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Editorial Advisory Board

A Review of Some Basics—Gas Laws During Mechanical Ventilation Impact on Compressible Volume Loss in Circuits

Edwin Coombs, MA, RRT, NPS, ACCS, FAARC

Recently a study was published that examined performance characteristics of high-frequency infant ventilators that may raise concerns over how measurement accuracy can be affected with respect to effective tidal volume delivery and/or impact on delivered pressure/amplitude. This brief article will review gas laws and how their respective variables can have an impact on the delivery of mechanical breaths.

The ideal gas law defines a relationship between pressure, volume, temperature, and the number of gas molecules. Pressure and volume are inversely related; whereas temperature is directly proportional to volume or pressure.[1]

Boyle's law states that at a constant temperature, pressure is inversely proportional to volume. This law predicts the relationship of a volume of gas to a pressure change.[1,2] Temperature (ie: warm ventilator tubing) also contributes to changes in tubing compliance.

Gay-Lussac's law of pressure and temperature describes the direct relationship between pressure and temperature. If the absolute temperature of a fixed volume of gas is increased, the pressure will increase proportionally.[1,2]

Charles's law predicts the effect of temperature on a fixed amount of dry gas. At a constant pressure, gas expands proportionally to changes in absolute temperature.[1,2]

The patient circuit of a mechanical ventilator conducts the breathing gas from the ventilator to the patient and from the patient to the expiratory valve of the ventilator. Tubing expansion can be seen when high pressure is generated within the patient circuit. The circuit can often be seen to expand during inspiration and then return to its original size during exhalation. Part of the inspiratory pressure or tidal volume delivered from the ventilator contributes to this tubing expansion, and as a result, it is attenuated before reaching the distal airways.

This phenomenon is extremely important when ventilating infants and children, especially when utilizing high-frequency ventilation. For this reason, a low-compliance circuit must be utilized.[2]

The use of HFOV in infants is to protect extremely premature and fragile lungs from ventilator-induced lung injury through a protective ventilation strategy. Typically, initial HFOV settings in infants are: a MAP of 2-3 cmH_2O above conventional ventilation; power to achieve an amplitude that results in visible "chest wiggle"; and a frequency of 10 Hz.[3]

While bench studies are an integral component that contributes to the advancement of science and our understanding of respiratory care products, researchers and clinicians must take into account all factors which can potentially impact how devices, accessories and related consumables deliver mechanical ventilation. Understanding research study design and methodology is critical when evaluating the results of equipment tests.

References

1 Hess, D. MacIntyre, N. Galvin, W. Mishow, S. "Respiratory Care: Principles and Practice" Third Edition; Jones & Bartlett Learning, 2016, pp 1210-1211.
2 Cairo, JM. Pilbeam, S. "Mosby's Respiratory Care Equipment" Seventh Edition; Mosby, 1999, pp 13-14.
3 High Frequency Oscillatory Ventilation (HFOV) : a guide to the use of HFOV in the neonate (scot.nhs.uk)

Edwin Coombs is the Sr. Director of Marketing, Intensive Care at Dräger.

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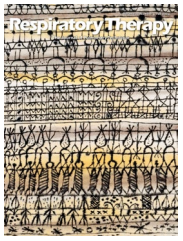

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News

■ Fall 2024

The Mixed Messages on Relationship Between COVID and Asthma

In one of several recently published studies on the relationship between COVID-19 infection and asthma, asthma symptoms in children declined as the proportion of the US population vaccinated against COVID-19 increased, according to data drawn from the National Survey of Children's Health (NSCH). The inverse correlation between symptoms and vaccination was strong and statistically significant, according to investigators led by Matthew M. Davis, MD, Physician in Chief and Chief Scientific Officer, Nemours Children's Health, Wilmington, Delaware. "With each increase of 10 percentage points in COVID-19 vaccination coverage, the parent-reported child asthma symptoms prevalence decreased by 0.36 percentage points ($P < .05$)," Dr Davis and his coinvestigators reported in a research letter published in *JAMA Network Open*. The reduced risk of asthma symptoms with COVID-19 vaccination in children at the population level is just one of several recently published studies exploring the interaction between COVID-19 infection and asthma, but two studies that posed the same question did not reach the same conclusion. In one, COVID-19 infection in children was not found to be a trigger for new-onset asthma, but the second found that it was. In a third study, the preponderance of evidence from a meta-analysis found that patients with asthma — whether children or adults — did not necessarily experience a more severe course of COVID-19 infection than in those without asthma. The NSCH database study calculated state-level change in scores for patient-reported childhood asthma symptoms in the years in the years 2018-2019, which preceded the pandemic and the years 2020-2021, when the pandemic began. The hypothesis was that the proportion of the population 5 years of age or older who completed the COVID-19 primary vaccination would be inversely related to asthma symptom prevalence. Relative to the 2018-2019 years, the mean rate of parent-reported asthma symptoms was 0.85% lower (6.93% vs 7.77%; $P < .001$) in 2020-2021, when the mean primary series COVID-19 vaccination rate was 72.3%. The study was not able to evaluate the impact of COVID-19 vaccination specifically in children with asthma, because history of asthma is not captured in the NSCH data, but Dr Davis contended that the reduction in symptomatic asthma among children with increased vaccination offers validation for the state-level findings. "Moreover, the absence of an association of COVID-19 vaccination administered predominantly in 2021 with population-level COVID-19 mortality in 2020 serves as a negative control," he and his colleagues wrote in their research letter.

US FDA Approves Verona Pharma's Inhaled COPD Therapy

The US Food and Drug Administration has granted approval to a treatment from Verona Pharma for a chronic lung disease that commonly affects smokers, the UK-based company said. The FDA's assent for the therapy, to be sold under the brand Ohtuvayre, is the company's first and provides a new inhaled non-steroidal treatment for chronic obstructive pulmonary disease. COPD, a chronic condition which causes restricted airflow and breathing problems, commonly affects cigarette smokers and is also known as "smoker's lungs". Other contributing factors for COPD include fumes, chemicals and dust in many working environments. It affects around 16 million Americans and is the sixth leading cause of death in the country, according to government data. Verona's application was backed by efficacy and safety data from two late-stage trials in which Ohtuvayre demonstrated improvements in lung function and symptoms, substantially reducing the risk of exacerbation in mild-to-severe COPD patients.

Masimo Announces Sleep Halo, Advanced Sleep Analysis

Masimo announced that the Masimo W1 Sport advanced health tracking wearable is gaining a powerful new feature: scientifically based sleep analysis with Sleep Halo. Sleep Halo offers overnight sleep data tracking with an unmatched 70,000+ daily measurements of second-by-second continuous health data. Sleep Halo uses continuous Masimo pulse oximetry and machine learning to provide meaningful insights into the quality of an individual's sleep, including overall timing, duration of sleep stages, periods of rest and wakefulness, episodes

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of desaturation, and more. The nightly analysis, including a Sleep Halo score—an algorithmic calculation representing your overall sleep quality—is visualized on the companion Masimo Health smartphone app. The Sleep Halo score and sleep analysis will be featured in all future Masimo wearables, including the upcoming Masimo Freedom Watch and Band. Joe Kiani, Founder and CEO of Masimo, said, "We're truly excited to launch Sleep Halo for Masimo W1 Sport. For 35 years, Masimo has been dedicated to using breakthrough engineering to help improve lives. Masimo W1 is unique among wearables in being able to continuously measure the wearer's SpO_2 and PR—and that gives us an opportunity to provide a truly informed, robust analysis of how one sleeps. As always, we are committed to providing scientifically backed measurements, which are based on our unmatched, accurate technology, not 'tarot card logic' novelties. We benchmarked Sleep Halo with EEG to confirm its stages of sleep are comparable to sleep analysis. We hope that with this new scientifically based Sleep Halo, our customers can improve their sleep hygiene, which has been shown to improve life." Today's consumers are limited to choosing from among a variety of consumer wearables, which use intermittent and often inaccurate data, heavily reliant on movement—which cannot provide reliable or actionable sleep metrics. Masimo W1—which has been shown to be significantly more accurate than the leading consumer wearable – is designed to provide sophisticated and insightful sleep analysis using technology based on Masimo SET, the primary pulse oximetry technology at all top 10 U.S. hospitals as ranked in the 2024 *Newsweek* World's Best Hospitals listing. Rigorously tested against reference laboratory measurements, including EEG data, Sleep Halo makes it possible to bring reliable, insightful sleep analysis to everyday people around the world, on a nightly basis, via a lightweight, comfortable wearable, from the convenience of their own home. Existing Masimo W1 Sport owners will soon be able to update their watch firmware and Masimo Health app to begin their sleep tracking journey. Masimo W1 is available for purchase at www.Masimo.com. Also available is Masimo W1 Medical, the first and only FDA-cleared watch to provide continuous, real-time SpO_2 and PR with an indicator when measurements are outside of their normal ranges. Masimo W1 Sport and Sleep Halo are for general health and wellness purposes.

New Product Released

Dale Medical Products, Inc., an industry leader in disposable medical products, announced the launch of its latest patent pending innovation, UltraGrip. This revolutionary NasoGastric Tube Holder sets a new standard in NG Tube Securement with its cutting-edge features and unparalleled performance. UltraGrip is the culmination of marketing research and engineering design. It represents Dale's commitment to delivering innovative patient solutions with clinician inspired enhancements that meet the evolving needs of patients and clinicians. Key features of the UltraGrip 163 include: Universal Design which allows it to secure all types/sizes of NG tubes, breathable fabric with a patient friendly adhesive and non-adherent tipped ends, easy to use and understand single tab design, non-adherent, cushioned foam bridge pad which provides superior comfort at the tip of the nose to help prevent medical device related pressure injury (MDRPIs). "We are thrilled to introduce the UltraGrip Single Leg NG Tube holder to the healthcare market. This new product is a great example of a clinical solution that satisfies the needs of patients and their caregivers," said Bob Simpson, President & CEO. The 163 UltraGrip becomes available on or about July 15, 2024 through distributors worldwide. For more information about the 163 UltraGrip, visit the Dale Medical website at www.dalemedical.com.

Measure Respiratory Signals with Insight

Company Hans Rudolph announced new features for its SmartLab Instrumentation System with Insight software, a flexible data-acquisition system for use in making measurements of respiratory signals. It is a modular system that can be configured for a variety of measurements. The base module consists of a main system circuit board that can accept up to four sensor modules. It also has an input for a Nonin xPod oximeter and a Masimo IRMA CO2 concentration sensor. An optional internal oxygen concentration sensor is also available. Digital I/O ports with eight outputs and four inputs can be connected to a valve controller or other device that can accept TTL level digital signals. An optional analog output module is available for retransmitting up to 4 measured or calculated values. In addition to these standard applications, they have recently launched a new ECG Sensors and Module, Lung Compliance and Air Way Resistance Processor upgrade and MRI Compatible Pulse Oximetry and Respiratory Band Sensors and Modules. New features include ECG Modules for both 110V and 230V applications with three leads and upgradable sensors, lung Compliance and Airway Resistance Processor upgrade, and MRI Compatible Pulse Oximetry and Respiratory Band Sensors and Modules. The base unit holds up to 4 sensor modules. Differential pressure sensor modules with full scale ranges from 2 cmH2O to 350 cmH2O. Absolute pressure sensor modules for barometric pressure or altitude compensation.

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More Evidence PTSD Tied to Obstructive Sleep Apnea Risk

Posttraumatic stress disorder (PTSD) may enhance the risk for obstructive sleep apnea (OSA) in older male veterans, the results of a cross-sectional twin study suggested. However, additional high-quality research is needed and may yield important mechanistic insights into both conditions and improve treatment, experts said. In the trial, increasing PTSD symptom severity was associated with increasing severity of OSA, even after controlling for multiple factors. "The strength of the association was a bit surprising," study investigator Amit J. Shah, MD, MSCR, Emory University, Atlanta, said. "Many physicians and scientists may otherwise assume that the relationship between PTSD and sleep apnea would be primarily mediated by obesity, but we did not find that obesity explained our findings." "Prior studies have shown an association between PTSD and sleep apnea, but the size of the association was not as strong," Shah said, possibly because many were based on symptomatic patients referred for clinical evaluation of OSA and some relied on self-report of a sleep apnea diagnosis. The current study involved 181 male twins, aged 61-71 years, including 66 pairs discordant for PTSD symptoms and 15 pairs discordant for PTSD diagnosis, who were recruited from the Vietnam Era Twin Registry and underwent a formal psychiatric and polysomnography evaluation as follow-up of the Emory Twin Study. PTSD symptom severity was assessed using the self-administered Posttraumatic Stress Disorder Checklist (PCL). OSA was mild in 74% of participants, moderate to severe in 40%, and severe in 18%. The mean apnea-hypopnea index (AHI) was 17.7 events per hour, and the mean proportion of the night with SaO_2 less than 90% was 8.9%. In fully adjusted models, each 15-point within-pair difference in PCL score was associated with a 4.6 events-per-hour higher AHI, a 6.4 events-per-hour higher oxygen desaturation index, and a 4.8% greater sleep duration with SaO_2 less than 90%. A current PTSD diagnosis is associated with an approximate 10-unit higher adjusted AHI in separate models involving potential cardiovascular mediators (10.5-unit; 95% CI, 5.7-15.3) and sociodemographic and psychiatric confounders (10.7-unit; 95% CI, 4.0-17.4). The investigators call for more research into the underlying mechanisms but speculate that pharyngeal collapsibility and exaggerated loop gain, among others, may play a role. "Our findings broaden the concept of OSA as one that may involve stress pathways in addition to the traditional mechanisms involving airway collapse and obesity," Shah said. "We should be more suspicious of OSA as an important comorbidity in PTSD, given the high OSA prevalence that we found in PTSD veterans."

Masimo and Cleveland Clinic Collaborate to Improve Hospital Remote Care

Masimo, a leading global provider of medical technology and hospital automation solutions, and Cleveland Clinic, a nonprofit academic medical center, announced today the launch of a new partnership centered around hospital-based remote patient monitoring (RPM), including TeleCritical Care. This will include the integration of Cleveland Clinic's critical care (eHospital) and non-critical care (eCMU) central patient monitoring platforms with the Masimo Hospital Automation platform. The goal is to provide tools for clinicians that offer enhanced situational awareness and clinical decision-support for hospitalized patients, including the critically ill. The collaboration will include joint development initiatives on predictive analytics and AI-based algorithms for improving cardiac care. Cleveland Clinic's existing critical care and non-critical care central monitoring platform provides continuous monitoring of a range of vital signs, including ECG, for both ICU and non-ICU patients at more than a 2,000-bed capacity. Its hospital-based RPM programs serve 11 hospitals, providing intensivist monitoring, 24/7 critical care nursing, and patient management. Cleveland Clinic's programs have reduced patient mortality and reduced ICU length of stay while increasing caregiver satisfaction. With this partnership, Masimo and Cleveland Clinic hope to bring these innovations and patient benefits to other healthcare systems in the future. The aim of the enhanced program is to increase awareness and facilitate triage with proactive responses to changes in a patient's condition. This improves patient care and saves lives by ensuring the highest risk patients are identified and receive timely treatment while maintaining quality of care for all patients. The Masimo Hospital Automation platform offers technologies designed to help clinicians improve patient care at the bedside, across the care continuum. Masimo Hospital Automation includes monitoring and wearable technologies, high-fidelity medical device integration, system-wide applications for surveillance and data visualization, and novel AI capabilities that support intelligent patient prioritization and help clinicians identify changes in patients' condition more efficiently. These decision-support tools are integrated into the Masimo Hospital Automation platform and utilize the Halo engine, technology which identifies deterioration patterns in multiple physiological parameters simultaneously, in real time. The Halo tools include Halo ION, a comprehensive, scalable, and customizable continuous early warning score to help streamline patient assessment and clinical workflows. As part of their work together, Masimo and Cleveland Clinic are partnering to jointly develop an additional Halo-based decision-support tool to support clinicians with earlier detection of adverse events—ultimately helping them manage and improve patient outcomes more effectively, for low-, mid-, and high-acuity patients. "We see great opportunities to enhance remote care, particularly for critically ill individuals," said Chiedozie Udeh, M.D., Medical Director of ICU Operations at Cleveland Clinic. "By combining our technical and clinical expertise, we aim to improve situational awareness for clinicians and continue to improve outcomes for patients." Thomas Callahan, M.D., Staff Cardiologist at Cleveland Clinic's Heart, Vascular & Thoracic Institute, and principal investigator for the AI study, added, "We look forward to exploring the effects of next-gen inpatient wearables, and as the capabilities of AI continue to advance, studying the potential impact on the care of cardiac patients, including those undergoing cardiac surgery." Joe Kiani, Founder and CEO of Masimo, said, "We are truly honored to have the opportunity to partner with Cleveland Clinic to advance patient care. By harnessing Masimo's AI-powered decision support tools, automation solutions, and monitoring devices, alongside Cleveland Clinic's vast clinical expertise and dedication to providing the highest quality, most innovative care, our partnership has the potential to significantly ease staff shortages, better standardize care, and promote intensivist- and specialist-led care. Ultimately, we will make significant strides in shifting

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INDICATION

INOmax is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

IMPORTANT SAFETY INFORMATION

- INOmax is **contraindicated** in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of INOmax may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO_2 levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOmax on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.
- In patients with pre-existing left ventricular dysfunction, INOmax may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO_2, inspired NO_2, and methemoglobin during INOmax administration.
- INOmax must be administered using a calibrated FDA-cleared Nitric Oxide Delivery System.

Please see Brief Summary of Full Prescribing Information on the adjacent page.

References: 1. INOmax EVOLVE™ DS Operation Manual. Madison, WI: Mallinckrodt Pharmaceuticals. **2.** INOmax. Package insert. Mallinckrodt Pharmaceuticals. **3.** INOmax DS_{IR} Plus Operation Manual. Hampton, NJ: INO Therapeutics LLC.

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Brief Summary of Prescribing Information

INDICATIONS AND USAGE

INOmax® is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

CONTRAINDICATIONS

INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

Hypoxemia from Methemoglobinemia

Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide

Nitrogen dioxide (NO_2) forms in gas mixtures containing NO and O_2. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO_2 concentration, or if the NO_2 concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO_2 analyzer should be recalibrated. The dose of INOmax and/or FiO_2 should be adjusted as appropriate.

Worsening Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Post marketing reports of accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

DRUG INTERACTIONS

Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO_2. Elevated NO_2 may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO_2 levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

from reactive to predictive and proactive care—improving patient outcomes, safety, and quality of care across the board." Dr Chiedozie Udeh has a conflict of interest with Cleveland Clinic's eHospital platform and may benefit from commercialization of eHospital technology developed by the Company. These financial interests are being managed by Cleveland Clinic and are within permissible limits established by the Institutional Conflicts of Interest Policy. eHospital is not a Masimo product.

RT Companies Issue Mission Statement

React Health and ReactDx, leading companies in respiratory, sleep, and cardiac care, announced the adoption of new, joint mission and vision statements that underscore their commitment to optimizing individuals' well-being through pioneering advanced diagnostics and therapeutics. The new mission, "To improve the lives of those we serve by delivering an innovative continuum of diagnostics and medical devices, with excellent respiratory, sleep and cardiac care." In addition to the new mission statement, React Health and ReactDx have articulated a bold new vision: "To seamlessly integrate end-to-end quality diagnostic medical device and service products to become the cost-effective standard in the detection, prevention, treatment and monitoring of respiratory, sleep, and cardiac conditions by removing barriers informed by the experiences of patients and customers." "With these new mission and vision statements, we are setting a clear direction for the future," said Dr Colleen Lance, Chief Medical Officer. "Our focus is on pioneering advanced diagnostics and therapeutics, and this mission encapsulates our dedication to optimizing the well-being of individuals and uplifting the quality of life for those in our care. Our vision further reinforces our aspiration to revolutionize holistic care and ensure universal access to innovative health solutions." The development of the new mission and vision statements was a comprehensive process that involved input from various stakeholders, including employees, patients, and industry experts. This initiative is part of the company's broader strategy to enhance patient care through innovation and excellence. "We believe this mission and vision will inspire our team and resonate with our providers and patients," added Bill Shoop, Chief Executive Officer. "They capture the essence of who we are and where we are headed, emphasizing our commitment to respiratory, sleep, and cardiac care, as well as our broader goal of revolutionizing holistic care."

Rheumatoid Arthritis Disease Activity Impacts Severity of Associated Interstitial Lung Disease

New findings reveal that rheumatoid arthritis (RA) disease activity significantly affects the severity of interstitial lung disease (ILD), both radiologically and physiologically, in patients with RA and comorbid ILD.Impaired pulmonary function negatively affects the survival of patients with RA-ILD, making it necessary to evaluate the effect of RA disease activity on the severity of ILD. Researchers assessed the associations between RA disease activity and ILD severity in 124 patients with RA (median age, 70.0 years; 25.8% men; median disease duration, 2.92 years) who visited a rheumatology center between December 2020 and March 2023. ILD severity was determined using high-resolution computed tomography (HRCT), with scores ranging from 0% (no involvement) to 100% (all lung fields affected), and pulmonary function tests such as forced vital capacity (FVC) and predicted FVC%. RA disease activity was assessed using the Disease Activity Score in 28 joints calculated with erythrocyte sedimentation rate (DAS28-ESR) and the Clinical Disease Activity Index (CDAI). HRCT revealed that 17 patients had ILD, with ILD severity being mild (< 10% lung involvement), moderate (≥ 10% to < 20%), or severe (≥ 20%) in 7.2%, 2.4%, and 4.0% patients, respectively. Both rheumatoid factor titer (standardized coefficient, 0.247; $P = .01$) and DAS28-ESR (standardized coefficient, 0.199; $P = .03$) were significantly associated with the radiological quantitative severity of ILD. Additionally, DAS28-ESR showed a significant association with predicted FVC% (standardized coefficient, −0.230; $P = .047$); however, no significant association was observed with CDAI.

Bronchial Rheoplasty Unplugs Mucus in Patients With Chronic Bronchitis

Bronchial rheoplasty (BR) significantly reduced mucus plugging in adults with chronic bronchitis (CB), based on new data presented at the American Thoracic Society International Conference. "Mucus plugging, opacities within the lumen of an airway seen on CT scan, is a relatively new measure in COPD that physicians are investigating," lead author Victor Kim, MD, of Temple University Hospital, Philadelphia, said. "These mucus plugs are comprised of excess mucus that cannot be expelled and obstruct the airway from participating in ventilation," he said. Previous research has shown an association between mucus plugging seen on chest CT and increased all-cause mortality, Kim and colleagues wrote in their abstract. "Mucus plugs can lead to airflow obstruction, hypoxia, exacerbation of COPD, and infection of the lower respiratory tract," Kim said. "The presence of mucus plugging has been related to increased mortality and increased exacerbations, and reducing or eliminating them is associated with clinical improvements in asthma," he said. CB is also associated with mucus plugs,

and BR has been shown to improve CB symptoms that can last up to at least a year, he noted. Therefore, Kim and colleagues hypothesized that BR could also reduce mucus plugs. The researchers recruited 52 adult patients with symptomatic CB (defined as Chronic Obstructive Pulmonary Disease [COPD] Assessment Test cough and phlegm scores > 7) who underwent bilateral BR procedures. CT was performed prior to the BR procedure and 6 months after the completion of the BR. The BR procedure involves nonthermal ablation of the airway epithelium and submucosa with pulsed electric fields, the researchers wrote in their abstract. Mucus plugging was defined as the occlusion of a segmental airway and was assessed as the number of airway segments (out of a total of 18) with one or more mucus plugs. The mean number of airway segments with mucus plugging was 2.9 out of 18 possible segments. A total of 35 patients (67%) showed mucus plugging before the intervention, and 17 did not, despite significant self-reported baseline CB symptoms, the researchers noted. Among the patients with baseline mucus plugging, the mean mucus plugging score decreased by approximately one segment from 4.3 to 3.4 after the procedure (P = .0392). More than half of the patients with mucus plugging (20 patients, 57%) improved by one segment or more. In addition, distal airway volume increased by 7.4% at follow-up, and total airway count increased by 4.9 airways. In patients without baseline mucus plugging, 65% continued to have no mucus plugging at 6 months' follow-up. Overall, changes in CT measures were consistent with changes in symptom improvement, with mean changes from baseline to follow-up of –6.8 points and 14.5 points on the COPD Assessment Test and St. George's Respiratory Questionnaire, respectively.

Understudied Patients With COPD Benefit From Bronchoscopic Lung Reduction

Bronchoscopic lung volume reduction (BLVR) significantly improved lung function in a subset of patients with chronic obstructive pulmonary disease (COPD) with alpha-1 antitrypsin deficiency (AATD), based on data from more than 200 individuals. BLVR has shown promising results in previous studies for carefully selected patients with COPD, said Michael J. Nicholson, DO, of Temple University Hospital, Philadelphia. However, those with AATD have often been excluded from large BLVR trials, so data on its effectiveness in this population are limited, he said. "The distinct pathophysiology of AATD poses challenges in extrapolating findings from trials involving COPD patients without AATD," Nicholson noted. "Variations in affected lung lobes and disease progression are major differences between the AATD and non-AATD populations; we sought to examine if BLVR could provide significant, sustained benefit to AATD patients despite their differences from the typical COPD cohort," he said. In a study presented at the American Thoracic Society (ATS) 2024 International Conference, Nicholson and colleagues reviewed data from 238 adults with COPD including 14 with AATD who underwent BLVR at a single center between August 2018 and December 2022. Pulmonary function test data were collected at baseline and at a median of 7 months post-BLVR. The mean age of patients with AATD was 61.5 years, and 79% were men. The primary outcome was the percentage of patients with forced expiratory volume per second (FEV1) improvement greater than 15%. Half of the patients with AATD achieved this outcome, with a median improvement in FEV1 of 110 mL and a significant difference in pre- and post-BLVR FEV1

Continued on page 63…

ABM Respiratory Care

Booth 1218

What products will you be presenting at AARC?
At ABM Respiratory Care, we are committed to advancing respiratory therapy through innovation. During the AARC conference, we will be showcasing our cutting-edge airway clearance products: the BiWaze Cough and BiWaze Clear systems.

BiWaze Cough is an innovative system designed to minimize bacterial contamination and help patients maintain optimal oxygen levels post-therapy. Its cutting-edge design offers unparalleled flexibility in programming, tailored to the unique needs of each patient. The user-friendly interface ensures a seamless experience for both patients and caregivers. Discover why BiWaze Cough is the most advanced and effective solution in assisted cough therapy.

BiWaze Clear is the next generation in oscillating lung expansion therapy, meticulously engineered to optimize airway clearance by mobilizing secretions and expanding small airways in the lower lobes of the lungs. Its integration with the advanced Aerogen nebulizer ensures precise aerosol delivery, eliminating medication waste and maximizing therapeutic effectiveness. The intuitive touchscreen interface guarantees a seamless experience, empowering both patients and caregivers with unparalleled ease and control. Discover why BiWaze Clear is setting a new standard in airway clearance therapy.

Discuss educational/training materials you'll be offering.
Our team will be offering live demonstrations and hands-on training sessions for both the BiWaze Cough and BiWaze Clear systems. This is an excellent opportunity to experience our technology in action and gain valuable insights from our experts.

What speakers or papers will you be featuring?
Explore our latest white papers that demonstrate the superiority of our aerosol delivery, high-frequency oscillations, and cough therapy. Our experts will be available at the booth to discuss the data, answer your questions, and provide you with detailed handouts.

Why should AARC participants visit your display?
AARC participants should visit our display to experience the future of respiratory care firsthand. We'll be offering live demonstrations of our two BiWaze systems, where you can try out the therapy and feel the difference yourself.

During the demonstrations, you'll see the advanced technology of the BiWaze Cough and BiWaze Clear systems in action, showcasing their effectiveness in improving airway clearance. Our team will be there to guide you through the features, answer your questions, and discuss how our products can enhance patient care and efficiency in your practice. Don't miss this opportunity to see our innovations in action—visit us at the AARC conference and discover how ABM Respiratory Care is shaping the future of airway clearance therapy.

Breas

Booth 522

What products will you be presenting at AARC?
Breas will be highlighting the Vivo 45LS life support ventilator at AARC. We're proud to showcase how the Breas life support ventilator is setting the new standard in patient comfort and mobility (light weight, up to 24+ hour battery life, eSync's patented inspiratory trigger to minimize uncomfortable auto-triggers), and improved clinical workflow and decisions (remote connectivity to EveryWare, VAPS and AE modes, monitoring of SpO2, FiO2, etCO2 and PTcCO2).

Are there any new products you wish to emphasize?
We're excited to showcase the Vivo 1, 2, and 3 bi-level ventilators. These new generation bi-level ventilators are designed for personalized and comfortable respiratory support — both non-invasive (Vivo 1 and 2), invasive and HFNT (Vivo 3) — for non-dependent patients with chronic breathing insufficiency. The Vivo 1-2-3 are currently pending FDA approval and not yet for sale in the US.

Discuss educational/training materials you'll be offering.
Our trained sales team is prepared to answer any questions attendees may have. We will also have product spec sheets available in our booth, as well as a full complement of online materials.

Why should AARC participants visit your display?
AARC attendees can get hands-on experience with the Vivo 45LS, Vivo 1-2-3 ventilators, as well as our Breas EveryWare Cloud connectivity solution by visiting our booth. They can see how portable, yet clinically powerful, these units actually are in order to support your patient's needs.

CAREstream America

Booth 532

What products will you be presenting at AARC?
Respiratory care and patient humidification is redefined at AARC with our extensive portfolio of Pharma Systems HME and Filter solutions at AARC 2024. Our wide range of trach, and HME/filter styles are the perfect match for short and long-term care, boasting bacterial and viral efficiencies greater than 99.99%. Discover advanced solutions for improved patient care.

Are there any new products you wish to emphasize?
When looking to nebulize through and maintain AARC guidelines look no further than the HME 12 from Pharma Systems. Other HMEs require switching to open air, with our HME 12 the patient continues to receive therapeutic humification while nebulization is dispensed. This economically priced, high quality therapeutic HME offers high moisture returns and is leading the way in respiratory care effectiveness.

Why should AARC participants visit your display?
Attention Respiratory Clinicians! Visit the CAREstream America booth at AARC to explore our comprehensive range of Pharma Systems HMEs and Filters designed to protect equipment, patients, and staff. From adult to neonate, explore these trusted essentials to enhance patient care and streamline your workflow. Plus, learn about exclusive volume discounts, request samples and quality breath by breath.

Dale

Booth 930

What products will you be presenting at AARC?
BreezeLock Endotracheal Tube Holder, Stabilock Endotracheal Tube Holder, Tracheostomy Tube Holder.

Are there any new products you wish to emphasize?
BreezeLock Endotracheal Tube Holder.

Discuss educational/training materials you'll be offering.
Perspectives in Nursing, webinars and articles.

Why should AARC participants visit your display?
Newest endotracheal tube holder on the market featuring a soft, low profile design to be used for both supine and prone patients.

Draeger

Booth 1001

What products will you be presenting at AARC?
We will be showcasing our newest ventilation equipment and consumables including the Evita V800, Babylog VN800, Savina 300, Bubble CPAP (Dräger Bubble), Bubble CPAP Pressure Monitor (Max O2 ME+P), Neonatal Respiratory Support System (BabyFlow Plus), Neonatal Heated Respiratory Circuits (VentStar Helix), Pediatric and Adult Non-Invasive Ventilation Masks (MiniMe and FitStar), Filters/HME, and the newest addition to our neonatal care portfolio, the Babyroo TN300 open resuscitation bed.

Are there any new products that you wish to emphasize?
While all our products on display are relatively new to the market, we suggest that you take a look at how our products complement each other with similar user interfaces and device interoperability while facilitating hygienic care with a line of cost-effective disposables.

Discuss educational training materials you'll be offering.
We will have an auditorium area in our booth this year where clinical lectures will be provided by our clinical applications specialists. Additionally, we will be showcasing our Dräger Virtuo, our VR (virtual Reality) platform for users to participate in realistic and immersive training simulations that closely mimic real-world experiences, allowing them to practice their skills and gain practical experience in a safe and controlled environment.

What speakers or papers will you be featuring?
Our clinical application specialists will present on topics regarding neonatal and adult invasive and non-invasive therapies that respiratory therapists encounter daily.

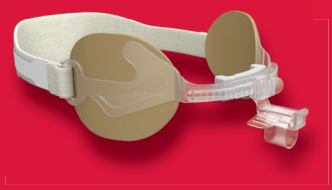
Why should AARC participants visit your display?
We know RTs have been working tirelessly throughout Covid and through the challenges of 2024. Come by, meet our Dräger Bubble CPAP whales: Bubbles and SeaSea, and let us express our thank you for the work you continue to do and the impact you have on patient's lives. Additionally, we'll be showcasing all the newest products and technology we have to offer. Products like our newest adult/pediatric ventilators and our innovative Bubble CPAP solution.

Innovation and choices from your trusted brand

AnchorFast™
Oral Endotracheal Tube Fasteners

Our Family of **Anchor**Fast Oral Endotracheal Tube Fasteners

AnchorFast
Oral Endotracheal Tube Fastener



AnchorFast SlimFit
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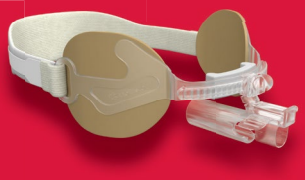

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Oral Endotracheal Tube Fastener

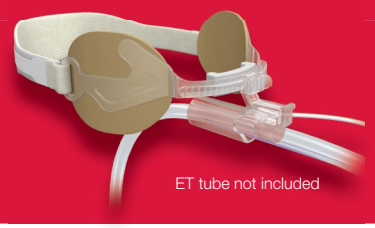

Image represents an actor wearing the AnchorFast SlimFit Oral Endotracheal Tube Fastener, who is not actually intubated. ET tube not included.

Every AnchorFast oral endotracheal tube fastener is innovated for you to leave tape behind. At Hollister Incorporated, direct feedback from critical-care clinicians like you is what drives our ongoing product line evolution to meet your patients' needs.

Learn more and request a sample at hollister.com/anchorfast

Scan to Learn More

Hollister®

Critical Care

Mercury Medical

Booth 1225

What products will you be presenting at AARC?

Mercury Medical will be displaying and demonstrating several innovative clinical solutions that meet the company's mission for dedication to delivering critical care technology that saves lives throughout the world. Such products include the first and only **Disposable Flow-Safe II+® BiLevel & CPAP system.** It is the only available disposable BiLevel/CPAP system on the market that can be available at the right time at the right place for GAP patients that have respiratory distress or difficulty breathing. It combines both BiLevel and CPAP in one complete single-patient use system with integrated manometer for verifying pressures. The lightweight disposable feature allows for easy CPAP or BiLevel CPAP therapy set-up and delivery during transport. Flow-Safe II+ is ideal for situations where backup BiLevel CPAP equipment is scarce or unavailable. Clinicians can now deliver BiLevel and CPAP therapy with just **ONE** disposable device.

Coupled with Flow-Safe II+, Mercury Medical will be showing **Flow-Safe II EZ®** CPAP & Nebulizer system with unparalleled advantages. Flow-Safe II EZ delivers consistent CPAP pressure while providing an integrated nebulizer using only one oxygen source. Additionally, it has an on/off switch that controls the nebulizer only, not the CPAP pressure. CPAP pressure is still controlled by the flow meter. Compared with other systems that require two O2 lines, Flow-Safe II EZ consumes less oxygen.

Also featured is the **Neo-Tee®** infant T-piece resuscitator product family, the first disposable T-piece and has achieved over 10 years of success in the global market. The latest version is the **Neo-Tee®** with higher PEEP (orange knob). This Neo-Tee version offers approximately 8-10 cm H_2O PEEP with less flow, saving on oxygen consumption especially during transport. All Neo-Tees are **MR conditional** and **DEHP-Free**. Neo-Tee's sister product, **Resusa-Tee®** Adult/Child T-piece resuscitator will be displayed along-side Neo-Tee for those patients above 10 kg. It is the only Adult/Child disposable T-piece in the world.

Delivering proper tidal volume at the proper pressure and rate are key elements for providing successful manual resuscitation. Mercury will be featuring **the new, CPR-2+® modern adult bag size (1,000 mL) manual resuscitator with tidal volume finger markings, LiteSaver® Manometer and PEEP valve.** This is a spectacular resuscitator combination for any facility with a Protective Lung Strategy Program. The CPR-2+ modern adult manual resuscitator with LiteSaver Manometer helps to reduce over inflation and breath stacking. This product is truly a "LiteSaver."

The Airtraq™ will also be featured, which simplifies video laryngoscopy with its ETT channel guide aiding in safety and in reducing intubation time. The optional lightweight Wi-Fi camera facilitates video recording and auto recording options. The Airtraq is simple to use and makes intubation easy for non-expert and expert clinicians. Not only is Airtraq compact, portable, and affordable, it allows an indirect visualization of the upper airway and improves the success rate of tracheal intubation.

Are there any new products that you wish to emphasize?

In addition to the new, CPR-2+ modern adult manual resuscitator with tidal volume finger markings, Mercury will be show casing BiWaze® Clear, a brand-new oscillating lung expansion (OLE) airway clearance system. The BiWaze Clear provides therapy to help treat and prevent atelectasis, remove retained secretions from deep in the lungs and reduce the work of breathing. BiWaze expands and clears the airways through a combination therapy in just 10 minutes! Alternating therapies of PEP and Oscillation combined with Aerogen nebulization enhance the therapy effectiveness by thinning and mobilizing mucus to the upper airways where it can be coughed or suctioned out. Based on a recent study, BiWaze Clear has shown to provide superior aerosol deposition to the lungs—five times more than the closest competitive system. BiWaze Clear is lightweight, easy to use, transportable and is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting. A lithium-ion battery is included with each system. The device recently received FDA clearance for connecting to a ventilator.

Also, BiWaze Clear's sister product, BiWaze Cough will be displayed. BiWaze Cough uses a combination of high-frequency oscillation, lung expansion and assisted cough therapy to break up mucus and clear airways. It clears mucus from the lungs with an assisted cough therapy by applying positive air pressure (inhale) to the airway and then rapidly shifting to negative air pressure (exhale). After exhale, the pause phase allows the person to rest before the next assisted cough cycle.

Discuss what educational/training materials you'll be offering?

Full product training will be provided at the booth by Mercury Medical Product Specialists. We will provide product information brochures and offer free samples of specific disposable products. The samples will be provided by fully trained Mercury Medical sales representatives who can answer your product questions and help fulfill your facility's clinical needs. Many training videos are available on the Mercury Medical website.

Why should AARC participants visit your display?

Mercury is a leading manufacturer of respiratory products and is highlighting several key products that reduce costs, improve processes and improve patient outcomes.

Mercury's innovation is evident with the introduction and unique concept of a disposable BiLevel and CPAP device. An alternative is when expensive equipment is not available at the right time. Additionally, Mercury was the very first company to bring a completely disposable infant T-piece system to market and the latest Neo-Tee version with higher PEEP (orange knob) continues the trend of improving patient outcomes at an economical cost for the NICU, L&D, ED and transport.

With respect to NRP and recent guideline recommendations, Mercury Medical strives to create products that help clinicians meet these industry guidelines. RT Directors, NICU Respiratory Specialists and nurses who visit our display will find resuscitation devices that meet NRP and AHA guideline requirements. For instance, the disposable Neo-Tee T-Piece Resuscitator offers more consistent inspiratory and expiratory pressure than other types of resuscitators. It is affordable for use at every NICU, L&D and ED bedside and transport. Furthermore, NRP recommends using a colorimetric CO_2 Detector on the OETT for intubated patients or supraglottic airway connector to ensure proper placement with rapid color change. Mercury provides a solution for premature infants

BREAS

Setting the NEW Standard

Vivo 45LS

Arguably the lightest, smallest life support ventilator available, the Vivo 45LS maximizes patient mobility and breathing comfort.

Built-in humidifier*
Heated wire circuit*
Comprehensive set of modes including:

- Auto-EPAP*
- High Flow Nasal Therapy*
- SpO_2, $EtCO_2$, FiO_2 and $PtcCO_2$ monitoring

Visit our **AARC booth 832** or scan the QR code to learn more.

*Modification in accordance with FDA's guidance, Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

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below 1 kg with the Neo-StatCO2 <Kg®—and it works for 24 hours. NRP also requires clinicians to use the right size mask for infants. With that in mind, Mercury developed and introduced the anatomical silicone preemie masks to help solve the issues of masks covering the baby's eyes, or having to intubate when the smallest sizes are not available. These preemie masks are not only soft and flexible, but they are ergonomically designed which offers a tighter seal and reduction in mask leakage. The anatomical silicone preemie masks will also be exhibited in the Mercury booth.

In summary, clinicians should visit the Mercury display to get a first-hand view of our products and advantages.

MGC Diagnostics

Booth 903

What products will you be presenting at AARC?
MGC Diagnostics is proud to present an impressive lineup of our latest products and technological innovations in the field of pulmonary function testing and gas exchange analysis.

As a leader in the industry, we'll be showcasing our advanced Pulmonary Function Testing systems, including the Platinum Elite™ body plethysmograph and the Ultima Series™ cardiorespiratory diagnostic systems. Both systems are equipped with our RTD™ real-time diffusion technology, which enables users to deliver clinically significant graphic data and immediate results. These tools are designed to streamline the diagnostic process and enhance the overall patient experience.

In addition to our Pulmonary Function Testing solutions, we're excited to showcase our Gas Exchange Testing systems. Among them, the Ultima CPX™ metabolic stress testing system and the Ultima™ CardiO2® gas exchange analysis system with integrated 12-Lead ECG stands out as powerful tools for comprehensive and accurate assessments. These advanced systems offer unparalleled insights into patients' respiratory health, assisting healthcare professionals in making informed decisions for optimal care.

We also invite you to explore our CPFS/D™ USB spirometer, a portable yet feature-rich spirometry device that empowers healthcare practitioners with flexibility and precision in respiratory testing. Additionally, we'll be presenting the Resmon PRO FULL V3 FOT (Forced Oscillation Technique) device, which offers valuable insights into lung function and airway resistance.

MGC Diagnostics is dedicated to respiratory healthcare, and our showcased products at AARC embody our commitment to innovation, accuracy, and patient well-being.

Are there any new products you wish to emphasize?
MGC Diagnostics is thrilled to present the much-anticipated release of Ascent™ cardiorespiratory diagnostic software for CPET testing. This groundbreaking software joins our Ascent™ pulmonary function software, creating a comprehensive, all-in-one solution for all your testing needs. Developed from the ground up, Ascent™ software stands at the forefront of technology, creating the most advanced testing software platform available. Designed to seamlessly integrate with today's hardware and with a vision for future innovations, Ascent™ software empowers users with an intuitive interface, guiding them through each step of the testing process, ensuring precise and effective patient outcomes.

Additionally, we are proud to introduce the all-new Meridian Series™ cardiorespiratory diagnostic systems, for exercise and metabolic testing. Engineered to deliver highly accurate results in a compact and efficient package, the Meridian Series is ideal for university settings, cath labs, and exercise labs. Keeping pace with the demands of modern labs, the Meridian Series offers versatile solutions to address your unique testing needs.

Our commitment to innovation and excellence shines through both the Ascent software and the Meridian Series. Join us to witness firsthand how these cutting-edge offerings are set to revolutionize cardiorespiratory diagnostics and enhance the overall quality of patient care.

Discuss educational/training materials you'll be offering.
Managing the MGC Diagnostics exhibit will be our best-in-class clinical, sales and support experts, ready to not only answer your product questions but also provide personalized consultations to meet your unique clinical application and cardiorespiratory business needs.

Discover more about our highly anticipated Cardiorespiratory Diagnostics Seminar, scheduled to take place in Las Vegas in October 2024. The seminar is thoughtfully designed to provide participants with in-depth knowledge and practical insights into the latest advancements in cardiorespiratory diagnostics, equipping attendees with the tools to excel in their practice.

Why should AARC participants visit your display?
As a global leader in cardiorespiratory diagnostics, 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 the cardiorespiratory industry. These attributes make us uniquely qualified to solve today's challenges and uncover solutions for tomorrow's opportunities. Through our comprehensive approach, we empower healthcare professionals worldwide to provide superior patient care and optimize treatment outcomes.

At MGC Diagnostics, innovation and dedication converge to create a company that stands out in the industry. Visit us at AARC to discover how MGC Diagnostics is shaping the future of healthcare through cutting-edge solutions and unwavering dedication.

Nonin

Booth 1236

What products will you be presenting at AARC?
Nonin is excited to have a variety of pulse oximetry devices on display at Booth 1236, available for you to touch, test, and wear firsthand. The Nonin booth will be staffed with our highly trained commercial team, ready to walk you through Nonin's portfolio of pulse oximetry solutions for respiratory health.

Are there any new products you wish to emphasize?
Nonin Medical, Inc. will be showcasing a broad range of pulse oximetry solutions. New this year will be the **Nonin Health® Data Solution –** Brought to you by a trusted innovator

TREASURE EVERY BREATH®

A full line of advanced ventilator solutions from Nihon Kohden

NEW

NKV-440
VENTILATOR

turbine-driven technology

NKV-550
SERIES VENTILATOR

NKV-330
NON-INVASIVE VENTILATOR

CONTACT US TODAY

to see how Nihon Kohden can support your respiratory therapy decisions.

1-855-550-VENT

us.nihonkohden.com

ventilator@nihonkohden.com

NIHON KOHDEN

15353 Barranca Pkwy, Irvine, CA 92618

Important safety information:
Caution: Federal (United States) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

MKT-01340 [A]

in pulse oximetry, the Nonin Health cloud-based solution was designed to streamline your workflow and improve your efficiency. The prevalence of remote care has grown exponentially in the past 3 years, and Nonin Health will allow for an improved experience in data access and workflow efficiency in the ever-evolving landscape of healthcare. Stop by Nonin's booth to learn more and test out a demo product.

Discuss educational/training materials you'll be offering.
SpO_2 monitoring is crucial for patients with chronic respiratory diseases. The Nonin Medical, Inc. booth will have information available for you to pick up that includes:

- COPD Patient 30-Day Hospital Readmission Reduction Program
- Clinical Summary of "The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment"
- Educational and informational brochures on key Nonin pulse oximetry products

What speakers or papers will you be featuring?
Nonin Medical, Inc. is thrilled to share the latest findings from the Open Oximetry Project, published in *eBioMedicine*, showcasing the performance of Nonin's Onyx Vantage 9590® fingertip pulse oximeter. In a comprehensive study conducted by the University of California, San Francisco, the Nonin Onyx Vantage 9590 emerged as the only device meeting FDA accuracy guidelines across all skin pigmentations and oxygen saturation ranges.[1]

The study highlighted significant disparities in accuracy among commonly used, low-cost pulse oximeters — particularly in patients with darker skin pigmentation and/or low oxygen saturation levels. Nonin's device delivers accurate readings, reducing the risk of misdiagnosis and hidden hypoxemia, a critical concern heightened during the COVID-19 pandemic.

Why should AARC participants visit your display?
For more than 38 years, Nonin Medical has designed and manufactured noninvasive patient monitoring devices for healthcare professionals and individual users. Nonin pulse oximeters, regional oximeters, sensors, and software deliver quality performance in durable formats. Nonin's exclusive pulse oximetry measurement system —which consists of PureLight® sensor technology and PureSAT® pulse oximetry technology—is FDA cleared in a variety of form factors, indicated for use to provide accurate oximetry measurements.

Nonin devices are designed to work wherever and whenever you need them—so you can deliver quality care efficiently and with confidence.

1 Leeb G, Auchus I, Law T, et al. The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment. EBioMedicine. 2024;102:105051. doi:10.1016/j.ebiom.2024.105051

Passy Muir

Booth 1301

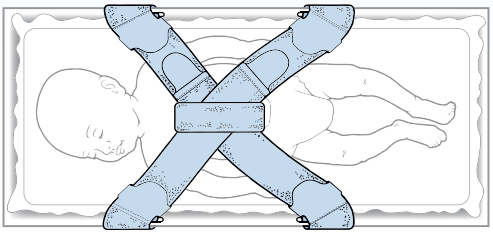
What products will you be presenting at AARC?
Our full line of Passy-Muir Valves, adapters, and educational products.

Are there any new products you wish to emphasize?
New Passy Muir HME, as well as our DigiSil and DB15 adapters.

Discuss educational/training materials you will be offering.
Badge Buddies, Visual Use Guide, newly updated Pocket Guide.

Why should AARC participants visit your display?
Meet our clinical specialists in person, engage in hands-on education, have your clinical questions answered, check out our full-line of PMVs, adapters and educational products.

Respiralogics welcomes two new products to the family!



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Using Oscillometry for COPD Patients

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Dr. Trinkmann, a pulmonologist for Heidelberg University in Germany.

Speaker 1: Welcome to the Exhale Podcast, a candid conversation about current matters related to respiratory, diagnostic and lung health. Today's host is Mark Russell, Marketing Communications Manager for Vitalograph in North America, a global leader in respiratory diagnostics.

Today, we talk to Dr. Frederik Trinkmann. Dr. Trinkmann is a pulmonologist for Heidelberg University in Germany and a specialist in intensive care medicine. Our discussion is about oscillometry, a method of testing using sound waves that are superimposed on normal tidal breathing.

Mark Russell: Well, Dr. Trinkmann, welcome to our podcast.

Dr. Frederik Trinkmann: Hello. Thanks for having me.

Mark Russell: Please give us a little background on yourself; education, experience and current responsibilities.

Dr. Frederik Trinkmann: My name is Frederik Trinkmann. I'm a senior physician here at Thoraxklinik in Heidelberg, which is one of the biggest lung centers or centers for respiratory medicine here in Europe. I'm trained in internal medicine, actually, and focusing now on respiratory medicine where I'm a professor for internal medicine here at Heidelberg University.

Currently, I'm the deputy head of Thoraxklinik Heidelberg, and I'm heading the asthma outpatient department, where we're primarily treating patients with severe asthma. I also have a second job. I am also in bioinformatics where I'm working as a scientist.

Mark Russell: Great. How did you learn about oscillometry?

Dr. Frederik Trinkmann: We've been using oscillometry for a really long time. That started in the early 2010s, actually, where we had growing interest in more sensitive and reproducible lung function tests that would not require much patient collaboration. This is a point where you easily learn about oscillometry because it perfectly fits in, in these things we needed, so this is when we started doing oscillometry. In my former department, which was in a cardiology department, we did that routinely in every patient, actually.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Mark Russell: How can oscillometry be used in COPD, and is there any data that supports this use?

Dr. Frederik Trinkmann: Yeah, I think there are at least three aspects for using oscillometry in COPD patients. First, we have these patients with an established diagnosis, but where we have a discrepancy between the reported symptoms on one hand, and the impairment in the conventional techniques that is mostly based on spirometry on the other side.

We have learned, from data we have, that small airway disease is frequent in quite a lot of these patients, which reaches numbers up to 90% with a known diagnosis. We have a close link to typical symptoms that occur in COPD, which is dyspnea, cough, or phlegm. This is one group where we have a discrepancy between the conventional diagnostic tests, which are insensitive to these small airway changes, and clinically reported symptoms and also reduced quality of life.

The second group relates to early diagnosis of COPD. This is anything that is currently discussed under the pre-COPD term, which is not that clearly defined, but I think it's a really relevant and huge topic. Because we often have these patients with preserved lung function in conventional tests and spirometry, namely, that these patients have typical symptoms. These cannot be detected with spirometry because it's insensitive to these changes.

That's something that was published in The New England Journal of Medicine nearly six years ago by James Hawk. He stated that the lung periphery has little impact on the total airway resistance in the healthy people, but when it comes to disease, this proportion of peripheral resistance increases dramatically. These changes, these early changes, they are really easily overlooked with spirometry. This is a second good point for using oscillometry in COPD in terms of early diagnosis.

The third point would be an improved functional phenotyping, which doesn't include only the patients we see in spirometry which suffer from central obstructive disease, but also other patients who have a predominant emphysema, for example, or small airway disease as we discussed.

It has been demonstrated, for example, in data we captured that these changes are associated with eosinophilic airway inflammation, so a type that is similar to asthma, but these

patients still suffer from COPD, so this is another really important topic, small airway disease, inflammation and functional phenotypes that we can use oscillometry to define these patients.

Mark Russell: How do you use oscillometry in your clinic, and what values does oscillometry add to the existing diagnostic standards such as spirometry?

Dr. Frederik Trinkmann: At the moment, we are using oscillometry primarily in patients with otherwise unexplained symptoms and a normal lung function testing report. Me, I can say that in Germany we have a really broad standard for lung function testing because we are doing the BodyBox every time we see a patient and also transfer factor and blood gas analysis.

So we do not see these patients with early diagnosis in our clinic, of course, because we have the severely ill COPD patients, and this is where we use oscillometry for phenotyping, as I just outlined before. We have, of course, studies going on where we're using oscillometry to specifically target these early disease patients as a central part of the protocol, actually.

For example, one of these studies we're performing here is a CAPTO-COPD where we try to distinguish mild COPD patients from patients with early disease that are not really patients, or considered as patients by definition now, and from healthy controls, for example. This is where I think the technique really adds value in a clinical workflow, also, because we often have the situation where the symptoms a patient reports are not fully explained, and where we have differential diagnosis excluded. For example, cardiovascular disease is a major topic, of course. This is something where oscillometry really adds to clinical decision making, also.

Mark Russell: So oscillometry is, obviously, very data intensive. It provides a whole range of different measurements during one test period. Is there a measure that you look specifically for COPD patients? What do you look for, a value or trend?

Dr. Frederik Trinkmann: Generally, we are looking at reactance and resistance parameters in oscillometry. In asthma, for example, we have a proportional increase in both of these parameters, which is specifically frequency dependence of resistance marking small airway obstruction on the one hand, and the reactance area, which resembles elastic components of the lung.

In contrast, in COPD, we have a disproportional increase in the reactance area, which is referred to AX, as compared to the frequency dependence of resistance, which is important for monitoring and therapeutic changes, but this also bears differential diagnostic information.

When we see the patient for the first time, we, of course, look for the specific value, and we have some reference values. We have to admit these are not as robust at the moment as for spirometry, but there are reference values for oscillometry, also. When we see the patient again, that becomes more easy because we can, of course, also look at trends in these parameters. Especially, AX is a really sensitive parameter when it comes to short term but also long-term changes in COPD, specifically.

Mark Russell: Do you also use oscillometry for patient monitoring, and how can these monitoring steps help clinical decision making?

Dr. Frederik Trinkmann: Yeah, we perform these oscillometry measurements as we do usually with lung function testing. In Germany, that's within three- to six-month intervals. For patients with asthma, for example, we could recently establish MCID values, so values for the minimal clinically important differences, which helps in assessing therapeutic effects.

Mark Russell: Can you think of some examples of how oscillometry has improved patient outcomes in your practice?

Dr. Frederik Trinkmann: Yeah, I will well remember one COPD patient with a really early or mild disease, he only had mild obstruction spirometry, but he reliably reported strong dyspnea that was not explained by lung function testing. At that time he was on anti-obstructive monotherapy, which was standard for the time we saw the patient for the first time.

In this patient, because we had this discrepancy between lung function testing and reported outcomes, we did oscillometry, and we were able to really reveal some severe small airway disease. Based on these findings, we decided for an early dual bronchodilator therapy, which we have to admit was some sort of disruptive at that time, because we did not have the clear data as we have today for dual bronchodilator therapy that can be introduced also early in these patients. In the end, we had a real clinical benefit because the energy levels increased, and the patient reported way less dyspnea. That was a good example where we had clinical impact after performing oscillometry on an individual patient journey.

Mark Russell: That's great. What do you recommend our listeners who want to learn more about this technology or want to get it started in their own clinic?

Dr. Frederik Trinkmann: For start, there is really good literature available. For example, there's a review by Omar Usmani published in CHEST, which focuses on the seven pillars of small airway disease in asthma and COPD. It gives a really practical overview, and a good idea of the concept of small airway disease and, also, the testing for it where oscillometry is a central part, of course. I think literature is a good first start.

I think then it would make sense just address a local affiliation of a manufacturer where you're living who will surely be able to support you with a demonstration device. For example, you can answer practical questions and often you can get a loaner of the device so that you can gain experience with the technique yourself. Then you can start asking questions and liaising with other experts in the field. This would be one way that I think would be very effective to learn about this really promising and helpful technique.

Mark Russell: I know in spirometry there's a lot more detailed tests in some of our software at Vitalograph. How easy is oscillometry to pick up as compared to spirometry?

Dr. Frederik Trinkmann: That's a good question that I get asked a lot, of course. I always like to do some provocation on that because I can say that oscillometry is actually way easier to perform as compared to spirometry. Maybe I can also support

that when I'm saying that because I don't want to talk bad about spirometry, first of all.

But spirometry uses a force maneuver, and we are all aware of data we have that the quality is really crucial for interpreting spirometry. That has a large variation depending on the setting where you're doing it, in the GP setting, for example, or in a lung clinic. The interpretation, of course, is also not that trivial.

In oscillometry, we have a tidal breathing maneuver which is real easy to perform, which only lasts like 20 seconds. You don't need much training either by the technician who performed the measurement, nor by the patient. Actually, it's really easy to learn.

Of course, the interpretation you have to gain experience with that just to have some basic aspects that will help in your everyday practice. That's really an easy-to-learn technique. As I said before, we have also good literature and a lot of experts in that field, so I think this is not a major impediment to the technique as compared to spirometry.

Mark Russell: So, basically, it really helps the patient outcome to having the two diagnostic technologies there to really be able to pinpoint any type of problems the patient has.

Dr. Frederik Trinkmann: Yeah, definitely. I totally agree.

Mark Russell: Hey, this has been wonderful information. We appreciate you being on our podcast today. Anything else you have left to mention to our listeners?

Dr. Frederik Trinkmann: Maybe one quote I like by Steve Jobs is, "Stay hungry, stay foolish," is a really good quote in this context because I think it would just really make sense to have the eyes open for new techniques and learn about these really interesting technique, that I think will help us in the future a lot with phenotyping and also early diagnosis of the disease.

Mark Russell: No, I wholeheartedly agree with you. Anything that you can think outside the box, or look at new technology to help better patient care is the best for patients in the future. Well, again, thank you again for being on our podcast.

Dr. Frederik Trinkmann: Yeah, thanks for having me.

Speaker 1: You've reached the end of another episode of the Exhale Podcast. Don't forget to follow us for upcoming new episodes, and please take our survey to help provide good content for the future. Thank you for listening. We look forward to you joining us again on the Exhale Podcast brought to you by Vitalograph.

UMC Health System Implements a High Level of OLE Therapy With the VOLARA System

It's no secret that each patient is unique, regardless of their condition or how they present. Comorbidities, age, ability to tolerate medication or therapy— every case has to be evaluated on its own. Having the technology to provide therapy that works for patients and therapists is crucial to achieving desired outcomes and adding value to how a hospital provides care.

Overview

As a large teaching hospital serving a large area, University Medical Center (UMC Health System) in Lubbock, Texas, has a technology forward focus. However, it's never just about technology for the sake of it, but how easy it is for therapists to use, how well a therapy can be tolerated by patients, and the value that adds to the organization. That's what UMC Health System discovered when they moved from the **MetaNeb** System to the **Volara** System to deliver Oscillation & Lung Expansion (OLE) Therapy.

Designed For Clinicians, Made For Patients

"The thing that makes the **Volara** System better is it gives you feedback and information so you can tweak things and make specific adjustments on the settings in real time," says Anthony Trantham, Respiratory Director of UMC Health System. "That's a big difference between the **Volara** and **MetaNeb** Systems." Helping patients tolerate the therapy was a noticeable improvement as well. "I think the biggest 'Aha!' moment for us was patient compliance," says Anthony. "We would have patients that wouldn't always be able to tolerate the therapy with the **MetaNeb** System. Now, we can tweak these settings for each patient. With the precise higher pressure, the **Volara** System is able to deliver what we need," Anthony says.

> "When you can get patients comfortable and they can tolerate the therapy, obviously the outcomes are going to be better."

Helping Burn Patients Breathe Easier

While the **Volara** System is being used throughout the hospital, Anthony notes one area in particular. "We're using it post-op, we're using it on patients with traumas. We're getting the most positive feedback out of our burn unit," he says. "When we have patients with significant inhalation injuries, they're the ones that seem to benefit the most, so we've incorporated that with our protocols in there. We'll start them with secretion clearance, we'll use the **Volara** System to deliver the heparin. When they come off the ventilator, we're able to continue the therapy. And those patients do well, it helps with their atelectasis."

HIGHLIGHTS

Facility
University Medical Center Health System, Lubbock, TX

Profile
- 500-bed teaching hospital serving a 500-mile radius
- Level 1 trauma center
- Level 4 NICU
- Burn ICU

Partner
Anthony Trantham, Respiratory Director

Reported Impact
- Due to precise therapy delivery staff noticed **Volara** System therapy was well tolerated
- Staff adoption and utilization
- Increased versatility for treating more patients
- Improved time efficiency of Respiratory Therapists

Anthony states,
"Overall for our inhalation injuries, almost every one of them are getting this therapy, and it's become standard practice."

Staff Adoption

UMC Health System is also finding that the respiratory staff quickly adopted the **Volara** System. "They're not getting as much pushback from patients," Anthony says. "Our staff feedback has been fantastic. The fact that it's portable really helps. We can

Provided by Baxter.

The **Volara** System is helping decrease ventilator days and decrease length of stay in the hospital.
–Anthony Trantham, Respiratory Director

take it to almost any unit in the hospital, and sometimes the same unit will follow the patient from the Emergency Center through the burn unit, take them to the step-down unit, and the **Volara** System will just follow them until they're discharged."

Therapy Versatility

Anthony and his team appreciate the versatility the **Volara** System provides in terms of therapy delivery. "One of the nice features is if you have a patient on a ventilator, maybe at night and then during the day they're on a trach collar, you can program those settings depending on which mode they're on. It's a time-saver for the clinician, but more importantly, you know you can offer different therapies with the same device based on what you know your patient needs."

UMC Health System is also using the **Volara** System in the Pediatric Unit. "We've had pediatric patients in the patient room but not even in their bed, or they're in a little activity area or the playroom, and we're able to provide the therapy in there with the **Volara** System," says Anthony.

An Easy Transition

For Anthony and his team, incorporating the new **Volara** System was a matter of being prepared. "Before we even got the units, our Baxter representative came out and provided education and training, as well as a clinical expert to work with our clinical educators. Our staff felt like they had a good understanding of it," he says. "Then they had the opportunity to interact with the equipment, use the interface, ask questions. And the day we received our **Volara** units, we were using them on patients right away."

Adding Value

A therapy or technology must be designed for both patients and clinicians. Ultimately, that's what adds value to an organization providing care. "I don't just want to buy equipment, I want to have a partnership with the product we're using," Anthony says. "One big push in the respiratory world right now is value-added services — is the work we're doing adding value? Respiratory therapists are hard to come by. We need to make sure we're utilizing their time efficiently. If it's not adding value to the patient or organization or the clinician at the bedside, there's no reason to even look at the product. And I feel we get all that with the **Volara** System. The ease of use, the patient compliance, those are all time-savers, so that's very helpful in the big picture."

Respiratory therapists are hard to come by. We need to make sure we're utilizing their time efficiently.
–Anthony Trantham, Respiratory Director

A Higher Level of OLE Therapy

Patient compliance, clinician adoption, therapy delivery — all have to work as seamlessly and efficiently as possible in order to deliver the best care while also delivering value. At UMC Health System, the **Volara** System is helping the respiratory team bring it all together.

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Comparison of Pulse Oximeters in Children

Martin Stegenga, Amanda Feddersen and William Enriquez

As home monitoring of oxygen saturation is on the rise along with increases in all remote monitoring, use of pulse oximeters for remote monitoring of children has become more common. Children pose a greater challenge for measurements, particularly related to the size of their fingers and the surface available for hemoglobin absorbance and relative to the size of the window for light transmission within the various devices.

We therefore performed an evaluation of four different pulse oximeters that are used for measurements in children. The evaluation included bench testing against an oxygen saturation simulator as well as human testing in a population of mostly healthy children whose parents volunteered them for the study. Understanding how different pulse oximeters function in children is important for the selection of appropriate devices. This study may provide additional information for their selection and use.

Methods

Two each of four (4) FDA cleared and commercially available pulse oximeter models were studied. These included the Nonin Medical (USA) model 3230, the ChoiceMMed (China) MD300CI218, the Viatom Wellue (China) FS20F and PC-60NW. All pulse oximeters use clip-on finger sensors.

Martin Stegenga, B.Eng. is a computer engineer and Technical Product Owner at Monitored Therapeutics, Inc., responsible for the integration of medical devices within its Remote Physiologic Monitoring (RPM) programs and for the development of patient interfaces and related platforms. During his 12 years in the RPM program, he was a key developer of MTI's GoSpiro spirometer, a core technology of its business.

Amanda Hope Feddersen is the Quality Assurance Manager at Monitored Therapeutics Inc., specializing in respiratory remote patient monitoring. With over a decade of experience in the pharmaceutical, medical device, manufacturing, and distribution industries, Amanda has cultivated a deep expertise in quality assurance practices. Amanda holds a CQA (Certified Quality Auditor) certificate from the American Society for Quality (ASQ), underscoring her commitment to excellence and continuous improvement in auditing quality management systems.

William Enriquez is an Operations Specialist at Monitored Therapeutics Inc., where he excels in quality testing to ensure the accuracy and reliability of medical devices. With a background as a former Emergency Medical Technician, William brings a wealth of experience with pulse oximetry and a deep understanding of critical healthcare technologies. His expertise ensures that Monitored Therapeutics Inc. delivers top-notch, precise solutions to meet the needs of the medical community.

Bench Testing

All pulse oximeters were first tested with a Contec SpO2 Simulator, Model MS100. This simulator has eight (8) preset simulation settings for patients who are normal, obese, geriatric, tachycardic, neonate, hypoxic, bradycardic and with a weak pulse. Additionally, the pulse oximeters were tested against six (6) manually set simulations with SpO2/Pulse rate pairs of 100%/250 bpm, 100%/65 bpm, 98%/75 bpm, 94%/55 bpm, 50%/50 bpm, and 80%/85 bpm. Heart rate percent errors and oxygen saturation absolute errors of all measurements were calculated.

Human Subject Testing

Child subjects were recruited via a neighborhood (Delaware, OH) Facebook page advertisement. Twenty (20) children were recruited for the study from parental respondents to the advertisement. Informed consent was collected from the parents of all subjects and a parent was present for the measurements in their child. Each subject was given a $15 gift card for their participation.

All pulse oximeters were tested in duplicate with measurements individually on each subject's right hand and left hand. Subjects rested for five (5) minutes prior to their first measurement. All subjects sat in a chair for the rest period and during all measurements. Pulse oximeters were placed on the middle fingers of each hand and confirmed that the finger was placed flat on the sensor window. Following at least seven (7) seconds to reach stability, the oxygen saturation and pulse rate were recorded. Another pair of oximeters were then placed on the fingers and measurements repeated. This continued until all eight (8) pulse oximeters (2 of each model) were tested in duplicate (right hand and left hand) resulting in 16 measurements per subject.

Results

Bench Testing

Below are tables 1 to 4 that reflect the bench testing results against the Contec SpO2 Simulator.

Pulse Oximeter Manufacturer		Nonin Medical Inc.							
Device Model		3230 Oximeter							
Serial Number		502078911				505238306			
Simulator Setting	**SpO2 / bpm**	SpO2 (%)	Error (Abs)	bpm	Error (%)	SpO2 (%)	Error (Abs)	bpm	Error (%)
Normal	98%/55	96	-2	55	0%	97	-1	55	0%
Obese	93%/90	91	-2	90	0%	91	-2	90	0%
Geriatric	92%/95	90	-2	95	0%	90	-2	95	0%
Tachycardia	85%/130	83	-2	130	0%	83	-2	130	0%
Neonate	90%/180	88	-2	180	0%	87	-3	180	0%
Hypoxic	70%/95	71	1	95	0%	72	2	95	0%
Bradycardia	88%/45	86	-2	45	0%	86	-2	45	0%
Weak pulse	90%/95	88	-2	95	0%	88	-2	95	0%
Manual max	100%/250	99	-1	250	0%	99	-1	250	0%
Manual	100%/65	98	-2	65	0%	99	-1	65	0%
Manual	98%/75	98	0	75	0%	96	-2	75	0%
Manual	94%/55	92	-2	55	0%	92	-2	55	0%
Manual	50%/50	58	8	50	0%	60	10	50	0%
Manual	80%/85	77	-3	85	0%	79	-1	85	0%
		Avg. (Abs)	-0.9	Avg. (%)	0%	Avg. (Abs)	-0.6	Avg. (%)	0%

Table 1. Bench Data Nonin Medical 3230 Oximeter.

Pulse Oximeter Manufacturer		ChoiceMMed							
Device Model		MD300CI218							
Serial Number		IHPX10100000007816				IHPX10100000009805			
Simulator Setting	**SpO2 / bpm**	SpO2 (%)	Error (Abs)	bpm	Error (%)	SpO2 (%)	Error (Abs)	bpm	Error (%)
Normal	98%/55	97	-1	55	0%	97	-1	55	0%
Obese	93%/90	91	-2	90	0%	91	-2	90	0%
Geriatric	92%/95	90	-2	95	0%	90	-2	95	0%
Tachycardia	85%/130	83	-2	130	0%	83	-2	130	0%
Neonate	90%/180	88	-2	180	0%	88	-2	180	0%
Hypoxic	70%/95	71	1	95	0%	70	0	95	0%
Bradycardia	88%/45	86	-2	45	0%	86	-2	45	0%
Weak pulse	90%/95	89	-1	95	0%	88	-2	95	0%
Manual max	100%/250	98	-2	250	0%	98	-2	250	0%
Manual	100%/65	98	-2	65	0%	98	-2	65	0%
Manual	98%/75	97	-1	75	0%	97	-1	75	0%
Manual	94%/55	92	-2	55	0%	92	-2	55	0%
Manual	50%/50	54	4	50	0%	54	4	50	0%
Manual	80%/85	79	-1	85	0%	79	-1	85	0%
		Avg. (Abs)	-1.1	Avg. (%)	0%	Avg. (Abs)	-1.2	Avg. (%)	0%

Table 2. Bench Data ChoiceMMed MD300CI218 Oximeter.

Pulse Oximeter Manufacturer		Viatom Wellue							
Device Model		FS20F							
Serial Number		03372				03375			
Simulator Setting	**SpO2 / bpm**	SpO2 (%)	Error (Abs)	bpm	Error (%)	SpO2 (%)	Error (Abs)	bpm	Error (%)
Normal	98%/55	98	0	55	0%	98	0	55	0%
Obese	93%/90	92	-1	90	0%	93	0	90	0%
Geriatric	92%/95	91	-1	95	0%	92	0	95	0%
Tachycardia	85%/130	84	-1	130	0%	85	0	130	0%
Neonate	90%/180	90	0	180	0%	90	0	180	0%
Hypoxic	70%/95	71	1	95	0%	69	-1	95	0%
Bradycardia	88%/45	88	0	45	0%	88	0	45	0%
Weak pulse	90%/95	89	-1	95	0%	90	0	95	0%
Manual max	100%/250	100	0	250	0%	100	0	249	0%
Manual	100%/65	100	0	65	0%	100	0	65	0%
Manual	98%/75	98	0	75	0%	98	0	75	0%
Manual	94%/55	94	0	55	0%	94	0	55	0%
Manual	50%/50	52	2	50	0%	51	1	50	0%
Manual	80%/85	81	1	85	0%	79	-1	85	0%
		Avg. (Abs)	0.0	Avg. (%)	0%	Avg. (Abs)	-0.1	Avg. (%)	0%

Table 3. Viatom Wellue FS20F Oximeter.

Pulse Oximeter Manufacturer		Viatom Wellue							
Device Model		PC-60NW							
Serial Number		7196				7463			
Simulator Setting	SpO2 / bpm	SpO2 (%)	Error (Abs)	bpm	Error (%)	SpO2 (%)	Error (Abs)	bpm	Error (%)
Normal	98%/55	97	-1	55	0%	97	-1	55	0%
Obese	93%/90	93	0	89	-1%	92	-1	89	-1%
Geriatric	92%/95	91	-1	95	0%	91	-1	95	0%
Tachycardia	85%/130	85	0	130	0%	83	-2	130	0%
Neonate	90%/180	90	0	181	1%	89	-1	181	1%
Hypoxic	70%/95	72	2	95	0%	70	0	95	0%
Bradycardia	88%/45	88	0	45	0%	86	-2	45	0%
Weak pulse	90%/95	89	-1	95	0%	89	-1	95	0%
Manual max	100%/250	99	-1	250	0%	99	-1	250	0%
Manual	100%/65	99	-1	65	0%	99	-1	65	0%
Manual	98%/75	98	0	75	0%	97	-1	75	0%
Manual	94%/55	94	0	55	0%	93	-1	55	0%
Manual	50%/50	53	3	50	0%	55	5	50	0%
Manual	80%/85	80	0	84	-1%	79	-1	85	0%
		Avg. (Abs)	0.0	Avg. (%)	0%	Avg. (Abs)	-0.6	Avg. (%)	0%

Table 4. Viatom Wellue PC-60NW Oximeter.

All four pulse oximeter performed well for measurements of oxygen saturation and heart rate across the wide range of settings and simulated conditions. The only level with less-than-optimal performance was at an oxygen saturation of 50%. While the error percentages were higher than at the other saturation levels, the absolute error in most cases was within the device specifications, due to the absolute error being a larger percentage of the target value. The Nonin 3230 had the largest error of an absolute error of 10%.

Human Subject Testing

Twenty (20) children who were not under medical care for hypoxemia, ages 5 to 11 (mean 8.3 years) including 8 male and 12 female subjects were enrolled in the study (See Table 5). Nineteen (19) subjects were Caucasian, and a single female subject (subject 17) was of African American descent. One subject had cytomegalovirus and one subject had cerebral palsy. Six (6) other subjects had individual difficulties with the ability to get readings, which were unrelated to subject age. Some of the difficulties required a longer stability wait time. One subject wore nail polish (subject 10), a known confounding factor in pulse oximetry measurements, and one subject had a fake nail (subject 17) on only one hand.

Subject	Sex	Age	Subject	Sex	Age
1	M	7	11	M	8
2	F	8	12	M	5
3	F	6	13	F	11
4	F	6	14	M	11
5	M	10	15	F	7
6	F	11	16	F	11
7	M	9	17	F	10
8	M	6	18	F	8
9	M	8	19	F	8
10	F	5	20	F	11

Table 5. Subject demographics.

Graphs 1 to 20 on the next page reflect the data from each individual subject. Data is presented for each device as left hand, right hand (1st serial number), left hand, right hand (2nd serial number) for each manufacturer's model. The models for each graph are in the order of Nonin 3230 (Red), ChoiceMMed MD300CI218 (Orange), Viatom FS20F (Blue) and Viatom PC-60NW (Purple).

Of the 320 spot measurements, nine (9) measurements (3%) in 7 children were unable to detect oxygen saturation or heart rate. An additional six (6) measurements (2%) would have been considered to have reached a level of hypoxemia while the measurements on the other hand or with other devices in the same child showed oxygen saturation to be within normal range.

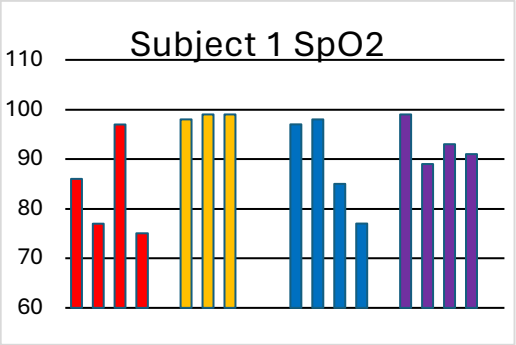
Discussion

As previously noted, testing in children poses additional challenges for fingertip pulse oximeters. The pulse oximeters evaluated in this study are all specified to be accurate at ±2% for oxygen saturation in the range found in the human subjects tested, and with the exception of the six measurements stated above, the human tests resulted in an acceptable spread of 4% from one oximeter to another.

The data collected suggests that measurements in children are reliable. However, it is evident that they should be performed in duplicate and on both hands. Since lay patients may be monitoring their own children at home, this is an important message for them so that they do not panic on single finger hypoxic measurements.

Conclusion

We found that with the notable exceptions discussed above, all four pulse oximeters performed well, and intra-device comparisons were within their specifications making them interchangeable. Caution should be noted when single measurements identify hypoxemia, particularly in children.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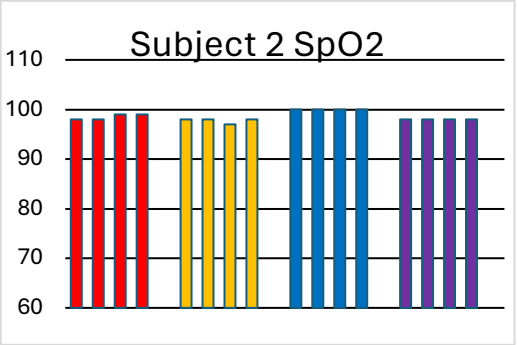
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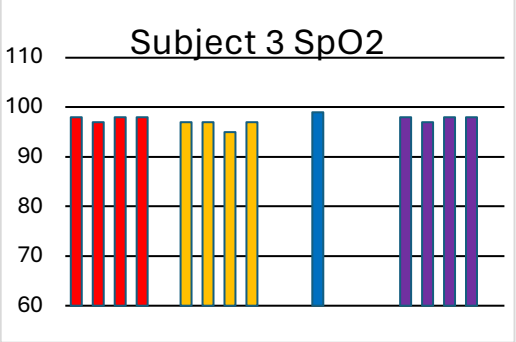
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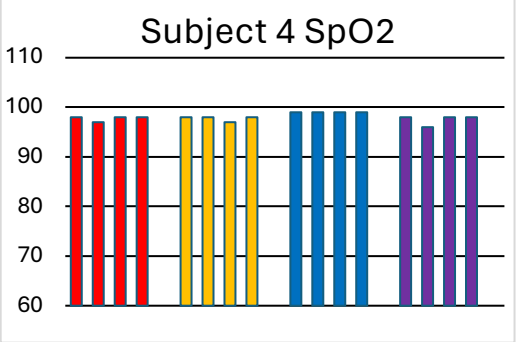
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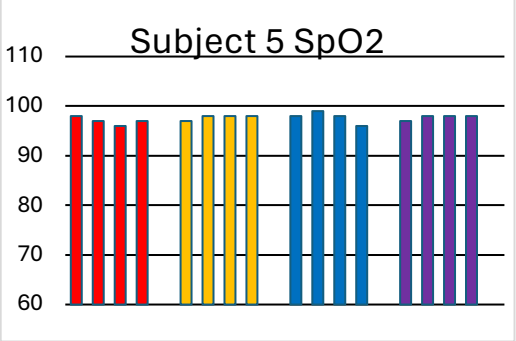
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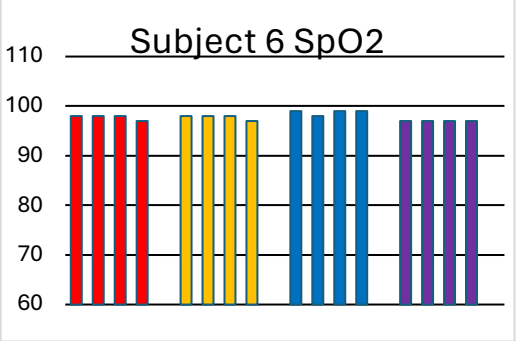
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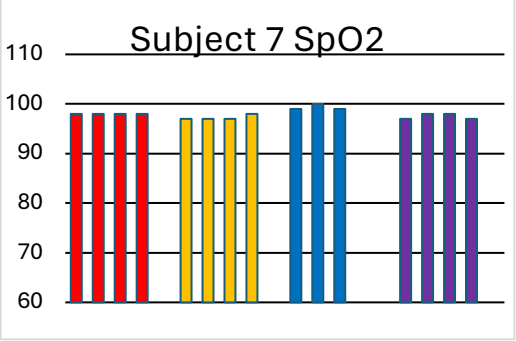
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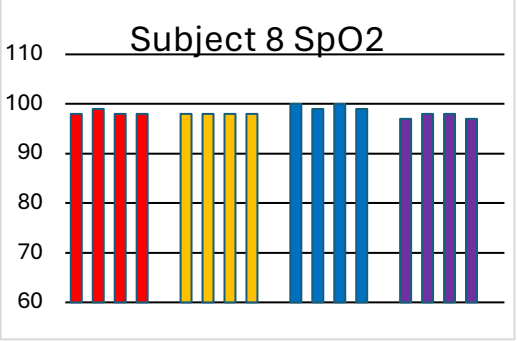
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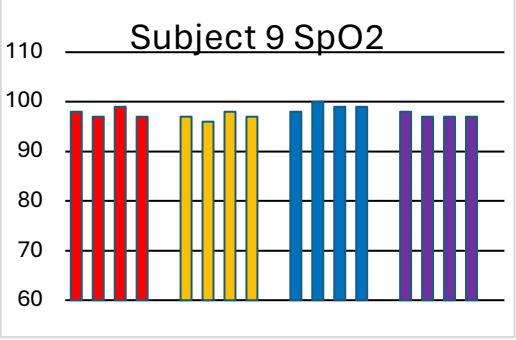
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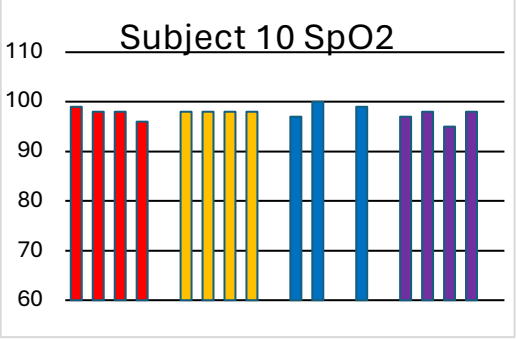
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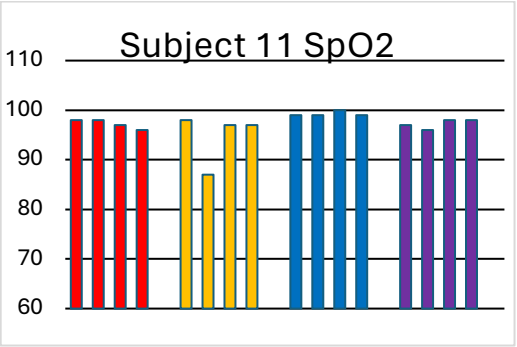
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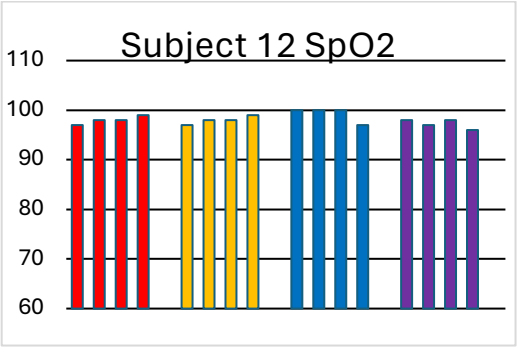
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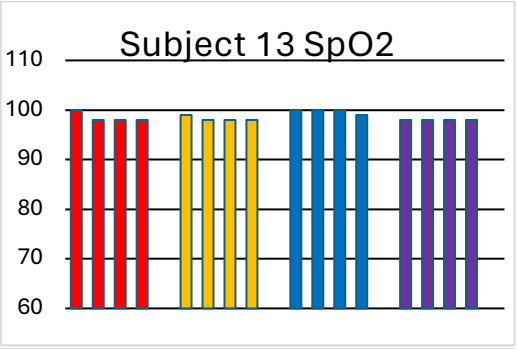
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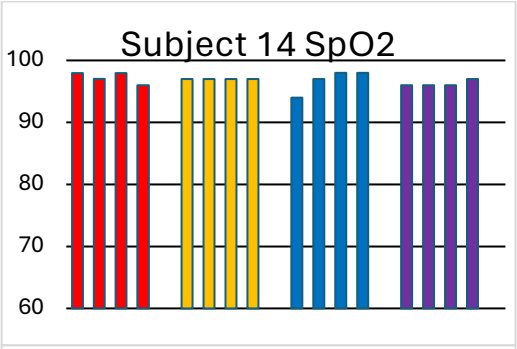
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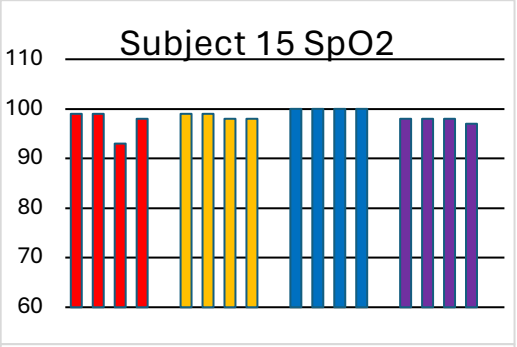
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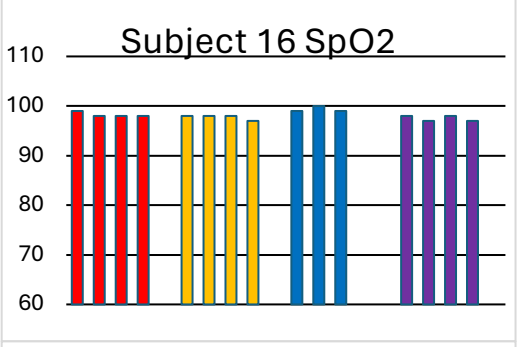
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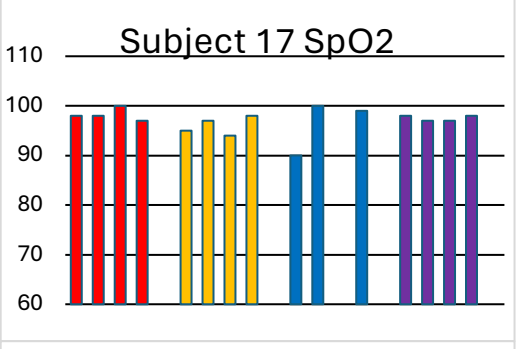
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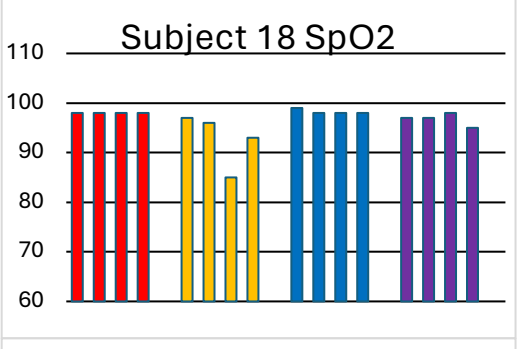
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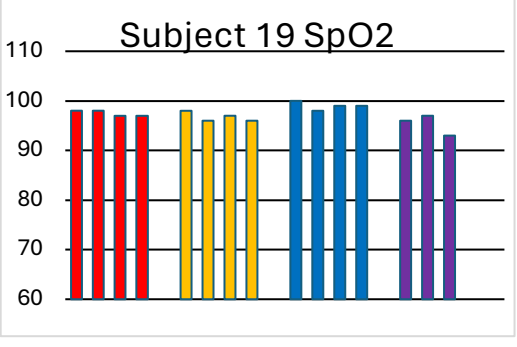
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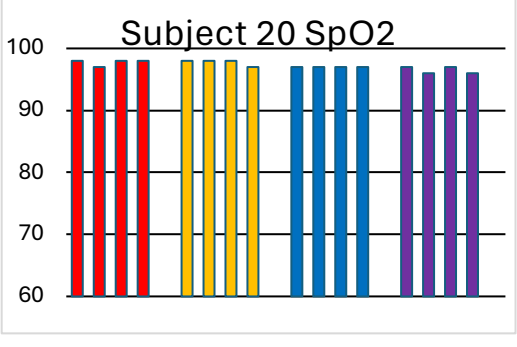
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Importance of Realistic Medical Simulation to Prepare for Ventilation Emergencies

In this feature, Respiratory Therapy hears from IngMar Medical about applying specific products and therapies. You will be hearing from Pete Monteverde, Product Specialist, and Justina Gerard, Director of Product Management at IngMar Medical.

Pete Monteverde: IngMar Medical was founded in 1993 and is located in Pittsburgh, PA. We are the global leader in respiratory simulation.

IngMar Medical's vision for the future is a world with fewer medical errors and adverse events for patients supported by respiratory devices.

Our mission is to provide lung-simulation solutions that help respiratory researchers and engineers develop and test products. We aim to help educators train clinicians to achieve the highest level of patient care.

Justina Gerard: Here at IngMar Medical, we strongly believe that simulation is the best way to standardize and improve ventilation training. We no longer depend on encountering real patients for training. Simulation allows us to create structured, repeatable practices that lead to more deliberate practice in patient care. For example, we can train three different students on three different types of patients in a very controlled environment, tailoring the training to be appropriately challenging for both first-year students and credentialed practitioners.

Simulation removes the risk of harming patients. Students can learn through hands-on experience, and if they make a mistake, it becomes a powerful teaching moment without risking patient safety.

When dealing with new conditions in healthcare environments, simulation allows for just-in-time training, delivered exactly when learners need it, so we no longer have to wait for a patient to arrive at the hospital. Simulation enables us to create standardized training plans based on best practices, which can be quickly disseminated to a large group of people. It opens up opportunities to train on low-frequency, high- risk patients. For example, during COVID-19, simulation allowed practitioners to create scenarios for handling patients they might never encounter otherwise.

Ventilation simulation is also excellent for fostering teamwork and effective communication. Successfully weaning a patient off a ventilator requires a team approach involving respiratory therapists, nurses, physicians, and physical therapists. Maintaining an efficient team approach leads to better patient outcomes.

Reflecting on my experience as a clinician, I made a list of common respiratory emergencies that require skilled intervention. While this list is not exhaustive, these 14 disease processes all affect the lungs and present differently depending on the patient. For example, a patient with a long history of COPD will react differently to ARDS than someone without COPD. The sickest patients tend to need ventilation support because their bodies are working hard to maintain homeostasis, and when that balance is disrupted, clinicians must intervene.

Respiratory emergencies require quick, skilled intervention by highly trained clinicians who understand the various disease states and their respiratory mechanics. Managing these patients can be complex and requires a high level of skill in using a ventilator.

Historically, we used trial and error training, but this approach has limitations. We often stick to what we know, which can limit patient care as technology and best practices evolve. Medical simulation allows us to train in a safe environment, learning the best ways to care for patients with highly realistic simulation equipment. This hands-on training bridges the gap between theory and practice, enhancing understanding and memory retention, ultimately translating into more effective care delivery.

Simulation allows learners to make controlled mistakes and learn from them without risking patient safety. Non-experienced and experienced clinicians alike can gain confidence in scenarios that are not frequently seen but require a high level of skill.

Advanced technology enables learners to incorporate more realistic patients into simulated environments, improving their practice and confidence. In a hospital setting, it's easy to become overwhelmed by monitors and numbers. Simulation helps learners develop the muscle memory to focus on the patient rather than the monitors, leading to better patient care.

Research shows that medical simulation improves outcomes for both patients and learners. According to the World Health Organization, unsafe medication practices and errors are the leading cause of avoidable harm in healthcare systems globally, costing an estimated 42 billion US dollars annually. Medical simulation can help reduce these errors and improve patient care.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Now, we'll describe a clinical simulation scenario built for this purpose and presented for a live audience during a recent webinar.

Pete Monteverde: Today, we're using the Aurora manikin, a highly realistic multidisciplinary ventilation simulator that can simulate virtually any respiratory disease state and trigger almost any ventilator in most modes. Aurora has an anatomically correct airway, enabling various airway management skills. It features unilateral and bilateral chest movement for proper patient assessment and a true-to-life patient monitor with vascular access for IV or IO medication administration.

The foundation of this solution is the internal simulated lung (ISL), derived from the world- renowned ASL 5000, known for its realistic interaction with a mechanical ventilator. The ISL technology inside Aurora creates our patient's respiratory mechanics based on instructions from the RespiSim software, which I'll control during the simulation. Aurora's bidirectional airflow mimics a real patient's breathing, providing realistic hands-on training scenarios. Fun fact: There are over 1000 ASL 5000s worldwide used for education, research, and development.

Justina Gerard: We'll now start the simulation. I'll be the clinician, and the audience will assist me in providing care to Jack, our patient today. Both the audience and I will have access to Jack's patient monitor, a real ventilator, and medication, just like in a real-world scenario. Please respond to the poll displayed on your screen when cued.

Jack is a 45-year-old male, recently recovered from a mild COVID-19 infection, with minimal complications. He is a construction worker with a history of hypertension and a 20-pack-year smoking history. He considers himself to be in good health. He presented to the emergency room with severe shortness of breath, a high fever, and a productive cough for the past 48 hours. He attempted a breathing treatment at home with little resolution. You are called to evaluate his distress and suggest the best course of action. He weighs approximately 75 kilos.

Let's look at our patient monitor. Jack's saturation is 92%, heart rate is 145, blood pressure is 150/89, and respiratory rate is 30. His X-ray shows some inflammation and patchiness, and his blood gas values are pH 7.28, CO2 55, O2 50, HCO3 24, and WBC 18,000.

Now, based on this assessment, what should we do to care for Jack? We have options to place him on BiPAP, CPAP, or high-flow oxygen therapy, or increase his oxygen settings.

Thank you for participating in the poll. The majority suggested BiPAP, so I'll place Jack on BiPAP settings targeting good chest movement.

Justina Gerard: Great job. Jack is now on BiPAP set at 18 over 6. His volumes are 688 on BiPAP, and his heart rate, blood pressure, and respiratory rate have improved. However, Jack's condition deteriorates again after three hours. His heart rate is 175, blood pressure is up, saturation is 87%, and respiratory rate is 30. He has diminished breath sounds and coarse crackles. What should we do next? Should we increase BiPAP settings, intubate with rapid sequence induction, or follow standard intubation protocols?

The majority chose rapid sequence induction intubation. I will intubate Jack, ensuring he is hyper-oxygenated, administer medication, and proceed with intubation. Jack's heart rate, blood pressure, and end-tidal CO2 are now stabilized. What ventilator settings should we target next? 6 to 8 mL per kilogram seems optimal.

Jack is now on appropriate ventilator settings, and his condition has improved. Thank you for your participation. Let's move to debriefing.

Pete Monteverde: Great job, everyone. Justina, how did the simulation make you feel?

Justina Gerard: The simulation made me feel more confident as a clinician. It allowed me to practice and make mistakes in a controlled environment. Team collaboration is crucial in these scenarios, and having more clinicians would enhance the experience.

Pete Monteverde: If you have any further questions or would like to connect with us, email us at sales@ingmarmed.com.

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Lowering Intubation Rates in Pediatric Patients Through Noninvasive Neurally Adjusted Ventilatory Assist

Chris Campbell

No patient wants to stay in a hospital any longer than they have to.

And nobody wants a patient home more than the parents of a pediatric patient. A 2021 study out of Milan, Italy offers hope to some parents by finding that the length of stay (LOS) in a hospital can be reduced by utilizing a certain treatment.

The condition studied by the team of Giovanna Chidini, Daniele De Luca, Edoardo Calderini, Stefano Scalia Catenacci, Tiziana Marchesi, Thomas Langer, Cesare Gregoretti and Giorgio Conti out of the Pediatric Intensive Care Unit, Department of Anesthesia, Intensive Care and Emergency, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico is called with acute hypoxemic respiratory failure (AHRF). The researchers conducted a study that was called, "Implementation of noninvasive neutrally adjusted ventilatory assist (early NIV-NAVA) in pediatric acute respiratory failure: a controlled before-after quality improvement study."

The study found that early NIV-NAVA versus noninvasive pressure support (NIV-PS) was associated with lower intubation rates and shorter PICU and hospital LOS – music to the ears of any parent of these pediatric patients.

"Pediatric noninvasive neurally adjusted ventilatory assist (NIV-NAVA) has been shown to improve patient-ventilator interaction but no data on clinical outcomes are available," wrote the authors. "Aim of this study was to compare NIV-NAVA with noninvasive pressure support (NIV-PS) in children with acute hypoxemic respiratory failure (AHRF), in a single-center before-after study."

The study authors also said there is a lack of data on this issue, hence the need for their study.

"To the best of our knowledge, this is the first pediatric study evaluating the early elective application of NIV- NAVA in a long-term treatment in comparison with NIV-PS," the authors wrote. "To date, no pediatric studies are published showing advantages of NAVA on long terms outcomes and it is not clear if a better synchronization during NRS ultimately leads to improved clinical outcomes. Data from the adult critical care population showed that a higher AI was associated with longer duration of mechanical ventilation as well as ICU and hospital mortality."

Chris Campbell is the Senior Editor of Respiratory Therapy.

The Study

A cohort of thirty-four NIV-PS patients (before group) admitted to a PICU within the 2 years prior NAVA introduction was compared with a cohort of thirty children treated with NIV-NAVA during implementation phase (after group). The primary end-point was intubation rate between groups. Days on mechanical ventilation, number of invasive devices, nosocomial infections, PICU/hospital length of stay (LOS), and physiological parameters at 2 and 24 hours after admission were considered.

The study outlines the devastating impact of Acute hypoxemic respiratory failure (AHRF) due to viral infection, which is the number one cause of admission in pediatric intensive care units (PICU).[1-4]

Treatments in PICUs have traditionally been endotracheal intubation and mechanical ventilation. The study authors looked at the use of NIV-PS, detailing some of the flaws of this method while also looking at the alternative known as NIV-NAVA.

"Recent experiences from pediatric studies showed that noninvasive respiratory support (NRS) has been associated with less adverse events and mortality compared to endotracheal intubation and invasive mechanical ventilatio,"[5-9] wrote the study authors. "Nonetheless, in small children, NRS delivered as noninvasive pressure support (NIV-PS) is often associated with the presence of asynchronies due to large leaks and intrinsic characteristics of pediatric respiratory system (high respiratory rate, low tidal volume, short neural inspiratory and expiratory times, weak inspiratory effort).[8,9] Consequently, NIV-PS frequently results in a poor patient-ventilator interaction with reported failure rates up to 43%."[10]

The study authors also detail the growing use of NAVA as an alternative form of ventilatory support synchronous and proportional to electrical activity of the crural diaphragm (EAdi).

"Of note, during invasive and noninvasive NAVA, cycling is completely under neural control," the authors wrote. "Indeed, the EAdi signal results from the activation of the respiratory centers, the conduction of the electric signal through the nuclei of the phrenic nerve, the phrenic nerves and the neuromuscular junction, and finally the activation of the muscular fiber of the diaphragm. Therefore, any pathological process involving the generation and conduction of the impulse from respiratory centers to the diaphragm fibers could interfere with the generation of EAdi signal.[10-13] Recent pediatric trials showed

that patient-ventilator interaction is unequivocally improved during both invasive NAVA and noninvasive NAVA compared to conventional pneumatically controlled modes."[14-17]

The study authors, however, said their research was needed because there remain questions about if NAVA significantly impacts the clinical outcomes of this group of patients in terms of intubation rate, and PICU and hospital LOS.

The authors conducted a before-after study. The before group was NIV-PS, while the after group was NIV-NAVA.

Study Findings

The study showed several benefits of NIV-NAVA.

"The major findings of the study are that NIV-NAVA was associated with lower intubation rate, lower number of invasive devices, shorter PICU and hospital length of stay, and an early improvement in physiological parameters compared to NIV-PS," the authors wrote. "Besides, NIV-NAVA and NIV-PS were found to be equally safe and no major adverse events due to technologic failure were reported across the entire hospital treatment."

The authors also discussed the best patient-ventilator interaction.

"During the early phase of pediatric AHRF, the appropriate patient-ventilator interaction is the key point to obtain an efficient ventilatory support.[16-25] Previous short-term pediatric physiological studies reported a poor interaction during NIV-PS showing an AI up to 45%, a value largely exceeding the 10% cut-off currently defining severe patient-ventilator asynchrony.[16,17,20] In these studies, the more frequent asynchronies were ineffective triggering, premature/late cycling, and autotriggering. High AI may be due to the difficult interaction between the intrinsic characteristics of pediatric breathing pattern (low tidal volume, weak inspiratory effort, high respiratory rate, and short neural timing) and the technical performances of PICU ventilators (inspiratory trigger sensitivity, expiratory cycling setting, and leaks compensation software)."[24,25]

The study said a major finding is the impact of NAVA on intubation rates early on in a PICU.

"The current study suggests that NAVA could reduce intubation rate in the first 24 h from PICU admission compared to conventional ventilation," the authors wrote. "This result is corroborated by the concomitant improvement in physiologic parameters during NIV-NAVA. We can therefore argue that inspiratory and expiratory neural triggers associated with ventilator-delivered pressure controlled by EAdi improved patient machine synchronization during NIV-NAVA. This leads to better patient's tolerance and more efficient support in respiratory function generating a reduced rate of tracheal intubation and improved hospital outcomes."

References

1 Balfour Lynn RE, Marsh G, Gorayi D et al (1999) Non-invasive ventilation for children with acute respiratory failure in the developing world: literature review and and implementation example. Paediatr Respir Rev 15:181–187

2 Murthy S, Kissoon N (2014) Management of severe viral infections in the pediatric intensive care unit. Journal of Pediatric Intensive Care 3(4):205–216. https://doi.org/10.3233/PIC-14103

3 Bontemps STH, van Woensel JB, BOS AP (2013) Acute viral lower respiratory tract infections in paediatric intensive care patients. Netherlands J Crit Care 17:13–18

4 Patria MF, Chidini G, Ughi L, Montani C, Prandi E, Galeone C, Calderini E, Esposito S (2013) Ventilator associated pneumonia in an Italian Pediatric Intensive Care Unit: a prospective study. World J Pediatr 9(4):365–368. https://doi.org/10.1007/s12519-013-0444-y

5 Ganu SS, Gautam A, Wilkins B, Egan J (2012) Increase in use of non-invasive ventilation for infants with severe bronchiolitis is associated with decline in intubation rates over a decade. Intensive Care Medicine 38(7):1177–1183. https://doi.org/10.1007/s00134-012-2566-4

6 Tassiou I, Papazoglou K, Patsoura A et al (2011) Non invasive ventilation in a pediatric intensive care unit. Pediatric Critical Care Medicine 12:3 Suppl. 1 (A129)

7 Gregoretti C, Pelosi P, Chidini G, Bignamini E, Calderini E (2010) Noninvasive ventilation in pediatric intensive care. Minerva Pediatr 62(5):437–458

8 Essouri S, Chevret L, Durand P, Haas V, Fauroux B, Devictor D (2006) Non-invasive positive pressure ventilation: five years of experience in a pediatric intensive care unit. Pediatr Crit Care Med 7(4):329–334. https://doi.org/10.1 097/01.PCC.0000225089.21176.0B

9 Yanez LJ, Yunge M, Emilfork M et al (2008) A prospective, randomized, controlled trial of noninvasive ventilation in pediatric acute respiratory failure. Pediatr Crit Care Med 9(5):484–489. https://doi.org/10.1097/PCC. 0b013e318184989f

10 Bernet V, Hug M, Frey B (2005) Predictive factors for the success of noninvasive mask ventilation in infants and children with acute respiratory failure. Pediatr Crit Care Med 6(6):660–664. https://doi.org/10.1097/01.PCC.0000170612.16938.F6

11 Alander M, Peltoniemi O, Pokka T et al (2012) Comparison of pressure-, flow-, and NAVA-triggering in pediatric and neonatal ventilatory care. Pediatr Pulmonol 47(1):76–83. https://doi.org/10.1002/ppul.21519

12 Piquillod L, Vignaux L, Bialais E et al (2011) Neurally adjusted ventilator assist improves patient-ventilator interaction. Intensive Care Med 37(2):263–271. https://doi.org/10.1007/s00134-010-2052-9

13 Langer T, Baio S, Chidini G, Marchesi T, Grasselli G, Pesenti A, Calderini E (2019) Severe diaphragmatic dysfunction with preserved activity of accessory respiratory muscles in a critically ill child: a case report of failure of neurally adjusted ventilatory assist (NAVA) and successful support with pressure support ventilation (PSV). BMC Pediatr 19(1):155. https://doi.org/1 0.1186/s12887-019-1527-2

14 Breatnach C, Conlon NP, Stack M, Healy M, O'Hare BP (2010) A prospective crossover comparison of neurally adjusted ventilator assist and pressure support ventilation in a pediatric and neonatal intensive care unit population. Pediatric Crit Car Med 11(1):7–11. https://doi.org/10.1097/PCC. 0b013e3181b0630f

15 Bengtsson JA, Edberg KE (2010) Neurally adjusted ventilatory assist in children: an observational study. Pediatric Crit Care Med 11(2):253–257. https://doi.org/10.1097/PCC.0b013e3181b0655e

16 Vignaux L, Grazioli S, Piquillod L et al (2013) Patient–ventilator asynchrony during noninvasive pressure support ventilation and neurally adjusted ventilatory assist in infants and children. Pediatr Crit Care Med 14(8):e357–e364. https://doi.org/10.1097/PCC.0b013e3182917922

17 Chidini G, De Luca D, Conti G et al (2016) Early noninvasive Neurally Adjusted Ventilatory Assist versus noninvasive flow-triggered pressure support ventilation in pediatric acute respiratory failure: a physiologc randomized controlled trial. Ped Critic Care Med 17(11):e487–e495. https://doi.org/10.1097/PC0000000000000947
18 Carlucci A, Schreiber A, Mattei A, Malovini A, Bellinati J, Ceriana P, Gregoretti C (2013) The configuration of bilevel circuit may affect compensation for nonintentional leaks during volume targeted ventilation. Intensive Care Med 39(1):59–65. https://doi.org/10.1007/s00134-012-2696-8
19 Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D (2016) Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ Qual Saf ;25:986–992. doi:https://doi.org/1 0.1136/bmjqs-2015-004411, 12.
20 Ducharme Crevier L, Beck J, Essouri S et al (2015) Neurally Adjusted Ventilatory Assist (NAVA) allows patients-ventilator synchrony during pediatric noninvasive ventilation: a crossover physiological study. Crit Care 19(1):44. https://doi.org/10.1186/s13054-015-0770-7
21 Venn RM, Hell J, Grounds RM (2000) Respiratory effects of dexmedetomidine in the surgical patients requiring intensive care. Crit Care 4(5):302–308. https://doi.org/10.1186/cc712
22. Center for Disease Control and Prevention. Atlanta (GA): Center for Disease Control and Prevention (2017). National Healthcare Safety Network (NHSN) Patient Safety component manual 2017
23 Blanch L, Villagra A, Sales B, Montanya J, Lucangelo U, Luján M, García- Esquirol O, Chacón E, Estruga A, Oliva JC, Hernández-Abadia A, Albaiceta GM, Fernández-Mondejar E, Fernández R, Lopez-Aguilar J, Villar J, Murias G, Kacmarek RM (2015) Asynchronies during mechanical ventilation are associated with mortality. Intensive Care Med 41(4):633–664. https://doi.org/10.1007/s00134-015-3692-6
24 Kallio M, Peltoniemi O, Anttila E, Pokka T, Kontiokari T (2015) Neurally Adjusted Ventilator Assist (NAVA) in pediatric intensive care. A randomized Controlled trial. Pediatr Pulmonol 50(1):55–62. https://doi.org/10.1002/ppul.22995
25 Baudin F, Pouyau R, Cour Andlauer F et al (2014) Neurally Adjusted Ventilatory Assist (NAVA) reduces asynchrony during noninvasive ventilation for severe bronchiolitis. Pediatr Pulmonol 50(12):1320–1327. https://doi.org/10.1002/ppul.23139

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Indication

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Noxivent is contraindicated in neonates dependent on right-to-left shunting of blood.

Warnings and Precautions
Rebound: Abrupt discontinuation of Noxivent may lead to worsening oxygenation and increasing pulmonary artery pressure.

Methemoglobinemia: Methemoglobin levels increase with the dose of Noxivent; it can take 8 hours or more before steadystate methemoglobin levels are attained. If methemoglobin levels do not resolve with decrease in dose or discontinuation of Noxivent, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide: Monitor nitrogen dioxide (NO2) levels. Nitrogen dioxide may cause airway inflammation and damage to lung tissue.

Heart Failure: In patients with pre-existing left ventricular dysfunction, Noxivent may increase pulmonary capillary wedge pressure leading to pulmonary edema.

Adverse Reactions

The most common adverse reaction of Noxivent is hypotension.

Drug Interactions

Nitric Oxide donor compounds may increase the risk of developing methemoglobinemia.

Administration

Use only with a calibrated, FDA-cleared NOxBOXi® Nitric Oxide Delivery System (NODS). Refer to the NODS labeling for needed information on training and technical support for users of this drug product with the NODS.

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Today's Drive Toward Better Quality Control

Quality Control is an ever-changing field designed to ensure patient safety, but what does the future of QC look like? In this informative webinar, Sten Westgard, Director of Client Services and Technology at Westgard QC, looks at the past for insight into how the next generation of QC will look. Westgard is a leader in the field, an adjunct faculty member and honorary visiting professor at schools around the world who has authored multiple books, essays and reports on the subject.

This webinar, *Today's Drive Toward Better Quality Control, and What Will the Next Generation of QC Look Like?* features Sten Westgard, and was hosted by Werfen.

The objectives of the webinar include: 1) to identify strategies to address the risks of variability in sample collection for enhanced patient safety, 2) to review quality by design, and 3) to discover how quality by design can help achieve higher quality in blood gas testing.

Sten Westgard is the Director of Client Services and Technology at Westgard QC and an adjunct faculty member at the Mayo Clinic School of Health Sciences in Minnesota, the University of Alexandria in Egypt, and the Kasturba Medical College of Manipal in India. He is an honorary visiting professor at Jiao Tong University in Shanghai, China. Sten has managed the Westgard QC website course portal and blog for well over 20 years. He has written and edited hundreds of reports, essays and applications on quality control, method validation, and Six Sigma among others. And finally, he has contributed numerous books on quality, including the basic QC practices, basic quality management systems, Six Sigma QC Design and Control, CLIA Final Rules, and the Poor Lab's Guide to the Regulations among others.

Sten Westgard: I'm very happy to have the opportunity to present this information and to have the support of Werfen in presenting these educational topics.

I need to make sure you understand which generation of Westgard I am. When the name Westgard is invoked, most often it's my father who people think of. He is the original, the classic, the reference Westgard. He's James O. Westgard. When we talk about Westgard Rules, he developed those. I am the next generation Westgard. I follow the Rules, I teach the Rules, but I did not come up with them, so you cannot blame me whenever they are frustrating you. But that puts me in a unique position to discuss what the next generation of QC will look like.

As we look ahead and take into account all of the changes in diagnostics and in the engineering of instruments, it's the same QC we used 40, 50 years ago, and what we're going to be using 10, 20 years from now.

Let's start by going back to the original Westgard Rules that were introduced in 1981. What was the first thing they were trying to address? Before the Westgard Rules, if you think about the dawn of the laboratory era, people were using the 1_{2S} rule. That's two standard deviations from the mean. And even in the early days of the laboratory, it was known that the 2SD, while sensitive, was very good at detecting errors, but was atrocious at generating false rejections. It created a lot of false alarms. Specifically, with two control measurements it was giving a 9% false rejection rate. And with three control measurements, it was giving a 14% false rejection rate.

Maybe it was that the laboratory of the past had less to do, fewer tests on their plate, fewer patients they were addressing, so they had more time to deal with false rejections. But if we talk about today's laboratory, we have a huge menu of tests. We have a massive volume of samples to address. And, we don't have time to add 9% or 14% more effort, particularly when it does not contribute anything useful to patient care. When you walk into work, I'm sure you don't look at your list of things to do and say to your supervisor or your administrator, "I know I have this very long list of things to do. I would like 9% more work, or I would like 14% more work today. And that 9-14% more work, please make it pure waste. Please make it an activity that doesn't help any patient and just drains the resources of the laboratory."

Back in the '70s, as more instruments were becoming more automated with more menu, and higher volumes, there was a need to address and try to eliminate the 1_{2S} false rejection problem. And that's what the first Westgard Rules were about, trying to eliminate all of the false rejection problems from 2SD. And it took that 1_{2S} rule and instead of making it a rejection, it said, "Okay, if that 1_{2S} alarm goes off, that's a warning. It's just a warning. What you need to do is check five other rules, and only if one of those is violated, will you reject the run. If you look at those five other rules and none of them are violated, you're in control." And that takes a 9 to 14% false rejection rate, and it reduces it to 2, 3 or 4%. It dramatically reduces the number of false rejections.

And at the same time, these other rejection rules, the five other rules after the warning rule, when combined, still provide a relatively high level of error detection. And even better, the

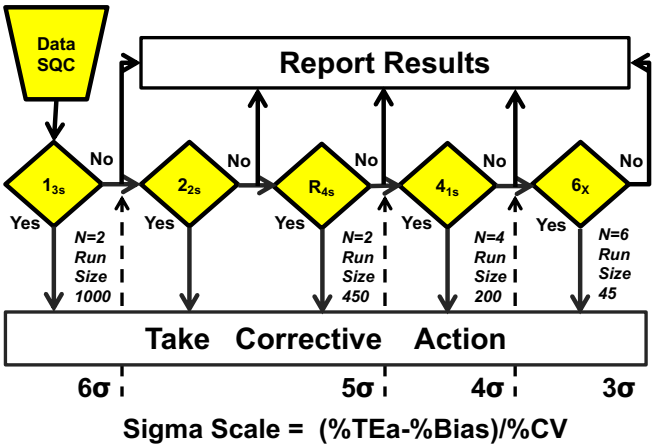
If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Westgard Rules allow you to use a few measurements and still get relatively high error detection.

Outside the laboratory, in other applications of quality control, if two controls aren't providing enough error detection, you run 10 controls. And if 10 controls aren't giving you enough error detection, you run 20, 30, 40, 50, 100 controls. Because in other applications, and especially in manufacturing, controls are inexpensive. Whereas in the laboratory, we can only afford two or three levels because controls are expensive. So we're trying to deal with our false rejection problem and still maximize our error detection problem with a relatively small number of measurements. This is a classic laboratory workaround. We're trying to do more with less.

That was the original Westgard Rules. They were quickly adopted worldwide because it became clear, "Oh, this big false rejection problem that laboratories are experiencing, we can dramatically reduce it if we switch to Westgard Rules." But that was 1981. Now we are far into the 21st century. Do we still need to use the same formulation of Westgard Rules that we were using four decades ago? Well, the Westgard Rules have not stayed in place. They haven't been carved in stone in 1981. The Westgards have been evolving the Westgard Rules to try to keep up with the changing and the improving quality of performance in today's instrumentation.

The latest version of Westgard Rules is called Westgard Sigma Rules, and that's where we take Six Sigma and combine it with the Westgard Rules. And with Six Sigma, we're trying to benchmark the level of quality. So how good is the method at achieving the level of quality needed by patients? The better it is, the closer that number is to Six Sigma. As you get closer to Six Sigma, you don't need as much QC. With the Westgard Sigma Rules, the flowchart looks similar. The 1_{2S} rule is gone because we no longer recommend it, even as a warning rule.



Westgard Sigma Rules with Run Sizes for the numbers of patient samples between SQC events. Note sigma-scale at the bottom of the diagram. To apply, determine sigma-metric, locate on the sigma scale, identify control rules, total number of control measurements (N), and frequency of SQC events specified as Run Size.

Figure 1. Westgard Sigma Rules

But the biggest change comes in at the bottom. See the bottom of that flowchart (Figure 1). It says Six Sigma, Five Sigma, Four Sigma, Three Sigma, and below that is a Sigma metric calculation. The equation tells you how good you are at achieving the required level of quality. There are three ingredients: 1) the allowable total error (TEa), 2) the bias, and 3) the CV.

The TEa is the quality goal you need to hit. It's often provided by regulations. In the US, CLIA, for most analytes defines how good you have to be. Then bias and CV, are things you operationally calculate already. It's not a difficult calculation because all of the ingredients, all of the variables are already at your fingertips. Once you know that Sigma metric, you can look at the Westgard Sigma Rules and determine how many actual rules are needed.

Six Sigma, which is world-class quality, represents less than four defects out of a million reported results. It's as close to perfect as most processes can get. But if you're at that level where you're almost completely defect-free, that's when you only need one rule. You don't need all the Westgard Rules, you just need one rule, and those limits are even wider.

They go to 3SD. Instead of 9-14% false rejection, now you're less than 1%. There's a benefit to having the best quality test because it allows you to perform the least amount of QC.

And then as your Sigma metric goes lower, which indicates lesser performance, Five Sigma being excellent, Four Sigma being good, and Three Sigma considered the minimum acceptable quality, you need more and more Westgard Rules. At Three Sigma, for instance, you need all the Westgard Rules. The minimum level of quality requires the maximum number of Westgard Rules. So now there's a flexible approach to how many QC rules are needed, depending on how well your method is performing.

But this can still be more advanced, once we start to think about closed box operations. To recap, if we can get to Six Sigma, we won't need all the Westgard Rules. And at Three Sigma we'll need all of the Westgard Rules. That's the minimum quality, requiring the maximum Westgard Rules. And that obviously means when we're in open system processes—systems that are more exposed to human error—we're going to need more Westgard Rules. As the Sigma metrics go down, the more pre-analytical and analytical errors are possible, are occurring, and we'll need more Westgard Rules. But if we have a closed system that can operate at a high level of quality, we may not need Westgard Rules at all.

Let's switch now from the technical application of Westgard Rules and QC to the operator of QC. Who is performing this QC? It would be nice if not only could we customize the QC, but also if we could automate it. A couple of years ago, we conducted a survey of point-of-care users and how they did QC, and more importantly, what they would like out of their point-of- care devices. Some of them said, "Well, we'd like more training on the device." Others said, "We need more directions from the manufacturer on how to run QC."

But the most common thing asked by users is, "Can you put more of the QC system inside the device?" Take more out of the hands of the user and automate it inside the device itself. That parallels many processes we see today in other industries. For instance, cars and car safety, we've seen a huge number of innovations in the area of helping cars not crash and helping cars minimize the impact of a crash. This is part of their QC system. They have lane and distance detectors.

I'm old enough to remember when automatic brake systems were new. The original Westgard was old enough to remember when seat belts didn't exist, much less airbags. But over the

decades, new systems keep being added. Many are automated and they take the safety part out of the hands of the driver. Because if you look at who causes accidents, few of them are caused by the car. And few of them are caused by the environment. Over 90% are caused by the driver. That's why there's this drive to make drivers driverless, to make the next car, completely automated and take the driving out of the hands of the human.

A year or two ago, we thought that we were going to see the end of driving. Now we're a more skeptical, but there is more automated driving. And we're at the point where you might look at yourself and if you have children, you might look at them and think, "Are my grandchildren going to be the first generation who doesn't drive or are they going to be the last generation who drives?" Basically, we're going to turn driving into a closed system that doesn't suffer from human error.

Let's pivot again and talk about quality in an abstract level. What are we trying to manage? Why do we run QC? Why don't we accept the device and say, "Well, they said it wasn't going to have errors, so I'll accept that and I don't need to do QC." The first thing you'll encounter is the manufacturer, people who sell you the device as well as the regulators of your operations, they will tell you, "No, no, you have to run QC. You cannot assume everything is going to be fine." And then as you go through your training, of course, you place at the center of your focus the patient's health. "I need to make sure every time I'm delivering the right answer, I'm not going to harm the patient."

Now, luckily, we're in a position where we can afford some QC, and we can see a benefit for ourselves when we do it correctly. There's also not an insignificant reason, that when we do QC, we get useful information. So if we have our Levey-Jennings charts, if we're plotting values, we not only can catch immediate errors, we can even see errors as they develop. We may even be able to anticipate problems and prevent them from occurring.

That's in the ideal application of QC. There are still laboratories all over the world that do QC as theater. They look at the regulations and say, "What's the least amount of effort I can make? Do you want me to run some controls? Well, I'll run some controls. Do I need a chart? Okay, I'll draw some lines. I'll throw some dots on the chart, but I'm not really paying attention to them." But we want to do something useful with these dots. And most relevant at the point of care is, we have an immediate answer and an immediate application. If that's a single result, it needs to be reliable. We need to know if it's reliable. We need to know, can we make a decision? Can we change a medical diagnosis or a therapy at that very moment?

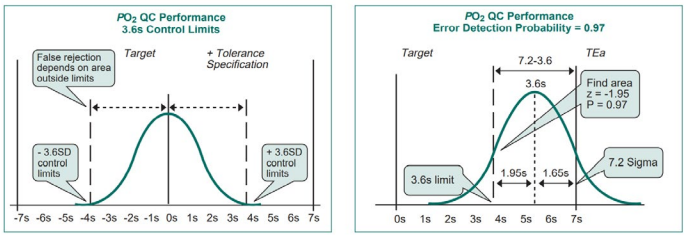
To support that, if that is our goal, we need a QC that will work immediately.

There's technical reasoning that goes behind the powering of immediate QC. One of the things we have to do is define all kinds of sources of errors. What could go wrong? Then we need to say, "Well, for every kind of error, we also need a way to monitor it." And not only do we monitor it, but we have to define, "How much error is acceptable and how much is unacceptable?" Because some little amount of variation is going to happen. There is no method, no instrument, no process that is perfect. There is variation and it exists.

Some variation can be tolerated. And if it's small enough, it doesn't change the final result and we can look at that and say, "Yes, there's some variation, but we're not going to raise an alarm over it." That's part of the Six Sigma theory. What we need to do is define the tolerance specification.

Let's figure out, "This is the size error that is acceptable and isn't going to change the diagnosis, isn't going to hurt the patient." But we're going to add another line and say, "Look, any error that goes over here or over there, that's too much error. That could flip a diagnosis. That could give a false positive, or a false negative. The patient isn't going to get the right diagnosis or the right treatment." Those are the things we need to prevent. So there's a technical way to do that. We can determine the total allowable error. And then we can model what happens to a method when an error occurs. What's going to be our ability to detect that error?

On the left of the screen below (Figure 2), is the way we want things to occur. This is the setup. There's no error. The distribution of results is centered where it should be and the limits are wide, so there's little false rejection. We're going to catch any error that occurs. And then on the right you see, "If an error does occur, if the error is of this size, we can look at the area under the curve between these two lines." We can say, "Oh, we've got 97%, that's a 97% chance we're going to detect that error with very little false rejection." There's a mathematical way to figure out how good we need to be, and when things go wrong, how likely we are to be able to detect that error.



SD control limits were determined for each assay. *Probability of error detection for medically important failures was determined.*

Figure 2. Defining Quality and Methods for Control: The Gritty Details.

We can take that error detection capability and turn it into an average run length, which tells us how quickly we will detect the error. You'd like your average run length to be 1 or less. If your average run length is 1, then you detect the error when it occurs. The same run, same time that the error occurs, you're going to detect it. But if your average run length goes up and up and up, it gets larger. If it's 2, then it says, "Ah, well, on average it's going to take me two runs before I detect the error. That means one run might go out the door and be acted upon and be used for diagnosis before I'm able to detect the error."

We want that to be less than one, but then we come to our definition of what a run is. Is a run a single result or is it 24 hours? If a run is 24 hours long, then a day could pass before we catch an error. And for some of those results, you don't hold them for a day, you act on them quickly.

Even having an average run length of 1, depending on the circumstances of how you're running QC and how you're defining the run, that could be too late. That's too long.

		pH	pCO_2 (mmHg)	pO_2 (mmHg)	Sodium (mmol/L)	Potassium (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Glucose (mg/dL)	Lactate (mmol/L)	tHb (gr/dL)	O_2Hb (%)	COHb (%)	MetHb (%)	HHb (%)	tBili (mg/dL)
PCS A (N>45000)	Mean	6.90	64	113	107	7.1	1.84	46	144	3.3	14.6	89.4	2.4	1.6	6.6	20.1
	SD (CV%)	0.003 (0.0%)	0.5 (0.8%)	1.1 (1.0%)	0.4 (0.4%)	0.03 (0.4%)	0.015 (0.8%)	0.2 (0.5%)	2.1 (1.5%)	0.06 (1.7%)	0.03 (0.2%)	0.01 (0.0%)	0.01 (0.4%)	0.00 (0.3%)	0.00 (0.1%)	0.03 (0.2%)
PCS B (N>530000)	Mean	7.41	33	181	156	2.0	0.79	85	0	0.0	0.0	N/A	N/A	N/A	N/A	0.0
	SD (CV%)	0.004 (0.1%)	0.5 (1.4%)	2.2 (1.2%)	0.7 (0.5%)	0.01 (0.5%)	0.007 (0.9%)	0.4 (0.4%)	1.6 (N/A)	0.03 (N/A)	0.04 (N/A)					0.04 (N/A)
PCS C (N>6000)	Mean	8.05	33	3.1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	SD (CV%)	0.007 (0.1%)	0.3 (1.0%)	1.0 (32.5%)												
PCS D (N>13000)	Mean	7.35	24	48	165	7.3	1.22	142	349	8.0	7.4	80.0	4.1	4.0	11.9	10.4
	SD (CV%)	0.004 (0.1%)	0.4 (1.5%)	3.2 (6.6%)	0.6 (0.4%)	0.04 (0.6%)	0.011 (0.9%)	1.6 (1.1%)	3.3 (1.0%)	0.24 (3.0%)	0.03 (0.4%)	0.14 (0.2%)	0.09 (2.1%)	0.10 (2.6%)	0.33 (2.8%)	0.03 (0.3%)
PCS E (N>13000)	Mean	7.22	69	92	129	4.5	0.56	101	71	1.6	16.5	50.0	10.1	8.1	31.9	20.0
	SD (CV%)	0.005 (0.1%)	1.0 (1.5%)	2.2 (2.4%)	0.5 (0.4%)	0.03 (0.6%)	0.008 (1.4%)	0.8 (0.8%)	1.0 (1.5%)	0.06 (4.1%)	0.07 (0.4%)	0.11 (0.2%)	0.05 (0.5%)	0.07 (0.9%)	0.23 (0.7%)	0.07 (0.4%)
Sigma Average		9.0	11.2	6.9	8.3	25.2	12.4	10.5	7.0	8.5	18.4	122.2	70.1	128.3	209.8	43.0
Overall Pfr		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.152	0.152	0.152	0.152	0.152	0.167
Overall Ped		0.974	0.953	0.938	0.412	0.979	0.990	0.950	0.097	0.933	0.997	1.000	0.957	0.957	0.998	0.923
Overall ADT (min)		2	2	2	5	2	2	2	21	2	2	2	2	2	2	2

Table 1. Method Sigma.

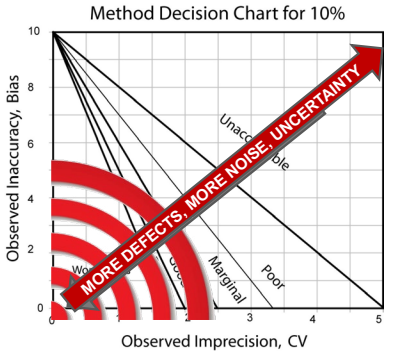
Now we're going to look at the actual performance that we see in the GEM® Premier™ 5000 blood gas system with Intelligent Quality Management 2 (iQM® 2). The table is dense (Table 1). Here are some points to anchor on. First, the columns represent different parameters that are going to be measured, from CO_2 to sodium, chloride, glucose, and then you have the five different process control solutions (PCS), that are run automatically inside the system at various times.

The last five rows at the bottom (Table 1) have the most important details. What's the Sigma that's being achieved by these methods? And if you look at the Sigma average across that row, they are all higher than six. We have better than Six Sigma performance on the whole battery of tests. What does that mean when it comes to average time of detection (ADT), which is essentially our run length, our average run length, how quickly can we detect errors? For most, it's two minutes. It's going to take us two minutes to pick up an error instead of the 24 hours traditional laboratory might be doing.

Another row in the bottom to take a look at is overall false rejection rate (Pfr) What is the false rejection rate that these QC techniques inside the box are going to generate? For most of them, it's zero. Or I should say it's 0.000. If we added more digits, we might see a little more false rejection.

But it's compared to what we see outside the box, in traditional laboratories. There are laboratories still doing 2SD and they've got 9% or 14% false rejection. And there are labs that might be using Westgard Rules and they've got it down to 2-4%. And then there are Six Sigma assays that might use the Westgard Sigma Rules, and they might use 3SD, which gets down to less than 1%. And then you have the GEM Premier 5000, which is running five different levels of QC at different intervals, and false rejections down to essentially zero. They aren't going to be bothered by false rejections.

To summarize Table 1, detection time is as small as two minutes for most analytes. And the average of the Sigma metric is greater than six for all analytes. You get world-class quality with very rapid error detection.



Westgard JO. A method evaluation decision chart (MEDx chart judging method performance. *Clin Lab Sci.* 1995;8(5):277-283.

Figure 3. Visualization of Sigma Performance: Method Decision Charts.
Westgard JO. A method evaluation decision chart (MEDx chart judging method performance. Clin Lab Sci. 1995;8(5):277-283.

Another way to look at the Sigma metric, other than calculating it, is to use a Method Decision Chart (Figure 3). The QR codes will take you to the original papers as well as a free tool that will generate these charts for you. Method Decision Charts provide a visualization of the Sigma metric, and it takes the same information that we used in the equation and displays it as a plot. Now we take the imprecision, on the X-axis, and the bias on the Y-axis. If you know the CV and bias of your methods, those are the X-Y coordinates. You now know where to plot your performance. And on this chart, are these diagonal lines, carving up that space into different Sigma zones. At the graph's origin near the zero point, that's world-class or Six Sigma performance. What is that? That's less than four defects per million reported results.

And then you have Five Sigma, which is excellent. That's about 233 defects per million. Four Sigma is around 6,200 defects per million. Three Sigma, the marginal quality or the minimum acceptable quality, is around 67,000 defects per million. Two Sigma is poor. Less than Two Sigma, we hope you'll consider unacceptable. And that's where we get into hundreds of thousands of defects per million reportable results.

If you want to simplify your thinking about this chart, those diagonal lines are the rings of a target and you're trying to hit the bull's-eye. The closer you get to the bull's-eye, the fewer defects you have, the more reliable your result is, the more confidence you and the laboratory and the clinician and the patient can have in that result and any decision being made, based on that result. As you have more imprecision, more bias, you're generating more defects, you're adding more noise around all of the signals. And in the upper right quadrant, you're probably confusing the clinician. You're not helping to confirm the diagnosis.

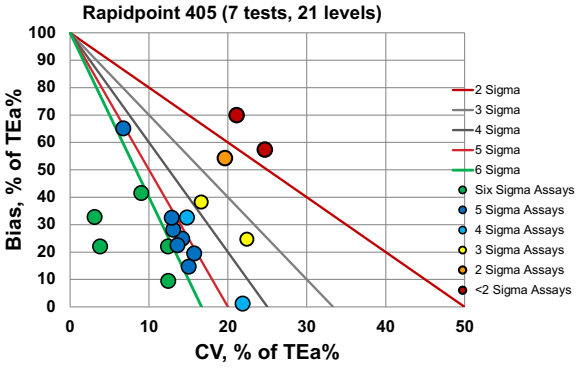


Figure 4. Cut to the Chase: Method Decision Charts Make it Clear.

We put that Method Decision Chart to use in hundreds of studies and laboratories around the world. One study that's particularly relevant to our topic today is from an institution in Belgium. They performed a study looking at three blood gas instruments. It's rare to have a head-to-head, apples-to-apples comparison and method performance. Here was an institution that had access and was able to perform a quality assessment of three different blood gas instruments. And when you look at the RapidPoint, you see seven tests where they had three levels of control (Figure 4). A handful of them are green or in the bull's-eye, and that's Six Sigma. Two are minimum quality, one that's Two Sigma. And two that are less than Two Sigma.

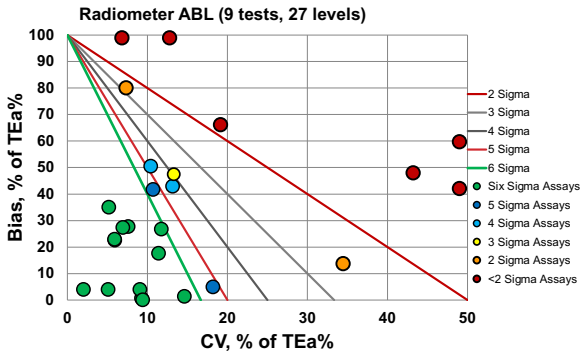


Figure 5. Cut to the Chase: Method Decision Charts Make it Clear.

When you look at the Radiometer (Figure 5), the performance gets worse. Yes, there are nine tests, 27 levels. You see a number of assays in the bull's-eye, but it's concerning that you have six levels below Two Sigma. Those could be generating errors. And if you're only doing your QC once every 24 hours, you probably have impacted results going out to clinicians and patients before the QC detects the error and you're able to address them.

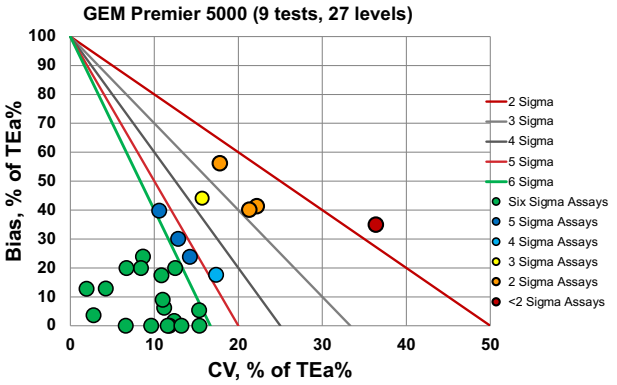


Figure 6. Cut to the Chase: Method Decision Charts Make it Clear.

And then finally, we have the GEM Premier 5000 (Figure 6). Again, another nine tests, three different levels. It's not a perfect box. There is no perfect box, but you have the vast majority of performance in the bull's eye. Of the three, the most number of levels in the bull's eye happens with the GEM Premier 5000.

How is that performance achieved? How are you able to do better QC on better performance? It comes down to the closed analytical system. You're taking things out of the hands of the users, which they appreciate. Less work for the end user, but by controlling it within a closed system, you also make it perform better. And in the figure (Figure 6), you can see all the different process control solutions. Remember, the system uses five different QC solutions, and the user does not have to prepare and insert five different levels. That would create an opportunity for more pre-analytical mishandling. And on top of the closed system, there's a pattern recognition software, which compares the current observations to essentially a database of all previous experiences with this instrument and this method and matches them up. "Oh, the way your performance looks right now, it matches historically to an error condition we've seen in the past." It can help catch errors that no other system is able to detect.

Then there's the frequency of QC. When we talk about 24 hours as the traditional QC frequency, that's an arbitrary choice. Why is 24 hours so magical? It's where the regulations and even the manufacturers of most devices came down. We don't know how often you should perform QC, so we'll say once a day.

If you venture into the United States, the CLIA regulations, there is a more extreme option called IQCP, the Individualized Quality Control Plan. If you do an IQCP, you no longer have to base your QC frequency on the earth. You can base it on the moon. That is, you can reduce your QC frequency to once every lunar cycle, once every month. A once a month QC frequency is literal lunacy. If you do that, it's crazy. If you have an error and you catch it one month later, how do you go back to patients and say, "Yeah, 20 days ago, three weeks ago, we ran a test on you, and now we just realized that it's wrong"?

So those are two ways that QC frequency occurs. There is another one that is driven once every eight hours, that's almost driven by the shifts. You have three shifts? You have the morning, you have the noon, you have the overnight. Every eight hours, you have every shift run QC. Interesting approach.

You're basing it on your personnel, but what should be the heart of our focus for QC? It should be the patient. We should have patient-based, performance-driven QC frequency.

What do we need to do to make sure the result we give the patient is not wrong? How do we eliminate or reduce to the number of erroneous results we're delivering to patients? That theory has been calculated and developed. One approach that has become more popular, at least to talk about, is patient-based real-time QC, or PBRT-QC. This gets offered as well. We don't need to worry about traditional QC because we'll do patient-based QC. And patient-based QC has the benefit of using patient samples. You don't have to spend extra money like with traditional controls.

But even PBRTQC requires that you accumulate a certain number of typically normal patient samples. It might be 10, it might be 20. If you work out the math, sometimes you need several hundred patient samples before you can calculate an average of normals and then be able to track the performance of the method. Your PBRTQC might give you signals faster than every 24 hours, but it's still behind the clock for an individual patient's sample.

The most patient-based QC would be to look at a single patient specimen and only focus on measurements on that specimen. This is one area where the GEM Premier 5000 excels. It takes 15 measurements in 15 seconds on a single patient specimen. That's the most patient-based QC of all. And then it will compare those measurements against, again, like a database of all well-performing tests, as well as the erroneous ones. And it'll match up and say, "The trajectory of that test in those 15 measurements in 15 seconds, looks like an error we've encountered in the past. We have to be careful about this particular test result." Which gives you a big contrast, because now you have a QC system that is executing on every patient sample. Not only is it doing pattern recognition, called IntraSpect, but it also has an interference detection. It detects micro-clots. This is in contrast to our traditional QC system, which may be happening only every eight hours, or only every 24 hours.

There might be a few additional electronic checks that a manufacturer promotes. "Well, we do traditional QC and we have some electronic system checks." But they're not looking at individual patient samples. This additional approach that the GEM Premier 5000 has taken expands the number of errors it's able to cover and monitor. Our traditional QC has been focused on the analytical step. But with the distribution of errors in the total testing process, many are happening at the pre-analytical level. And then a lot of them also occur in the post-analytical era phase of the total testing process. To provide a better QC system, we would like to use something like the GEM Premier 5000, that will encompass the pre-analytical, post-analytical, and the analytical phases of the total testing process.

One example is bubbles. In one paper, bubbles were introduced into samples and then different devices were tested to see if they could detect these micro-bubbles in the samples themselves. And the GEM Premier 5000 rejected all of them. It was able to effectively respond, "There are micro-bubbles in here and we can't use these samples."

Another device, the ABL 90, had different error messages. The system didn't recognize what was going on. It flagged results with strange errors and reported results that were impacted by those bubbles. Here's an area where that pre-analytical error, introduction of bubbles into the specimen, is only addressed and detected by the GEM Premier 5000, and its predecessor, the GEM Premier 4000.

Now let me wrap up the discussion. We've tried to show you that the next generation of QC is here. It's present in the GEM Premier 5000, with iQM® and IntraSpect™, and the additional systems Werfen has brought to the instrument. It has a wider reach of monitoring.

It looks beyond the analytical phase. It has novel ways to monitor quality. It has an unmatched ability to detect and to perform QC on each patient sample. And it will catch errors that traditional QC cannot. Approximately one out of every 100 patient samples has an error that only iQM2 can detect, and other devices will miss those errors.

And with that, I thank you.

Disclosure. Sten Westgard received a consultant fee and a speaker fee for this presentation from Werfen.

Improving Quality of Life for Patients With Tracheostomies

Robin Helms, BSRT, RRT

Each year, more than 100,000 tracheostomies are performed in the United States.[1] According to Durbin (2010), there are four indications for performing a tracheotomy: upper airway obstruction, prevention of upper airway damage, secretion management, and prolonged intubation.[2]

Some patients who undergo tracheotomy may only require having a tracheostomy tube for a short time while others may need a long-term tracheostomy tube. For example, a patient who requires mechanical ventilation may only require a tracheostomy tube for a short period as their underlying condition improves. In contrast, a patient with a progressive neurologic disease, like ALS, may require the tracheostomy tube for their lifetime. The length of time a patient has a tracheostomy tube will depend on diagnosis and treatment plans.

Living with a tracheostomy tube will significantly change a person's way of life. Patients with tracheostomies may face challenges in the ability to care for themselves, financially and physically, and the reaction of others to their medical condition may impact their self-perception.[3] Having a tracheostomy tube and loss of voice has an impact on patients often causing frustration, anger, and grief which are considerations for psychological well-being.[4] For patients with both short- and long-term tracheostomies, their quality of life may suffer due to such a drastic change from their previous way of life.

What is Quality of Life?

Testa and Simonson (1996) defined quality of life as the physical, psychological, and social domains of health, seen as distinct areas influenced by a person's experiences, beliefs, expectations, and perceptions.[5] From this definition, quality of life is not based on measurable data, rather it is based on subjective data. Each person experiences life differently, even two patients with the same diagnosis could have different qualities of life due to having different encounters and views.

Because quality of life is based on subjective data, a common way to gauge the quality of life is through questionnaires. These questionnaires often contain different items that relate to a patient's perception of their well-being.[5] Items included in questionnaires may be such areas as perception of their disability, symptoms, personal relationships, psychological well-being, physical well-being, and many more that probe how a patient is feeling and coping.[5] The data in these questionnaires are converted and calculated into a "score" that indirectly relates to that patient's quality of life measurement.[5]

How is Quality of Life Affected After Tracheostomy?

Once a tracheostomy tube is placed, many physiologic changes occur which have a direct effect on one's perception of quality of life. When a tracheostomy tube is placed, the upper airway is bypassed. This impacts some of the most basic human needs: respiration, nutrition, and communication.[6] Gilony et al. (2005) found that patients who received a tracheostomy reported an overall diminished quality of life even after they had been decannulated.[7] They also reported a reduced overall satisfaction with life and having a poor body image.[7] Gal and Karadag (2010) found that patients who underwent tracheostomies also reported a negative impact on quality of life due to the complications arising from communication, breathing, and psychological well-being all changing.[6] Freeman-Sanderson et al. (2016) observed that patients with tracheostomies also report experiencing anxiety, frustration, anger, fear, and depression due to the changes that occur once the tracheostomies are in place.[4] These studies indicate a need to support a patient's quality of life post-tracheostomy to ensure improved psychological well-being during and after recovery.

Ways to Improve Quality of Life for Tracheostomy Patients

Healthcare is often focused on the physical domain of health but because quality of life focuses on the different domains of health, including psychological, social, and physical, it is important to support patients with tracheostomies in each domain.

Psychological Health

When it comes to quality of life, one important consideration is psychological health. Psychological health is defined as the presence or absence of distress as well as the presence or absence of positive well-being and psychological growth.[8] Research has indicated that poor psychological health may lead to poor physical health and disease.[9]

To support a patient's psychological health, it is beneficial to support self-esteem. One study conducted by Freeman-

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Improving quality of life by restoring the ability to communicate with others through the use of a Passy-Muir Valve. Image supplied.

Sanderson et al. (2016) reported that a return of voice was associated with improved self-esteem and improved cheerfulness.[4] Patients who undergo tracheotomies lose their voice due to a change in their normal breathing pathway. Restoring their voice is a key factor in addressing psychological health and this can be done by using a speaking valve. The Passy-Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) is a one-way valve that restores a patient's natural exhalation pathway and allows them to generate voicing. Once a patient's voice has been restored, not only will they be able to participate in their healthcare, but research has shown that they will have improved self-esteem and engagement in meaningful relationships with family and friends due to their voice being restored and improving communication.[4,10]

Social Health

Another domain of health, social health, is also extremely important. Research has shown that social ties play a large role in well-being.[11] Patients who have undergone a tracheotomy have had a drastic change in their normal way of life and may even feel a sense of disfigurement which can lead to social isolation.[12]

A great way to support patients' social health is to have a social support system. Social support has been shown to play an important role for patients with tracheostomies to accept their illness.[13] Many patients with tracheostomies will require a caregiver if they are unable to perform activities of daily living. Caregivers are often family members, but if a patient returns home and needs at-home care, some agencies can provide support for many levels of care. In addition to family members, hired caregivers are also a great source of social support for the patient. Besides having a strong social support system at home, it is also important to feel a sense of belonging and community. This often can be achieved through peer support groups. Peer support groups have been shown as a great resource for many patients who live with chronic illnesses.[14]

Physical Health

Finally, improving and maintaining physical health will play a vital role in maintaining quality of life for patients with tracheostomies. Marshall-Seslar (2024) defines physical health as more than how fit one is but also how well their organs and body systems function.[15] Because the body functions of a patient with a tracheostomy have changed in many ways, it will be important to support their physical health.

One important aspect of maintaining physical health for patients with tracheostomies is conducting proper tracheostomy care and cleaning. Proper tracheostomy care includes cleaning the tracheostomy tube and the stoma. Tracheostomy care and cleaning should be conducted regularly, and the stoma and surrounding areas should be kept dry to avoid infection.[16] It is paramount that the patient, family members, and caregivers are all trained in proper care and maintenance to avoid complications.

Nutrition is also important for maintaining proper physical health. When patients are malnourished, this will have a direct effect on respiratory function and recovery.[17] The presence of a tracheostomy tube is not a deciding factor in whether a patient may receive oral intake; each patient must be assessed individually.[18] However, some patients may have impaired swallowing due to underlying disease processes that may impact their ability to sustain oral nutrition. If this is the case, then referral to a speech-language pathologist for evaluation is essential.[19]

Another consideration with physical health is the patient's status with mobility. Mobility plays a role in overall physical health. However, patients who undergo tracheotomies are often in bed and not active, leading to muscle wasting and weakness.[21] When mobility is a concern, having consultations for both physical therapy and occupational therapy can begin to address mobility concerns. When a patient has an open system with a tracheostomy tube, one way to improve overall trunk support and postural control is to close the system. This occurs by redirecting airflow to the upper airway while using the PMV and allowing the glottal structures to be engaged, assisting with restoring pressures. A study conducted by Ceron et al. (2020) found that the use of the PMV improved the patient's capacity for mobility.[20]

Conclusion

Because patients with tracheostomies experience a major change in their way of life, it is important to help maintain their quality of life. There are many aspects to consider when it comes to quality of life: psychological, social, and physical. It is crucial to support patients with tracheostomies in each of these areas to improve and preserve their overall well-being.

References

1 Yu, M. (2010). Tracheostomy patients on the ward: Multiple benefits from a multidisciplinary team? *Critical Care*, *14*(1), 109. https://doi.org/10.1186/cc8218

2 Wrapson, J., Patterson, N., Nakarada-Kordic, I., & Reay, S. (2017). A life-changing event: Patients' personal experiences of living with a long-term tracheostomy. *Design for Health*, *1*(2), 256–271. https://doi.org/10.1080/24735132.2017.1386432
3 Durbin, C. G. (2010). Tracheostomy: Why, when, and how? *Respiratory Care*, *55*(8), 1056–1068.
4 Freeman-Sanderson, A. L., Togher, L., Elkins, M. R., & Phipps, P. R. (2016). Quality of life improves with return of voice in tracheostomy patients in intensive care: An observational study. *Journal of Critical Care*, *33*, 186–191. https://doi.org/10.1016/j.jcrc.2016.01.012
5 Testa, M. A., & Simonson, D. C. (1996). Assessment of quality-of-life outcomes. *New England Journal of Medicine*, *334*(13), 835–840. https://doi.org/10.1056/nejm199603283341306
6 Gul, N. D. & Karadag, A. (2020). An evaluation of the quality of life in patients with tracheostomy. *Pakistan Journal of Medical Sciences*,*26*(2): 444-449.
7 Gilony, D., Gilboa, D., Blumstein, T., Murad, H., Talmi, Y. P., Kronenberg, J., & Wolf, M. (2005). Effects of tracheostomy on well-being and body-image perceptions. *Otolaryngology–Head and Neck Surgery*, *133*(3), 366–371. https://doi.org/10.1016/j.otohns.2005.04.025
8 Andrykowski, M. A., Lykins, E., & Floyd, A. (2012). Psychological Health in Cancer Survivors. *Seminars in Oncology Nursing*, *24*(3), 193–201. https://doi.org/10.1016/j.soncn.2008.05.007.
9 Levine, G. N., Cohen, B. E., Commodore-Mensah, Y., Fleury, J., Huffman, J. C., Khalid, U., Labarthe, D. R., Lavretsky, H., Michos, E. D., Spatz, E. S., & Kubzansky, L. D. (2021). Psychological health, well-being, and the mind-heart-body connection: A scientific statement from the American Heart Association. *Circulation*, *143*(10). https://doi.org/10.1161/cir.0000000000000947
10 Wallace, S., McGowan, S., & Sutt, A.-L. (2022). Benefits and options for voice restoration in mechanically ventilated intensive care unit patients with a tracheostomy. *Journal of the Intensive Care Society*, *24*(1), 104–111. https://doi.org/10.1177/17511437221113162
11 Kawachi, I. (2001). Social Ties and Mental Health. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*, *78*(3), 458–467. https://doi.org/10.1093/jurban/78.3.458
12 Nakarada-Kordic, I., Patterson, N., Wrapson, J., & Reay, S. D. (2017). A systematic review of patient and caregiver experiences with a tracheostomy. *The Patient - Patient-Centered Outcomes Research*, *11*(2), 175–191. https://doi.org/10.1007/s40271-017-0277-1
13 Zarzycka, J., Kobos Ewa Małgorzata,Czarnecka Józefa , Imiela Jacek Rafał: Social support and the acceptance of illness among patients with a tracheostomy tube, Journal of Public Health, Nursing and Medical Rescue (JPHNMR), no. 1, 2015, pp. 17-25.
14 Delisle, V. C., Gumuchian, S. T., Rice, D. B., Levis, A. W., Kloda, L. A., Körner, A., & Thombs, B. D. (2016). Perceived benefits and factors that influence the ability to establish and maintain patient support groups in rare diseases: A scoping review. *The Patient - Patient-Centered Outcomes Research*, *10*(3), 283–293. https://doi.org/10.1007/s40271-016-0213-9
15 Marshall-Seslar, A. (2023, January 5). *Body health basics: What is physical health?* McMillen Health. https://www.mcmillenhealth.org/tamtalks/physical-health
16 Björling, G. (2009). Long-term tracheostomy care: How to do it. *Breathe*, *5*(3), 204–213. https://doi.org/10.1183/18106838.0503.204
17 Ambrosino, N., & Clini, E. (2004). Long-term mechanical ventilation and nutrition. *Respiratory Medicine*, *98*(5), 413–420. https://doi.org/10.1016/j.rmed.2003.11.008
18 Mullender, J. L., Wheatley, E. C., & Nethercott, D. R. (2014). Oral feed for patients with a tracheostomy: Balancing risks and benefits. *Journal of the Intensive Care Society*, *15*(4), 336–339. https://doi.org/10.1177/175114371401500414
19 Divya, P. S., Vijay, A., & Ganesh, A. (2020). Role of speech-language pathologist in Tracheostomy Care – a case study. *Indian Journal of Medical Sciences*, *71*, 97–99. https://doi.org/10.25259/ijms_19_2019
20 Ceron, C., Otto, D., Signorini, A. V., Beck, M. C., Camilis, M., Sganzerla, D., Rosa, R. G., & Teixeira, C. (2019). The effect of speaking valves on ICU mobility of individuals with tracheostomy. *Respiratory Care*, *65*(2), 144–149. https://doi.org/10.4187/respcare.06768

Sustainable Infection Prevention Methods in Respiratory Therapy

In this feature interview, Respiratory Therapy addresses the topic of the operational implications surrounding sustainability, infection prevention and the costly plastic waste stream. Our conversation is with Richard Radford, who was a Director of RT and other clinical areas for over 30 years. Radford is the founder and CEO of Cenorin, which is focused on infection prevention, sustainability, and cost reduction in healthcare. Radford was also the founder of Clear Medical, an early entry into the FDA-regulated 3rd Party Reprocessor business.

The following questions are posed to inform and raise awareness, concern and feasible remedies that Respiratory Care and Sleep professionals can apply when addressing issues they face related to sustainability, infection prevention, healthcare waste and professional stewardship.

In your view what are the big issues facing health care managers that have the most impact on excellent patient care, Infection prevention and sustainability?
Well now, that's a big question to begin our discussion with and it's not a simple one. I am flattered that you'd ask me to share my views with your readers on such important topics. Healthcare is filled with many complex issues, and these are certainly in the top ten. Naturally, the solutions to challenges like these are multifaceted, and center around people, organizational structures, mission, and a commitment to finding quality outcome solutions.

Shaping the achievement of high quality of patient care, infection prevention and sustainability can only be done with focused programs for each. Leaders need to mold the working environment with defined outcomes and protocols for each process and modality of care. Having structures in place will form a foundation for defining what you do and how you do it. Protocols and defined outcomes are the basis of training staff and auditing their performance. The audit process will provide the data that is needed to determine the level of compliance to the desired outcomes.

With this in place, a retrospective review of performance can identify where performance needs improvement and then you can make appropriate changes. The entire process forms what is known as a 'Quality Circle'.

In my experience, staffing is always an issue managers face in producing good quality outcomes. Staffing begins with the hiring process. It probably goes without saying that you should hire the best trained and experienced people available. Onboard them with a structured and understandable process, including regular feedback and reviews. Maintain a positive learning environment and culture. Support local training programs and professional organization participation. Most people enter healthcare with a 'helping/caring' gene…support and nurture this trait and their training and commitment will be a personal guide to excellent patient care.

What infection prevention methods have been utilized in RT and Sleep?
Well, many have been used over the years and science, research, clinical evidence, failures and practical experience have moved us a great distance towards the methods we commonly use today. The Spaulding Principle outlines how various medical devices need to be disinfected based on the level of risk associated with their use. Critical devices, which contact the vasculature or sterile tissue, require sterilization. Semi-critical devices that contact intact mucous membranes need to be high-level disinfected. Non-critical devices, where they touch only intact skin, require only low- or medium-level disinfection. This structure is a simple and practical guide in shaping infection prevention practices.

Typical methods used to decontaminate RT and Sleep devices fall into these three categories:

Critical devices: Sterilization is the recommended process and is achieved with various methods such as steam, plasma, vaporized hydrogen peroxide and ETO. All of these provide terminal disinfection for bacteria, viruses, fungi and endospores. Surgical instruments are the typical items undergoing this process. The one exception to the rule of touching blood or sterile tissue might be high-risk endoscopes, which are technically categorized as semi-critical. Because of documented cases of high-risk endoscopes such as bronchoscopes transmitting infection, according to AAMI ST91, the preferred disinfection method for these scopes would be sterilization.

Semi-critical devices: High Level Disinfection (HLD) is the recommended process and can be achieved typically utilizing three different methods, each with its own pros and cons.

The first method is chemical. Chemical disinfectants (glutaraldehyde, peracetic acid, OPA) are well studied and deemed highly effective. This method is pretty convenient for small batches of devices; however, it is expensive and in respiratory departments typically relies on manual processes

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

and manual documentation. Another issue is potential 'residue' of chemicals on devices, which may not be eliminated due to poorly performed or non-validated manual rinsing. My observation is that the labor costs, lack of process control, and focus of Joint Commission auditors on process management can be challenging for departments which are still disinfecting manually. Furthermore, disposal of these chemicals may violate sustainability and toxic waste disposal standards in many municipalities.

Method two is thermal disinfection. Thermal disinfection is the accepted international standard for disinfecting critical medical devices—steam is an example of thermal disinfection that is used everywhere. Thermal HLD (THLD) utilizes the same methodology, killing the relevant microorganisms with high temperature over a specified time. Compared with thermal disinfection for critical devices, the time and temperature requirements are different for semi-critical device disinfection. In scientific terms, we would describe it as the required 6 log reduction in living organisms to conform to HLD standards is typically performed with full immersion in liquid water instead of steam.

It's interesting that with RT/Sleep devices, the time and temperature required to achieve THLD makes this process an excellent choice for the large family of medical devices made of plastic. RT and Sleep therapies typically use plastic devices and THLD is a superior choice for reprocessing them, given it does not cause structural deformation and retains the devices' intended functional use.

THLD systems have been used worldwide to process these devices for over 40 years with few, if any, reported failures. Furthermore, some of these systems are FDA cleared, automated for both cleaning and HLD in large batches. With automation, you get standardized documentation and hard copy records, which is perfect for a controlled system that will meet auditors' scrutiny. It's my understanding from RT and Sleep Departments who use that THLD batch-processing consumes minimal time, and the automation frees staff to attend to other duties. While these systems are a capital equipment item and subject to the typical bean-counter budget reviews, many users report the reduction in device costs that comes with device re-use has offset the capital purchase in less than one year.

The third method involves disposable Single Patient Use (SPU) devices. Disposable devices are part of an infection prevention strategy that assumes devices are decontaminated and determined safe for single use. It is a convenient choice. However, I should note that disposable SPU items are not without issues related to sustainability, waste stream, and costs. For your readers, continued use of disposable SPU devices should be analyzed from a cost/benefit perspective to confirm whether it's really a beneficial strategy. Examples of these disposable device categories include:

- Critical: Sterile surgical devices or syringes for ABG (SPU).
- Semi-Critical: Ventilator or CPAP circuits or masks.
- Non-Critical: Blood pressure cuffs.

The term 'Single Patient Use' has an interesting history. That term has evolved over the past two decades. Originally it was a term that manufacturers used as it presented a profitable marketing strategy as well as implying a significant improvement in patient safety for some applications. An example of this is the simple disposable plastic syringe. This innovation replaced the calibrated glass syringe that required staff to clean the barrel and plunger, then match the engraved numbers on both parts to assure the custom fit and finally sterilize it. If you haven't done it, you can probably imagine the labor and time that went into it. I recall it as being time-consuming and a source of worry. Furthermore, if you can believe it, the needles were individually cleaned and 'sharpened' during this process and sterilization followed. What a relief to have very inexpensive SPU packaged syringes without all that work.

In the early 2000's the FDA began addressing the issue of SPU and determined that reprocessing them was safe, if conducted under the auspices of FDA oversight, GMP's, and formal registration of 3rd party reprocessors. The FDA required 3rd party reprocessors to file for a 510(k) clearance for each device they reprocessed. Being able to reprocess SPU devices has saved hospitals millions of dollars and assured safe reuse of many devices. However, the term Single Patient Use began to evolve given various ways it was used. Did this designation mean, "use on a single patient for a single 'event' (sterile syringe)"? Or did it mean, "use for several events on a single patient (a ventilator circuit used over several events/days)"? The FDA has now made this term 'official' and provided guidance in its use.

Many companies started using the term "Disposable" to describe these devices, as they didn't want to lose money by having hospitals realize they could be reprocessed. That change in description, in turn, has led to a huge increase in the costs to manufacture an endless supply of plastic devices that end up in the waste stream. All of this is a reaction to your question about infection prevention methods. Disposable or Single Patient Use devices haven't proven any safer from an infection prevention standpoint than properly processed reusable devices, but they sure have caused a lot of purchasing, inventory and waste management problems for the facilities that use them. If a hospital complies with safe reprocessing protocols for a surgical pack, why is it unsafe to reprocess a sleep mask using safe reprocessing protocols?

Why is documentation of Procedure and Process important?
Documentation is the bane of providers in medicine today. Healthcare depends on and is required to keep documentation. It's a never-ending activity to generate and maintain information. And there is a lot of it! Objective data for audits and quality reviews, patient information systems, financial process, and reports. Staff productivity, device clinical information, laboratory reports. Your readers deal with this all the time - I'm sure they could come up with other examples. We do trend analysis and improvement plan development using a variety of tools and forms. In some ways documenting these various types of information shapes the 'consciousness' of an organization. And of course, we use it to guide patient care and how we go about moving forward, keeping track of activities and processes to promote good outcomes and safety.

Daily operation of RT and Sleep requires productivity and budgeting information tools like the RT-validated Relative Value Unit system and patient assignment slips from which staffing assignments can be planned and budgeted. Documentation is also essential for benchmarking department and individual performance and improvement. Charting and ABG data are present in documentation activities every day. If you don't have

a plan for where you're going, and a tool to measure change, you won't know whether you ever got there. Or if your hospital is sued, you want to be able to prove you followed the correct protocols or procedures. As they say: if it isn't documented, it didn't happen.

You mentioned medical waste and sustainability as issues for RT and Sleep Departments. What is the extent of US medical waste and specifically waste attributable to single-use, disposable plastics?
Let me tell you, the enormity of the plastics issue is staggering and the downstream effects on waste disposal costs and the effects on the environment and biosphere are astonishing. Waste in the US healthcare system leads the world—not exactly the leadership position we're seeking, in my view. Here are a few statistics for perspective:

- Plastic waste in the US averages 33 pounds, per bed, per day.
- There are 350 million metric tons of plastic medical waste per year.
- 25% of healthcare waste is plastic.
- 91% of this waste ends up in landfills or natural environments and may take hundreds of years to degrade.
- 85% of plastic waste could be recycled. Less than 10% is recycled.
- Most devices that touch or connect to a patient in RT/Sleep are plastic.

Maybe the saddest aspect of this is, plastic devices thrown into the waste stream will not completely disintegrate over time, they'll just become 'micro particles' that enter living structures and persist with mostly unknown effects. While disposable SPU devices can have a positive contribution to infection prevention for a select set of devices, the general overuse practice found in healthcare institutions results in a significant contribution to the waste stream. Reprocessing reusable devices could have a big impact on the environment by decreasing the amount of plastic medical waste.

How can managers of RT and Sleep participate in efforts to improve Sustainability and Waste/cost reduction?
As a long time RT observer/practitioner, I'm astounded that disposable SPU plastic devices are the norm today compared to a few decades ago, when devices were typically reprocessed. This reliance on single use plastic devices is, in my opinion, antithetical to the clinical mission 'to do no harm.' It is apparent that many in healthcare share my opinion and are making great efforts to deal with the plastics issue and many other waste reduction opportunities. The increasing participation in sustainability-focused organizations like AMDR (the Association for Medical Device Reprocessing), Practice Greenhealth and CleanMed are excellent examples that RT and Sleep Departments can follow.

At the CleanMed annual conferences, I've learned that cost and waste reduction strategies can be straightforward. An obvious one: Choose a re-use solution in place of disposable SPU devices and significantly reduce plastic consumption. Re-use strategies will also reduce the large portion of packaging waste attributable to SPUs. Additionally, re-use will reduce associated costs in logistics (like shipping and fuel costs, inventory storage costs and waste disposal costs). Where possible, reprocess it locally, within the hospital, and add to savings.

I'm encouraged to see RT/Sleep departments that practice re-use and onsite reprocessing have found the labor and capital costs for many reusable devices are minor compared to the savings from eliminating plastic SPUs. These hospitals utilize FDA-cleared cleaning and disinfection systems, along with automated drying systems, which are simple to operate and provide controlled and automated process management, including documentation of disinfection.

We all know budgeting and acquiring capital equipment can be difficult in healthcare, and it's no different in RT. Fortunately, acquisition strategies to implement onsite reprocessing have proven to be ROI positive and need to be applied in RT and Sleep. Capital equipment acquisitions are typically made for three reasons:

- Required by statute or governance for operations
- Provide state of art technology
- Create savings (ROI) that pays for the device over a short time

One or all of these strategies should be included in a justification for capital acquisitions. I also think that AMDR is a terrific organization - this is the Association for Medical Device Reprocessing. Their website has a number of resources, and they have a quarterly newsletter that provides insights into strategies that real people are using in real-life scenarios. Your readers might find some ideas there to help them improve their sustainability profile.

How can re-use of devices support the durability of the supply chain?
During COVID, we all experienced that Supply Chains were severely tested. This very trying time served as a real lesson in supply chain durability. Re-use and localization of reprocessing protected hospitals from supply shortages. Including reusable devices over single patient use items is insurance against future supply disruptions. Sleep and RT, with shortages of masks and tubing, all managed better if they were already prepared to reprocess and reuse their devices. Patient care and inventory frustrations were mitigated with re -use and local device processing. Longer term policies and practices paid off.

Like so many issues in our society, advocacy in improving patient care and improving sustainability profiles is the only way to effect positive change. Today these advocacy efforts are a growing opportunity for RT and Sleep professionals. Sustainability challenges are found in all departments and services in healthcare. National organizations have addressed this challenge and have supported the structure and venues for collaborative initiatives and real solutions. Advocacy can be as simple as having discussions among staff and department managers on simple changes that might reduce waste or a change in select devices from disposable to reusable devices. Furthermore, expanding these discussions to include Sterile and Central Processing, Material Management and the hospital Infection Prevention team may result in new and helpful approaches.

How does professional stewardship enter the mix?
Well, maybe we could coin a new phrase: Do no harm…and do good.

Continuing Education is personal stewardship. Participating in policy reviews and implementation with changes in technology

and standards can move the ball in a more sustainable way. Seeing quality patient care beyond an individual patient and envision it encompassing the larger healthcare system and its impact on society can shape the continuum of care, professional standards, and the effects on the larger healthcare environment.

Give us a few examples of practice changes in RT and Sleep that have impacted sustainability and improved patient outcomes.
Early in my RT career I became aware of the significant waste created using multiple suction kits to remove secretions from the trachea of ventilated patients (also at significant patient risk, discomfort, and daily costs). Attempting to address this problem, I developed the original 'Trach Care' in-line suction system marketed by Ballard Medical. When Trach Care came to market not only did costs go down, but patient care and practitioner safety was significantly improved. This is an example of safe re-use and of reducing the volume of SPU's by using the same device on the same patient several times. It became commonplace to see this done with devices like ventilator circuits.

Sleep centers have improved patient outcomes by maintaining a large inventory of reusable CPAP masks so patients can try on as many as necessary to find the optimal fit. Finding the best fit achieves better comfort and compliance. These centers can afford to maintain this inventory because they reprocess each mask after its use, even if it was just five minutes long, at a very low cost. Again, better patient outcome and reduced costs via re-use. And, as I've been noting, choosing re-use also results in a reduction in packaging waste because you're purchasing many fewer devices than before—perhaps as many as 20 or 30 times fewer for each mask.

Many hospital RT and Sleep departments are committed to device reuse; they choose to clean and THLD many of their devices. The estimated cost saving is reported to be in the six-figure level annually. There was a case study published in RT magazine last spring that illustrated this outcome.

What activities are available that would assist managers to adopt policies and practices that would enable more re-use of medical devices?
Forgive my personal advocacy …. Do your research! Become informed about the abundant sources of waste and waste reduction options that exist in hospitals and at the national level. Advocate to your professional societies to develop a national cost-benefit analyses protocol of single use vs. reusable devices. Collaborate with other professional groups (like HSPA, the Hospital Sterile Processing Association, and AMDR, the Association for Medical Device Reprocessing) for accepted and validated reprocessing practices, training standards, global standards and certification processes. Contact other RT and Sleep 'early adopters' about their device re-use strategies.

Become engaged in how you and your department can become a part of the solution to improve sustainability, while maintaining patient safety and reducing healthcare costs. Share this opinion piece with your supervisor. Include Sustainability and device re-use in the curriculum of RT and Sleep training programs. Not to beat a dead horse, but also share this opinion piece with a RT/Sleep instructor.

What changes could RT and Sleep professionals make that will improve their ability to enhance sustainability, infection prevention, reduce waste, reduce costs, and streamline workflow?
There are many things we can change and improve to strengthen each of these. To begin, develop a personal philosophy and assume a personal responsibility for sustainability, supply chain durability and patient safety, to strengthen your commitment to advocacy.

Collaborating with others to create principled, rational guidance for the use of reusable semi-critical medical devices in RT and Sleep is a large step in the right direction. As a caring profession we can innovate and create platforms that can be employed to improve not only the clinical outcomes for patients but the economics of device reuse and their capital payback rationale.

Recognize these are big payback activities that will take a plan, time and an expanded vision. Progress will be made with support and collaboration with fellow professionals. Assume personal responsibility for sustainability, supply chain durability and patient safety to strengthen your advocacy commitment.

We know that safe and proven tools are available for processing reusable devices in RT and Sleep. Early adopters have many examples and data to document the feasibility of these choices and how they implemented the changes they made. Be smart and future-focused, and make sustainability, infection prevention and related subjects a required subject in RT and Sleep training … not just in school training, but every day.

How would you summarize the key outcomes you'd expect to see if people in RT and Sleep implement your ideas about infection prevention and sustainability?
My friends would tell you it's a challenge for me to be brief, but in short, I'd say that RT and Sleep departments would enjoy an equivalent or even better standard of infection prevention for their plastic devices if they move to reprocessing reusable devices with an eco-friendly method such as thermal high-level disinfection. They will also enjoy a major positive impact on their operating expenses and on their sustainability efforts. They'll be purchasing less, managing less inventory, throwing away fewer devices, and helping to minimize the damage that's done by "forever plastics" that never leave the environment.

Thank you for an interesting discussion and the opportunity to share my views with your readers. If your readers would like more information on sustainability in RT and Sleep reach out: **sustainability@cenorin.com.** I would be happy to talk with them.

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The Performance of 11 Fingertip Pulse Oximeters During Hypoxemia in Healthy Human Participants With Varied, Quantified Skin Pigment

Nonin Onyx Vantage 9590® is the Only Pulse Oximeter Within FDA ARMS Guidelines Across All Skin Pigmentations and Oxygen Saturation Ranges

Summary

In a controlled study conducted by researchers at the University of California, San Francisco and other institutions, the performance of 11 fingertip pulse oximeters was evaluated in 34 healthy human participants with varied skin pigmentation.* This study was the first to incorporate both objective and subjective measurements of skin pigmentation, addressing a historical lack of reliable standardization in how skin pigmentation is identified within pulse oximetry studies. The study sought to deliver a more accurate picture of pulse oximeter performance, especially in people with dark skin pigmentation.

> "Device performance is largely unregulated and poorly characterized, especially in people with dark skin pigmentation," the authors noted.

The study measured oxygen saturation (SpO_2) levels in participants with different skin pigmentation, ranging from 70-100% SpO_2. It compared the bias and absolute bias of the 11 pulse oximeters against a reference device (Radiometer ABL90 Flex Plus Hemoximeter) across the different skin pigmentation and SpO_2 ranges. Only four of the devices have FDA 510(k) clearance (Nonin Onyx 9590, Masimo MightSat, Contec, Biolight).

The data found that five of the 11 devices resulted in greater than 3% root mean square error (A_{RMS}) and did not meet FDA criteria for accuracy (less than 3% A_{RMS}). Seven of the fingertip pulse oximeters are part of the ubiquitous low-cost devices flooding the market. None of the low-cost devices met FDA A_{RMS} guidelines in dark skin pigmentations at both of the low blood oxygen saturations (70-80% and 80-90%). In the 80-90% saturation range, when many clinicians are initially alerted to issues, Nonin was the only device to perform under 2% A_{RMS} in the darkest skin pigmentations. The risk of low cost and non-regulated devices reading inaccurately and potentially misdiagnosing hypoxemia in patients of color continues to be a problem.

Equitable and accurate pulse oximetry has been a significant issue, which the COVID-19 pandemic highlighted. Nonin's fingertip pulse oximeters outperform low-cost oximeters, especially in patients with darker skin pigmentation.

Methods

The study tested the performance of fingertip pulse oximeters in participants with skin pigmentation ranging from light to dark. Participants underwent controlled desaturation protocols to achieve stable oxygen saturation (SaO_2) levels between 70-100%, while pulse oximeter readings (SpO_2) were recorded. Skin pigmentation was assessed both subjectively using the Fitzpatrick scale (pFP) and objectively using spectrophotometry to measure individual typology angle (ITA).

Participants were grouped into light, medium, and dark pigmentation categories based on both the pFP and ITA measurements.

The bias and absolute bias of each pulse oximeter was calculated by comparing the SpO_2 readings to the reference arterial SaO_2 measurements, across the different skin pigmentation groups. Statistical analyses included Bland-Altman plots, linear regression, and calculation of A_{RMS} to evaluate the performance of the pulse oximeters.

Key Takeaways

Only the Nonin Onyx 9590 met the FDA's accuracy criteria of less than 3% A_{RMS} across all skin pigmentation levels (light, medium, dark) and all oxygen saturation ranges (70-80%, 80- 90%, 90-100%). The Nonin Onyx Vantage 9590 outperformed the Masimo MightySat® and all low-cost devices, particularly in participants with darker skin and lower SpO_2 levels. For example, in participants with the darkest skin pigmentation and SpO_2 levels between 80-90%, the Nonin Onyx Vantage 9590 had a bias of 0.8% (95% CI 0.5, 1.2), which was lower than nine other devices tested.

Claims fall short of actual performance

The study found that the performance of the 11 fingertip pulse oximeters varied widely, with some devices meeting regulatory accuracy standards while others did not, especially for participants with darker skin pigmentation.

This article was written by Nonin Medical, Inc. It is a summary of the work written and published by Leeb G, Auchus I, Law T, et al. The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment. EBioMedicine. 2024;102:105051. doi:10.1016/j.ebiom.2024.105051.

*Tested devices include the Nonin Onyx Vantage 9590, Masimo Mightysat, Walgreens MD300CN350R, Zacurate CMS 500DL, Walgreens OxyWatch C20, Choice MMed MD300CN340, Zacurate 500C, Bodymed BDMOXMTRBLK, Roscoe POX-ROS, CONTEC CMS50M and Biolight M70.

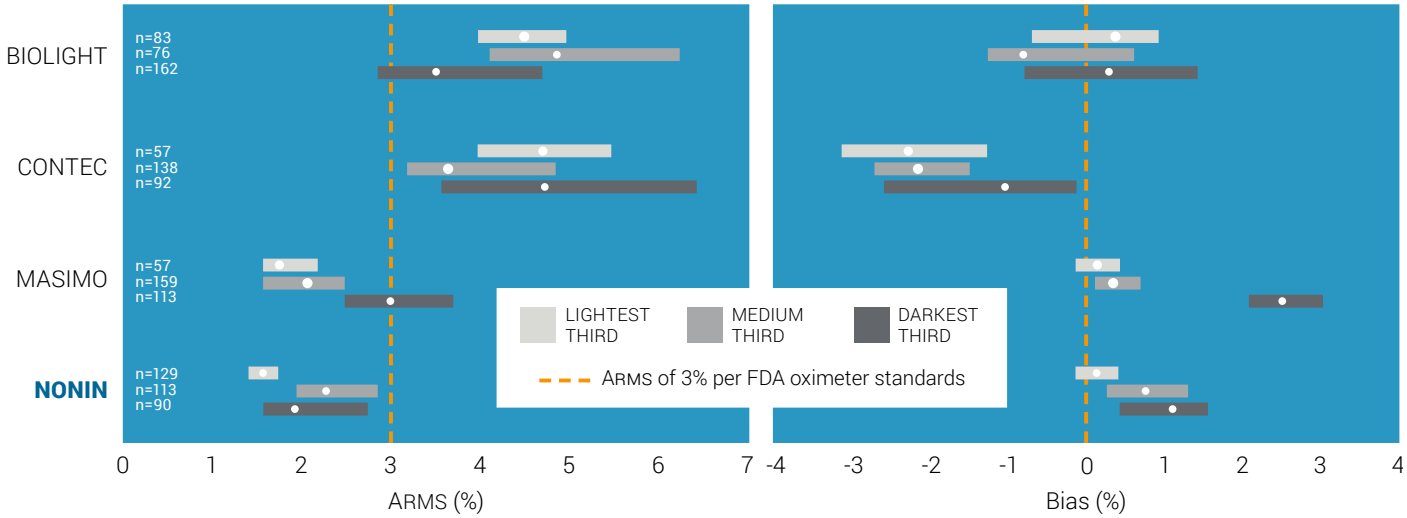

Figure 1. Performance of devices with FDA 510(k) clearance across different skin pigmentations.

As described in figure four of the study: Forest plot showing ARMS and bias for each device (lines show 95% confidence interval). Within each device the ARMS and Bias are determined among participants with the lightest, medium, and darkest pigmentation (defined by ordering participants by DDP ITA and selecting ITA cutoffs that create equal groups). For each device, n represents the number of samples among the light, medium, and darkly pigmented groups, and the size of the circles within each line is proportional to n.

None of the low-cost devices (under $60 USD) met the FDA accuracy guidelines for the darkly pigmented participants at low blood-oxygen saturation levels. In fact, some of these low-cost devices had A_{RMS} readings 2-3 times higher than the regulatory guidelines.

More objectivity is needed in device evaluation

The study compared the subjective Fitzpatrick skin type (pFP) assessments to the more objective individual typology angle (ITA) measurements using spectrophotometry.

> "Fingertip POXs (pulse oximeters) have variable performance, frequently not meeting regulatory requirements for clinical use, and at times contradicting claims made by manufacturers," the authors said.

The results showed that relying solely on the subjective pFP scale may not accurately represent the optical properties at the fingertip measurement site. The objective ITA measurements provided a more comprehensive assessment of the participants' actual skin pigmentation across the full spectrum, providing a more confident demonstration of device performance.

Accuracy is essential

Unregulated, low-cost pulse oximeters often perform below FDA standards and inconsistently across patients. Clinicians and patients cannot afford to use devices that do not perform reliably. In contrast, Nonin's technology exceeds FDA requirements and outperforms both low-cost and other FDA-cleared oximeters, providing accuracy and dependability across all skin pigmentations.

SOURCE: Leeb G, Auchus I, Law T, Bickler P, Feiner J, Hashi S, Monk E, Igaga E, Bernstein M, Chou YC, Hughes C, Schornack D, Lester J, Moore K Jr, Okunlola O, Fernandez J, Shmuylovich L, Lipnick M. The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment. EBioMedicine. 2024 Mar 7;102:105051. doi: 10.1016/j. ebiom.2024.105051. Epub ahead of print. PMID: 38458110; PMCID: PMC10943300. www.shorturl.at/quvKT

Key Terminology

- Bias is the mean difference between the pulse oximeter oxygen saturation (SpO_2) and the arterial blood oxygen saturation (SaO_2) measured by a reference hemoximeter.
- Absolute bias is the mean of the absolute differences between the pulse oximeter oxygen saturation (SpO_2) and the arterial blood oxygen saturation (SaO_2) measured by a reference hemoximeter. It represents the average magnitude of the difference between the two measurements, without regard to the direction of the difference.
- Average root mean square error (A_{RMS}) represents the square root of the mean of the squared differences between the pulse oximeter oxygen saturation (SpO_2) and the arterial blood oxygen saturation (SaO_2) measured by a reference hemoximeter. It is a measure of the overall accuracy of the pulse oximeter compared to the reference standard.

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High Flow Therapy…an Underutilized Tool To Extend Respiratory Support, Enhance Adaptation to Noninvasive Ventilation, and Improve Patient Outcomes?

David Troxell BS, RRT-SDS and Laura Roth, RRT

Abstract
High flow therapy (HFT) saw a large increase in utilization during the height of the COVID-19 pandemic as an alternative to intubation and mechanical ventilation for hypoxic respiratory failure. Emerging evidence has shown the utility of HFT to provide noninvasive respiratory support in a variety of disease states associated with hypercapnic respiratory failure. This article will review recent clinical evidence for HFT as well as potential indications that this form of respiratory support may be underutilized in the home setting. The article will also feature a case study that highlights the potential utility of HFT as a tool that may hold promise for improving habituation and adherence to noninvasive ventilation (NIV).

Introduction

The origin of HFT can be initially traced back to 1987 when the Oxygen Enrichment Company released the Transpirator MT-1000, an intervention to improve mucociliary clearance in cystic fibrosis. A few years later, a device was developed to treat exercise-induced pulmonary hemorrhage in racehorses.[1] It wasn't until 1999; when Bill Nylan founded Vapotherm; with the idea to modify what was already being used in the horse racing industry for human use, that HFT began gaining traction for use as a noninvasive respiratory support strategy.[2]

Mechanism of Operation

HFT is known by a variety of terms and acronyms such as high flow nasal cannula (HFNC), heated, humidified high flow therapy (HHHFT), high flow oxygen therapy (HFOT), and high velocity therapy (HVT). The mechanism of operation is the same or similar and is comprised of warming and humidifying gas, the ability to deliver precise levels of FiO_2, servo-controlled flow rates typically within the 20-70 lpm range for adults, and variable levels of derived PEEP achieved when the mouth is closed during venting against the resistance of the flow rate being delivered to the nares. One proprietary HFT algorithm purports increased turbulent velocity as a feature designed to increase flushing of CO_2 from the labyrinth-like structures of the nasopharynx.

Warming gas to a body temperature pressure saturated (BTPS) threshold of 37°C and humidifying targeted to 100% relative humidity serves to hydrate the respiratory tract while decreasing inspiratory resistance and improving patient comfort with the delivery of higher liter flows. Hydrating the respiratory tract is an important aspect of HFT as increased mucus production and impaired mucociliary escalator function is associated with disease states such as COPD. Optimized ciliary beat function; critical to airways clearance, is dependent upon adequate mucus hydration. Additionally, the delivery of cold dry gas has been associated with respiratory tract epithelial damage, bronchoconstriction, diminished ciliary function, increased mucus viscosity, and increased airways inflammation.[4]

In the US durable medical equipment (DME) market, home mechanical ventilation (HMV) is reimbursed under the E0466 (noninvasive), and E0465 HCPCs codes. Both E0465 and E0466 are structured as uncapped rentals under an umbrella reimbursement scheme. For DME providers that offer their patients HFT + NIV as a dual respiratory support strategy, they do not receive additional reimbursement when providing a heated humidifier, the appropriate circuit, and a high flow nasal cannula (HFNC). Although DME providers are not financially incentivized to provide the appropriate equipment when providing HFT in the home, for optimized adherence and patient outcomes, it is critical to ensure the appropriate HFT setup includes a heated humidifier capable of warming the delivered gas to 37°C at 100% relative humidity for liter flows up to 70 lpm.

HFT functionally serves as a CO_2 flushing mechanism for the pulmonary toilet. HFT flushes CO_2 from anatomical dead space while simultaneously priming the same anatomical functional reservoir with supplemental oxygen that is associated with a more stable alveolar FiO_2 as compared to conventional treatments.

HFT delivers a dynamic level of extrinsic PEEP as nasal venting is met with flow-based resistance during the exhalation phase of breathing. PEEP levels vary and are dependent upon mouth closure, nasal venting, and the resistance to the delivered flow rate, however it has been estimated that derived, resistance-based PEEP levels can be approximated by the formula that for every 10 lpm of flow, roughly equals 1 cmH_2O of pressure.

Benefits of High Flow Therapy

A robust pipeline of emerging clinical evidence points to the clinical utility of HFT beyond hypoxic respiratory failure. HFT implementation as a principal or a dual approach respiratory

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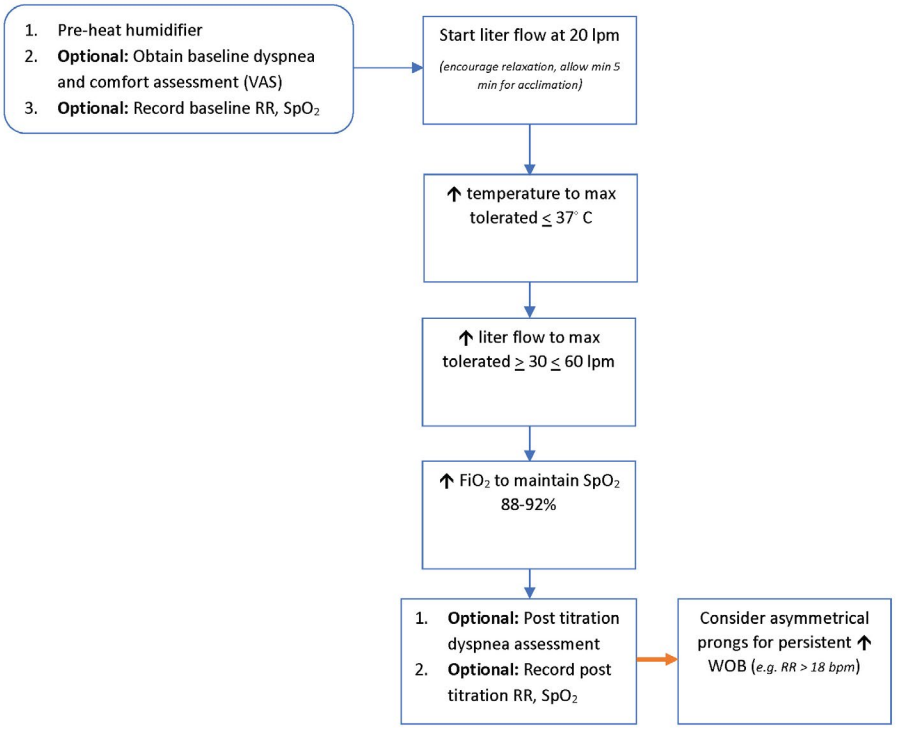

Figure 1. Protocol for Home HFT Implementation in CHRF.

support strategy in chronic hypercapnic respiratory failure (CHRF) has yielded some compelling clinical results.

- HFT improves alveolar ventilation while simultaneously decreasing neuro-ventilatory drive and work of breathing.[5]
- HFT has been associated with significantly reduced number of acute exacerbations of COPD (AE-COPD) days and AE-COPD frequency.[6]
- Daily use of HFT has been associated with a reduction in yearly AE-COPD events.
- Additionally, HFT has been linked to increased exercise capacitance and fewer hospitalizations.[7]
- HFT has been demonstrated to lower respiratory rate and result in a decreased work of breathing in individuals suffering from COPD.
- HFT is associated with a reported high level of comfort and patient acceptance.[8]

Considered in aggregate, the evidence suggests that HFT may be an important treatment strategy for the CHRF patient profile.

HFT Implementation

Although widely used in acute and critical care settings, HFT has not yet been widely adopted as an in-home respiratory support strategy. A recent article by Groessl and colleagues concluded that the addition of HFT to long-term oxygen therapy (LTOT) in individuals with COPD, yielded both significant health outcomes as well as beneficial reductions in healthcare cost expenditures.[9] Physicians familiar with HFT in the ICU setting may not fully appreciate the indications and benefits of HFT in the home. For the COPD profile, HFT in the home primarily serves to lower CO2, hydrate the respiratory tract improving mucus clearance, lower inspiratory resistance by decreasing airways inflammation, and deliver variable levels of PEEP. Which may help to offset dynamic hyperinflation and expiratory flow limitation as opposed to delivering a precise level of FiO2—the primary benefit of HFT when addressing acute hypoxic respiratory failure in the ICU.

A variety of approaches for implementing and initial titration of HFT settings have been described in clinical literature. A recent review of HFT evolving clinical practices by Roca and colleagues proposes an approach that can be adapted for use both in the acute and home care settings.[10] Figure 1 captures the main hypercapnic respiratory failure specific elements of the proposed titration approach with the hypoxic respiratory failure titration elements, physiologic benefits, and patient monitoring aspects removed for purposes of simplification. This approach can be combined with varying elements of in-home patient assessment as well as other tools such as a patient-friendly visual analog scale (VAS) to help assess subjectively reported increases or decreases in patient comfort as illustrated in Figures 2 and 3. Evidence suggests that optimal HFT flow rates are typically within the 30-40 lpm range in COPD.[11] It should be noted that the higher the flow rate, the more air entrainment and oxygen mixing will take place resulting in a lower FiO_2 delivered to the patient. Conversely higher flow rates, with the mouth closed, increase the net level of dynamic PEEP during nasal venting. Pulse oximetry is a tool that can assist the respiratory therapist when titrating oxygen in the home to reach and maintain a desired SpO_2 range, for example 88-92%.

Figure 2. Example VAS.
A novel, 7-point VAS tool designed to remove perception bias from subjectively reported levels of comfort, dyspnea, etc.

VAS Scoring						
C	B	A	0	A	B	C
1	2	3	4	5	6	7

Figure 3. Optional VAS Scoring Guide for Trending Responses Over Time.

Dual Respiratory Support Strategy of HFT + NIV

Treatment trends for CHRF in the home continue to evolve over time. Anecdotally, exploration into a dual approach utilizing both HFT as well as mask-based NIV appears to be on the rise. NIV has been positioned as being intended as the principal respiratory support strategy during time spent asleep, with an extension of respiratory support during activities of daily living (ADL) being facilitated by the addition of HFT. Multiple manufacturers of home mechanical ventilators have added HFT as an optional feature or mode to their platforms. Unfortunately, however, there is a paucity of clinical evidence evaluating whether a combined approach of HFT + NIV is a strategy for addressing the respiratory support needs of CHRF in the home setting. In 2018 Thille and colleagues proposed a combined approach to NIV + HFT in the acute care setting. They collectively proposed a hypothesis that HFT implementation during mask-free breaks in NIV sessions may further decrease the rates of reintubation as compared to NIV treatment alone.[12] Other studies have evaluated whether HFT may be used in place of NIV, while others have evaluated whether one approach is superior to the other. At the time of the creation of this article, no studies were identified that specifically evaluated the dual approach of HFT + NIV in the treatment of CHRF in the home setting.

Case Study: Improved Habituation to NIV

Consider the following case study that highlights an example of utilizing HFT to successfully habituate an individual to regular NIV adherence. The case study comes from Apria Healthcare's Bolingbrook, Illinois branch office. The individual, a female in her late 70s, had history of obesity, type II diabetes, chronic hypoxia, comorbid OSA, and home oxygen use. The patient was noted to have had 2 acute exacerbation of COPD (AE-COPD) events within the past 6 months. A recent sleep study revealed an AHI of 51 events per hour and frequent sleep-related oxygen desaturations. The patient presented at the emergency department with complaints that included shortness of breath and fatigue. Her ECG revealed atrial fibrillation and there were signs of fluid overload. A battery of testing was performed, and findings included acute on chronic hypoxemia, hypercapnic respiratory failure, pulmonary edema, OSA, obesity hypoventilation syndrome, as well as chronic, left lower lobe atelectasis. NIV was implemented, pressures were titrated to 18/14 cmH_2O. An ABG was performed on 4 lpm of oxygen with the following results 7.39 pH, PCO_2 67, PO_2 65, HCO_3 41, BE 13, SpO_2 92%. The patient initially refused to continue using NIV in the hospital, however after medical counseling, agreed to make an attempt to utilize NIV in the home setting. She was discharged with an order for home NIV with an option to use HFT as an alternative to NIV if she continued to struggle with mask-related discomfort.

Initially, the patient struggled with using NIV at night. The respiratory therapist, managing her ventilation equipment, suggested trying HFT during the day to extend respiratory support. This marked a turning point. The patient quickly acclimated to HFT, finding the nasal cannula interface comfortable and easy to use. She noticed a reduction in dyspnea, leading to increased activity levels. As her daytime symptoms improved, she successfully habituated to regular nocturnal NIV use, which averaged between 6-8 hours. Her pulmonologist noted improved activity levels, regular NIV use, and her ability to resume sitting outside at the family pool, a favorite activity she had given up due to worsening shortness of breath.

Conclusion

While not presented as compelling evidence that proves the superiority of the dual HFT + NIV approach, the case study featured in this article suggests that some patients may benefit from this approach in the home setting. In general, increasing the time spent under some form of respiratory support is anticipated to be associated with some positive outcomes in the CHRF patient population. Admittedly, much more evidence is needed to fully investigate whether this approach is associated with either improved habituation and adherence to NIV and or whether the approach is associated with significantly better outcomes than a strategy of NIV alone. The key takeaway however is that the emerging evidence is compelling enough for clinicians to consider the dual HFT + NIV approach when implementing NIV in the home setting. Additionally, the dual HFT + NIV approach should be considered when a patient is non-adherent or struggling to habituate to NIV.

References

1 Waugh J., High Flow Therapy – Trends in Noninvasive Respiratory Support, Continuum of Care, Clinical Foundations, L-1111-0601

2 https://newenglandvc.medium.com/2018-nevys-nominee-spotlight-vapotherm-36c337f33b16

3 Arunava Gosh, R.C. Boucher, Robert Tarran, Airway Hydration and COPD, Cell Mol Life Sci. 2015 October ; 72(19): 3637–3652. doi:10.1007/s00018-015-1946-7

4 Al Ashry HS, Modrykamien AM. Humidification during mechanical ventilation in the adult patient. Biomed Res Int. 2014;2014:715434. doi: 10.1155/2014/715434. Epub 2014 Jun 25. PMID: 25089275; PMCID: PMC4096064

5 Frat J-P, Thille A.W., High Flow Nasal Oxygen at Home to Prevent Chronic Obstructive Pulmonary Disease Exacerbations? Am J Respir Crit Care Med Vol 206, Iss 11, pp 1303–1316, Dec 1, 2022

6 Rea H, McAuley S, Jayaram L, Garrett J, Hockey H, Storey L, et al. The clinical utility of long-term humidification therapy in chronic airway disease. *Respir Med* 2010 Feb; 104(4):525-533.

7 Storgaard L H, Hockey HU, Laursen BS, Weinreich UM, Long-term effects of oxygen-enriched high-flow nasal cannula treatment in COPD patients with chronic hypoxemic respiratory failure. International Journal of COPD 2018:13 1195–1205

8 Hill, Nicholas, High Flow Nasal Cannula, Is There a Role in COPD? Thorax 2017;72(4):373-375

9 Groessl, Erik J, Tally, Steven R, Hillery, Naomi, Cost-Effectiveness of Humidified, High-Flow Therapy (HHFT) for COPD Patients on Long Term Oxygen Therapy, ClinicoEconomics and Outcomes Research 2023:15 239–250

10 Roca O, Li J, Tommaso M, High-flow nasal cannula: evolving practices and novel clinical and physiological insights, Intensive Care Med https://doi.org/10.1007/s00134-024-07386-8

11 Vega Pittao ML, Schifino G, Pisani L, Nava S. Home High-Flow Therapy in Patients with Chronic Respiratory Diseases: Physiological Rationale and Clinical Results. J Clin Med. 2023 Apr 3;12(7):2663. doi: 10.3390/jcm12072663. PMID: 37048745; PMCID: PMC10094854

12 Thille AW, Muller G, Gacouin A, Coudroy R, Demoule A, Sonneville R, Beloncle F, Girault C, Dangers L, Lautrette A, Cabasson S, Rouzé A, Vivier E, Le Meur A, Ricard JD, Razazi K, Barberet G, Lebert C, Ehrmann S, Picard W, Bourenne J, Pradel G, Bailly P, Terzi N, Buscot M, Lacave G, Danin PE, Nanadoumgar H, Gibelin A, Zanre L, Deye N, Ragot S, Frat

JP; REVA research network. High-flow nasal cannula oxygen therapy alone or with non-invasive ventilation during the weaning period after extubation in ICU: the prospective randomised controlled HIGH-WEAN protocol. BMJ Open. 2018 Sep 5;8(9):e023772. doi: 10.1136/bmjopen-2018-023772. PMID: 30185583; PMCID: PMC6129104.

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volume based on a Wilcoxon signed rank test (W = 11.5; $P <$ .05). Patients with AATD also showed significant improvement in several secondary outcomes including BODE index, residual volume (RV), total lung capacity (TLC), RV/TLC ratio, and inspiratory capacity/RV ratio between pre- and post-BLVR.

Company Set For Conference

ECO PHYSICS, INC. is once again going to be an exhibitor at the American Thoracic Society's International Conference. "We are proud to be welcomed back to the ATS 2024, scheduled to be held in the beautiful downtown San Diego Convention Center." Last year over 10,300 professionals attended, 28% of which were international. This will be ECO PHYSICS, INC.'s 24th straight year as an exhibitor. The annual ATS International Conference is the home of pulmonary, critical care, and sleep professionals; from those in the earliest stages of their careers to those whose research or strides in clinical care have gained them international recognition. In years past, on average 11,000 of these respiratory professionals chose to attend, present, and learn about the latest advances. This year's Conference will be held May 13th-18th. ECO MEDICS offers a broad range of research Pulmonary Function Testing (PFT) capabilities, including Lung Clearance Index (LCI). The EXHALYZER D provides sensitive multiple breath washout measurements, revealing detailed information on the small airways. The Analyzer CLD 88sp instrument is used for exhaled nitric oxide (FeNO), alveolar (AlvNO), and nasal (nNO) measurements.

Medixine and Nonin Medical partner to co-develop remote digital monitoring services

Finnish health tech company Medixine has strengthened its presence in the US market, announcing a deepened technological partnership with Nonin Medical, a leading manufacturer of wearable and noninvasive medical monitoring devices. With the US market for remote patient monitoring expected to exceed USD 25 billion by 2028, the collaboration is an important milestone in Medixine's continued US growth. An aging population and pressure to reduce costs are accelerating digitalization in the health sector. Remote patient monitoring has been steadily gaining prevalence as an effective and efficient healthcare solution for common chronic diseases, including diabetes, heart disease, respiratory issues, and COPD. It is estimated that chronic diseases account for approximately 86% of the total healthcare costs in the United States, with similar figures recorded worldwide. These impacts and costs are projected to rise for years to come. "In deepening our partnership with Nonin Medical, we're setting ambitious goals together to bring remote digital care's substantial benefits to both patients and clinicians across the United States. The U.S. is an important market for Medixine; demand for remote patient care is high, as there are often vast distances between patients and healthcare providers," said Lasse Rousi, CEO at Medixine. "Furthermore, it's especially significant for us that a renowned market leader like Nonin Medical has chosen our remote patient monitoring platform for its first transition from devices into digital services." The new partnership is set to combine Medixine's digital remote patient monitoring software platform with Nonin's U.S. market-leading pulse oximetry devices. The collaboration highlights how integrating physical devices with software-driven solutions has the potential to significantly improve patient comfort, convenience, and care quality, while also reducing the burden on overworked
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The Benefits of Using a Wearable Device to Monitor Patients

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Nick Delmonico, CEO and Co-Founder of Strados Labs.

Please tell us about your technology. What is the RESP® Biosensor?
The RESP® Biosensor is a first-of-its-kind wearable device we developed at Strados Labs to help respiratory therapists and clinicians better monitor patients with chronic respiratory diseases such as COPD and asthma. The device, which is FDA 510(k) cleared, continuously captures lung sounds including cough, wheeze and crackles similar to a digital stethoscope — lung sound data then gets transferred to the cloud where clinicians can observe the frequency of adventitious events (e.g. cough, wheeze) and understand how patients are doing remotely. It is often described as a Holter monitor for the lungs. The goal of the technology is to allow clinicians to receive objective reports into patients' lung events when they're home (away from clinician), offering greater diagnostic information and allowing for earlier insight into exacerbations.

What was the inspiration for developing this technology?
There were a few inspirations for developing this technology. I originally had the idea for our device based on my experience as an asthma patient not feeling adequately checked on and monitored after being discharged from the hospital. While I was asked by clinicians to watch and report on my symptoms, it was difficult for me to keep track and remember (especially as a kid). I learned that I was not alone in this, with most patients reporting that they have difficulty remembering their symptoms or identifying an acute event. This helps to explain the high re-admission rates for COPD and pediatric asthma. It seemed like there was a need to more effectively monitor at-risk pulmonary patients the way we do with cardiac patients.

Another inspiration for the technology was the limitations of auscultation with a stethoscope. While auscultation is considered to be one of the gold standards for diagnosing lung health, it is episodic, limited to in-person visits and typically lasts only minutes. It is also prone to inter-observer variability; some clinicians may hear a wheeze while others might not. With the advent of wearables and also the pandemic, we saw an opportunity to extend the gold standard to patients remotely, offering clinicians greater and more objective insight into patient lung health while reducing the frequency that patients have to visit their clinician.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

What benefits does this device offer clinicians and patients?
We designed the RESP Biosensor to improve care and outcomes for patients while also helping to increase clinician efficiency and effectiveness. The device combines lung sound events with other vitals like heart rate, respiratory rate and activity levels (not yet FDA-cleared).

For patients, the device offers a way to feel safer and more secure especially after an acute event, with our studies so far showing promise that the device may help patients avoid a readmission that is both costly and unpleasant. It offers the convenience of being monitored or assessed in the comfort of patients' homes rather than having to come into the office for a visit. This was especially important during the pandemic and is also helpful for patients who have issues with transportation, live in rural areas or lack general mobility. Additionally, it eliminates the burden of having to self-document, remember and report symptoms back to clinicians. As for the clinician, it allows for the convenience of receiving reliable data, which can help create a more optimal treatment plan and decrease the number of appointments needed. Follow up care can be done in office or virtually.

The device allows for 24/7 monitoring of the patient's day-to-day activities, enabling clinicians to detect if there are common factors to symptom onset. Often with asthmatic or pulmonary compromised patients, one will see that many triggers can affect a patient. Exercise can induce asthma symptoms; their environment can cause a flare-up or patients can experience nocturnal wheezing which may affect their quality of sleep. By pinpointing the trigger for the symptoms, the clinician can set up a treatment plan that is more suitable for the patient's lifestyle.

How do you see the device being used in patient care?
While we hear new requests and applications from clinicians for the RESP Biosensor almost every day, we see the device mostly being used to help clinicians and patients' better control and manage COPD and asthma from home and in inpatient settings.

As mentioned earlier, COPD is extremely difficult for clinicians and patients to manage, with 30-day readmissions often exceeding 20%. Similarly, pediatric asthma is also difficult to control and one of most common reason for pediatric ER visits in the US. Because of the urgent need for clinicians to prevent readmissions in both of these diseases and the burden placed on health systems, we see the device being used primarily to

monitor at-risk patients in inpatient acute care, transitional care settings, outpatient settings and at home post-acute discharge.

Some additional use cases we see for the RESP Biosensor that we're excited about include being used in pulmonary rehabilitation to reduce the need for patients to come to hospitals or clinics, in hospital-at-home programs, and in rural areas where patients often live hours from clinics.

What challenges have you faced in clinicians and RTs adopting the device?

One of the biggest challenges we've faced that has prevented clinicians from adopting the device right away is proving that our technology can accurately detect and measure changes in lung sound events including wheezing, crackles, and cough. Fortunately, in the past few years we have successfully proven the device is accurate through not only our 510(k) clearances but also through our scientific and clinical research efforts. In these studies, we have collected over thirty million breaths and five hundred thousand cough and lung sound events, which has allowed us to train our machine learning algorithms based on respiratory therapist and physician assessments of the sound files.

Another reality in healthcare is reimbursement and cost, which has been a barrier for widespread adoption despite the excitement we hear from clinicians. Currently we are relying on remote monitoring codes (RPM and RTM) for reimbursement, but we're working towards achieving different pathways that can offer much greater reimbursement, making it more feasible for most patients and clinicians to use.

How do you see the RESP® technology offering an advantage over standard of care such as pulse oximetry and pulmonary function tests?

We see our technology as providing unique value and insight into patients' lung health not offered by episodic pulmonary function tests (PFTs) and pulse oximetry. First, PFTs are typically not used to predict exacerbations like we anticipate our device will be able to do, and are used more for diagnostic purposes. PFTs are a valuable diagnostic tool, but we think our device can offer clinicians additional diagnostic insight by measuring symptoms such as coughing, wheezing and crackles, which directly impact patient quality of life and may be associated with disease severity.

Pulse oximetry has traditionally been used to predict exacerbations, similar to how we see our device being primarily used. However, drops in O2 saturation often occur once exacerbations are already moderate, and we see our device potentially offering clinicians a warning earlier than that. Pulse oximeters are also traditionally used during in-patient visits and less as a 'continuous monitor' in patients' homes like our device was designed to do.

What results have you seen so far with patients wearing the device?

In our clinical trials with over six healthcare systems, we have seen some very promising initial results. As a patient myself, I'm personally thrilled by the amazing feedback we've received from patients, saying that they forget that it's there and feel safer with the device on. We have demonstrated strong accuracy in the device detecting lung sound events compared to gold standards such as the Littman 3200 digital stethoscope, while also capturing significantly more events than episodic auscultation. Most importantly, we have seen several cases where a spike in lung sound events (cough, wheeze, and crackles) precedes a patient readmission or exacerbation. Because our studies so far have been observational only, clinicians were unfortunately not allowed to act on the warnings or alerts, which may have led to better outcomes.

Where has the technology been used?

Our technology has been used in several patient populations including COPD, asthma, infectious disease, and heart failure as part of clinical trials to demonstrate the utility of our device. Some of the hospitals and healthcare systems where these trials have taken place have included Einstein Health Network in Philadelphia, Mission Hospital, which is part of HCA Health System, Metropolitan Hospital which is part of NYC Health + Hospitals, and most recently Lurie Children's in Chicago as part of a pediatric asthma validation study.

In addition to healthcare settings, we have found that drug developers have a strong need to collect objective data on lung sounds and have used our device in phase I-IV clinical trials to demonstrate treatment efficacy. The RESP Biosensor has been used in large pharmaceutical clinical trials in three continents and thirty languages.

What's next for Strados Labs?

The next step that we're currently focused on is starting a new COPD interventional study with the RESP Biosensor. As mentioned earlier, the device has so far only been used in non-interventional studies with COPD patients—this will be the first time where clinicians will be able to intervene based on data provided by our device which is a very big step. We will be specifically measuring the device's ability to improve outcomes compared to standard of care such as pulse oximetry. The results from the study will also help position us to receive broader insurance coverage, making it more available to patients and clinicians.

As I also mentioned, we recently finished a clinical trial with Lurie Children's as part of a pediatric asthma validation study of our device. Results from this study will help us receive FDA 510(k) clearance for use in children (the device is currently only cleared for adult use). Because there's such an urgent need for new solutions in pediatric asthma and my own personal experiences when I was younger, this is something I'm especially excited about.

Nick Delmonico is the CEO and Co-Founder of Strados Labs, a digital health company focused on improving respiratory care through leading remote patient monitoring technology. Nick is an asthma patient who developed the company's technology based on his own healthcare experiences.

Can a T-Piece Resuscitator Provide Continuous Positive Airway Pressure (CPAP)?

Captain Steven C LeCroy Sr (Ret) MA, CRT, EMTP

Before answering this question there is a term in cognitive psychology called the "Illusory Truth Effect." The Illusory Truth Effect refers to the tendency for a person to believe something to be true because they have heard the information repeatedly, even if it runs counter to their prior knowledge. A simple Google search provides plenty of papers and opinions that show that CPAP can be provided with a T-piece resuscitator, however none explain how. Everyone knows that if it is on the internet, it must be true, right? What is interesting only one manufacturer of a T-piece resuscitator includes an indication for CPAP in their Directions for Use (DFU). The one exception does not provide the steps, only states that you can. I have had many discussions with clinicians including at least one physician that said they have routinely provided CPAP with a T-piece resuscitator, so it must be true right? The truth is, based on current designs, a T-piece resuscitator is not capable of providing CPAP. Remember it is a resuscitator. I believe the controversy stems from the volume of information readily available on-line about positive pressure therapy. If you search for information on CPAP (with or without a T-piece), it is obvious there is some confusion about the difference between CPAP and PEEP (Positive End Expiratory Pressure) which is often defined as pretty much the same thing.

If a T-piece resuscitator provides (PIP) Peak Inspiratory Pressure to facilitate an inspiratory breath and PEEP to provide expiratory resistance, why can't a T-piece provide CPAP to a spontaneously breathing patient? The simple truth is the only time inspiratory pressure is provided with a T-piece resuscitator is when the user covers the PEEP hole. By covering the PEEP hole oxygen flows towards the patient. When the PEEP hole is not covered most of the gas flow diverts out of the PEEP hole into the environment with little gas flow going to the patient. The minimal gas flow going to the patient is insufficient to meet the patient's inspiratory flow demands. When the inspiratory flow demands are not met, the patient will be starved for air and will over breathe the device reducing inspiratory pressure to zero. So, by definition, if the pressure is not continuous, then it is not Continuous Positive Airway Pressure (CPAP).

What is being provided is PEEP with a minimal amount of free flow oxygen to the patient. A T-piece resuscitator can provide a mix of consistent PEEP delivery and limited PIP when the hole is uncovered. If a patient is effectively spontaneously breathing, PEEP can help prevent atelectasis while the free flow oxygen can assist oxygenation. If the user elects to provide more gas flow during free flow oxygen administration and placing a finger over the PEEP hole, the mask should not be placed in contact with the patient's face. Inadvertently making a seal with the mask and occluding the PEEP hole, could accidentally give a large indefinitely sustained inflation a significant hazard for a newborn or infant. Even though the NRP 6th Edition did recommend placing a finger over the PEEP hole during free flow oxygen the NRP Steering Committee now recommends against this practice "Given the potential to improve safety we recommend leaving your finger off the cap of the T-piece when giving free flow oxygen." The PEEP hole should only be covered during the inhalation phase of manual ventilation. Doing so during blow-by oxygen administration can put the patient at significant risk of injury.

Providing PEEP as a form of ventilatory support can be an effective therapy IF the patient has effective spontaneous ventilation. PEEP is not wrong, it is simply a different therapy but should not be confused with CPAP, the two terms cannot be used interchangeably.

This line of thinking brings up another consideration when it comes to CPAP and neonates. If a T-piece resuscitator is used in an attempt to provide CPAP, could it be an unknown factor contributing to CPAP failure in newborns? According to a paper by Sivanandan published in the Indian Journal of Pediatrics "20-40% of neonates initiated on CPAP might fail and require intubation and mechanical ventilation". If clinicians use an infant T-Piece resuscitator as a CPAP device that cannot maintain inspiratory pressure could this be a contributing factor leading to CPAP therapy failure. Final thought: What if it is the device?

Mr LeCroy spent more than 30 years with St Petersburg Fire & Rescue and retired as a Captain Paramedic. Currently he is the Director of Clinical Support for Mercury Medical. In addition, he has been an adjunct instructor at St Petersburg College since 1984 and has been certified as a Respiratory Therapist since 1978. He has been retained as an EMS Expert in over 100 cases. Steven has been a national speaker and has published articles in both EMS World and JEMS magazines. He is also the author of the Equipment Technology for Noninvasive Ventilation in the Pre-hospital Setting chapter in the text Noninvasive Mechanical Ventilation: Theory, Equipment, and Clinical Applications published by Springer International Publishing Switzerland.

References

1 Abdallah Y, Mkony M, Noorani M, Moshiro R, Bakari M, Manji K. CPAP failure in the management of preterm neonates with respiratory distress syndrome where surfactant is scarce.

A prospective observational study. BMC Pediatr. 2023 May 3;23(1):211. doi: 10.1186/s12887-023-04038-6. PMID: 37138252; PMCID: PMC10155133.

2 Sivanandan, S., Sankar, M.J. CPAP Failure in Neonates: Practice, Experience, and Focus Do Matter!. *Indian J Pediatr* 87, 881–882 (2020). https://doi.org/10.1007/s12098-020-03501-x

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clinicians and under-resourced care providers by reducing the number of unnecessary hospital visits. "At Nonin Medical, we have an extensive background in producing first-class pulse oximetry devices in terms of hardware, including several industry-firsts," said Aaron Lobbestael, Sr. Director of Advanced Technology at Nonin Medical. "But to unlock their full potential in the world of digital healthcare, devices need to be paired with an equally reliable and robust software platform; we see Medixine as the perfect fit, and they align with our objectives to deliver the most patient-centric care possible." One significant area the collaboration aims to progress is overnight oximetry during sleep, for example, as pre-screening to determine if patients need and qualify for supplemental oxygen. Such sleep screenings can also determine if patients need to be tested further for potential sleep disorders like obstructive sleep apnea. This chronic condition is estimated to affect up to 30 million people in the U.S., with only 6 million of these clinically diagnosed. Left untreated, the condition can lead to an increased risk of high blood pressure, heart disease, Type 2 diabetes, stroke, and depression. "Combining physical monitoring devices with Medixine's digital platform offers huge potential benefits in understanding the need for overnight oxygen," Lobbestael continues. "At present, it may take months to acquire an accurate reading using overnight devices that patients need to take to and from the health care provider multiple times. Our digital solution would require just one night of measurement, which would be downloaded automatically to the patient's records. By digitizing our healthcare services, patients can access all the same services they have received previously,

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Development and Implementation of a Lung Expansion Protocol in Pediatric Critical Care

Christopher J Moore, BS, RRT, RRT-NPS, RRT-ACCS, RPFT, AE-C, Ronald Wong, DO, Jove H Graham, PhD, Amber Herlt, AS, RRT-NPS, and Amanda Young, MS

Abstract

Patient-driven protocols are difficult to implement in pediatrics. We prospectively investigated the implementation of a pediatric lung expansion protocol (PLEP) in the pediatric intensive care unit (PICU). We evaluated 107 pediatric patients during the first year of protocol implementation using a triage scoring system in which breath sounds, oxygen requirements, ability to cough, age-appropriate respiratory rate, chest X-ray results, and pulmonary history were assessed by respiratory care practitioners (RCPs). Each assessment category was assigned a score of 0 to 4.

Assessment category scores were totaled, and each patient was placed into a triage level of 1 (most severe) to 5 (least severe). Patient re-evaluation and RCP therapy intervention frequencies were driven by triage level. All patients were re-evaluated once daily, at minimum, as soon as PLEP was initiated via physician order. 100 patients were included in this study with a mean age of 9.9 years (median 11, IQR 5.0, 14.5). Patients (n = 22) whose initial triage score fell into a more severe category transitioned to Triage 5 in just over 2 days, on average (mean = 2.27 days). Protocol accuracy was monitored throughout this implementation year. Protocol accuracy was 94.3% (n = 274, multiple encounters per patient). Most errors (5.7%, n = 17) were early in protocol start-up. Most patients, at a more severe triage level, improved their scores suggesting improvement in lung expansion. Patients who fell into triage level 5 after their initial assessment did not regress, suggesting PLEP may have prevented any regression in lung expansion.

Introduction

Introduction of patient driven protocols (PDPs) began, initially, in the 1980's in effort to bring expertise of the registered respiratory therapist (RRT) into the national spotlight through using their assessment skills in specific disease processes based on evidence-based practice.[1,2]

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Decreased costs were also found be a result of RRT's proficiency in patient evaluation.[3-13] According to a 2017 published survey of New York state RRTs, when asked to weigh the most important clinical responsibility, "ability to assess patients / develop a care plan" was the top response.[14] Some examples of PDPs used in acute care facilities today include volume expansion, secretion management, medicated aerosol, respiratory mechanics, asthma management, and invasive/noninvasive ventilator management protocols.[15-21] Unfortunately, less than half of the interventions provided by respiratory care services is protocol-driven even though data clearly indicates that protocol use improved patient outcomes.[1,22]

Many challenges in protocol implementation exist. These challenges include maintaining constant and consistent use of the established clinical pathway, inconsistent clinician practice styles, and physician buy-in / fear of losing control concerning therapeutic interventions.[24-25] In pediatrics, however, another challenge exists in that, unlike adults, not all patients fall into a "one size fits all" algorithm due to varying age groups and size.

This prospective study evaluated the effectiveness of a pediatric lung expansion protocol (PLEP) in the pediatric intensive care unit (PICU). Since PDPs have been shown to be highly effective in the adult population by providing specific interventions tailored to a patient's individual needs while improving clinical benefit, increasing RRT autonomy, and preventing unnecessary therapies, we investigated implementation of the new pediatric lung expansion protocol in our PICU.[1-12] Our objective was to design a pediatric protocol algorithm and pediatric lung scoring tool that would include and assess these variables, evaluate both current clinical environment and potential changes, increase RRT autonomy and scope of practice. Our secondary objective was to evaluate the importance of each variable used in the pediatric lung scoring tool.

Methods

Data was collected from October 2018 through September 2019 during the first year of protocol implementation. The pediatric lung expansion protocol (Figure 1) uses a standardized clinical severity scoring tool, Pediatric Lung Score (Figure 2), which is based on pediatric age-appropriate parameters in six categories. These categories include oxygen therapy, breath sounds, chest X-ray, cough ability, pulmonary history, and respiratory rate. Each category is scored as 0 (best) to 4 (worst) and documented in as templated note in the electronic health record (EHR). Each category score is added together to obtain a total score

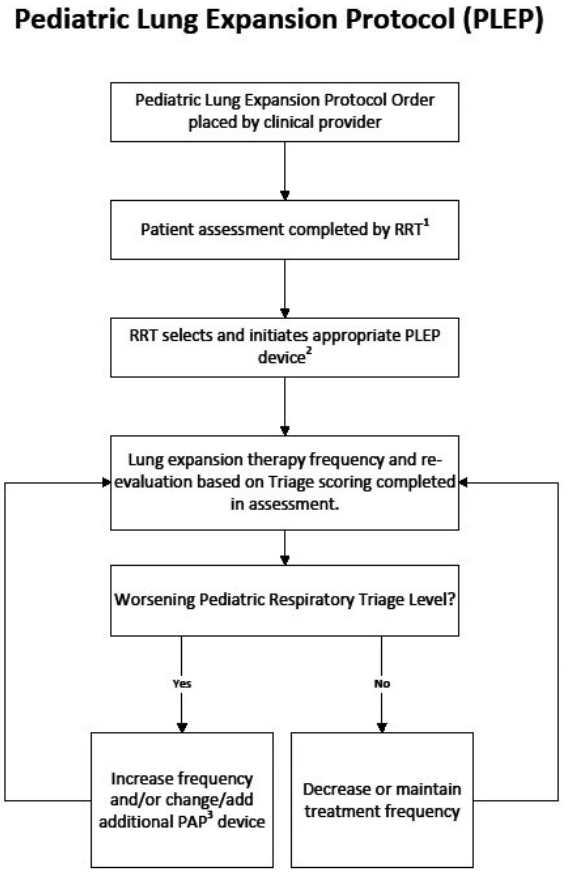

Figure 1. PLEP algorithm. 1. RRT - Registered Respiratory Therapist. 2. Devices: a) incentive spirometry, b) oscillatory positive expiratory pressure, c) EZPAP, d) positive expiratory pressure, e) inexsufflator, f) intermittent percussive ventilation. 3. PAP - Positive Airway Pressure.

which assigns a patient triage level of 1 (most severe) to 5 (least severe).

Triage level (Figure 3) determines both therapy intervention and patient assessment re-evaluation frequency. The initial PLEP order was placed by a physician and appropriate therapy intervention(s) was determined by the RRT via PLEP algorithm during patient assessment. Therapy intervention(s) utilized in PLEP are listed below:

- Incentive spirometry (IS)
- Oscillatory positive expiratory pressure (OPEP)
- EZPAP (EZ)
- Inexsufflator (INE)
- Positive expiratory pressure (PEP)
- Intermittent percussive ventilation (IPV)

All patients were re-evaluated, at minimum, once a day depending on their triage level via protocol scoring template and, potentially, up to every 6 hours. However, patients could be reassessed any time if there was a change in their clinical status allowing the RRT to implement therapy changes, if needed.

Exclusion from PLEP included intubated and non-invasive positive pressure ventilation. Since these patients are receiving lung expansion by way of positive pressure ventilation (PPV), it would be difficult to prevent lung expansion regression in these patients by interrupting PPV using external interventions. Additionally, patients with hemodynamic instability and untreated pneumothoraces were also excluded to prevent worsening of conditions associated with PPV.

Pediatric Lung Scoring (PLS) Tool

Oxygen Therapy:

Score	< 1 year	1-3 years	4-5 years	6-12 years	13-18 years
0	21% or baseline O_2	21% or baseline O_2	21% or baseline O_2	21% or baseline O_2	21% or baseline O_2
1	NC 0.025 - 2 l/m	NC 0.5 - 3 l/m	NC 1 - 3 l/m	NC 1 - 3 l/m	NC 1 - 3 l/m
2	HFNC 2-3 l/m but FiO_2 <40%	>4 l/m NC or HFNC 2 l/m and/or FiO2 <40%	4 l/m NC or HFNC 8 - 12 l/m and/or FiO_2 <40%	4-5 l/m NC or HFNC 10-15 l/m and/or FiO_2 <40%	4-5 l/m NC or HFNC 10-15 l/m and/or FiO_2 <40%
3	HFNC 4-8 and/or FiO2 40-60%	HFNC 3-10 l/m and/or FiO2 40-60%	5-6 l/m NC or HFNC 12-15 l/m and/or FiO2 40-60%	6 l/m NCor HFNC >15 l/m and/or FiO2 40 - 60%	6 l/m NC or HFNC >15 l/m and/or FiO2 40 - 60%
4	HFNC > 8 l/m and/or FiO_2 >60%	HFNC > 10 l/m and/or FiO_2 >60%	HFNC > 15 l/m and/or FiO_2 >60%	FiO_2 >60%	FiO_2 >60%

Breath Sounds:

Score	Description
0	Clear
1	Diminished Unilaterally
2	Diminished Bilaterally
3	Crackles, Mild to Moderate Wheeze, Upper Airway Noises
4	Severe Wheezes, Stridor, Rhonchi

Chest X-Ray:

Score	Description
0	Clear/Not Performed in the past 48 hours
1	Pending
2	Infiltrates/Atelectasis
3	Infiltrates/Atelectasis > 1 lobe
4	Bilateral Atelectasis/Infiltrates/Air bronchograms

Cough:

Score	Description
0	Strong, non-productive
1	Strong productive
2	Weak non-productive
3	Weak productive
4	No cough/requires suctioning

Pulmonary:

Score	Description
0	No history
1	Acute or viral component, but at baseline oxygen requirement
2	Post-operative or acute/viral component requiring supplemental oxygen
3	Chronic without pulmonary exacerbation
4	Chronic with pulmonary exacerbation

Respiratory Rate:

Score	< 1 year	1-3 years	4-5 years	6-12 years	13-18 years
0	24-40	20-30	20-25	16-20	12-16
1	41-45	31-35	26-30	21-25	17-20
2	46-50	36-40	31-35	26-30	21-25
3	51-55	41-45	36-40	31-35	26-30
4	>55	>45	>40	>35	>30

Figure 2. Pediatric lung scoring tool. NC - Nasal Cannula, l/m - liter per minute, HFNC - High Flow Nasal Cannula, FIO2 – Fraction of Inspired Oxygen.

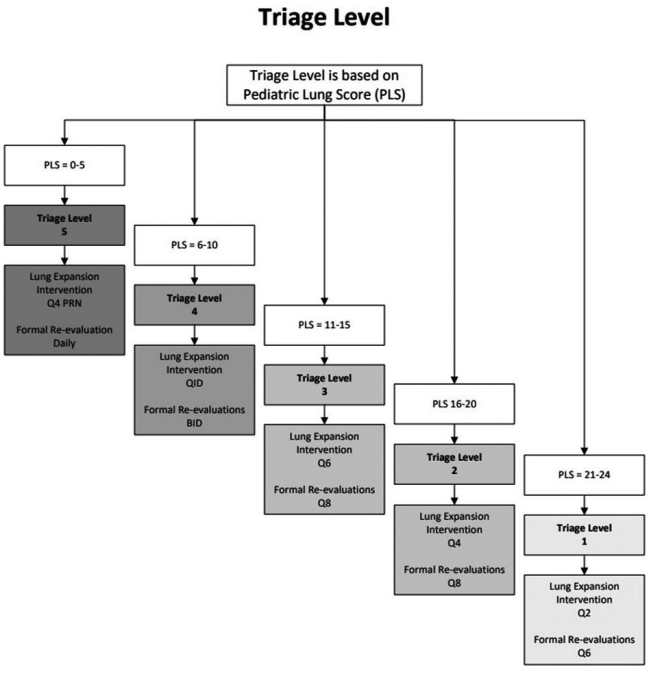

Figure 3. Triage levels.

Protocol accuracy was audited over the first year of protocol implementation.

Appropriate therapy intervention, frequency, and reassessment were regularly audited to provide the best care for our patients.

Data from each patient encounter was collected via the EHR.

Patient category (i.e., medical, surgical, and trauma), age, gender, category assessment scores, triage scores, and therapy interventions/frequency were recorded. These were entered into a spreadsheet where descriptive statistics were completed using SAS statistical software (SAS 9.4, SAS Institute, Cary, NC).

Results

A total of 107 patients were included in this study with multiple records per patient totaling 274 encounters (n = 274) listed in Table 1. 60.7% were male (n = 65) and 39.3% (n = 42) were female. The median age and weight were 11.0 years (IQR 5.0-14.5) and 44.1 kg (IQR 18.8-59.2), respectively. The most common primary admission category was medical (n = 51, 51%) followed by surgical (n = 33, 33%) and trauma (n = 16, 16%).

Patient Characteristics	Total n = 107
Age (years)	
Mean (SD)	9.5 (5.95)
Median (IQR)	11.0 (4.0, 14.0)
Range	0.3, 21.0
Gender, n (%)	
Female	42 (39.3%)
Male	65 (60.7%)
Height (cm)	
Mean (SD)	168.1 (231.48)
Median (IQR)	141.0 (100.1, 164.6)
Weight (kg)	
Mean (SD)	42.9 (31, 51)
Median (IQR)	40.8 (15.6, 57.4)
Patient Type, n (%)	
Medicine	56 (52.3%)
Surgery	35 (32.7%)
Trauma	16 (15.0%)

Table 1. Baseline patient characteristics.

Days on Protocol	Total (n = 107)
Mean (SD)	2.3 (1.69)
Median (IQR)	2.0 (1.0, 3.0)
Range	1.0, 10.0

Table 2. Protocol duration.

Triage level	Score Range (when assessment categories are totaled)	n (%) of scores
1	21-24	0 (0%)
2	16-20	10 (3.6%)
3	11-15	45 (16.4%)
4	6-10	67 (24.5%)
5	0-5	152 (55.5%)

Table 3. Distribution of triage scores, n = 274.

Protocol accuracy was continually audited over this first year of implementation and was 94.3%. Most errors (5.7%, n = 17) were early in protocol start-up while RRT staff were becoming familiar with protocol workflow, documentation, and re-evaluation frequency.

Protocol duration data is listed in Table 2.

PLEP triage level distribution is listed in Table 3 (n = 274). No patients in our data set received triage level 1 designation. A total of 63% of patients fell into a triage level 5 after their initial PLEP assessment was completed and remained there while on protocol. 22% (n = 22) of our patients, who were placed into a more severe triage level, transitioned to level 5 in just over 2 days on average (mean = 2.27 days). 4% (n = 4) were placed into triage level 4, initially, and did not progress to triage level 5 while 2% (n = 2) showed no improvement in lung expansion while on protocol. Distribution of the 6 PLEP assessment categories used to place a patient into an assigned triage level is listed in Table 4.

In reference to oxygen requirement, 61% of patients (n = 61) began PLEP while on 21% fraction of inspired oxygen (F_IO_2) and remained there throughout the protocol suggesting no regression in lung expansion. Supplemental oxygen days in PICU while on PLEP per patient was just over 3 days, on average (mean = 3.28). The most common occurrence in oxygen therapy was transition from high flow nasal cannula (HFNC) to low flow nasal cannula (LFNC) and then 21% F_IO_2 in 18% of patients (n = 18) indicating improvement in lung expansion. Only 2% (n = 2) returned to PICU after being transferred to the general floor for worsening clinical conditions. Respiratory care interventions used in our data set are listed in Table 5. The most frequently administered modality was EZPAP (n = 109, 39.8%). When multiple therapies were used, the combination of EZPAP, incentive spirometry, and oscillatory PEP were most utilized (n = 13, 4.8%).

In our investigation we also wanted to evaluate if one assessment category carried more weight than others when assigning a patient particular triage level. Data was analyzed by 2 methods. First, we looked at assessment category scores individually when one scoring variable of six was removed from the triage score. The logic in this analysis is that, if a variable could be removed from the score and most patients would still be assigned to the same relative category anyway, then that specific variable would not be significant to the overall triage calculation. In contrast, if removing a variable resulted in a significant percentage of patients being reassigned to different triage categories, then that specific variable must be more important in deciding the final score. These results are numerically listed in Table 6 and graphically shown in Figure 4.

When ability to cough was removed from total scoring it had the greatest effect placing only 78% of our total patient assessments

Score	0	1	2	3	4
Pulmonary history	136 (49.6%)	22 (8.0%)	80 (29.2%)	20 (7.3%)	16 (5.8%)
Respiratory rate	126 (46.0%)	59 (21.5%)	46 (16.8%)	30 (10.9%)	13 (4.7%)
Chest X-ray	143 (52.2%)	17 (6.2%)	79 (28.8%)	30 (10.9%)	5 (1.8%)
Breath sounds	151 (55.1%)	12 (4.4%)	60 (21.9%)	41 (15.0)	10 (3.6%)
Oxygen requirements	157 (57.3%)	51 (18.6)	8 (2.9%)	48 (17.5%)	10 (3.6%)
Ability to cough	188 (68.6%)	27 (9.9%)	33 (12.0%)	6 (2.2%)	20 (7.3%)

Table 4. Distribution of scores in each assessment category (n = 274, multiple encounters per patient).

Intervention / device	n (%)
EZ	109 (39.8%)
EZ + OPEP	3 (1.1%)
EZ+ IPV	1 (0.4%)
EZ + IS	1 (0.4%)
EZ + IS + OPEP	13 (4.8%)
EZ + PEP	1 (0.4%)
OPEP	9 (3.3%)
INE	12 (4.4%)
IPV	15 (5.5%)
IS	92 (33.6%)
IS + OPEP	10 (3.6%)
IS + PEP	7 (2.6%)
IS + EZ + PEP	1 (0.4%)

Table 5. Respiratory care interventions used in PLEP (n = 274, multiple encounters per patient).

into the same triage level. However, it overestimated severity for 19% of patients and underestimated 3%. In contrast, breath sounds had the least impact when removed from total scoring, keeping 89% of patients in the same triage grouping. Breath sounds over estimated severity for 7% of the encounters and underestimated severity only 4%.

In evaluating one variable alone to assign a triage score, seen in both Table 7 and Figure 5, both breath sounds and oxygen therapy most closely align with original scoring at 57%. Of the remaining 43% of patients that each of them classified correctly, breath sounds were likely to overestimate patient severity by putting 35% of patients in a more severe category. Oxygen therapy also overestimated severity patient severity by placing 30% of patients in a more severe triage category.

Pulmonary history was the worst at predicting triage level by itself. If used alone, pulmonary history would only place 47% of patients in the correct triage level and overestimated severity of in 41% of patients. The remaining 3 components (respiratory rate, chest X-ray, and ability to cough) would only correctly classify 49% of patients if used themselves.

Discussion

Protocol development, implementation, and physician buy-in

Our first implementation challenge was that patient / therapist-driven protocols tend to be difficult to implement in pediatrics. Primarily, this barrier has previously been dependent on varying patient size and age groups unlike adults which have a more uniform approach in reference to size. Mechanical ventilator weaning protocols are an excellent example where it has been difficult to successfully implement an RRT-driven protocol in pediatrics. Until PLEP implementation began, physicians were tasked with driving lung expansion interventions and frequencies based on the surrounding clinical environment.[26] Since our intention was to change both our clinical practice culture and behavior, naturally, physicians were apprehensive concerning PLEP development and implementation phases in our pediatric population early-on.

To overcome apprehension among physicians and staff during these phases and changes, a constructivism learning theory was

			Variable to be removed from score					
Triage level	Corresponding score range	Actual Scores, N (%)	Pulmonary history	Respiratory rate	Chest X-ray	Breath sounds	Oxygen requirements	Ability to cough
1	17-20	0 (0%)	0 (0%)	0 (0%)	3 (1%)	1 (<1%)	0 (0%)	0 (0%)
2	13-16	10 (3%)	15 (5%)	15 (5%)	12 (4%)	11 (4%)	14 (5%)	22 (8%)
3	9-12	50 (17%)	43 (15%)	52 (18%)	50 (17%)	48 (16%)	48 (16%)	56 (19%)
4	5-8	74 (25%)	83 (29%)	72 (25%)	70 (24%)	77 (26%)	82 (28%)	73 (25%)
5	0-4	158 (54%)	150 (52%)	151 (52%)	156 (54%)	154 (53%)	147 (51%)	140 (48%)
Patients whose Triage scores would stay the same, N (%)			247 (85%)	239 (82%)	244 (84%)	258 (89%)	238 (82%)	227 (78%)
Patients whose Triage scores would get closer to 1, N (%)			28 (10%)	37 (13%)	31 (11%)	20 (7%)	35 (12%)	56 (19%)
Patients whose Triage scores would get closer to 5, N (%)			16 (6%)	15 (5%)	16 (6%)	13 (4%)	18 (6%)	8 (3%)

Table 6. Original vs new triage scores if variable was removed from total triage score, one at a time.

			Variable to be used by itself					
Triage level	Corresponding score range	Actual Scores, N (%)	Pulmonary history	Respiratory rate	Chest X-ray	Breath sounds	Oxygen requirements	Ability to cough
1	17-20	0 (0%)	18 (6%)	14 (5%)	6 (2%)	11 (4%)	11 (4%)	23 (8%)
2	13-16	10 (3%)	21 (7%)	30 (10%)	31 (11%)	52 (18%)	54 (19%)	7 (2%)
3	9-12	50 (17%)	89 (31%)	47 (16%)	88 (30%)	59 (20%)	9 (3%)	33 (11%)
4	5-8	74 (25%)	23 (8%)	67 (23%)	18 (6%)	13 (4%)	54 (19%)	32 (11%)
5	0-4	158 (54%)	140 (48%)	133 (46%)	148 (51%)	156 (54%)	163 (56%)	195 (67%)
Patients whose Triage scores would stay the same, n (%)			137 (47%)	143 (49%)	144 (49%)	165 (57%)	165 (57%)	143 (49%)
Patients whose Triage scores would get closer to 1, n (%)			118 (41%)	106 (36%)	107 (37%)	101 (35%)	87 (30%)	71 (24%)
Patients whose Triage scores would get closer to 5, n (%)			36 (12%)	42 (14%)	40 (14%)	25 (9%)	39 (13%)	77 (26%)

Table 7. Original vs new triage scores if variable is to be used by itself, one at a time.

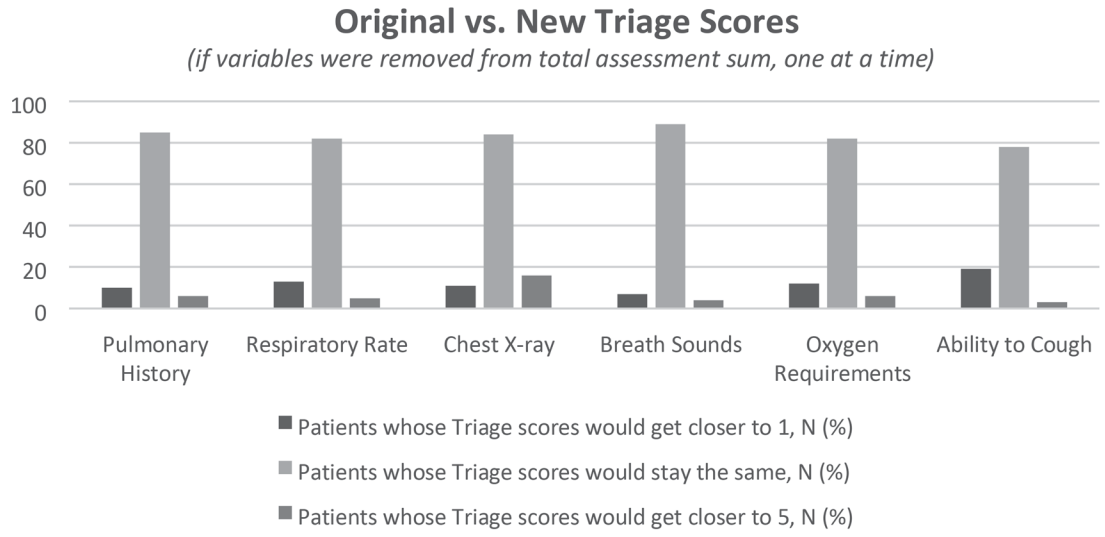

Figure 4. Graphic representation of original vs triage scores shown in Table 6.

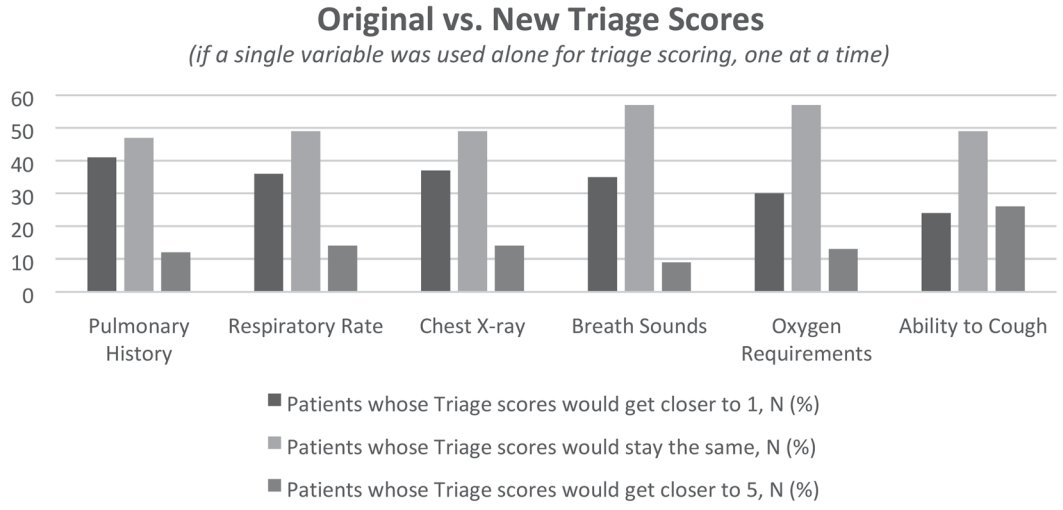

Figure 5. Graphic representation of original vs. new triage scores shown in Table 7.

adopted.[27-29] That is, this protocol was based on both previous pediatric clinical experience and practice standards in other cohorts. We had seen the numerous clinical and practitioner benefits in our adult population and, as a team, we were able to effectively transition these methods into pediatric care. However, constructivism produces continual learning opportunities and protocolization requires periodic reassessment to provide the best patient care possible. Therefore, we are continually open to updating our PLEP clinical pathway as needed.

Physicians were quickly impressed with not only the value of RRT assessment skills, and their ability develop appropriate care plans or adapt current therapy interventions based not just on scheduled re-evaluations, but anytime there was a change in patient clinical status. This flexibility quickly provided RRT autonomy to focus on patients requiring a higher level of watchfulness and alter current care plans to provide our patients with improved respiratory care based on the PLEP scoring template. As a result, unwarranted therapies were negated based on PLEP triage scoring providing both improved utilization of RRT resources and communication between RRT, physicians, mid-level providers, and nursing staff.

Assessment category vs triage score

The second obstacle is that our protocol documentation note needed to be simple, but effective in that the RRT would not have to spend vast quantities of time documenting lengthy initial protocol notes and daily re-evaluations which would take away from patient care. Our PLS was developed as an efficient and simple tool for the RRT to document and improve communication regarding changing patient clinical status.

In turn, we were curious to find if one PLS assessment category held more weight than another when assigning a patient to a specific triage level and, therefore, both a specific treatment and re-evaluation frequency. Results in both analyses did not reveal a definitive category that was markedly superior to another. However, collected data suggests that some overlap may exist where one category may also be represented in an adjacent category. As individual categories they are not specifically noteworthy. Nonetheless, when they are combined, they become a highly effective patient assessment tool.

PLEP Effectiveness

Our data suggest that PLEP is effective in a pediatric population.

63% of patients fell into a triage level 5 after their initial PLEP assessment was completed and remained there while on protocol suggesting no regression in lung expansion. Secondly, 22% (n = 22) of our patients, who were placed into a more severe triage level, transitioned to level 5 in just over 2 days on average (mean = 2.27 days) also suggesting improvement in their lung expansion. Finally, the most common occurrence in oxygen therapy was transition from high flow nasal cannula to low flow nasal cannula and then 21% F_IO_2 in 18% of patients (n = 18) indicating improvement in lung expansion.

In reviewing our data, no patient achieved a Triage 1 status. It is possible that patients requiring this level of intervention were already placed on escalating therapy, such as noninvasive PPV, which would exclude them from PLEP. Additionally, there were only 10 encounters with patients assigned to triage level 2. These patients improved their triage level in 1.8 days on average also indicating improvement in lung expansion. We acknowledge two important limitations of our study: first, that this was a single-center PICU study only, and second, that we did not utilize a comparison group. We look forward, however, to opportunities moving forward to compare future protocol data collection against our original implementation data.

Conclusion

We have successfully developed and implemented a pediatric lung expansion protocol in our PICU utilizing a pediatric lung scoring system which drives both treatment and patient reevaluation frequency. This team initiative has positively impacted pediatric patients' pulmonary health by providing appropriate assessment and intervention without evidence clinical regression. Additional benefits include maximizing RRT and physician resources. PLEP has improved collaboration and trust between RRTs and physicians creating a clinical environment that is open to learning, RRT autonomy, and new avenues for providing consistent and quality patient care moving forward.

References

1 Ford, R. M. (2015). Therapist-driven Protocols: New Incentives for Change. Respiratory Care, 60(5), 757-759. https://doi.org/10.4187/respcare.04123

2 Betit, P. (2015). Guidelines, Pathways, Bundles, and Protocols: Clinical Recipes for Success. Respiratory Care, 60(3), 469-470. https://doi.org/10.4187/respcare.03985

3 Becker, E. A., Hoerr, C. A., Wiles, K. S., Skees, D. L., Miller, C. H., & Laher, D. S. (2017). Utilizing Respiratory Therapists to Reduce Costs of Care. Respiratory Care, 63(1), 102-117. https://doi.org/10.4187/respcare.05808

4 American Association for Respiratory Care. (n.d.). ACCP Position Paper on Respiratory Care Protocols. https://www.aarc.org/resources/clinical-resources/protocols/accp-position paper-on-respiratory-care-protocols/.

5 Metcalf, A. Y., Stoller, J. K., Fry, T. D., & Habermann, M. (2015). Patterns and Factors Associated with Respiratory Care Protocol Use. Respiratory Care, 60(5), 636-643. https://doi.org/10.4187/respcare.03699

6 Myers, T. R. (2013). Thinking Outside the Box: Moving the Respiratory Care Profession Beyond the Hospital Walls. Respiratory Care, 58(8), 1377-1385. https://doi.org/10.4187/respcare.02542

7 Lowe, G. R., Willis, J. R., Bai, S., & Heulitt, M. J. (2016). Implementation of a β agonist/Airway Clearance Protocol in a Pediatric ICU. Respiratory Care, 62(3), 259-267. https://doi.org/10.4187/respcare.04857

8 Hoerr, C. A. (2015). Therapist-directed Protocols Designed with Health-care Reform in Mind. Respiratory Care, 60(2), 304-305. https://doi.org/10.4187/respcare.03898

9 Kallam, A., Meyerink, K., & Modrykamien, A. M. (2013). Physician-ordered Aerosol Therapy Versus Respiratory Therapist-driven Aerosol Protocol: The Effect on Resource Utilization. Respiratory Care, 58(3), 431-437. https://doi.org/10.4187/respcare.01907

10 Kollef, M. H. (2017). Evaluating the Value of the Respiratory Therapist: Where Is the Evidence? Focus on the Barnes-Jewish Hospital Experience. Respiratory Care, 62(12), 1602-1610. https://doi.org/10.4187/respcare.05807

11 Kollef, M. H., Shapiro, S. D., Clinkscale, D., Cracchiolo, L., Clayton, D., Wilner, R., & Hossin, L. (2000). The Effect of Respiratory Therapist-initiated Treatment Protocols on Patient Outcomes and Resource Utilization. Chest, 117(2), 467-475. https://doi.org/10.1378/ chest.117.2.467

12 Todd Tzanetos, D. R., & Calhoun, A. W. (2020). Respiratory Therapy-driven protocols: An Important Component to Decrease Overutilization in Medicine. Respiratory Care, 66(1), 175-176. https://doi.org/10.4187/respcare.08742

13 Mauri, L., & D'Agostino, Sr., R. B. (2017). Challenges in the Design and Interpretation of Noninferiority trials. The New England Journal of Medicine, 377, 1357-67.

14 Smith, S. G., Endee, L. M., Benz Scott, L. A., & Linden, P. L. (2017). The Future of Respiratory Care: Results of a New York State Survey of Respiratory Therapists. Respiratory Care, 62(3), 279-287. https://doi.org/10.4187/respcare.04768

15 Armaghan, R., Geesey, B., Juby, J., Amador-Castaneda, J., Bollinger, A., Roberts, K. J., Newberry, R., Harshberger, M., Radabaugh, N., Pierce, M., & Napolitano, N. (2020). Practice of Respiratory Therapists in Pennsylvania: A Statewide Survey. Respiratory Care, 65(7), 972-976. https://doi.org/10.4187/respcare.07153

16 .Krawiec, C., Carl, D., Stetter, C., Kong, L., Ceneviva, G. D., & Thomas, N. J. (2017). Challenges with Implementation of a Respiratory Therapist–driven Protocol of Spontaneous Breathing Trials in the Pediatric ICU. Respiratory Care, 62(10), 1233-1240.https://doi.org/10.4187/respcare.05477

17 Peterson, R. J., Hassumani, D. O., Hole, A. J., Slaven, J. E., Tori, A. J., & Abu-Sultaneh, S. (2020). Implementation of a High-Flow Nasal Cannula Management Protocol in the Pediatric ICU. Respiratory Care, 66(4), 591-599. https://doi.org/10.4187/respcare.08284

18 Kollef, M. H., & Watts, P. (2019). Moving the Practice of Respiratory Therapy Forward. Respiratory Care, 64(8), 1014-1016. https://doi.org/10.4187/respcare.07017

19 Modrykamien, A. M., & Stoller, J. K. (2013). The Scientific Basis for Protocol-directed Respiratory Care. Respiratory Care, 58(10), 1662-1668. https://doi.org/10.4187/respcare.02195

20 Myers, T. R. (2019). Respiratory Therapist-driven Asthma Protocols Must Be a Standard of Care. Respiratory Care, 64(11), 1445-1446. https://doi.org/10.4187/respcare.07430

21 Peterson, R. J., Hassumani, D. O., Hole, A. J., Slaven, J. E., Tori, A. J., & Abu-Sultaneh, S. (2020). Implementation of a High-Flow Nasal Cannula Management Protocol in the Pediatric ICU. Respiratory Care, 66(4), 591-599. https://doi.org/10.4187/respcare.08284

22 Miller, A. G., Haynes, K. E., Gates, R. M., Zimmerman, K. O., Heath, T. S., Bartlett, K. W., McLean, H. S., & Rehder, K. J. (2019). A Respiratory Therapist-driven Asthma Pathway Reduced Hospital Length of Stay in the Pediatric Intensive

Care Unit. Respiratory Care, 64(11), 1325-1332. https://doi.org/10.4187/respcare.06626
23 AARC Protocol Implementation. (2008). AARC Barriers to Protocol Implementation Survey Results [PowerPoint slides]. https://www.aarc.org/wp-content/uploads/2014/08/pdp_survey.ppt
24 Kurtin, P., & Stucky, E. (2009). Standardize to Excellence: Improving the Quality and Safety of Care with Clinical Pathways. Pediatric Clinics of North America, 56(4), 893-904. https://doi.org/10.1016/j.pcl.2009.05.005
25 Stoller, J. K. (2010). Implementing Change in Respiratory Care. Respiratory Care, 55(6), 749-762.
26 Maue, D. K., Tori, A. J., Beardsley, A. L., Krupp, N. L., Hole, A. J., Moser, E. A., & Rowan, C. M. (2019). Implementing a Respiratory Therapist-driven Continuous Albuterol Weaning Protocol in the Pediatric ICU. Respiratory Care, 64(11), 1358-1365. https://doi.org/10.4187/respcare.06447
27 Ertmer, P. A., & Newby, T. J. (2013). Behaviorism, cognitivism, constructivism: Comparing critical features from an instructional design perspective. Performance Improvement Quarterly, 26(2), 43-71. https://doi.org/10.1002/piq.21143
28 Yilmaz, K. (2011). The cognitive perspective on learning: Its theoretical underpinnings and implications for classroom practices. The Clearing House: A Journal of Educational Strategies,
29 Issues and Ideas, 84(5), 204-212. https://doi.org/10.1080/00098655.2011.568989 Hess, D. R. (2021). Evidence-based Respiratory Care. Respiratory Care, 66(7), 1105 1119. https://doi.org/10.4187/respcare.08950

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but much more easily, while clinicians' workflows are made significantly more efficient." Lobbestael concludes.

New Test Receives Approval

Roche announced that the US Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test, an automated multiplex real-time polymerase chain reaction (RT-PCR) assay on the cobas liat system. Producing results in just 20 minutes on a compact analyser suitable for most healthcare settings, the test uses either a single nasopharyngeal or anterior nasal-swab sample to confirm or rule out infection with SARS-CoV-2, influenza A virus, influenza B virus and respiratory syncytial virus (RSV). "Diagnostics play a critical role in the fight against respiratory illness," said Matt Sause, CEO of Roche Diagnostics. "We are proud to provide this innovative test to address the significant burden placed on healthcare systems. Now, healthcare professionals will be able to detect and differentiate these respiratory viruses within a single patient visit, enabling improved public health outcomes." Introducing rapid multiplex PCR diagnostic tests into near-patient care environments such as emergency departments, urgent care facilities, and physician office labs has the potential to provide swift and precise results, expediting clinical decision-making processes. This approach can help reduce unnecessary antibiotic usage, facilitate targeted treatment strategies, and ultimately enhance patient outcomes and healthcare system efficiency. According to the US Centers for Disease Control and Prevention (CDC), respiratory diseases in the United States reached high levels during the most recent autumn and winter seasons, with SARS-CoV-2 causing the most emergency department visits. Hospitalisations due to respiratory illness place a strain on hospitals and can result in delayed diagnosis and treatment for patients. In the 2023-2024 respiratory season, infants, children, and adults ages 65 and older were observed to have the highest rates of emergency department visits and hospitalisations caused by SARS-CoV-2, influenza, and RSV. Nationwide, the percentage of recent total deaths due to these respiratory viruses was highest among patients 65 and older. The cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test authorised for emergency use further expands and complements Roche's broad portfolio of single and multiplex tests intended to help diagnose and address the needs of patients presenting with symptoms of respiratory illness, including the following assays: cobas SARS-CoV-2, cobas Strep A, cobas SARS-CoV-2 & Influenza A/B, and cobas Influenza A/B & RSV for use on the cobas liat system. In 2025, Roche intends to seek FDA 510(k) clearance and a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver in the United States for the new test, with plans for commercial launch in other markets worldwide following CE-IVDR approval. The cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test is an automated rapid multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus, influenza B virus and respiratory syncytial virus (RSV) RNA in anterior nasal (nasal) swab and nasopharyngeal swab specimens collected from individuals with signs and symptoms of respiratory tract infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza and RSV can be similar. Testing is

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TrachPhone HME: A Comprehensive Approach to Tracheostomy Humidification

Carmin Bartow, MS, CCC-SLP and Elena Gonzalez, PhD, CRA

Conventional external humidification systems (CEHS) have long been the standard of care for spontaneously breathing patients with a tracheostomy. However, these systems come with several drawbacks that can negatively impact patient outcomes and increase facility costs. Given these disadvantages, it is essential for clinicians and healthcare facilities to consider alternative humidification methods, such as Heat and Moisture Exchangers (HMEs), which offer significant benefits in terms of patient outcomes, ease of use, and cost-effectiveness. The tubing and masks required for CEHS use are costly and place high demands on nursing time at the patient's bedside and respiratory therapy resources for setup and follow-up. The tracheostomy collar often becomes misaligned, leading to inadequate or totally absent humidification delivery due to suboptimal use. These systems limit patient mobility due to the tethering effect of the tubing. The noisiness of the water condensing and bubbling in the tubing may impact the patient's sleep quality, recovery and overall well-being. For these reasons, clinicians seek alternatives to external humidification, increasingly favoring using HMEs for patients with tracheostomy tubes. This article will discuss the significance of humidification options in this patient population, provide an overview of HME features and benefits, and highlight the Atos TrachPhone — a multifunctional HME that delivers humidification through its hygroscopic core and offers several additional advantages.

Importance of adequate humidification

The upper airway, particularly the nose and nasopharynx, is critical in humidifying inspired air. Proper humidification ensures that inspired gases are adequately saturated with water vapor and warmed to body temperature. This process is essential for maintaining intact mucociliary function and for hydrating mucus to manage viscosity and mucus transport.[1] When mucociliary transport is optimal, it effectively clears contaminants and excess secretions from the respiratory tract. In patients with tracheostomy, the upper airway is bypassed. Consequently, the air is no longer conditioned before reaching the trachea which may lead to negative effects on pulmonary health. In this patient population, the addition of artificial humidification is essential.

Carmin Bartow has over 20 years of clinical experience treating patients with tracheostomy in acute care. She recently joined Atos Medical as a full-time Tracheostomy Clinical Educator.

Elena Gonzalez has a special interest in tracheostomy as a Clinical Research Associate with Atos Medical.

Types of artificial humidification

Two common types of artificial humidification for patients with tracheostomy include Conventional External Humidification Systems (CEHS) and Heat and Moisture Exchangers (HMEs). CEHS act by allowing air to pass through a reservoir of water which is typically heated before being delivered to the patient. Heated humidification has been shown to improve mucociliary transport, leading to improved secretion management and less suctioning needs when compared to cold air nebulization.[2]

An HME is a device that attaches directly to the tracheostomy tube, retains moisture and heat from the expired air, and returns it to the patient's respiratory tract during inspiration. It consists of a housing that provides structural support and a core where the heat and moisture exchange occur. The core is typically made of materials with high thermal capacity and large surface area to improve the humidification benefit from the HME. Materials such as foam or paper that are saturated with a hygroscopic compound, such as calcium chloride, have increased ability to absorb and release moisture and improve the performance of the HME.[3,4]

Humidification ladder

An assessment of the most appropriate humidification method includes factors such as mucus viscosity, amount of coughing, oxygen needs, and suctioning frequency. The UK National Tracheostomy Project (NTSP) recommends a "humidification ladder", which is a stepwise approach to optimize the level of humidification that a patient requires. According to the NTSP ladder, a first line of humidification for a spontaneously breathing patient with no supplementary needs would be an HME or similar passive humidifier.[5] However, HMEs may be contraindicated in patients with heavy secretions (bloody, thick or copious), or mechanical ventilation combined with a heavy secretion load.[6] In these cases, an active, heated humidifier may be necessary. Regular assessment and adjustment of humidification methods is essential.

HME Evidence and Benefits

Besides offering adequate humidification, an HME also increases breathing resistance compared to breathing through an open stoma. Although an HME does not fully restore the breathing resistance that occurs when breathing through the upper airway,[7] it does help to create positive expiratory pressure, which can prevent alveolar collapse and increase lung volume.[8]

Several systematic reviews and meta-analyses have compared and evaluated the impact of HMEs and CEHS during mechanical ventilation. None of them found the superiority of HMEs or CEHS for outcomes such as ventilator-associated pneumonia, mortality, length of intensive care unit stays, airway occlusion, or duration of mechanical ventilation.[9,10]

In the laryngectomy patient population, the use of HMEs has shown short-term effects such as reduced dispersion of droplets, better management of secretions, decreased tracheal dryness and irritation, and improved tracheostoma hygiene. Long-term effects have also been reported. After two weeks of HME use, researchers found reduced mucus production and plugging, shortness of breath, and pulmonary infections. Significant improvements were reported in sleep, fatigue, psychosocial aspects, and quality of life.[11-17]

A systematic review comparing active humidification (heated CEHS) and passive humidification (HME) in spontaneously breathing patients with a surgical airway reported HME to be the preferred choice of humidification due to the reduction in pulmonary complaints and better patient compliance. Authors reported, "In the context of critical care, heated humidification is most commonly used despite a lack of consensus about the ideal means of providing humidification."[18]

Although an HME may not be appropriate in every situation (e.g.: patients with thick, copious secretions), research indicates that HMEs are an effective method of humidification and should, therefore, be strongly considered when making clinical decisions about humidification approaches.

Atos TrachPhone–The Multifunctional HME

An HME often favored by patients and clinicians is the TrachPhone HME (Figure 1). This multifunctional HME, designed for spontaneously breathing patients, incorporates a speech valve, oxygen port, and suction port. The HME contains a hygroscopic compound, which has been shown to provide better moisture output to the respiratory system when compared to non-hygroscopic HMEs.[19]

Figure 1. TrachPhone HME.

TrachPhone offers the following additional features:

- Speech valve: TrachPhone contains a valve with a spring that can easily be depressed with a finger to facilitate speech. After releasing the finger, the valve will open automatically. See Figure 2.

Figure 2. Speech valve.

- Suction port: The integrated suction port allows for tracheal suctioning without removing the HME. See Figure 3.

Figure 3. Suction port.

- Oxygen port: TrachPhone has an O_2 port (4 mm) that allows for integrated administration of supplemental oxygen, up to 4 liters. See Figure 4.

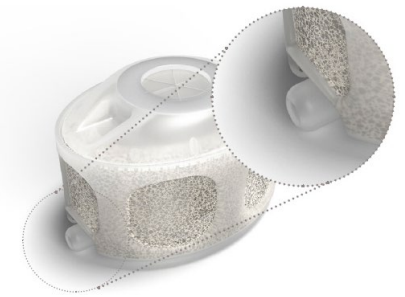

Figure 4. Oxygen port.

TrachPhone Study Results

In a recent quality improvement project at Stanford University School of Medicine, researchers evaluated the feasibility and effectiveness of using TrachPhone HMEs by patients who underwent a tracheotomy in a hospital setting. They compared this approach to the CEHS. The efficacy of TrachPhone HMEs was assessed by monitoring patients' tolerance to the HME (assessed by respiratory status and suction needs), reviewing nursing notes, and conducting questionnaires. Seventy-one spontaneously breathing patients with tracheostomy were enrolled in this study and, the following results were reported:

- 97% (69/71) of patients tolerated TrachPhone HME immediately post-op
- 3% of patients (2/71) did not tolerate the HME due to elevated suctioning needs via tracheostomy
- None of the patients developed respiratory distress, air trapping, or mucus plugs.
- 89% of nurses preferred TrachPhone HME over traditional CEHS
- The primary reasons for nursing preference for the TrachPhone HME over CEHS were improved patient

mobility, decreased noise in the patient's room, and ease of set-up. See Figure 5.

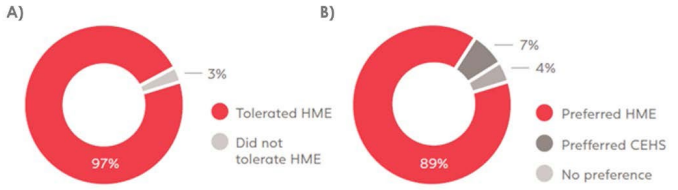

Figure 5. HME tolerance and Preference. A) 97% (69/71) of patients tolerated the TrachPhone HME immediately post-op, B) 89% (24/27) nurses preferred the TrachPhone HME over traditional CEHS for inhaled air humidification.

- Additional positive results included:
  - Patient satisfaction. The authors stated that several patients reported that the HME was more comfortable than CEHS and that the reduction in noise allowed them to sleep better.
  - Cost savings. The projected annual cost reduction was $68,000 (based on projected annual 325 tracheostomy procedures, based on 1 HME/day, in the USA). See Figure 6.
  - Increased patient communication. Nurses reported that patients who used TrachPhone speech valve function were able to communicate earlier compared to the CEHS. With an increase in effective communication, less anxiety regarding care and improved overall well-being were reported.
  - Less training for patients and caregivers. The authors reported ease of patient and family training when HMEs were substituted for CEHS and stated that patients could often apply the HME independently, which promotes self-care.
  - Decrease in suction requirements. The authors mention that tracheostomy collars are sometimes displaced and misaligned, which prevents optimal and steady humidification. They surmise that because the HME is attached directly to the tracheostomy tube, more consistent heat and humidification are delivered, which may decrease the tenacity of secretions.[20]

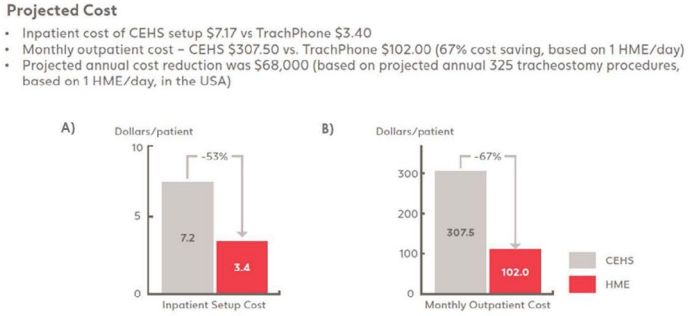

Figure 6. Cost Analysis of CEHS compared to HME use. A) Inpatient setup cost is 53% less for HMEs compared to CEHS, and B) monthly outpatient cost is 67% lower with HMEs compared to CEHS.

Summary

Optimal pulmonary health relies on adequate humidification. In patients with tracheostomy, artificial humidification is essential since the upper airway is bypassed. HMEs offer several advantages over traditional external humidifiers, including improved patient compliance, reduced training requirements for patients and caregivers, reduced pulmonary complaints, and cost savings. Given these advantages, clinicians and healthcare facilities should consider incorporating HMEs into the care plans for patients with tracheostomy to enhance their overall pulmonary health and quality of life.

References

1 Mercke U, Toremalm NG. Air humidity and mucociliary activity. Ann Otol Rhinol Laryngol. 1976 Jan-Feb;85 (1 Pt 1):32-7.

2 Birk R, Händel A, Wenzel A, Kramer B, Aderhold C, Hörmann K, Stuck BA, Sommer JU. Heated air humidification versus cold air nebulization in newly tracheostomized patients. Head Neck. 2017 Dec;39(12):2481-2487.

3 Wilkes AR. Heat and moisture exchangers. Structure and function. Respir Care Clin N Am. 1998;4(2):261-79.

4 van den Boer C, Vas Nunes JH, Muller SH, van dN, V, van den Brekel MW, Hilgers FJ. Water Uptake Performance of Hygroscopic Heat and Moisture Exchangers after 24-Hour Tracheostoma Application. Otolaryngol Head Neck Surg. 2014;150(6):999-1004.

5 Project NTSP. Day-to-day management of tracheostomies and laryngectomies: Humidification. Available from: https://tracheostomy.org.uk/.

6 Restrepo RD, Hirst KR, Wittnebel L, Wettstein R. AARC clinical practice guideline: transcutaneous monitoring of carbon dioxide and oxygen: 2012. Respir Care. 2012;57(11):1955-62.

7 Zuur JK, Muller SH, de Jongh FH, van Zandwijk N, Hilgers FJ. The physiological rationale of heat and moisture exchangers in post-laryngectomy pulmonary rehabilitation: a review. Eur Arch Otorhinolaryngol. 2006;263(1):1-8

8 Scheenstra RJ, Muller SH, Vincent A, Ackerstaff AH, Jacobi I, Hilgers FJ. Short-term endotracheal climate changes and clinical effects of a heat and moisture exchanger with an integrated electrostatic virus and bacterial filter developed for laryngectomized individuals. Acta Otolaryngol. 2010;130(6):739-46.

9 Gillies D, Todd DA, Foster JP, Batuwitage BT. Heat and moisture exchangers versus heated humidifiers for mechanically ventilated adults and children. Cochrane Database Syst Rev. 2017;9:CD004711.

10 Vargas M, Chiumello D, Sutherasan Y, Ball L, Esquinas AM, Pelosi P, et al. Heat and moisture exchangers (HMEs) and heated humidifiers (HHs) in adult critically ill patients: a systematic review, meta-analysis and meta-regression of randomized controlled trials. Crit Care. 2017;21(1):123.

11 Jones AS, Young PE, Hanafi ZB, Makura ZG, Fenton JE, Hughes JP. A study of the effect of a resistive heat moisture exchanger (Trachinaze) on pulmonary function and blood gas tensions in patients who have undergone a laryngectomy: a randomized control trial of 50 patients studied over a 6-month period. Head Neck. 2003;25(5):361-7.

12 Bien S, Okla S, van As-Brooks CJ, Ackerstaff AH. The effect of a Heat and Moisture Exchanger (Provox HME) on pulmonary protection after total laryngectomy: a randomized controlled study. Eur Arch Otorhinolaryngol. 2010;267(3):429-35.

13 Dassonville O, Merol JC, Bozec A, Swierkosz F, Santini J, Chais A, et al. Randomised, multi-centre study of the usefulness of the heat and moisture exchanger (Provox HME(R)) in laryngectomised patients. Eur Arch Otorhinolaryngol. 2011;268(11):1647-54.

14 Merol JC, Charpiot A, Langagne T, Hemar P, Ackerstaff AH, Hilgers FJ. Randomized controlled trial on postoperative

pulmonary humidification after total laryngectomy: External humidifier versus heat and moisture exchanger. Laryngoscope. 2012;122(2):275-81.
15 Parrilla C, Minni A, Bogaardt H, Macri GF, Battista M, Roukos R, et al. Pulmonary Rehabilitation After Total Laryngectomy: A Multicenter Time-Series Clinical Trial Evaluating the Provox XtraHME in HME-Naive Patients. The Annals of otology, rhinology, and laryngology. 2015;124(9):706-13.
16 Foreman A, De Santis RJ, Sultanov F, Enepekides DJ, Higgins KM. Heat and moisture exchanger use reduces in-hospital complications following total laryngectomy: a case-control study. J Otolaryngol Head Neck Surg. 2016;45(1):40.
17 Ebersole B, Moran K, Gou J, Ridge J, Schiech L, Liu JC, et al. Heat and moisture exchanger cassettes: Results of a quality/safety initiative to reduce postoperative mucus plugging after total laryngectomy. Head Neck. 2020
18 Wong CY, Shakir AA, Farboud A, Whittet HB. Active versus passive humidification for self-ventilating tracheostomy and laryngectomy patients: a systematic review of the literature. Clin Otolaryngol. 2016;41(6):646-51.
19 Mebius C. A comparative evaluation of disposable humidifiers. Acta Anaesthesiol Scand. 1983;27(5):403-9.
20 Kearney A, Norris K, Bertelsen C, Samad I, Cambridge M, Croft G, et al. Adoption and Utilization of Heat and Moisture Exchangers (HMEs) in the Tracheostomy Patient. Otolaryngol Head Neck Surg. 2023.

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limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test is authorised for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A, influenza B and RSV viral RNA in clinical specimens and are not intended to detect influenza C virus. SARS-CoV-2, influenza A, influenza B and RSV RNA are generally detectable in nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A, influenza B and/or RSV RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, influenza B and/or RSV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information. The cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test is intended for use by trained operators specifically instructed in the use of the cobas liat system and the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test. The cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test is only for use under the Food and Drug Administration's Emergency Use Authorization.

O2matic's Proprietary Technology to be Evaluated by the University of Colorado

O2matic, a Danish medical device company focused on developing next-generation oxygen therapy and monitoring technologies, has announced that its proprietary technology is the subject of research led by Adit Ginde, MD, Professor of Emergency Medicine and Anesthesiology at the University of Colorado School of Medicine. Dr Ginde and his team's work has paved the way for the SAVE-O2 trial, a multicenter randomized clinical trial funded by the US Department of Defense. The SAVE-O2 trial focuses on redefining oxygen requirements in critically ill trauma patients through targeting normoxemia. Preliminary results from analyzing data from approximately 12,000 randomized patients have unveiled promising outcomes. Manually targeting normoxemia successfully reduces hyperoxemia without increasing hypoxemia, resulting in lower mortality rates, shortened hospital stays, and decreased supplemental oxygen requirements. Dr Ginde presented initial results at the Military Health System Research Symposium in 2023, earning his team the distinguished recognition of Outstanding Research Accomplishment. Their advancements in oxygen therapy protocols have already begun to influence guidelines, with updates to 10 relevant Joint Trauma System guidelines. Dr Ginde and his team are now evaluating the efficacy of automatic oxygen therapy technology, with O2matic's proprietary technology chosen for a multi-center study involving 300 patients. This study, named SAVE-O2 AI, and initiated in May 2024, aims to publish results by early 2026. "We at O2matic are deeply honored to be part of this significant study and eagerly anticipate the potential impact of our technology on acute and

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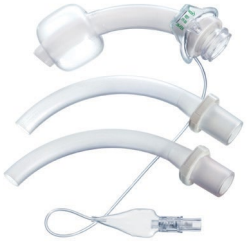

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How RTs are Using Clinical Decision Support for Better Patient Outcomes

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Kathryn Butler, Director of Clinical Development, Etiometry.

As Director of Clinical Development for Etiometry, a clinical intelligence platform for high-acuity care teams, Kathryn Butler, RRT-NPS, leads the development, coordination, and implementation of the system's analytics and pathways into clinical workflows worldwide. A trained respiratory therapist, she has over a decade of experience in critical care procedures, clinician training, and award-winning clinical research.

She spoke about the role clinical decision support platforms like Etiometry can play in the day-to-day work of RTs.

You began your career as an RT. Why were you drawn to the field of respiratory therapy?
I have several family members working in health care, and I always looked up to them when I was growing up. They inspired me to pursue a career that would involve caring for people and helping them in their time of need. At the same time, medicine itself has always fascinated me. I love the technical aspect and multidisciplinary involvement of respiratory therapy.

As a new RT, what surprised you most about the work?
I was struck by the impact you can make. There's an art to decision-making; it's not just memorizing and following protocols. At the same time, I saw how difficult it was to prioritize when things get busy. This has always been challenging, and it's gotten worse post-COVID with RT shortages nationwide and short staffing.

What are some of the ways Etiometry is helping RTs in their day-to-day jobs?
Etiometry is a clinical decision support platform that aggregates the patient's physiological data in real-time for a more holistic view of how the patient is doing. As a tool, it can reduce the workload for RTs, enabling more timely, data-driven decisions around things like the escalation and de-escalation of care. It can also provide a source of ground truth, giving RTs a more powerful voice to advocate for their patients. Data doesn't lie.

How are technologies like AI-based clinical decision support affecting real-world patient outcomes?
Independent, published research studies have found that using Etiometry can reduce ventilation time by up to 22%,[1] and reduce hospital length of stay by up to 36%.[2] Not only does this mean better patient care, but it also reduces costs. Patients are being extubated earlier and leaving the hospital sooner, which reduces the likelihood of additional complications, and improves their outcomes. Not coincidentally, we also see a reduction in ICU readmissions of up to 41%.[3]

Tell us more about Etiometry's automated clinical pathways. What is the top request you get from your RT users?
"Can you automate our unit-specific protocols?"
And yes we can. Whether it's for ERT, ARDS, PARDS or LPV — if its data driven we can do it!

What do you wish more people knew about the role of an RT?
Respiratory therapists are an extremely important part of the care team. RTs need to provide care that's both standardized and individualized to a complex and diverse patient population at different levels of severity that are constantly changing. RTs work in all types of hospital settings — from the ICU, to the floor, to the ER, to outpatient clinics — and we see all types of patients, from neonates to geriatric, and everything in between.

Do you have a favorite story about how RTs are using Etiometry in the real world?
We've seen ICUs change their practice from doing a daily Extubation Readiness Assessment every morning to using Etiometry to continuously and automatically scan for patient eligibility throughout the shift. This has not just saved time and reduced the workload for staff, it significantly reduced time on mechanical ventilation across the entire ICU.

What does the future look like for RTs in the area of technology use?
Respiratory therapists have always been early adopters of technology, and that's not going to change. Etiometry and AI-driven clinical decision support represent the future of medicine. The technology behind these platforms will increasingly automate care, making clinicians' jobs easier and, most importantly, improving patient outcomes.

References

1 Borasino, S. et al. (2023) Automated Extubation Readiness Tool is Associated with Improved Outcomes Following Pediatric Cardiac Surgery. WCPCCS.
2 Salvin et al, AHA '17.
3 Gaies et al, Circulation '23.

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trauma patients," said Arnt Lund, O2matic's CEO. "We are also grateful to the IDE sponsor for this study, IDTS Medical, Inc. and its CEO, Mario Nozzarella, who guided us through the US Food and Drug Administration Investigational Device Exemption (US FDA IDE) process and received our final (non-conditional) letter regarding the submission G230325/A001 with a strong sense of urgency." The award is funded by the US Department of Defense through the Medical Technology Enterprise Consortium (MTEC) to further oxygen research using autonomous solutions.

IntelliPAP Option Released by React Health
React Health, a sleep and respiratory device manufacturer and distributor, announced the release of the IntelliPAP option for the V*Home, V+Pro, V+C and VC+Pro ventilators. IntelliPAP is an optional tool that physicians may use when providing noninvasive ventilation in diseases that are associated with both respiratory insufficiency and obstructive sleep apnea (OSA). It enables the automatic adjustment of delivered PEEP levels in response to the detection of sleep disordered breathing (SDB) events. As an added safeguard, clinicians can limit the range of the automatic PEEP adjustment by setting the PEEP min and PEEP Max settings. "React Health is committed to advancing healthcare solutions that contribute to improved patient outcomes and operational efficiency. The most recent launch of IntelliPAP along with the new E0468 HCPCS code for our V+C ventilator with integrated cough assist (ICAT), further reflects that commitment to our partners and patients," said Jeff Ward, EVP of Ventilation for React Health. React Health is a sleep and respiratory company based in the United States. For more information on the launch of the IntelliPAP, reach out to your local React Health sales representative or ventec-info@reacthealth.com.

New Research Provides Evidence of the Effectiveness and Critical Role of Positive Airway Pressure Therapy
A number of accomplished medical and scientific experts presented critical new research on sleep conditions and their effect on cardiovascular health at the American Thoracic Society International Conference. The ResMed-supported research provided new insights into the effectiveness of PAP therapy in treating sleep-disordered breathing and its associated clinical benefits. The studies were among 26 supported by ResMed in collaboration with leading scientists including Michael Arzt, MD, Universitätsklinikum Regensburg, Germany; Jean-Louis Pépin, MD, Grenoble Alpes University, France; Atul Malhotra, MD, University of California, San Diego; and Holger Woehrle, Ulm Lung Centre, Germany. With growing attention on the use of anti-obesity medications, such as GLP-1s in clinical practice, a timely study was presented by Dr Atul Malhotra which explored the real-world relationship of GLP-1 medication use and PAP therapy in patients with OSA. The use of GLP-1s did not lead to higher discontinuation rates of PAP therapy, rather this analysis found that patients who were adherent to their GLP-1 medication had higher levels of PAP therapy use than those who were non-adherent to their GLP-1 medication. Several studies demonstrated findings showing continued effectiveness of PAP therapies for patients with sleep disorder conditions like obstructive sleep apnea. Among these was an analysis of data from 27 randomized control trials and non-randomized control studies on the effects of PAP on patients with OSA. This meta-study, presented by Dr Atul Malhotra, found mortality was 37% lower on average in patients with PAP-treated OSA vs untreated OSA. An additional study, presented by German

physician and sleep researcher Holger Woehrle, looked at 17,000 treatment-naïve patients in both PAP-treated and untreated cohorts and showed PAP treatment reduces hospitalization in patients with OSA over the first four years of treatment. This finding demonstrates a correlation between the use of PAP therapy and a reduction in use of healthcare resources. A study presented by ResMed's research scientist Elroy Boers projected an increase in OSA cases in the United States using patient data calibrated across subgroups of age, sex and body-mass index (BMI). According to this research, due to the growing and aging population in the United States as well as increased BMI trends, the already substantial burden of OSA is expected to increase by 27.6% by 2050 in men and women aged 30-70, with an overall prevalence within this group projected to be 26%. As OSA continues to increase, reliance on PAP therapy will rise as it remains the gold standard for treatment. Two studies evaluated the effects of Adaptive Servo-Ventilation (ASV) therapy in two populations, patients with TE-CSA and patients on long-term opioid therapy. The former, presented by German physician and sleep researcher Dr Michael Arzt, demonstrated ASV therapy showed a reduced symptom burden and an improvement in quality of life for patients with TE-CSA, with or without comorbid cardiovascular disease, a comorbidity present in a majority of patients with TE-CSA. The second study, presented by French physician and researcher Dr Jean-Louis Pépin, studied 86 CSA patients on long-term opioid therapy and who used ASV treatments for at least one year. This study showed a -1 median reduction in Epworth Sleepiness Scale (ESS) values and a median increase of .96 on the Functional Outcomes of Sleep Questionnaire (FOSQ), demonstrating a lower symptom burden and improved quality of life. Another study, also presented by Dr Jean-Louis Pépin, looked at nearly 50,000 adults with COPD who were treated via domiciliary NIV. The study showed long-term home use of NIV was strongly associated with a reduced risk of death. "The host of critical research presented by influential and accomplished experts at ATS continues to show the effectiveness and importance of PAP in treating sleep disordered breathing and limiting their impact on adverse health effects," said Carlos M. Nunez, MD, Chief Medical Officer at ResMed. "The increasing prevalence of cardiovascular conditions, obesity and an aging population in the United States demonstrate why increasing awareness of sleep health and conducting research into how best to improve sleep quality and overall health outcomes is so critical today." In addition to the ResMed-supported abstracts, Dr Nunez served as a panelist at two ATS sessions: The Healthcare of Today, Looking Towards Tomorrow: Digital Innovations and Patient Centricity, which examined the imperative for investing in digital health and driving innovations for personalized patient experiences, as well as Enabled Clinicians, Enhanced Care: Best Practices for Leveraging Digital Health Solutions, which showcased how digital health solutions and digital therapeutics can find a place in today's clinical workflows. ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

Product Line Acquired

Respiralogics announces the Asset Purchase of the Children's Health First Product Line, a Carlsbad, CA company. Respiralogics, a leader in Bubble CPAP and Non-Invasive Respiratory Support of the Newborn, is proud to expand their product portfolio with the StatStrap Neonatal Positioning Strap, Preemie Beenie Poly Lined-Knit Hats and StatStrap Circuit Holder. These quality products fulfill unique niches to help bedside and transport clinicians with ELBW and full-term infants. StatStrap is a single patient-use safety strap set that safely secures and positions newborn infants within an incubator. It easily and securely attaches to the mattress tray of the incubator. StatStrap helps to prevent accidental falls of preterm and term infants receiving care in an incubator. Preemie Beenie is a specially designed Poly-Lined Knit Cap designed for ELBW and Term Infants to aid in their thermoregulation. The snug fit of the soft knit minimizes movement, pressure on the head and color-coded to easily identify the size of the Preemie Beenie StatStrap Circuit Holder assists in keeping tubing's securely attached to the bed clothes for stability and/or the parent during Kangaroo Care. All products are made in the USA, designed for single patient use and Latex Free. Respiralogics specializes in providing innovative respiratory care products to meet the challenging needs of respiratory patients, especially the most vulnerable preterm infants. To benefit clinicians, we have joined with leading specialty respiratory distributors to provide expert local assistance and the training required for successful implementation of our products. Respiralogics' complete line of products is available from Respiralogics and our specialty respiratory care distributors. Respiralogics, Respiralogics Logo, Preemie Beenie are trademarks and StatStrap is a registered trademark of Global Respiratory Solutions, Inc.

Breas Medical, Inc. Partners with VGM and Associates

Breas Medical, Inc., a global leader in home mechanical ventilation and sleep therapy, announces that it has executed a vendor partner agreement with VGM and Associates, the nation's largest and most comprehensive Member Service Organization (MSO) for post-acute healthcare. The partnership allows Breas to connect with and support the VGM membership, ultimately helping patients receive the highest level of care. This aligns with Breas' mission to improve the quality of life and care of respiratory patients around the world through a personal commitment to innovation, quality, and customer focus. "We are honored to be able to partner with VGM and Associates," said Chris Southerland, General Manager of Breas Americas, Breas Medical, Inc. "This exciting opportunity allows us to share our expertise in ventilation with the VGM membership and continue to provide support to the industry with our innovative life support ventilation units that set the standard in clinical workflow, technology, and patient comfort and mobility." "We are thrilled to announce a partnership between Breas Medical and VGM and Associates, uniting two leaders in healthcare innovation," said Boone Lockard, VP of Clinical Services, VGM and Associates. "This collaboration is set to enhance the quality of care for patients across the US, leveraging Breas Medical's expertise in respiratory care and sleep apnea treatment with VGM's business solutions." (MSO) for post-acute healthcare including DME/HME, respiratory, sleep, wound care, complex rehab, women's health, home modifications, and orthotics and prosthetics providers. 3,000 providers with nearly 7,000 locations rely on VGM to connect them to valuable resources every single day. For more information, visit www.vgm.com.

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