-6. The IPI reliably reflected the respiratory status of patients in multiple areas of care.²⁴

In a separate analysis, data sets were scored by 18 medical experts (nurses, respiratory therapists, physiologists and anesthesiologists) using data sets from 85 patient cases. The IPI results agreed with the experts' average (mean absolute differences =0.64±0.5). Comparing to all experts and cases, the average absolute difference between experts and model is 1±0.35 indicating that IPI closely mirrored clinician assessment of respiratory status.²⁵



Figure 3. IPI combines four parameters into a single index.

pa	atients that	respiratory arr potentially avo	
	IPI	Patient Statu	s

IPI	Patient Status
10	Normal
8-9	Within normal range
7	Close to normal range; requires attention
5-6	Requires attention and may require intervention
3-4	Requires intervention
1-2	Requires immediate intervention

Figure 4. IPI patient status scale

IPI is displayed on a scale from 1-10 with 10 indicating a normal respiratory status. To aid clinicians in monitoring respiratory status over time, IPI is captured and analyzed to show upward and downward trends.

Postoperative Monitoring

IPI has particular appeal on the postoperative GCF and in the post-anesthesia care unit (PACU). It provides a single number indicating respiratory status, helping to save busy nurse time when caring for multiple patients. It also offers a simplistic method of respiratory status monitoring for clinicians who may not be as familiar with more advanced monitoring such as capnography, which may not traditionally be used on the GCF.

When examining the use of IPI in post-operative applications, one hospital monitored capnography and oximetry using an interventional protocol guided by the IPI algorithm on three surgical care floors for patients with higher risk of Obstructive Sleep Apnea. The protocol resulted in a 65% reduction in code blue events in the 24 months following implementation compared to a 20 month baseline.²⁶ None of the high-risk patients who were monitored with IPI experienced a code blue event since implementing the program.

In an analysis of 293 patients in the PACU, 18 patients (6.1%) suffered RC. The RC group had a significantly lower admission IPI than that of non-RC group (p<0.0001), demonstrating that IPI on admission to PACU can predict onset of respiratory adverse events better than SpO_2 alone.²⁷ Other papers have shown that IPI has been shown to correlate with the respiratory status of adult patients after surgery under general anesthesia. Since it is displayed as a single value, it may simplify the monitoring of patients in a busy PACU.^{28,29}

IPI also shows promise as a 'smart alarm', where in one study, IPI alarms were found to be more effective than those of the individual parameters. The number of total alarms was reduced by two-thirds (66%) without losing sensitivity to clinicallysignificant events. Hence it can be used safely and may reduce alarms fatigue.³⁰



Figure 5. Current IPI displayed on the monitor with an IPI trend line.

Procedural Sedation

Patients receiving moderate to deep sedation during minimally invasive procedures may also be at risk for developing respiratory depression which undetected may result in patient injury or even deaths.³¹ The American Society of Anesthesiologists requires capnography for moderate to deep sedation and recently the European Board of Anaesthesia strengthened their recommendations stating capnography—by facilitating early detection of ventilation problems—should be used in all patients undergoing procedural sedation.^{32,33} It is not uncommon for non-anesthetists to provide and monitor sedation for cases under the direction of the interventional physician. IPI may provide a valuable tool to assist clinicians in the early identification of evolving RC during procedural sedation.

Hirofumi et al demonstrated that IPI was able to detect all respiratory depression events in patients receiving sedation while pulse oximetry detected only 12.9% of the clinical respiratory depression events.³⁴ Garah et al found that IPI alerted all apnea episodes and hypoxia episodes, whereas pulse oximetry captured only the hypoxia episodes (IPI sensitivity = 1, specificity 0.98, positive predictive value 0.95).³⁵ Yamanishi et al state that IPI was more sensitive in detecting respiratory depression events during sedation than individual parameters of $etCO_2$, RR, or SpO₂, and contributes to increasing sedation safety for pancreatobiliary endoscopy.³⁶

Beyond the adult patient, IPI is also designed to work with children over the age of one year and has been shown to correlate well with the respiratory status of pediatric patients for procedures under sedation. 3740

Invasive and Non-Invasive Ventilation

Several studies have also shown that IPI may be useful for patients being ventilated, either invasively or non-invasively. In non-invasively ventilated subjects, Waugh et al found that IPI appears to allow detection of abnormal breathing events caused by over-ventilation, rapid shallow breathing, and bradypnea and indicate that the integration of the capnography and oximetry values into one parameter in the form of IPI appears to allow non-invasive detection of hyperventilation and hypoventilation.⁴¹

For invasively ventilated patients, studies have shown that:

- IPI may predict the duration of postoperative mechanical ventilation and may be a valuable adjunct to the bundle of postoperative monitoring after Off Pump Coronary Artery Bypass.⁴²
- IPI was consistent with the interpretation of the respiratory status reflected by the ABG values.⁴³
- The IPI may be a useful tool in establishing and maintaining optimal MV settings and may be useful to decrease time on a MV or reduce ABG.⁴⁴

For evaluating weaning/extubation success:

- IPI values are higher in successful spontaneous breathing trials (SBTs) than in failing SBTs in obese patients undergoing evaluation for weaning. Further studies and larger sample size are needed to more clearly define the value of IPI during weaning from mechanical ventilation.⁴⁵
- IPI demonstrates reasonable agreement with clinical evaluation of Spontaneous Breathing Tests by Respiratory Therapy staff and may be useful in predicting readiness to discontinue mechanical ventilation.⁴⁶
- In post-operative CABG patients, IPI demonstrates reasonable agreement with clinical evaluation of SBTs by Respiratory Therapy staff and may be useful in predicting readiness to discontinue mechanical ventilation.⁴⁷⁻⁴⁸
- During early postoperative period after CABG, IPI can predict the success of tracheal extubation and reflects the changes in respiratory function. Thus, IPI may be a valuable adjunct to the routine perioperative monitoring, facilitating early detection of respiratory problems.⁴⁹
- Using IPI in patients post extubation may provide an indication of impending extubation failure.⁵⁰
- IPI value ≤ 9 at 6 hours after extubation demonstrated moderate predictive ability for early postoperative complications after Off-Pump Coronary Artery Bypass.⁵¹
- Cumulative IPI data may be able to differentiate between patients who will eventually require intubations for critical deterioration and those who will improve without intubation.⁵²

Summary

Clinicians are increasing challenged by healthcare dynamics to effectively monitor patients for evolving RC. Early identification and subsequent intervention may help prevent many cases of RC from developing into respiratory failure requiring rapid response calls, 'codes', intubation, ventilation, and high costs.^{53,54} IPI is an algorithm developed to help clinicians continuously monitor complete respiratory status in a single number.

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Effects of PMV[®] In-line with Mechanical Ventilation on Communication and Swallowing

A Speech-Language Pathologist's Perspective

Maribel Ciampitti, MS, CCC-SLP

Annually, more than 100,000 patients in the United States experience medical events that require a tracheostomy, with 24 percent of those necessitating mechanical ventilation (Yu, 2010). It is estimated that by the year 2020, there will be over 600,000 patients requiring prolonged mechanical ventilation (Zilberberg, 2008). Most vented patients are on prolonged bedrest during hospitalization. In intensive care units across the country, efforts are being made to implement early mobility programs as there is significant evidence indicating that many patients in intensive care units on prolonged mechanical ventilation experience a marked decline in functional status (Spicher, 1987). After one week of bedrest, muscle strength may decrease by as much as 20 percent with an additional loss of 20 percent each subsequent week of bedrest (Perme, 2009; Sciaky, 1994). Why is this significant to speech-language pathology?

The loss of strength extends to the muscles of respiration and the oropharyngeal musculature, which affects communication and swallowing (Griffiths & Jones, 1999). Muscle weakness is an independent predictor of pharyngeal dysfunction and symptomatic aspiration. Patients with muscle weakness often have greatly reduced cough strength and poor control over their swallowing and upper airways (Griffiths & Jones, 1999). The implementation of early mobility and rehabilitation in the fields of physical and occupational therapy has shown positive outcomes in ICU patients (Adler, 2012). The same principles used to promote strength for mobility can be applied to strengthening the oropharyngeal and respiratory musculature to improve swallowing and communication (Burkhead et al., 2007). Two examples of these principles would be the overload principle, where physical capacity is challenged, and the principle of "specific adaptation to imposed demands" when the exercise is linked to the demand and function of the muscle (Trees, Smith, Hockert, 2013). The therapeutic intervention plans developed for voicing, communication, or swallowing often reflect these principles, addressing the muscles involved by using functional tasks which also directly address the demand and function of the muscles.

However, many times the medical team prefers to wait until the patient is weaned from the ventilator before consulting the speech-language pathologist on the basis that the patient is "too sick" to begin intervention for communication and

Maribel Ciampitti, MS, CCC-SLP is a Speech Pathologist at Specialty Hospital, Jacksonivlle, FL, and a Clinical Site Instructor at Jacksonville University. swallowing. Considering that research has shown how disuse leads to muscular atrophy and weakness in relatively short periods of time, waiting to intervene may contribute to significant dysfunction of the speech and swallow mechanisms. Additional contributing factors in this patient population are that the anatomy and physiology of the swallowing and voicing mechanisms are significantly altered when a patient is tracheostomized and ventilated. The placement of a tracheostomy and prolonged mechanical ventilation with an inflated cuff causes a disconnect between the upper and lower airway. The lack of airflow through the upper airway can often lead to multiple negative changes affecting speech and swallowing: reduced subglottic pressure (Eibling & Gross, 1996), decreased sensation to the pharynx and glottis (Eibling & Gross, 1996), reduced laryngopharyngeal reflex (Sasakai, Suzuki, Horiuchi, Masatoshi & Kirchner, 1997), decreased ability to manage secretions requiring more frequent suctioning (Siebens et al., 1993), decreased sense of taste and smell (Lichtman et al., 1995), inability to vocalize, increased aspiration risk, and muscle disuse and atrophy (Griffiths & Jones, 1999). The weight of the tracheostomy tubing and an inflated cuff can decrease the range of motion of the hyolaryngeal mechanism by causing a tethering effect (Ding & Logemann, 2005; Bonanno, 1971).

Furthermore, patients on mechanical ventilation can experience discoordination of breathing, which can negatively impact speech and swallowing (Pringent et al., 2011).

The effects of tracheostomy and vent dependence are not just physical. For patients, the loss of the ability to communicate their everyday needs can lead to increased psycho-emotional distress, (Khalaila et al., 2011), including anxiety and depression (Chen et al., 2011). It robs patients of the ability to participate in their own care and decision making process. Studies have shown that the Passy Muir® Valve used in-line can, in many cases, restore early verbal communication to vent-dependent patients, facilitate the care given by healthcare personnel, enhance their mental outlook, and allow participation in their own care without observed complications (Sutt et al., 2015; Manzano et al., 1993; Passy et al., 1993). Communication is not just a patient right but a basic and important human right. Efforts should be made to facilitate the communication needs of ventilator dependent patients who are in both a vulnerable and difficult position.

The speech-language pathologist (SLP) is in a unique position to provide early intervention and rehabilitation to patients who

Communication is not just a patient right but a basic and important human right

are tracheostomized and on mechanical ventilation via early assessment for the use of a bias closed, no leak speaking valve (Passy Muir Valve) for in-line use with the ventilator. Early intervention by the SLP should begin by identifying patients on mechanical ventilation who are candidates for trials using the Passy Muir Valve (PMV[®]). The benefits of early assessment and implementation with the PMV are many. First and foremost, use of the PMV helps to restore the physiology of the upper airway to its more "normal" state by returning airflow through the upper airway during exhalation. This restoration of airflow to the upper airway allows evaluation of airway patency, vocal cord function, secretion management, and communication skills. In many cases, voicing is restored, allowing the patient to communicate basic needs and participate in their daily care. The restoration of communication also allows the SLP to conduct more thorough speech/language and cognitive assessments, which lead to earlier therapeutic intervention for patients who may have experienced other co-morbidities, such as stroke or traumatic brain injury. Without verbal communication or vocalizations, assessment of speech and language deficits would otherwise be very limited for patients on mechanical ventilation. With early assessment comes early therapeutic intervention and planning for care.

Swallow function is often negatively affected in patients who are tracheostomized and on mechanical ventilation. It is estimated that 50-87% of patients with tracheostomy aspirate, including silent aspiration (Elpern et al., 1987, 1994, 2000). Research suggests that tracheostomy speaking valves may positively impact swallowing function and rehabilitation (Blumenfield, 2011). Research also has demonstrated that early implementation of a swallowing rehabilitation program is feasible for patients on mechanical ventilation (Rodrigues et al., 2015). Physiologically, the bias closed, no-leak valve design of the PMV allows for restoration of subglottic air pressure

Swallow Impairment	Therapeutic Intervention	Adaptation for Trach/Vent Patient
Secretion Management	 PMV[®] trials to allow airflow and sensory stimulation to upper airway RMST (Respiratory Muscle Strength 	 Train inhaling/exhaling through semi-occluded airway (straws) for low level patients Use various IMST/EMST devices on the
	Training)	market to strengthen respiratory system
Low Lung Volumes	IMST (Inspiratory Muscle Strength Training) Supraglottic Swallow	Requires PMV use to engage entire respiratory system, restore subglottic pressure
Weak Cough Strength	Cue patient to cough/clear own secretions EMST (Expiratory Muscle Strength Training)	Requires PMV use to restore subglottic airway pressure
Decreased Vocal Cord Closure	Supraglottic Swallow/Voluntary Breath Hold Adduction Exercises with resistance Sustained phonation	Requires PMV to establish a closed system, restore subglottic pressure
Reduced Laryngeal Elevation	Falsetto Exercises Mendelsohn Maneuver	Requires PMV to establish a closed system, restore subglottic pressure
Reduced Hyolaryngeal Excursion	Super-Supraglottic Swallow	1. Both require restoration of subglottic pressure-place PMV
	Shaker Maneuver	2. Shaker: Place PMV to restore pressure, do not lay patient completely flat, ensure trach does not displace or occlude
Weak Pharyngeal Wall Construction	Effortful Swallow Masako	Requires PMV to close system, restore subglottic pressure
Reduced Cricopharyngeal Opening	Shaker Maneuver Mendelsohn Maneuver	Shaker: Place PMV to restore pressure, do not lay patient completely flat, ensure trach does not displace or occlude

Speech-Language Pathology Therapy Chart | King, Ciampitti

which has been shown to decrease or prevent aspiration in some patients (Dettelbach et al., 1995). Implementation of the PMV in-line allows for more reliable swallow assessment both at the bedside and with instrumentation. Reliability increases with the return of functions such as cough, throat clear, and voicing. With the PMV in-line on mechanical ventilation, the SLP is able to evaluate the integrity of the aerodigestive tract and more thoroughly assess potential risk factors related to the function of the vocal cords, cough strength, and secretion management abilities. Furthermore, the redirection of airflow provides sensory stimulation to the oropharynx and can improve management of secretions, as well as improve taste and smell (Lichtman et al., 1995).

By providing earlier intervention and evaluation, many patients are able to progress safely to an oral diet, even while on mechanical ventilation. For those patients with dysphagia that are not candidates to begin an oral diet, PMV use can be instrumental in the swallow rehabilitation process. Almost all swallowing rehabilitation techniques require the restoration of subglottic pressure to achieve effective results. Almost all oral motor exercises, pharyngeal exercises, swallow maneuvers (such as the Mendelsohn and Supraglottic Swallow), and respiratory muscle strength training require a closed system and subglottic airway pressure. The rehabilitation process may begin with tasks as simple as getting the patient to relearn breathing through the upper airway again and working on managing secretions during PMV trials.

Many patients on prolonged mechanical ventilation also have decreased volumes and poor expiratory strength, which affect swallowing and may place a patient at higher aspiration risk (Gross et al., 2003). PMV use allows patients to participate in respiratory muscle strength training, which has been shown to improve voicing and swallow function (Sapienza & Trocher, 2012). Although many patients successfully tolerate PMV trials on initial attempts, not all tracheostomized patients will be immediately successful. Furthermore, not all swallowing function is improved by tracheostomy tube occlusion; therefore, other variables will need to be considered and evaluated (Donzelli et al., 2006). It is important to work with a multidisciplinary team to troubleshoot potential issues that may affect PMV tolerance, such as trach tube size, upper airway pathology, and underlying medical issues or co-morbidities, so that patients receive the best standard of care and are set up for success with the PMV.

Healthcare professionals who work with medically complex patients on mechanical ventilation face many challenges. Tracheostomized and vented patients are best served by multidisciplinary teams including physicians, respiratory care practitioners, nurses and speech-language pathologists. Other important team members include dieticians, physical and occupational therapists, psychologists, and social workers. The research evidence suggests that early intervention with the Passy Muir one-way valve on mechanical ventilation may lead to improved outcomes. Research has suggested reduced weaning times, improved communication and swallow function, reduced hospital length of stays, reduced cost of care, and overall improvement in the quality of life (Speed & Harding, 2013; Cameron et al., 2009). Studies have shown that waiting until the patient is weaned to intervene can contribute to disuse and atrophy of the speech and swallowing mechanisms leading to significant communication and swallowing deficits. Furthermore, patients on mechanical ventilation often experience psychosocial distress related to their inability to communicate with family and caregivers and to participate in their own care. Early implementation of the Passy Muir Valve, in-line during mechanical ventilation, increases the opportunity for patients to speak, swallow, and participate in direct therapy sooner and has the potential to reduce anxiety, wean times, and lengths of stay. Delayed intervention could potentially complicate efforts to liberate patients from the ventilator, as prolonged ventilation carries risks.

Practices in the timing of speech-language pathology intervention for patients on mechanical ventilation vary across medical settings. Because early intervention addressing communication and swallow function has been shown to have a significant impact on patient outcomes, efforts should be made by speech-language pathologists to evaluate current protocols in ICUs and other medical settings to promote early intervention for patients with transient or chronic vent dependency.

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A Technique of Mechanical Ventilation for the Cardio-Thoracic Post-Operative Open Heart Patient

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History

Mechanical ventilation protocols driven by the respiratory therapists have been shown to decrease ventilation hours and days. A ventilation protocol currently exists for our intensive care unit. However, a ventilation protocol did not exist for our postoperative cardiothoracic open-heart patients. Historically, the mode of ventilation utilized within our cardiothoracic intensive care unit was volume control with a set tidal volume of 10ml/kg/IBW, and positive end expiratory pressure (PEEP) of +5 cm H₂O and 100% FiO₂ initially. Once the patient is noted to be hemodynamically stable and able to spontaneous breathe, a mechanical ventilation spontaneous breathing trial was initiated with pressure support (PS) 10 cm H₂O and PEEP +5 cm H₂O, then dropped to PS 5/ PEEP +5 cm H₂O or PS 7/ PEEP +5 cm H₂O and 40% FiO₂ for two hours.

In 2015, both Cardio Thoracic Surgery and Critical Care medicine desired a set ventilation protocol that was deemed both safe for lung protection and adequate to meet the patient's ventilator demand post-operatively.

Upon observing 1000 open hearts from the period of 2013 to 2015, data showed that based on a tidal volume delivery of 10/ml/kg/IBW and RR of 14, our post-operative open heart patients were both hemodynamically and acid/base stable on two initial set minute ventilations (V_E). For a male, an initial V_E of at least 7.5L was observed, and for a female at least a V_E of 7.0L. Using this philosophy, we incorporated them into a new mechanical ventilation protocol.

Goal of Protocol

The goals for the new ventilation protocol includes, a targeted pH of 7.35, a delivered tidal volume less than 10/ml/kg/IBW, and a mode of mechanical ventilation to assist with extubating postoperative cardiothoracic open hearts within a 6-hour window. For every open heart patient where mechanical ventilation was initiated from March 2015 to December 2016, data was collected to ensure safety of the patient. Arterial blood gas analysis, delivered tidal volumes, respiratory rates, peak and plateau airway pressures, and ventilation hours.

Methods

March 3, 2015-2016, 700 post-operative open hearts were initiated on a new ventilator protocol. The mode of choice is adaptive

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support ventilation (ASV). ASV is mode of ventilation that allows the registered respiratory therapist (RRT) to set a target minute ventilation rather than dialing in both a respiratory rate and a tidal volume. The initial targeted minute ventilation is 7.0L for a female and 7.5L for a male. This mode takes the patient's lung compliance into consideration. Based on the patient's lung compliance a tidal volume range is delivered from 7 to 10/ml/kg/ Ideal body weight (IBW), (50 or 45.5) + (2.3x inches > 5ft) and the respiratory rate is reflected to deliver and reach the goal of the targeted minute ventilation.

Targeted pH

A standard of care for the open hearts at our facility is to obtain an arterial blood gas within minutes of the patient arrival to the ICU. The purpose of the ABG is to note the patient's pH and electrolyte balance. Arterial pH and the electrolytes are used to assess patient stability while transporting from the operating room to the critical care unit and to ensure an extubation time within the 6-hour window. The targeted pH per our cardiothoracic surgeons is 7.35-7.45. A second ABG is obtained 30 to 45 minutes after the patient has been in the intensive care unit. At this time the ABG will reflect the effects of mechanical ventilation. Daily auditing is performed to note optimal ventilation and ph. looking at 2016 the mean pH 30 minutes postinitiation of ASV was 7.34 with a standard deviation ± 0.02 .



Figure 1. Average PH 30 minutes' post admission to HFAM 7 for 2016: Goal 7.35

Positive End Expiratory Pressure (PEEP)

Traditionally, over the years the tidal volume of 10/ml/kg/IBW was set to reverse the degree of post-operative atelectasis. Initially, PEEP was set at +8 cm H₂O and for 2016. PEEP was then increased to +10 cm H₂O at the discretion of critical care medicine. PEEP has been proven to treat atelectasis. During weaning, the PEEP is decreased to +8 cm H₂O. Also, if the patient is intubated > 6 hours, then the PEEP is turned down to

+8 cm H₂O. All open heart patients are extubated from a PEEP of +8 cm H₂O. Examining our data collected from post-operative open heart cases from January-December 2016, there was no negative hemodynamic impact of PEEP of +10 cm H₂O in regards to decrease venous return or cardiac tamponade. Observing PaO₂ 30-minute post-admission to the ICU, the mean PaO₂ was 220 ± 50 .

Delivered Tidal Volumes and Respiratory Rates

To reach a goal of delivering a lower tidal to the post-operative open-heart population, the respiratory therapists set a targeted minute ventilation in ASV mode. The tidal volume delivered are dependent on very important select details. The RRT must correctly enter both the patient's height and gender into the mechanical ventilator upon initiating onto the desired patient. Doing so this allows the ventilator to better assess the patient lung compliance and, in turn, deliver a tidal volume range of 7-10/ ml/kg/IBW including a corresponding respiratory rate to achieve the desired set minute ventilation by using the OTIS equation.

$$f = \frac{1 + 2a \times \text{RC} \times \frac{\text{Min Vol} - (f \times V_d)}{V_d} - 1}{a \times \text{RC}}$$

Additionally, the set pressure limit within the setup of ASV mode helps to control or limit the tidal volume being delivered. Using this process, mean tidal volume and respiratory rate delivered were 8.5 ml/kg/IBW and 16 with a standard deviation of ± 0.22 ml/kg/IBW and ± 2 , respectively.

Using this method, no changes were needed in 98% of the sample to correct the acid/ base status during the case. Once a patient begins to emerge from anesthesia, they are allowed to spontaneously breathe for 30 minutes to ensure alertness, ability to protect their airway, and readiness to extubate. None of the data sample in this investigation needed to be reintubated due to lethargy over the 2-year span of our protocol.



Figure 2. Mean Tidal Volume Delivery with ASV for the post-operative open hearts.

DISCUSSION: Modes of ventilation Comparison of two modes of ventilation

ASV: Minute Ventilation target set at a minimal 7.0L for a Female, and 7.5L for a male, PEEP +10. *Weaning*: MV 70%, PEEP +8 for 30 minutes.

Volume control: Respiratory Rate 16-18, Tidal Volume 8.0-8.5/ml/kg/IBW, PEEP +10. *Weaning*: 5/5 or 7/5, PEEP +8 for 30 minutes.

Airway Pressures

Lung protection strategy has been the current thought process when ventilating any patient. ASV, with the consideration of lung compliance, has effectively delivered a sustained tidal volume that reflects safe airway ventilating pressures. Our goal for every intubated patient is to deliver a peak inspiratory pressure of <35cm H₂O and a plateau pressure <30 cm H₂O. Observing postoperative open hearts cases for 2016, the mean peak inspiratory pressure delivered via mechanical ventilation was 24.5, cm H₂O with a standard deviation of ±1.01.



Figure 3. Mean Peak Inspiratory Pressures with Tidal Volume Delivery in ASV

Weaning

Once the patient is noted to be hemodynamically stable and able to spontaneously breathe, ASV minute ventilation is decreased to 70%, PEEP decreased to +8 cm H_2O and FiO_2 decreased to 40%. The patient is then weaned for 30 minutes to ensure readiness to extubate. The patient is extubated to a 4-6 liter per minute (lpm) nasal cannula.

Ventilation Hours

Optimizing a specific method of mechanical ventilation accomplishes two goals. First, the protocol provides safe and effective mechanical ventilation to protect patient lungs. Second, extubate the patient in both a quick and safe manner. Mean mechanical ventilation hours for our study population in 2016 was 4.49 hours with a standard deviation of ± 0.71 hours.



Figure 4. Mean Ventilation Hours for the Post-Operative Open Hearts

Discussion

Mechanical ventilation of a cardiothoracic open heart surgery patient can be ventilated different ways. Adopting ASV as a technique has been shown to be beneficial for our patient population. Some patients may be dyssynchronous in the ASV mode. Asynchronous patients in ASV tend to require higher flowrates (ie shorter inspiratory times), which can be corrected using a volume mode, and where inspiratory time is better controlled. Example: Emphysema or severe COPD. When the RRT has experienced this occurrence, they choose a tidal volume of 8/ml/kg/IBW and a RR of 16-18, initially. PEEP is kept at +10 cm H₂O, as in ASV mode, to help reverse postoperative atelectasis. Close loop communication is made with the cardiothoracic team. Both modes are suitable to optimize

ventilation post-operatively. However, we start with ASV. Target minute ventilation is kept in the range of 7.0- 7.5/ml/kg/IBW initially. Our target pH is 7.35.

Results

Seven hundred open hearts have been initiated on ASV since March 2015. Retrospectively, looking at the first complete year post initiation in 2016, we have optimized our mechanical ventilation, delivering safe tidal volumes, peak inspiratory ventilating pressures, and are able to extubate our patients, on average, in 4.49 hours.

For the current year, we have data for 197 post-operative heart patients from January to June 2017. The average tidal volume delivery in ASV is 8.3 ml/kg/IBW and a corresponding average peak inspiratory pressure of 23 cm $\rm H_2O$. Team collaboration at the bedside permits the timeliness of weaning and ensuring liberation from mechanical ventilation. 100% of our sample population were extubated after 30 minutes of weaning and no reintubations occurred due to patient lethargy.

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