Volume 20 Number 4 Fall 2025

Respiratory Therapy™

The Journal of Pulmonary Technique

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1. FDA 510K, K201874, 2. FDA 510K, K192604, 3. FDA 510K, K230173

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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.

Scan to learn more about mini-cylinders and the device they pair with

Mallinckrodt Pharmaceuticals

INOmax® EVOLVE™ DS

INOmax®(nitric oxide) gas

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.

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Editorial Advisory Board

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The Journal of Pulmonary Technique

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Table of Contents

News

■ Fall 2025

Sentec Receives FDA Clearance

Sentec, a global leader in non-invasive patient monitoring, announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance for its LuMon Electrical Impedance Tomography (EIT) system for premature infant, infant, adolescent, and adult patients—making it the first EIT technology in the United States available for premature infants and for spontaneously breathing patients. The LuMon EIT System delivers functional lung imaging directly at the bedside—without radiation—helping clinicians better tailor therapy to each patient's unique needs. While the LuMon System can be used to monitor a variety of patients, whether ventilated or spontaneously breathing, the premature infants and other patients in the NICU may stand to benefit the most from EIT's insights at the bedside. "Neonatal patients present enormous complexity, especially for ventilation; there's very little room for error, particularly in our smallest patients—and the consequences can follow these babies all their lives," said Dr David Tingay, Clinical Neonatologist and Respiratory Physiotherapist at Royal Children's Hospital in Melbourne, Australia. Dr Tingay has done extensive research with the LuMon EIT system in infant patients continued, "Without EIT, there's been no way for us to continuously see what is happening inside the lungs at the bedside to understand the impact of our interventions better as we perform them." The ability to safely visualize lung function at the bedside, continuously and in real time, has enormous potential for guiding neonatal care and, according to Dr Tingay, "EIT provides immediate imaging of regional lung function at the bedside. That visualization helps us better understand each patient's respiratory condition and determine the strategies we need to employ for their specific needs." With the first-ever FDA clearance for premature infants and soft, fabric belts small enough for even very low birthweight infants, the LuMon System is positioned to help clinicians deliver gentle and effective respiratory care for the uniquely fragile and complex patients in the NICU. While the basis of electrical impedance tomography and its use for imaging regional lung function has been present in research for many years, the LuMon system is first EIT technology available for routine clinical bedside use with premature infants in the United States, and can impact patient care and clinical decision making today. Electrical impedance tomography works by sending gentle, alternating currents through the thorax via a comfortable, skin-friendly fabric belt and measuring the resulting voltages to produce dynamic images of regional impedance variations due to breathing. This enables clinicians to evaluate real-time responses to regional ventilation changes such as those resulting from positioning, ventilator settings, and pharmaceuticals, facilitating more precise and individualized care decisions.

Masimo O3 Regional Oximetry Receives FDA Clearance

Masimo announced the FDA 510(k) clearance of expanded indications for the delta hemoglobin parameters provided with O3 Regional Oximetry. The parameters display relative changes in hemoglobin that can help clinicians identify the underlying mechanisms responsible for changes in tissue oxygen saturation. With this latest clearance, this capability is now available for use in both cerebral and somatic applications as well as for all patient populations, including pediatric and neonatal patients.

O3, available on Masimo's Root patient monitoring and connectivity platform, uses near-infrared spectroscopy (NIRS) to monitor and display continuous regional oxygen saturation values (rSO2) in the tissue of interest. rSO2 reflects the balance between oxygen delivery and metabolic demands in the organ being monitored. However, rSO2 alone may not always indicate the reason for any imbalance. With the addition of delta hemoglobin parameters, clinicians can

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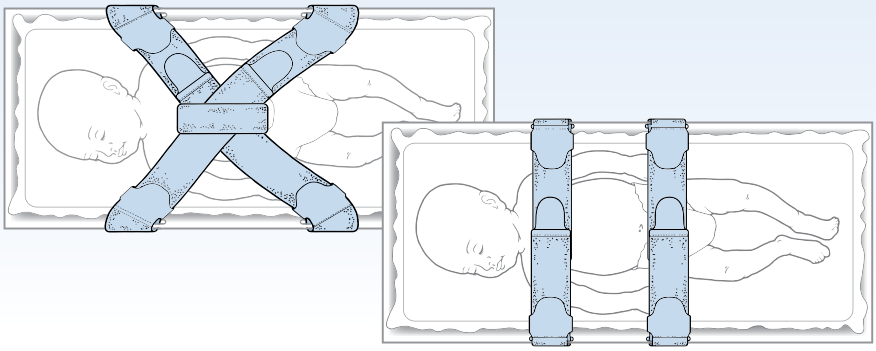

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To start using StatStrap and Preemie Beenie, contact us at 4info@respiralogics.com.

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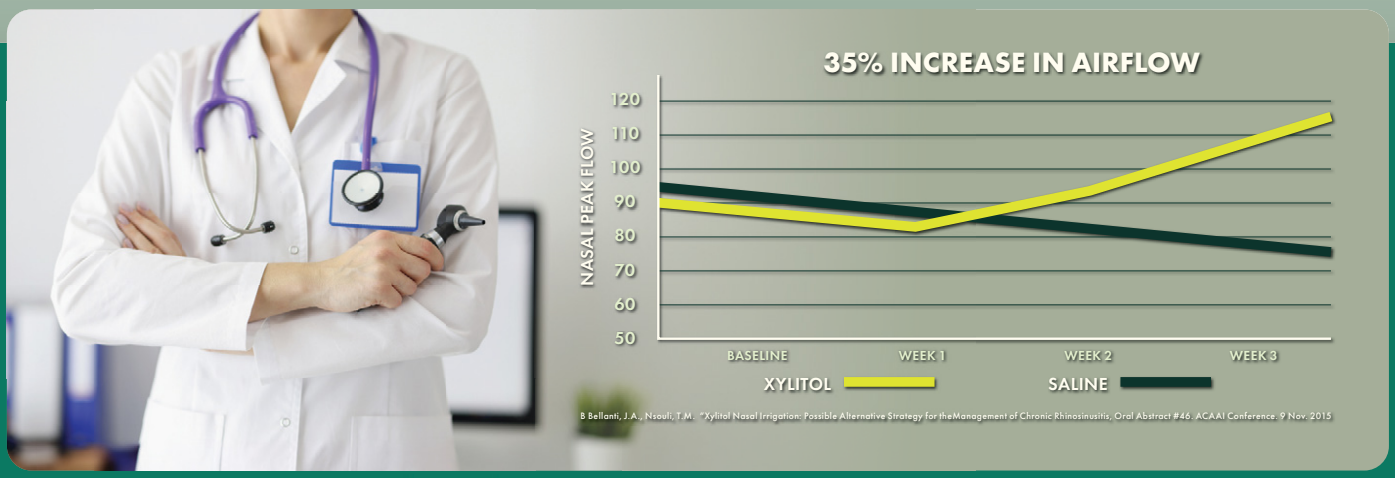

B Bellanti, J.A., Nsouli, T.M. "Xylitol Nasal Irrigation: Possible Alternative Strategy for theManagement of Chronic Rhinosinusitis, Oral Abstract #46. ACAAI Conference. 9 Nov. 2015

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gain the insight needed to better understand why a patient's rSO2 is changing by monitoring relative changes in the underlying components used to determine it: total hemoglobin (cHb), deoxygenated hemoglobin (HHb), and oxygenated hemoglobin (O2Hb). These additional data support more informed clinical assessment of the appropriate intervention, ultimately helping drive improvements in the patient's care.

Each of these parameters can provide valuable additional context for helping clinicians assess a variety of physiological conditions. For example, venous congestion, a slowing or pooling of blood that has been associated with negative outcomes in a variety of scenarios, such as the failure of reconstructive flaps, has been found to increase total hemoglobin (cHb) in tissue.

O3 Regional Oximetry uses Masimo's proprietary technology to provide both trending and absolute accuracy, giving clinicians confidence that the numbers they see reflect actual current tissue oxygenation. With delta hemoglobin parameters now available for all applications and populations, O3 prioritizes insight into the physiology of each individual patient. And with the combination of O3 and SedLine Brain Function Monitoring on Root, Masimo is proud to offer the only brain health solution on the market to provide comprehensive data about the bilateral brain on a single platform. Basil Matta, MD, SVP of Global Clinical Affairs & Solutions for Masimo, said, "Ensuring vital organs and tissues are receiving enough oxygen to meet their metabolic needs is the cornerstone of optimal anesthesia and critical care. Masimo SedLine provides a measure of brain activity and thus indirectly oxygen demand. O3 provides an indication of the balance between vital organ oxygen delivery, by tracking relative changes in oxygenated hemoglobin (O2Hb), and demand, by tracking the changes in deoxygenated hemoglobin (HHb). By using SedLine and O3 together, the clinician can investigate why this balance may have changed, as indicated by concomitant changes in delta hemoglobin parameters—and take advantage of this complementary information, as part of their overall clinical assessment, in initiating the appropriate intervention to restore the balance of oxygen delivery to demand baseline. Masimo Root with O3 and SedLine is a true Brain Health Platform and provides a truly multimodal view of the brain."

Early-Onset Asthma, Not Aeroallergen Sensitization, Linked to Impaired Lung Function in Young Adults

A recent study indicates that early-onset asthma, not aeroallergen sensitization, is independently associated with impaired lung function in young adults. This finding suggests that the features of asthma, rather than sensitivity to airborne allergens, are the primary determinants of lung impairment. The study, published in Clinical and Translational Allergy, found that individuals with early-onset asthma, even those whose asthma was in remission by age 19, exhibited lower lung function compared to those without asthma. Here's a more detailed breakdown: **Early-onset asthma and lung function:** The study specifically focused on the relationship between early-onset asthma and lung function in young adulthood. Early-onset asthma was defined as asthma that began in childhood. **Aeroallergen sensitization and lung function:** Contrary to expectations, the study found no significant association between aeroallergen sensitization (i.e., being sensitive to airborne allergens like pollen, dust mites, etc.) and lung function, regardless of the age at which sensitization occurred, according to the researchers of the study. **Implications:** This suggests that factors other than allergen exposure, potentially related to the inflammatory processes or airway remodeling associated with asthma, are more crucial in determining lung function in young adults with asthma, according to researchers at Umeå University. **Study limitations:** The study had a relatively small sample size, which may have limited the ability to perform more detailed analyses based on specific asthma phenotypes. **Clinical significance:** The findings highlight the importance of early asthma diagnosis and management, as early-onset asthma can have lasting effects on lung function.

Does Age Affect Care Outcomes in Patients With COPD on Noninvasive Ventilation?

Health-related quality of life (HRQOL) did not differ significantly between younger and older patients with chronic obstructive pulmonary disease (COPD) suffering from chronic hypercapnic respiratory failure receiving long-term noninvasive ventilation (NIV), despite a higher comorbidity burden in older patients. Researchers conducted a prospective, observational study to investigate the differences in HRQOL between younger and older patients with COPD and chronic hypercapnic respiratory failure receiving long-term NIV. They enrolled 237 patients between June 2015 and October 2021, with 41.8% enrolled as inpatients and 58.2% as outpatients, categorized into two age groups: younger (< 65 years) and older (≥ 65 years). HRQOL was assessed using the severe respiratory insufficiency (SRI) questionnaire, and factors affecting HRQOL—including anemia, autonomy impairment, exacerbation history, and comorbidities—were evaluated. A five-tier scale categorized autonomy impairments by severity, with level 1 denoting minor impairments and level 5 indicating the most severe loss of independence or ability, which poses substantial challenges

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for nursing care. No significant differences were found in SRI summary scores between age groups, despite older patients having a significantly higher burden of comorbidities (P = .014). Exacerbation frequency had a significant negative impact on SRI scores in both younger and older patients. Anemia was linked to a significant reduction in SRI scores only in younger patients, in whom it was more prevalent (29.1% vs 17.5%; P = .045). Any level of autonomy impairment negatively affected HRQOL in younger patients, whereas only higher levels (level of care ≥ 2) affected HRQOL in older patients. "Understanding of COPD with comprehensive care plans that address both medical and functional aspects, patient outcomes, and HRQOL might be improved," the authors wrote.

Continuous Positive Airway Pressure May Prevent Rise in Blood Pressure in Normotensive Sleep Apnea

Among normotensive patients with severe obstructive sleep apnea (OSA) and a dipping blood pressure (BP) pattern, continuous positive airway pressure (CPAP) prevented increases in BP over a 3-month follow-up period, with significant reductions in nighttime diastolic BP compared with usual care. Researchers conducted a randomized, prospective, controlled trial to assess the effect of CPAP on BP in normotensive individuals with severe OSA and a dipping BP pattern. Overall, 60 normotensive adult patients (mean age, 52.2 years; 66.7% men) with severe OSA (apnea-hypopnea index, ≥ 30 per hour) and a dipping BP pattern (reduction of ≥ 10% from daytime to nighttime BP) were randomly assigned to receive either CPAP or usual care for 12 weeks. Primary outcomes were changes from baseline to 3 months in ambulatory BP monitoring parameters: mean 24-hour BP; mean daytime and nighttime BP; 24-hour systolic and diastolic BP; and daytime and nighttime systolic and diastolic pressures. The secondary outcome was the change over 3 months in these ambulatory BP parameters according to adherence to CPAP, with a mean use of 4 or more hours per night defined as adequate adherence. Over the study period, the CPAP group showed no significant change in ambulatory BP parameters, whereas the usual care group showed significant increases in 24-hour systolic BP, mean nighttime BP, and nighttime systolic and diastolic pressures. The CPAP group had a significantly greater reduction in nighttime diastolic BP than the usual care group (mean difference, -3.4 mm Hg; P = .015), but no other BP parameters differed significantly. Participants with inadequate adherence to CPAP had significantly greater increases in mean nighttime BP, nighttime systolic BP, and nighttime diastolic BP than those with adequate adherence. "Overall, this randomised trial provides novel insights into the potential benefits of CPAP therapy as a preventive measure for the development of hypertension. Further larger studies, including a greater proportion of women and potentially guided by polysomnography-based phenotypes, are needed to better understand the impact of OSA therapy in individuals with normal BP," experts wrote in an accompanying editorial.

Health Platform Launched

Nonin Medical, a leading global manufacturer of wearable and noninvasive medical monitoring devices, has announced the launch of the Nonin Health platform. The purpose-built cloud-based data ecosystem and software platform is designed for durable and home medical equipment (DME/HME) providers, sleep dentists, and sleep labs. With more than 1.5 million Americans currently requiring supplemental oxygen and millions

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More options

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more managing sleep-related breathing disorders, health care providers face mounting logistical and economic obstacles in delivering efficient, high-quality service. The Nonin Health platform supports clinicians, homecare providers, independent diagnostic testing organizations (IDTFs), sleep dentists, and sleep physicians in managing overnight oximetry testing and follow-up care by accelerating the provision of supplemental oxygen for patients with chronic respiratory conditions and facilitating oral sleep appliance titration. By streamlining clinician workflows with centralized, cloud-based access to patients' data, the solution marks Nonin Medical's evolution from a trusted hardware manufacturer to a full solution provider in remote patient care.

"Many homecare providers, respiratory care clinicians, and sleep specialists rely on overnight oximetry testing to assess the need for oxygen therapy or evaluate the effectiveness of sleep therapy," says John Hastings, CEO at Nonin Medical. "However, this process often involves multiple manual steps, including shipping devices, retrieving and manually uploading data via USB, potential re-testing, and coordinating follow-up care. All of these tasks delay clinical decision-making and increase the workload for non-reimbursed services." The Nonin Health platform enables the remote delivery of overnight test results, reducing the need for physical pickups and minimizing delays in diagnosis. This efficiency-focused design is especially valuable for durable medical equipment (DME) and home medical equipment (HME) providers, who frequently conduct non-reimbursed overnight oxygen tests and face pressure to reduce costs per test. In addition, the Nonin Health software enables care providers to control their inventory of devices, ensuring all equipment is accounted for and synchronized with the correct patient accounts. The remote access to data and device inventory management significantly reduces administrative workload and costly retests. The mobile app-based platform allows patients to run and complete overnight oximetry tests prescribed by their healthcare providers using Android or iOS devices. It connects to Nonin's trusted WristOx2® Model 3150 via Bluetooth, allowing users to sleep normally while the oximeter works in the background, measuring SpO2 levels. Clinicians have immediate remote access to study results via a secure web portal upon completion of the overnight test. Michigan-headquartered CareLinc Medical Equipment is one of the first customers to leverage the Nonin Health platform. "The Nonin Health platform has significantly improved our overnight oximetry testing process. We've cut down the time it takes to assess a patient's therapy needs by several days. The platform requires fewer manual steps, less paperwork, and allows us to access results more quickly. This means we can return test results to the treating physician more quickly, helping to adjust patient therapy to meet their needs more effectively while reducing our workload. Nonin Medical is not just a device maker—they're truly a partner in enhancing respiratory care," says Chrysalis Ashton,

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MKT-01602 [A]

Director of Clinical Operations, CareLinc Medical Equipment. "At Nonin Medical, we have a strong legacy of developing top-tier oximetry hardware and software, including multiple industry firsts," Hastings continues. "However, realizing DME and HME's full value in today's healthcare landscape requires pairing devices with digital platforms for remote data retrieval and access. Co-developed in close collaboration with homecare providers and sleep professionals, Nonin Health is an example of an end-to-end software platform developed specifically to enhance patient care." Nonin Health is currently available exclusively within the United States. Future iterations may include support for additional markets, as well as expanded device compatibility.

Self-Management Asthma App Boosts Symptom Control in Adults

In adults with asthma, a digital asthma self-management (DASM) program improved symptom control compared with usual care, although its effectiveness varied by race, with weaker results observed among African American participants. Researchers conducted a randomized trial to evaluate the impact of a DASM program on symptom control among adults with asthma. A total of 899 participants (mean age, 36.6 years; 71.1% women; approximately 61.3% with uncontrolled asthma) were recruited via email between October 2020 and November 2021 to receive either the DASM program (n = 450) or usual care (n = 449). All the enrolled participants installed a custom smartphone app and utilized wearable devices during the trial. The DASM group received a full-featured self-management version with symptom tracking and alerts, whereas the usual care group received a limited version with only the asthma control test and collection of patient-reported outcomes. The primary outcomes included the 12-month change from baseline in asthma control test scores (scores ≤ 19 indicated uncontrolled asthma), and secondary outcomes included participants' counts of symptom logs and patient-reported outcomes. Among participants with uncontrolled asthma, the DASM intervention improved mean asthma control test scores by 4.6 points at 12 months compared with a 1.8-point improvement with usual care (adjusted difference, 2.8 points; $P < .001$). The treatment effect varied by race, with between-group differences in asthma control test scores showing improvements of 1.0 point ($P = .26$) in African American participants and 3.3 points ($P < .001$) in non-African American participants. Symptom logging rates were comparable across insurance and ethnicity subgroups, with no significant differences observed. However, African American participants logged symptoms less frequently than non-African American participants. Patient-reported outcomes—self-reported medication adherence, readiness to change self-management behaviors, confidence in the ability to manage one's health, and asthma-related work productivity impairment—also favored the DASM intervention over usual care ($P \leq .001$ for all). "Findings reveal an opportunity to adapt the DASM program for more consistent effects throughout diverse populations. Future research is needed—quantitative and qualitative—to elucidate causes of differences in outcomes," the authors wrote.

Continued on page 34…

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Product availability may vary from country to country and is subject to varying regulatory requirements.

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Archeon Medical

Booth 618

What products will you be presenting at AARC?
Archeon Medical will be presenting our range of Ventilation Feedback Devices, including the **EOlife**® (clinical device) and **EOlife X** (training device), designed to optimize manual ventilation and improve patient outcomes during emergency and critical care situations.

Discuss educational/training materials you'll be offering.
We will provide hands-on demonstrations and educational materials focused on improving manual ventilation practices. Attendees will have access to digital resources and real-time simulation exercises.

What speakers or papers will you be featuring?
We will highlight a groundbreaking position paper in the *European Journal of Emergency Medicine*, authored by a renowned group of scientists from around the world. The paper strongly advocates for the universal adoption of Ventilation Feedback Devices (VFDs), showing they can triple survival rate and boost favorable neurological outcomes by up to five times. This global endorsement reinforces the critical role of **EOlife**® in modern resuscitation practices. Visit our booth to learn how these findings can transform your clinical protocols.

Why should AARC participants visit your display?
Participants should visit our booth to experience firsthand how real-time feedback and smart technology can significantly improve manual ventilation and resuscitation performance. Our team will be available for live demonstrations, Q&A sessions, and to discuss tailored solutions for hospitals, EMS providers, and training centers.

Atos Medical: Tracoe

Booth 804

What products will you be presenting at AARC?
We will be showcasing our entire line of tracheostomy care products including:

- Pediatric tracheostomy tubes
- Adult tracheostomy tubes
- TrachPhone HME
- PhonAssist Speaking Valve
- Freevent XtraCare HME (adult)
- Freevent XtraCare Mini HME (pediatrics)
- Dual Care HME/Speaking Valve
- Neckbands and dressings

Visit the Tracoe booth to see and feel the full range of our products. Our team will be available to demonstrate their use and function and answer questions about how they can best support your patients' needs. We are excited to showcase TrachPhone, our multifunctional HME. TrachPhone HME helps to return humidification and warmth to the air patients breathe through a tracheostomy tube. In addition, the TrachPhone HME

is equipped with a speaking valve, integrated suction port, and oxygen port. We are excited to share more about the TrachPhone HME and help discuss how your patients can benefit from this versatile HME!

Discuss educational/training materials you'll be offering.
Our Tracoe team will be available to provide an overview of all Tracoe products currently available. Products will be available for hands-on learning and education. Additionally, both in-depth product handouts and full Tracoe tracheostomy catalogs will be available. QR codes will be at the booth to scan for information that can be accessed on your mobile device for easy storage and to share with colleagues.

What speakers or papers will you be featuring?
We will feature the article Adoption and Utilization of Heat and Moisture Exchangers (HMEs) in the Tracheostomy Patient and will have a Clinical Summary of this article on hand. The summary provides an overview of Kearney et al.'s 2023 study on the use of TrachPhone HMEs compared to active external humification and highlights key findings and benefits of TrachPhone HME.

Additionally, we are featuring an article in this publication, "Optimizing Patient Outcomes with the Tracoe Twist Plus Tracheostomy Tube". Check it out to learn about the exciting features and benefits of this tracheostomy tube! We are most excited to talk about the importance of humidification and filtration for patients with a tracheostomy. Our Tracoe HMEs all effectively provide heat and humidity to the air your patients breathe through a tracheostomy tube. We want to help you think about how your patients can utilize Tracoe HMEs in their daily life.

Why should AARC participants visit your display?
Take this opportunity to learn about Tracoe tracheostomy tube availability, product features and benefits, overall service, and clinical education. Our team will be available to talk through specific patient scenarios, discuss how to start implementing Tracoe products in your facility, and discuss opportunities for site visits and hands-on training with your entire team. We hope to see you there!

Passy Muir

Booth 716

What products will you be presenting at AARC?
Our full line of tracheostomy products including our new APF filter and HME.

Are there any new products you wish to emphasize?
The new Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15), is designed to fit onto the 15mm hub of a tracheostomy tube and effectively filters out >99.9% of all airborne particles.

Intended for use in clinical settings including hospitals, sub-acute, rehabilitation, outpatient, skilled nursing and home setting, the new Heat Moisture Exchanger (HME) is designed to be positioned on a tracheostomy tube to warm and humidify gases breathed in by a patient. Both products are latex free and made in the USA.

Discuss educational/training materials you'll be offering.
Badge Buddies, Visual Use Guide, Pocket Guide

Why should AARC participants visit your display?
Engage with our clinical specialists in person, have your clinical questions answered, participate in hands-on educational opportunities and check out our full-line of tracheostomy and educational product offerings.

Spirometry

Booth 838

What products will you be presenting at AARC?
MIR will be showcasing its full range of advanced spirometry solutions. These products are designed to support accurate pulmonary diagnostics in both clinical and remote care settings. We will also present our MIR Plus Line, the latest evolution in spirometry, delivering enhanced features and expanded connectivity.

MIR Original Line
- Spirolab (oximetry option)
- Spirodoc with oximetry
- Spirobank ll Smart (oximetry option)
- Spirobank ll Basic
- Minispir
- Spirobank Smart
- Spirobank Smart Oxi
- Smart One

MIR Plus Line
- Spirolab Plus (oximetry option)
- Spirobank ll Plus (oximetry option)
- Spirobank ll Light
- Minispir Plus
- FlowMIR Plus

Are there any new products you wish to emphasize?
Yes, we are excited to highlight the MIR Plus Line of spirometers. This next-generation line integrates seamlessly with telehealth platforms and EMRs, offers optional oximetry, and provides real-time data for physicians and patients alike. The new RFID FlowMIR turbines do not require calibration and have perfect sensitivity to low flows. This reflects MIR's ongoing commitment to innovation in respiratory care.

Discuss educational/training materials you'll be offering.
Visitors will have access to a variety of training and support resources, including brochures, spirometry quick guides, and information on integrating MIR spirometers into remote patient monitoring (RPM) programs. Our team will also provide live demonstrations and answer questions about maximizing device performance.

Why should AARC participants visit your display?
AARC attendees should visit our booth to explore how MIR's spirometry solutions can elevate their respiratory care programs. Whether you're focused on in-clinic diagnostics or expanding into RPM, MIR provides trusted, FDA-cleared devices that deliver reliable, real-time results. Plus, attendees can get a hands-on look at our newest innovations and learn how to integrate them into practice with ease. We welcome all AARC participants to stop by and experience the future of pulmonary diagnostics.

Better Ways Needed to Identify Patients With COPD

Reply to Paul Jones: "Using Symptoms Together with Peak Flow Measurement to Identify Patients Who Require Spirometry to Confirm COPD"

Alex Stenzler

Paul W Jones, PhD, FRCP from the Institute of Infection and Immunity, City St George's University of London, published an editorial in the *American Journal of Respiratory and Critical Care Medicine* on the worldwide problem of access to spirometry (https://www.atsjournals.org/doi/10.1164/rccm.202502-0431ED?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed).[1] He states that spirometry is labor-intensive in terms of time and technician skill set in all health economies, so a process for efficient case finding is required. The editorial proposes that measurement of peak expiratory flow (PEF) alone is insufficiently well correlated with FEV1:FVC ratio to be an adequate screening surrogate. However, he suggests that the combination of PEF and a 50-question assessment of symptoms using the St George Respiratory Questionnaire can better identify patients in Primary Care who should have diagnostic spirometry performed, even though he states that it does not seem logical to use a 50-item instrument for this, because it is time consuming to administer, which will undoubtedly form a barrier to its use. There have also been previous attempts to create screening tools using briefer symptom questionnaire and PEF, however, these as well have not been effective at confirming COPD.[2,3] Neither of these efforts, and particularly with the diagnostic limitations of PEF measurements, can diagnose COPD, but only create a greater need for evaluation by pulmonologists or testing at pulmonary laboratories.

Jones has correctly identified the need to identify patients with COPD and who would benefit from diagnostic spirometry. However, his solution does not solve the problem, at least not in the United States. The need for a program for patients with lung diseases such as asthma and COPD is considerable. The NCHS (2023) reported more than 27 million people in the US have asthma.[4] Almost 15.7 million Americans (6.4%) reported that they have been diagnosed with COPD. More than 50% of adults with low pulmonary function were not aware that they had COPD, so the actual number may be higher.[5] Additionally, pulmonologists have patients with other respiratory disorders, including the 250,000 new lung cancer cases a year and an estimated 654,841 cases of interstitial lung disease.[6,7] Therefore there are at least 43 million patients in the US that require pulmonary disease management.

However, to manage those 43 million patients, there are only 4,867 (2021 data[8]) active pulmonologists who each would need to see nearly 9,000 patients on an annual basis. And the situation with pulmonologists is only getting worse as they are becoming an endangered species. In 2019, there were 5,104 pulmonologists and the 2021 data reflects a net loss of 237 pulmonologists (5%).[8] Additionally, it is the oldest specialty with 92% of pulmonologists over the age of 55.[9] Pulmonary training programs are not producing pulmonologists at a rate to keep up with their retirement rates. Therefore, a system as suggested by Mr Jones that better identifies patients who need to be seen by pulmonologists for spirometry, only increases the pressure on pulmonologists and pulmonary laboratories. An analysis of national data on the time from the initial clinical impression to definitive diagnosis of COPD showed taking an average of six to seven months and during that delay period, around a 60% incidence of ER visits.[10]

The actual need is not to identify more patients that should be referred for spirometry, but to develop a functional platform for primary care physicians (PCP) to perform spirometry testing in their offices so as to triage only those patients who really need to see a pulmonologist or be tested in a pulmonary lab. There are approximately 135,000 family practice and internal medicine practices in the US. The moderately severe and severe patients can appropriately be referred to pulmonologists, while the mild and moderate patients can be managed by the PCP with treatment support. Developing this capability is critical to the US healthcare system.

There is technology available today, using avatars and AI that can collect ATS/ERS quality spirometry without the need for highly trained laboratory personnel.[11] The avatars coach patients through their Bluetooth linked spirometry measurements knowing exactly where the patient is within the breathing maneuver, and can coach the patient through the measurement. They know whether the patient held their breath too long, didn't blast the air out, and if the patient has reached a plateau on

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exhalation. They can encourage the patient to keep blowing until a plateau or 15 seconds of exhalation has been reached. A review of the measurement against ATS/ERS requirements can inform the patient if they did something wrong and how to correct the maneuver. This can produce hospital quality data, and following the ATS/ERS interpretation strategy guidelines, can provide the PCP with an automated clinical impression that can also include recommendations for pulmonologist referral or the need for lung volume measurements.

The first principle regarding the importance of screening is that if you don't know the disease is there, you can't manage it. I firmly believe that if we can identify lung disease early, and most importantly, where the patients are most likely to be seen, we can have a significant impact. Getting gold standard spirometry in the PCP office is the key to affecting this impact.

Note: Bluetooth is registered trademark of Bluetooth Sig, Inc.

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Integrating Myofunctional Therapy Into Airway Care: A Case for Obligate Nasal Breathing

Shirley Gutkowski, RDH, BSDH, AOMT-C

Proper oral rest posture promotes obligate nasal breathing, a cornerstone of systemic health.[1] The primary role of a dental hygienist is to prevent disease and help patients prevent the need for restorative care.[2,3] In this article, we explore the evolution of oral health practices from the late 1990s to today, highlighting the shift toward orofacial myofunctional therapy. Read on to discover how the modern model of dental hygienists working with respiratory therapy can improve patient outcomes.

The mouth is the evolutionary emergency hatch for breathing, but chronic oral breathing leads to low oral pH and creates an oral environment favorable to pathogens that lead to dental decay and periodontal disease, and it breeds pathogens associated with pneumonia and ear infections,[4,5] eventually giving respite to pathogens that have been found in cardiovascular and cerebral lesions.[6,7]

Addressing the bacteria responsible for oral diseases traditionally relied on broad-spectrum mouthwashes that are "mostly effective" but not specific. They damage tissues and kill commensal species critical for a balanced microbiome. Recent trials find that daily use of alcohol-based and chlorhexidine rinses reduces overall microbial diversity, wiping out beneficial bacteria and risking dysbiosis.[8,9]

Once Costerton described biofilm as an eco-dome protecting bacteria from up to 10,000x the strength of antibiotics used to safely treat infections, the game had to change.[10,11] Costerton found that certain bacteria gathered to launch the biofilm; Streptococcus species were on that list of early colonizers. In the right low-pH environment, the early colonizers produced a sticky matrix protecting the colony as the inhabitants called for more and more diverse bacteria into the matrix. Disease is not caused by a single species but by complex, protected biofilm communities.

About the time biofilm's defensive nature was entering medicine and dentistry, free thinkers developed a field study to alter the biofilm, and they began to show that xylitol chewing gum can alter it. In the late 1990s, Söderling and colleagues showed that mothers chewing xylitol gum significantly reduced mutans streptococci in both themselves and their children, confirming that decay is transmissible.[12] They used the gum given to mothers to show a lowered number of the early colonizer found in dental decay, Streptococcus mutans, in their children—confirming that dental decay was transmissible.[12]

By chewing xylitol gum three times a day, mothers drove down salivary mutans streptococci counts by nearly 80 percent as compared to control mothers who had fluoride varnish applied quarterly. When sharing utensils or kisses, far fewer cariogenic bacteria transferred to their children. A few years later, follow-up research reported a 70 percent reduction in decay in those children whose mothers chewed xylitol gum compared to controls.[13] A 2015 meta-analysis of eleven randomized controlled trials confirmed a 40–60 percent reduction in early colonization and a lasting decay reduction.[14,15]

What was xylitol doing? Xylitol hijacked the sugar-uptake systems of early colonizers. Streptococcus mutans particularly preferred xylitol for energy, trapping them in a "futile cycle" that drained their energy.[16] With pioneer cells starved, the sticky matrix never formed. Without a mature biofilm, there are fewer protected niches for pathogens to hide behind and survive brushing or host defenses.[17]

According to Socransky and Haffajee's model, biofilms in periodontal pockets mature through color-coded "complexes," shifting from health-associated to disease-driving communities.[18] Next-tier orange-complex bacteria like Fusobacterium nucleatum and Prevotella intermedia are central to periodontal breakdown and were recovered from coronary artery lesions in atherosclerosis patients.[19] The red-complex tier, the most damaging level, includes Porphyromonas gingivalis, Tannerella forsythia, and Treponema denticola and correlates with advanced periodontal disease and systemic inflammation; P. gingivalis DNA and antigens appear in atheromatous plaques and Alzheimer's-affected brain tissue.[20,21] Additionally, members of the early colonizer Streptococcus anginosus group have been implicated in increased stroke risk and poorer post-stroke outcomes.[22] So, affecting the early colonizers should be job one! It is hard to get into the interior of a mature biofilm to attack this or that species.

Xylitol strikes at the biofilm's foundation, blocking energy production in early colonizers—including Streptococcus species, Actinomyces viscosus, and Haemophilus influenzae—so the matrix never matures.[23,24] No mature biofilm means fewer cavities,[25] less chronic sinus inflammation,[26] and an easier job for our defenses to clear unattached bacteria.[27]

Author information at the end of this article.

This was also the moment when xylitol nasal spray entered dental clinical practice. Dental hygienists assess oral breathing, often by gingival color, and encourage patients to stop mouth breathing. Recognizing that nasal obstruction can prevent this, clinicians began using xylitol nasal spray to reduce nasal mucus obstructions. The spray thins out thick mucus made by the goblet cells and seromucous glands while disrupting pathogenic biofilms in the nasopharynx—making Streptococcus pneumoniae and Haemophilus influenzae more vulnerable to immune clearance[28,29] while maintaining a healthy microbiome.

Many hygienists then embraced orofacial myofunctional therapy to support the airway—re-establishing muscle harmony of the nose, lips, tongue, and pharynx.[30,31]

Chronic oral breathing, especially in children, alters craniofacial development. The tongue rests low instead of supporting the palate, leading to a high-arched, narrow maxilla. This deformation reduces sinus volume, compromises airflow, and contributes to congestion, sleep-disordered breathing, and increased susceptibility to upper respiratory infections.[32,33]

Focusing on nasal breathing makes it imperative that the nasal passages remain clear and structurally supportive. The sinuses should be free of anatomical obstructions like a deviated septum, enlarged turbinates, or ostiomeatal complex narrowing. The paranasal sinuses produce nitric oxide, our first line of defense against airborne bacteria and viruses.[34] Xylitol nasal irrigation has been shown to increase nasal nitric oxide levels, upregulate inducible nitric oxide synthase mRNA, and improve mucociliary clearance in chronic rhinosinusitis patients.[35]

One interesting case is Brianna, age 43. She had teeth removed as a child to accommodate an underdeveloped maxilla and suffered from an unreleased tongue tie, forcing the tongue into her pharyngeal airway and setting the stage for apneas.[30,36] She quickly preferred xylitol nasal spray, which relieved excessive nasal mucus and gave her myofunctional therapy a running start to resolving oral breathing.[29,27]

Matt, age 43, presented with severe sinus blockages on CBCT—his right maxillary sinus completely obstructed, the left one-third blocked, and the ostiomeatal complex severely inflamed. His sleep apnea exceeded 60 respiratory events per hour, and he could not tolerate CPAP. He required three root canal retreatments (infecting his sinuses) and sinus surgery to remove inflammatory tissue and reduce turbinate size. Postoperative use of xylitol nasal spray—shown to accelerate healing, reduce crusting, and decrease turbinate inflammation—was prescribed.[37] Discomfort forced oral breathing for four weeks, and he never established a consistent spray routine. He continues to experience nocturnal oxygen desaturations below 90 percent for 30–90 minutes nightly, as measured by a Circul+ ring.

Joan, age 72, presented for myofunctional therapy with sleep apnea causing brain fog and daily misery. She was referred for an ENT evaluation resulting in a similar surgery to Matt. Joan used xylitol spray before and after her procedure with excellent results. She recovered quickly, tolerated CPAP, and saw a 50 percent improvement in sleep scores even before full healing. Ongoing spray use keeps her sinuses clear.

Summary

Orofacial myofunctional therapy represents a promising frontier in integrative airway care, yet its full potential remains understudied. Respiratory therapists are uniquely positioned within this kaleidoscope of collaborating practitioners to design and implement robust clinical trials.[38,39] While xylitol-based sprays (e.g., Xlear),[40] silver colloids[41] (indiscriminate bactericide), and hypochlorous acid solutions [41] (less harmful to the microbiome) each show antiseptic and biofilm-disrupting properties, isolating the individual effects of these interventions in real-world settings remains difficult.

Given its safety profile, ease of use, and broad antimicrobial action, xylitol nasal spray serves as an ideal candidate—offering near-universal applicability as both a standalone intervention and an adjunct to orofacial myofunctional therapy.

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About the author

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Over the last decade, Shirley has specialized in integrating orofacial myofunctional therapy into clinical airway management. Her passion emphasizes how nasal breathing supports optimal oral pH, reduces pathogen load, and improves systemic health, and she is an advocate for multicenter trials comparing topical antimicrobials, breathing-retraining exercises, and nasal-clearance techniques.

A vocal proponent of interprofessional practice, Shirley developed The Kaleidoscope Collaboration to eliminate care fragmentation and empower all health care with evidence-based myofunctional protocols. She holds a Bachelor of Science in Dental Hygiene from Marquette University, Orofacial Myofunctional Therapy certification from Academy of Orofacial Myofunctional Therapy (AOMT), and Advanced Orofacial Myofunctional Therapy credentialing (AOMT).

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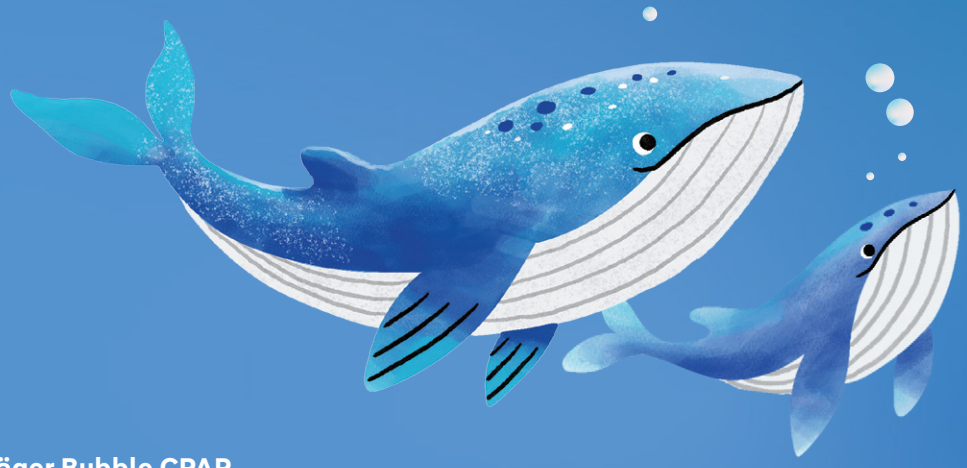

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Aerosol Therapy Protocol in Patients With Acute Respiratory Failure With and Without Non-Invasive Mechanical Ventilation vs High Flow

Gonzalo Sempere Montes and José Manuel Carratalá Perales

Definition

The inhalation route is commonly used to administer drugs in the treatment of many respiratory diseases (COPD, asthma, etc.).

Aerosol therapy is a form of treatment based on the administration of drugs in aerosol form via inhalation. An aerosol is a stable suspension of solid or liquid particles in air or other gas such as oxygen. Inhalers are devices used to generate aerosols of solid particles that can be inhaled and nebulizers are devices responsible for generating aerosols of liquid particles.[1]

This protocol focuses on nebulization systems. We consider them to be ideal from a feasibility perspective in situations of acute respiratory failure, where patient cooperation with other devices may be impossible or very difficult. The protocol considers patients with or without non-invasive mechanical ventilation (NIMV) vs high flow nasal therapy (HFNT).

Determining factors and nebulization systems

The success of aerosol therapy relies on an adequate amount of the drug reaching the alveolar bronchioles. This is known as pulmonary deposition (PD). There are many factors that determine the extent of PD (Table 1).

Table 1. Determinants of pulmonary deposition of drugs.

Related to the patient	Severity of airway obstruction Presence of secretions Presence of dynamic hyperinflation Patient-ventilator synchrony * Patient's breathing pattern (Vt, RR, inspiratory flow and Ti) *
Related to the inhalation system	Type of device used (MMAD) Filling volume Gas flow Residual volume
Related to the ventilator, interface and tubing	CPAP level and pressure support* Leaks * Temperature and humidity ** Location of the aerosol therapy system * Type of mask *

Vt. Tidal volume; Ti. Inspiratory time; * Patient with NIMV ** It is likely that humidification has little effect on PD, as some in vitro studies have pointed out.[6] MMAD: mass median aerodynamic diameter. RR: respiratory rate.

Gonzalo Sempere Montes – Dr. Peset University Hospital Valencia
José Manuel Carratalá Perales – Dr. Balmis General University Hospital Alicante.

From a methodological point of view, we are primarily interested in the type of device used and the factors that are present during NIMV.

The type of nebulization device must be capable of delivering the majority of the drug loaded into the system (nominal dose), minimizing expiratory losses and residual volume in order to obtain the maximum inhaled dose. Only a percentage of the inhaled dose will reach the terminal airway and achieve the therapeutic effects. This is known as the breathed dose or pulmonary deposition (PD). PD will depend, *inter alia*, on the particle size generated by the nebulization system or MMAD. Particles > 5 µm impact the airway and are responsible for side effects. Particles between 1-5 µm reach the lower respiratory tract (respiratory particles) and are responsible for the therapeutic effect. Particles <1 µm are too small to be deposited and 80% are exhaled. It is recommended that at least 50% of the particles generated by the nebulizer should be < 5 µm.

There are various kinds of nebulization system. These are listed in table 2. The most frequently used ones are shown in Figure 1.

Table 2. Main nebulization systems.

Jet or pneumatic nebulizer	With continuous flow With active Venturi effect during inspiration Dosimetric or adapted delivery
Ultrasonic nebulizer	
Mesh nebulizer	Static mesh Vibrating mesh

Due to their affordability, continuous flow gas-powered jet nebulizers (oxygen or medical air) are the most commonly used in the hospital environment. They generate a continuous aerosol flow, in both the inspiratory and expiratory phases, which results in a large part of the aerosol being lost to the environment, especially during expiration.

Ultrasonic nebulizers, widely used in home therapy, denature certain drugs by heat, generate a lot of mist loss and achieve a low level of pulmonary deposition,[2] which is why they are not recommended in NIMV.

Mesh nebulizers (static or vibrating) are based on a 5 mm diameter circular sheet of palladium with 1000 micro-perforations. This sheet acts like a mesh, so that the aerosol is generated when the liquid to be nebulized passes through the holes in the sheet. The vibrating mesh aids the sieving process as it is capable of vibrating 128 times/sec.

Mesh nebulizers are much more effective than jet nebulizers in all in vitro studies, in that they manage to double the inhaled dose, while minimizing expiratory loss both in NIV and non-NIV situations.[2-4]

Aerogen Solo® mesh nebulizer Jet nebulizer

Figure 1. Nebulization systems.

Nebulization in patients with non-invasive ventilation

NIV should not be discontinued to administer aerosol therapy during NIV.

A) Choice of system

The performance of nebulization systems diminishes during NIV. Nonetheless, mesh nebulizers are more effective than continuous flow jets, with a higher inhaled dose (23.1% vs 6.1%) and a higher PD (5.5% vs 1.5%).[4] They require up to 2.5 times less nominal dose of the drug and side effects are reduced when continuous nebulization is required.

For all these reasons, the mesh nebulizer will be the nebulizer of choice for patients with NIV (Figure 3).

B) Application of the technique

1. Minimize peri-mask and circuit leaks.
2. With an in-line expiratory port, we will place the nebulizer between the port and the mask. With jet systems, expiratory losses have been found to be lower here than if we place the nebulizer distal to the port[2,7] (25% vs 37%). Ventilated masks (with an expiratory port) have a loss of 12%.[7]
3. Fill the nebulization chamber with a volume of between 4 and 6 ml (jet nebulizer) or 6 ml (Aerogen Solo® mesh nebulizer). The nebulization chamber must be kept vertical (Figure 2).
4. Select optimal pressures for aerosol delivery. A CPAP of 5 cm H2O or BiPAP of 15/5 H2O are those that deliver the highest percentage of nominal dose.[7]
5. Minimize the temperature if using active humidification systems.
6. Switch on the current generator (mesh system) or open the gas flow to 6–8 lpm (jet systems) to start nebulization of the drug.
7. To avoid adding dead space to the circuit, remove the system when nebulization is complete.

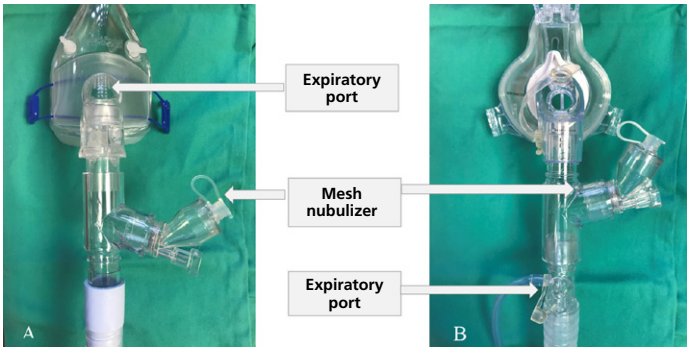

Figure 2. Assembly of a mesh nebulizer with expiratory port in mask (A) and in-line (B).

Nebulization in non-ventilated patients

A) Choice of system

In vitro studies show that the greatest efficiency (delivery of percentage of nominal dose) is obtained using a mesh nebulizer with valve mask or pipette with no added O2 flow.[3]

A recent study has shown that, compared with a jet nebulizer, a mesh nebulizer used in an emergency department results in a lower percentage of admissions and shorter emergency stays, as well as reducing the dose of drug required to resolve the clinical picture.[5]

Since they are more effective, it is recommended that mesh nebulizers should be used instead of jet nebulizers where serious factors are present such as respiratory failure in gasometry, risk of bioaerosol contagion or admission to critical care units (Figure 3).

B) Application of the technique

1. Assemble the mesh or jet nebulization system (Figure 4).
2. Whether using a mouthpiece or mask, it is important to instruct the patient to inhale through the mouth throughout the treatment.
3. To avoid depositing the aerosol on the face, eyes and nasal passages, the use of a pipette or mouthpiece is preferable. With a mesh nebulizer, if the situation permits, it is preferable for the patient to use a pipette with a spacer bottle not connected to O2.
4. Fill the nebulization chamber with a volume of between 4 and 6 ml (jet nebulizer) or 6 ml (Aerogen Solo® mesh nebulizer). The nebulization chamber must be kept vertical. Remember that mesh nebulizers are more effective than jet nebulizers, so 2 mg of a nebulized drug with a mesh nebulizer is equivalent to 5 mg with a jet.
5. Select a flow of 6 to 8 lpm (jet) or switch on the generator (mesh)

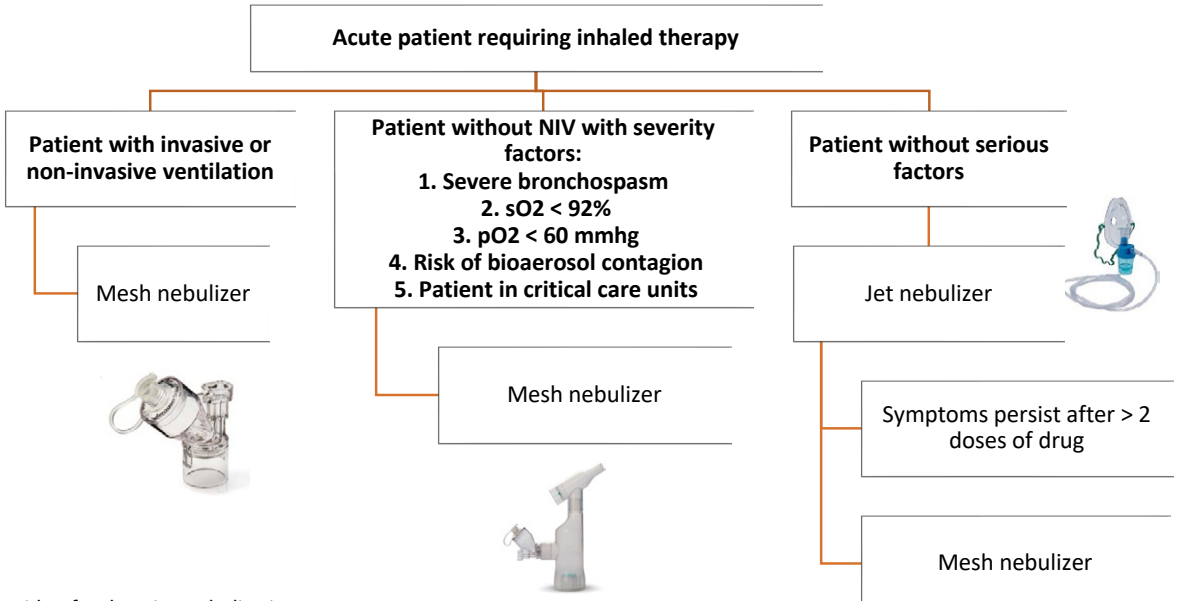

Figure 3. Algorithm for choosing nebulization system.

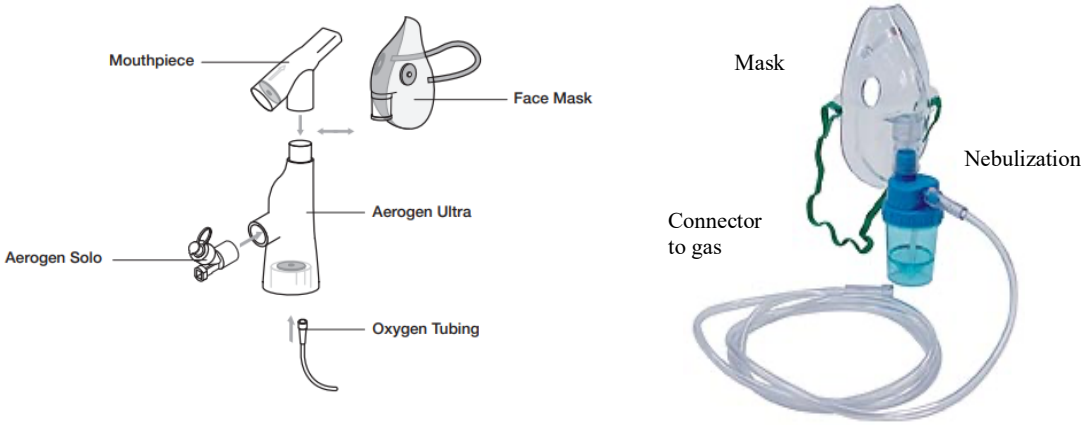

Figure 4. Assembly of mesh and jet nebulizer for patients without NIV.

Nebulization in patients with high-flow nasal therapy

As in patients with NIV, it is not recommended to discontinue high-flow nasal therapy (HFNT) in order to administer aerosol therapy. However, from a methodological point of view, there is not as much evidence as regards patients with NIV or non-ventilated patients.

There are a series of recommendations on location, type of nebulization system and optimal flow that need to be considered:

1. Vibrating mesh systems are more efficient than jet systems when connected in line with the HFN (PD of 2%-12% vs 1%).[8-10]
2. The mesh nebulizer must be placed before the humidifier ("dry branch" of the circuit)[10] (Figure 5). Some active humidification systems have a port directly in the humidification chamber or at its outlet, although this is not ideal. One option is for the patient, during high-flow therapy, to use the mesh with a pipette connected to a nebulization chamber.[11]
3. To optimize PD, during nebulization we will need to adjust the gas flow to the patient's inspiratory flow and ask the patient to breathe with the mouth closed. Usually in a work-of-breathing situation, we will program 30 bpm but with a eupneic patient 10 bpm can be programmed.[10]

Nebulization and risk of bioaerosol contagion during non-invasive ventilation

The risk of bioaerosol contagion is another factor to be considered when choosing the system to be used to administer aerosol therapy.

In NIV, turbulence is generated in the gas flow during pressurization. In jet nebulizers, these turbulences result in a large deposit of the drug in the tubing and mask and a greater loss of the drug during expiration. This greater dispersion of the drug would entail a greater risk of bioaerosol contagion.

The mist generated by mesh systems is finer, contains a greater number of drug particles and a laminar flow situation is maintained for longer. All of this means less contact with the components of the pressurized circuit, reducing deposits in the tubing and mask and expiratory losses and therefore the risk of bioaerosol contagion.[6]

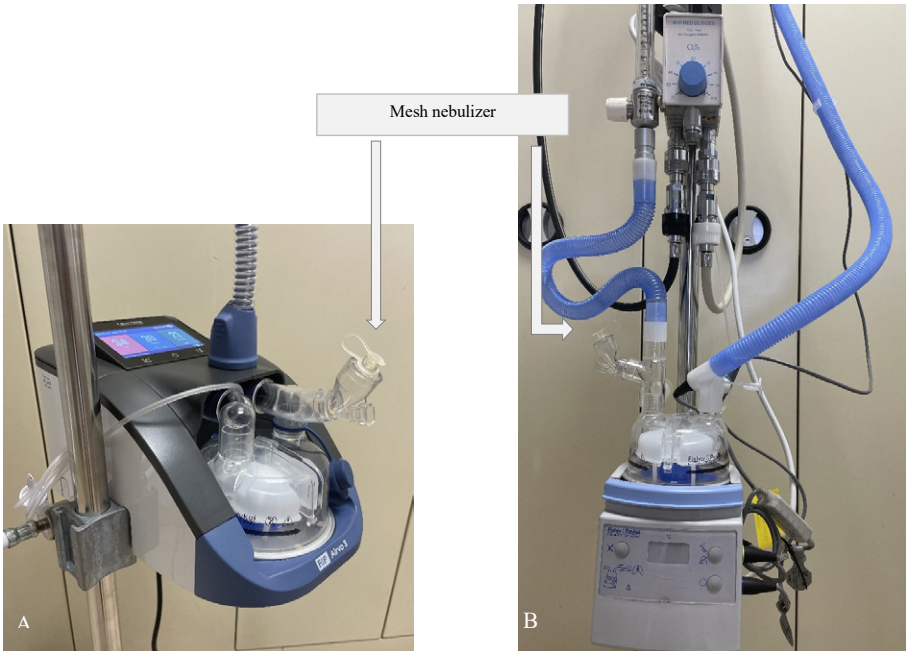

Figure 5. Assembly of mesh nebulizer for a patient with high flow nasal therapy. F&P Airvo 3 compact system (A) and modular system (B).

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Building Trust in New Technology: One NICU's Experience With TCOM

A Q&A with the NICU Team at Woman's Hospital

The NICU team at Woman's Hospital in Baton Rouge, Louisiana, reintroduced transcutaneous CO_2 monitoring ($TcPCO_2$) as part of a broader harm-reduction initiative and reduced blood gases performed in their NICU by 50%. In this conversation, NICU team members Mark Schorr, RRT, and Meagan Dexter, RNC-NICN, reflect on the challenges, breakthroughs, and process changes that helped make the technology effective and sustainable. This interview has been lightly edited for clarity, grammar and length. Ellipses (…) and brackets [ ] indicate minor editorial changes made for clarity or to reflect the structure of the conversation. The clinicians interviewed were not compensated by Sentec and do not have a financial relationship with the company.

Why CO_2 and Why Continuous?

Sentec Education Team (SET): Why is CO_2 such a critical parameter in neonatal care, and what makes continuous monitoring particularly important for extremely premature infants?

Mark Schorr, RRT: Most of the premature babies' problems are respiratory in nature. Their lungs are not developed enough, so they all need support. And we'd struggled for long periods of time with trying to prevent lung problems. We'd had O_2 saturation monitoring for decades, and hadn't had the ability to measure CO_2 other than drawing a blood gas, which is pretty invasive, and a point-in-time measurement. The ability to monitor CO_2 and see the impact of the changes we make with the ventilator guides us as we try to deliver the safest ventilation strategy possible to help prevent lung damage.

Meagan Dexter, RNC-NICN: The main focus from the nursing perspective is to not have as many pokes and blood draws for our babies. Regardless of whether or not the infant has a line in, you're still making hemodynamic changes by drawing blood from that baby. If you draw too fast, the vessels in those [premature] babies' brains are extremely fragile, and any drawing of blood from those infants can shift blood volume in these fragile vessels and cause damage. So this was a way for us to minimize those things, and to see how the baby was reacting to the changes that were being made.

Mark Schorr, RRT: I've been in this business for over 30 years, and I didn't realize the effects we can have on the neonatal brain. When we have to draw so many blood gases, we're changing the wiring of the baby's brain. Over the course of time that a baby is in our unit, by reducing the pokes and sticks, that means less negative wiring of the baby's brain. I think we really learned that just in the last 10 years.

The Quality Improvement Initiative

The successful initiative undertaken by the team at Woman's Hospital is outlined in detail in their white paper "Reducing Pain in the NICU: A Quality Improvement Initiative" which is featured in the 2025 Summer issue of Neonatal Intensive Care.

The paper outlines the broader clinical context and data behind their unit's effort to reduce invasive procedures and improve outcomes for extremely low birth weight infants.

The initiative by the the NICU team at Woman's Hospital allowed them to:

- Reduce blood gas draws by over 50% in extremely premature infants
- Build clinical trust in $tcPCO_2$ monitoring across RT and nursing teams
- Standardize CO_2 monitoring protocols to limit noxious stimuli
- Empower staff to use real-time, noninvasive CO_2 data for clinical decision-making

Read the paper here: nicmag.ca

Why the First Attempt at Adoption Failed

SET: Previously your team tried adopting transcutaneous CO_2 monitoring, and it didn't pan out. What do you think was the difference the second time around? Did you make specific changes in your approach?

Mark Schorr, RRT: I remember that when we first installed transcutaneous monitoring, we were taught to use saline [instead of contact gel, where the sensor makes contact with the patient's skin], and that did not allow us to get accurate measurements. So people thought, "*This is not going to work. I don't believe these measurements*." So we were provided the wrong education, but also no one in our unit had experience with transcutaneous. But they had tons of experience with blood gas. Everybody—especially RTs—had a lifetime of experience with drawing blood gases, but nobody had an idea of how they could depend on transcutaneous monitoring. They didn't understand how the technology worked. It took a lot of education to get them to understand that transcutaneous CO_2 measurements

were reliable. So, it took education, time, and a whole lot of data, as we mentioned in our webinar and paper, to make them understand that this really works.

Starting Fresh, With the Right Strategy

SET: Were the two of you the ones who were the first to say, *"Hey, let's try it again?"*

Mark Schorr, RRT: The NICU director brought it up. We had done a lot of work on improvement in our unit on all kinds of different things, and we had moved to a more volume-targeted ventilation strategy. The director wanted to have continuous CO_2 monitoring along with this initiative to change ventilator strategy. I said, "*Okay, if we're going to do this, then we have to do it a different way [this time]*." We're going to have to do it in a way using all the things that I had learned from my experience with quality improvement over the last 10 years. That's the only way I know. And it worked out.

SET: So the NICU director introduced it as you were changing focus to a new ventilation strategy, as an improvement initiative, and when you launched it, you wanted to focus on good education: how to use the monitor, and get accurate readings?

"We have found that face-to-face education is the most important. It allows for people to voice their concerns, ask questions, and think of things that maybe we didn't think of initially."

Mark Schorr, RRT: And the timing was right. Our RTs—all of our staff—had been developing a mentality of less harm. We developed a mental state: less harm is better for the babies. So it was an easier sell to the staff, I guess, because everybody wants the best for the babies, right?

SET: That makes sense. There's already a culture shift happening.

Mark Schorr, RRT: Yeah, I believe so. Definitely.

Training and Education at Scale

SET: As leaders on your staff, how many people—RTs and nurses—are we talking about trying to get educated when you started this protocol?

Meagan Dexter, RNC-NICN: We have almost 300 nurses.

Mark Schorr, RRT: We have about 50 RTs.

SET: So how do you ensure, once you've created the initiative and are rolling it out, that 350 people stick to it?

Mark Schorr, RRT: Well, we collected and presented a lot of data.

Meagan Dexter, RNC-NICN: And from the nursing perspective, we had some champions—just a few people who would check on other nurses caring for small babies and say, "*We're trying to do this process. We need you to stick to it.*" If they saw the protocol not being followed, they'd ask, "*What happened? Why did we deviate from the plan*?" If our people aren't following what we need to do, how do we change that?

Mark Schorr, RRT: And the quality improvement team met regularly. We were meeting at least every two weeks, and then maybe monthly for probably two years. We were constantly talking about it, and we were constantly monitoring the data and identifying what was going on.

Meagan Dexter, RNC-NICN: If you don't stay on top of it… you can put out computer-assisted in-services, you can send out emails, but we have found that face-to-face education is the most important. It allows for people to voice their concerns, ask questions, and think of things that maybe we didn't think of initially. And then we go back and talk about it as a group and say, "*This came up. How do we handle this and tweak it as we're going?*"

Protocol Development and Process Tuning

SET: Were there any specifically difficult or hard decisions that had to be made when you were forming those first protocols or processes for adopting transcutaneous monitoring?

Mark Schorr, RRT: Well, in the very beginning, our protocol was for every baby less than 30 weeks. And that made it hard to identify whether the process was working because if you're getting a lot of high acuity babies, you're going to be doing lots of blood gases. So for this second attempt, we revamped the protocol and separated the babies by gestational ages because you can't have the same protocol for a 22-weeker as you have for a 28-weeker. They're not the same babies.

Measuring Impact

SET: When do you think you realized the new protocol and new adoption process were working?

Mark Schorr, RRT: To be honest with you, we realized it was working pretty early in the process. Probably in the first few months we started to realize this was going to work. I had a feeling it was going to work because I understood the value of transcutaneous monitoring. I think it was the first few months that I saw that the process was reducing blood gases tremendously.

"For me as a respiratory therapist, the future is TCOM. The future is CO_2."

The hardest thing was getting people to follow the protocol. It wasn't that if they followed the protocol it wouldn't work—it's just, people are nervous. The easiest thing to do is to draw a blood gas. If the baby's status was changing and they didn't fully trust the transcutaneous value, they would fall back on what they knew, which was to draw a blood gas. I mean, it's hard to rely on a technology that you're a little unsure of. Maybe it's easier just to draw an arterial blood gas.

Meagan Dexter, RNC-NICN: I knew that it was working, but I did not know how well it was working until Mark started showing the rest of the group the numbers. 50% reduction. I knew we weren't performing as many gases—I just didn't realize we had cut that number in half. Walking around, I could see we were relying on the TCOM a significant amount more than what we had previously been. So I knew there was a difference, but I was thinking 25%, 30%. I didn't realize it was a 50% reduction.

SET: Did you have a target for percent reduction in blood gases performed?

Meagan Dexter, RNC-NICN: I want to say it was 10%.

Mark Schorr, RRT: We targeted a 10% reduction; we didn't want to overpromise. We did very well, I guess.

Can This Be Replicated in Other NICUs?

SET: Do you think the strategy you used to incorporate transcutaneous monitoring is replicable in other NICUs?

Meagan Dexter, RNC-NICN: Yes. Because it was a true P.D.S.A. cycle that we did: Plan. Do. Study. Act.

SET: For anyone unfamiliar with that kind of cycle, what does it involve?

Mark Schorr, RRT: You plan out the change you're going to make—for us, that was to implement monitors on all of our babies—then we wrote out the process and did it. We collected data. We studied it. If we found that parts of the protocol were not being followed, we'd go back, meet, make a decision and ask: *"What can we do about that?"* And then we'd make the change; we'd act. You can do that with any process.

Meagan Dexter, RNC-NICN: As a nurse, you want to throw as many things as possible at whatever the problem is to fix it, but you're never going to know what fixed the problem unless you set out with a plan and test what changes. You have to (a) make sure that the changes that you are making are replicable, and (b) you have to know which change actually made the difference.

Shifting Culture

SET: For both nursing and respiratory departments did you have to make sure that, as a quality improvement initiative, the plan and the "*why*" was communicated? Was that a big factor in improving compliance to a new change or a new initiative?

"If that was your baby… and your baby had 10 sticks you could avoid, wouldn't that be of value to you?"

Mark Schorr, RRT: Definitely. I've worked in other industries where the boss says something, puts an email out, and that's the way it's got to be. But just because you say something doesn't mean it's going to happen. The change happens because of, like you said, *the why* and communicating it to the staff.

SET: We want to ask about cultural shifts. A lot of people in the NICU might consider blood draws an unfortunate but necessary process. How do you shift toward the idea that, in a lot of cases, this is unnecessary harm, and there are alternatives?

Mark Schorr, RRT: That's a great question. I think we still do a lot of blood draws, and for other things I wish we could reduce. I wish we had the technology to reduce a lot of different labs that we draw, but we're just not there yet. But to me, even if it is one [blood draw you're avoiding], then that matters, because if it was your baby, it would matter. And that's what I would say to anybody. If that was your baby and your NICU stay and your baby had 10 sticks you could avoid, wouldn't that be of value to you?

Meagan Dexter, RNC-NICN: To me, it's an educational journey. When I first started back in 2003, we did the micro preemie flip—so you picked up your baby and flipped them. We don't do that anymore. I didn't know the impact of flips until I was educated on the 10 or 15 years of data that showed us what we thought was a good thing was actually harming these babies. It made a huge difference. Once I got that knowledge and was able to pass that knowledge on to the rest of the staff… and the data actually supports what we're doing. As a nurse, if I understand the impact, then yeah, I'm going to do what I have to do, but I'm going to do it with a conscious effort to minimize negative impacts on my patient.

Building a More Collaborative Team

SET: Mark, you mentioned since 2015 or 2016 that you really started this initiative of reducing pain in the NICU. Do you feel like having these initiatives has helped create a more cohesive working relationship between RTs and nurses?

Mark Schorr, RRT: I think the transcutaneous implementation was a very cohesive process between the nurses and the RTs. I didn't realize how much it was going to be, but it was probably the most unified initiative of all of the projects that I've worked on.

SET: So this was an RT-focused initiative that brought the nurses in more to care about ventilation and understand how management and the ventilator can affect CO_2. Do you feel like there's been a nursing initiative that has resonated pretty well with the RTs the other way around?

Meagan Dexter, RNC-NICN: When we started our small baby protocol, everybody had to go through the PowerPoint, the education, all those things. And I think it was an awakening for both sides because you didn't know what you didn't know and how you were affecting babies. It was a good unified effort on that part as well.

Mark Schorr, RRT: I think having that continuous CO_2 number in the room, on the baby [has created cohesion] because everybody in the room knows what that number is related to. Everybody who enters the room is seeing the whole [ventilation] picture, and they're seeing it continuously. The nurses are primarily at the bedside more than the RTs. The RTs are assigned to more patients and are moving in and out So it lets nurses become really aware of the ventilator connection. That's what has been added by transcutaneous. They see when the CO_2 starts to climb, they see they need to call the RT to discuss what's happening, and it's been brought about by this continuous monitor.

Meagan Dexter, RNC-NICN: Right? It's in your face. It's right there. You can't ignore it.

Final Reflections

SET: What would you want any readers to take away from this conversation, or from your white paper, if you could have them understand just one thing?

Mark Schorr, RRT: Well, I know the financial cost of TCOM is a factor, but the value of it is tremendous. I don't know

how common transcutaneous monitoring is now throughout other patient care areas, but for me as a respiratory therapist, the future is TCOM. The future is CO_2. I know that, today, transcutaneous is primarily in the NICUs, but we're mandating CO_2 monitoring on post-operative adult patients now. CO_2 is telling you everything about the patient, not pulse ox. CO_2 is everything. So I hope more respiratory therapists see it and voice it, and that hospital administrators understand it.

SET: Meagan, is there anything you'd want readers to take away?

Meagan Dexter, RNC-NICN: I'd want them to not write off new technology that is reliable if you have the right process in place. Work with other disciplines and be an advocate for your patient to enable those processes to work like they should.

News…continued from page 16

Does Age Affect Care Outcomes in Patients With COPD on Noninvasive Ventilation?

Health-related quality of life (HRQOL) did not differ significantly between younger and older patients with chronic obstructive pulmonary disease (COPD) suffering from chronic hypercapnic respiratory failure receiving long-term noninvasive ventilation (NIV), despite a higher comorbidity burden in older patients. Researchers conducted a prospective, observational study to investigate the differences in HRQOL between younger and older patients with COPD and chronic hypercapnic respiratory failure receiving long-term NIV. They enrolled 237 patients between June 2015 and October 2021, with 41.8% enrolled as inpatients and 58.2% as outpatients, categorized into two age groups: younger (< 65 years) and older (≥ 65 years). HRQOL was assessed using the severe respiratory insufficiency (SRI) questionnaire, and factors affecting HRQOL—including anemia, autonomy impairment, exacerbation history, and comorbidities—were evaluated. A five-tier scale categorized autonomy impairments by severity, with level 1 denoting minor impairments and level 5 indicating the most severe loss of independence or ability, which poses substantial challenges for nursing care. No significant differences were found in SRI summary scores between age groups, despite older patients having a significantly higher burden of comorbidities (P = .014). Exacerbation frequency had a significant negative impact on SRI scores in both younger and older patients. Anemia was linked to a significant reduction in SRI scores only in younger patients, in whom it was more prevalent (29.1% vs 17.5%; P = .045). Any level of autonomy impairment negatively affected HRQOL in younger patients, whereas only higher levels (level of care ≥ 2) affected HRQOL in older patients. "Understanding of COPD with comprehensive care plans that address both medical and functional aspects, patient outcomes, and HRQOL might be improved," the authors wrote.

Dräger Receives Global Company of the Year Recognition

Frost & Sullivan announced that Dräger has received the 2025 Global Company of the Year Award in the respiratory devices industry for its outstanding achievements in clinical innovation, cost-effective solutions, customer-centric strategy execution, and global market impact. This recognition underscores Dräger's continued leadership in transforming respiratory care through advanced technologies, comprehensive training programs, and a deep-rooted commitment to improving patient outcomes and caregiver wellness in intensive care environments. Frost & Sullivan evaluates companies through a rigorous benchmarking process across two core dimensions: visionary innovation and customer impact. Dräger excelled in both, demonstrating its ability to align its innovation roadmap with market demand while executing with precision, scalability, and clinical relevance. "Keeping the customer need in mind, Dräger's designs focus on a range of consumer needs, including scalability, flexibility, low infection rates, low readmission rates, reduced costs, high return on investment for healthcare providers, workplace safety, process improvement, human error reduction, enhanced patient and family experiences, patient comfort, and operational efficiencies," said Utkarsha Soundankar, Industry Analyst at Frost & Sullivan. Guided by a long-term growth strategy focused on digital innovation, clinical partnerships, and value-based care, Dräger has demonstrated its ability to lead in a rapidly evolving respiratory care landscape. The company's sustained investment in smart ventilator technology, workflow integration, and

Continued on page 38…

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Optimizing Patient Outcomes with the Tracoe Twist Plus Tracheostomy Tube

Carmin Bartow, MS, CCC-SLP

Appropriate tracheostomy tube selection is critical for supporting optimal patient outcomes and minimizing complications such as hemorrhage, pressure induced tissue necrosis, and tracheal stenosis. Since no single tube suits every patient, an individualized approach is necessary. Healthcare providers must consider several factors including the patient's height, weight, airway anatomy, indication for tracheostomy, respiratory function, secretion management, communication needs, and overall safety and comfort when making tracheostomy tube decisions. Therefore, tube characteristics, like material, type, inner and outer diameter, length, neck flange mobility, and special features for communication and suctioning must be carefully considered to ensure each patient receives the most suitable tracheostomy tube at every stage of care. Tracoe Twist Plus tracheostomy tubes (Figure 1) offer a wide range of features designed to meet patients' needs throughout their journey, from insertion to decannulation.

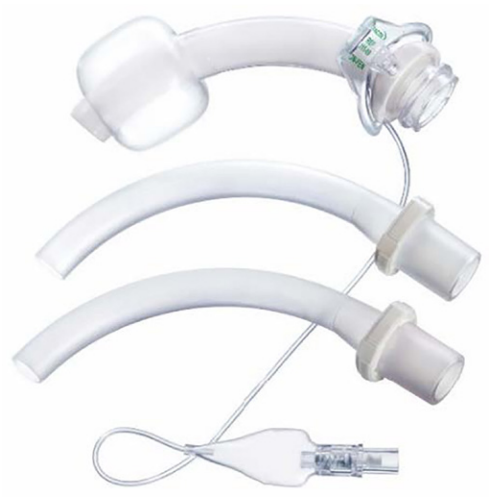

Figure 1. Tracoe Twist Plus Tracheostomy Tube. Image of Tracoe Twist Plus with a high-volume, low-pressure cuff and two inner cannulas.

Features and Benefits of Tracoe Twist Plus

The Tracoe Twist Plus tracheostomy tubes offer numerous benefits designed to enhance patient comfort, care, and outcomes. These tubes feature dual cannulas, with a locking ring to secure the inner cannula in place for enhanced stability and safety. The tube's sizing corresponds to the inner diameter of the inner cannula, which serves as the patient's actual airway. Distinct labeling on the neck flange and intuitive sizing provides clarity for both patients and healthcare providers. These tracheostomy tubes are available with a high volume, low-pressure cuff or in a cuffless option, as well as fenestrated or non-fenestrated options to suit various clinical needs. Additionally, the pivoting neck flange swivels both vertically and horizontally, accommodating natural head and neck movements. The tube's thin, stable walls optimize the inner to outer diameter ratio, improving airflow, and enhancing patient comfort.

The Importance of Optimizing the Inner to Outer Diameter Ratio

The Intensive Care Society recommends tracheostomy tubes with a large functional inner diameter to reduce airway resistance and a small outer diameter to allow airflow around the tube when the cuff is deflated, as well as to minimize tracheal trauma.[1]

Small changes in tracheostomy dimensions significantly impact respiratory workload.[2] For example, if the inner diameter of the tracheostomy tube is reduced from 8mm to 7mm, airflow is decreased by 41% (based on Hagen-Poiseuille equation for laminar flow). Therefore, **every millimeter counts.** Selecting a tracheostomy tube with an optimal inner diameter is critical for minimizing work of breathing and ensuring adequate ventilation.

In addition to an optimized inner diameter (I.D.) for increased airflow, a tracheostomy tube with a small outer diameter (O.D.) is crucial for facilitating airflow around the tracheostomy tube and into the upper airway once the cuff is deflated. This may enable the use of a speaking valve and support upper airway functions such as phonation, swallowing, and coughing. Furthermore, because adequate airway patency is a prerequisite for decannulation, many patients require tracheostomy downsizing to ensure sufficient exhalation around the tube and to tolerate capping. Most decannulation pathways include tracheostomy downsizing or capping trials[3] — both of which depend on an outer diameter that does not take up excessive space in the airway. Therefore, careful consideration of outer diameter is essential in tracheostomy management.

To address these needs, the Tracoe Twist Plus was designed to optimize the inner-to-outer diameter ratio by maximizing the inner diameter for airflow while minimizing the outer diameter to preserve airway space (Figure 2).

Carmin Bartow is a speech pathologist and tracheostomy clinical educator with Atos Medical.

Size	I.D. (mm)	O.D. (mm)
07	7.0	9.8
08	8.0	10.8
09	9.0	11.8
10	10.0	12.8

Figure 2. Tracoe Twist Plus Tracheostomy Tube Sizing Chart. This chart shows the corresponding inner diameter and outer diameter measurements for sizes 07 to 10.
I.D. = inner diameter of the inner cannula
O.D. = outer diameter of the outer cannula

One center investigated whether switching from their previous brand of tracheostomy tube to the Tracoe Twist Plus with its optimized inner to outer diameter ratio impacted outcomes. Their quality improvement study reported the following results:[4]
- Reduced number of tracheostomy tube changes
- Reduced critical care length of stay
- Decreased time to decannulation

Tracoe Twist Extract Tracheostomy Tube

Tracoe Twist Plus is also available with a subglottic suction channel. This version, the Tracoe Twist Plus Extract (See Figure 3), offers all the features and benefits described above, with the addition of an innovative flat subglottic suction channel that can be connected to a syringe or suction tubing to effectively remove secretions pooling above the cuff. Subglottic suctioning reduces the volume of secretions and consequently increases the risk of bacterially contaminated secretions entering the lower respiratory tract. For this reason, subglottic suctioning is recommended as a preventative measure against ventilator-associated pneumonia.[5,6]

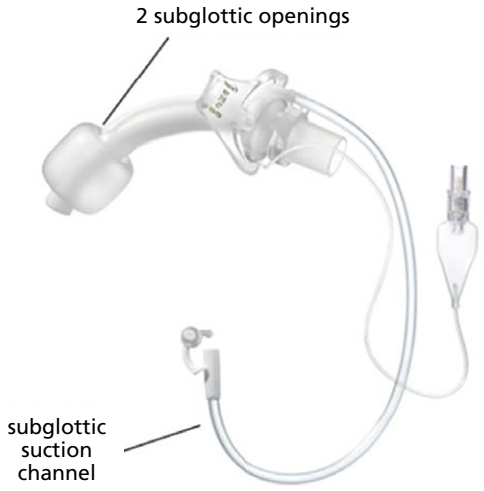

Figure 3. Tracoe Twist Plus Extract Tracheostomy Tube. This version of the Tracoe Twist Plus includes a flat subglottic suction channel designed for effective secretion management and use in above cuff vocalization (ACV).

Tracoe Twist Plus Extract for Above Cuff Vocalization (ACV)

Above cuff vocalization (Figure 4) is a voicing technique typically used with patients who are alert, cooperative, and require an inflated cuff during mechanical ventilation. Since cuff inflation prevents the use of a speaking valve, ACV enables phonation for patients who would otherwise be voiceless. To facilitate ACV, the suction channel is used to introduce compressed air into the subglottic lumen. This airflow travels into the upper airway, passing through the vocal folds restoring audible voice.[7,8] Use of ACV has been shown to be safe, restore earlier communication, and improve quality of life.[7-10] Additionally, improvements in swallow frequency and aspiration ratings with use of ACV have been reported.[10]

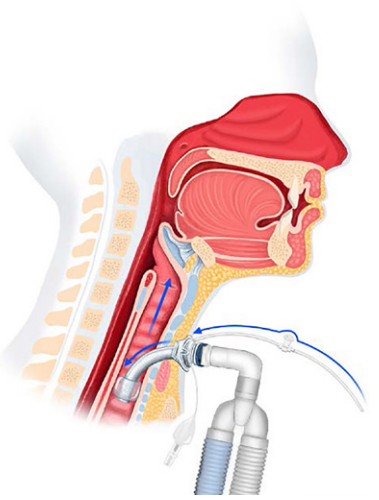

Figure 4. Above Cuff Vocalization (ACV) Airflow Pathway. Illustration showing airflow during ACV. The blue arrows indicate the flow of air introduced through the subglottic suction channel, above the cuff and into the upper airway to enable phonation.

Key Takeaways

Selecting the right tracheostomy tube is critical to reducing complications and improving patient outcomes through an individualized approach that considers patient anatomy, respiratory needs, and comfort. The Tracoe Twist Plus tracheostomy tubes offer a range of features and benefits including an optimized inner to outer diameter ratio. Additionally, the Tracoe Twist Plus Extract includes a subglottic suction channel for effective secretion management and supports above cuff vocalization (ACV), promoting earlier communication and improved quality of life. These design advancements help clinicians deliver more personalized, efficient, and patient-centered tracheostomy care and may lead to few tracheostomy changes and faster decannulation.

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News…continued from page 34
clinician training has enabled it to scale its solutions across diverse healthcare systems globally. Innovation remains at the heart of Dräger's approach. Its V-Series ventilators—featuring SmartCare/PS, integrated capnography, proportional pressure support, and high-flow oxygen therapy—are purpose-built to support the improvement of clinical outcomes, reduce the duration of mechanical ventilation, and support bundled payment models. Dräger's recent achievement in securing Authority to Operate (ATO) certification for its Evita V800/V600, Babylog VN800, and Savina 300 ventilators from the US Department of Defense marks a significant milestone in medical device security, interoperability, and deployment in mission-critical environments.

"Given the recent wave of market consolidation of vendors in the ventilation market, today's decision makers are seeking more than just high-quality devices—they're looking for trusted partners who are deeply committed to supporting the respiratory care community," said Lothar Thielen, President and CEO of Draeger, Inc. "This award is a powerful affirmation of Dräger's unwavering commitment to our customers to deliver exceptional value through a combination of industry-leading products, cost-effective accessories and comprehensive service solutions that help hospitals provide the highest standard of care." In addition to product innovation, Dräger is redefining the respiratory care ecosystem through its full-service offerings, including responsive maintenance programs, biomedical training, and digital education platforms. In 2024, the company introduced Dräger Virtuo, an immersive virtual reality platform for ICU, OR, and NICU training, unveiled at the American Association for Respiratory Care (AARC) Congress.

Alongside this launch, the revitalized Dräger Academy continues to expand its impact by delivering more than 84,500 hours of CRCE credits annually and offering micro-learning modules tailored for clinicians' evolving needs. This integrated education model is designed to build clinical confidence and ensure rapid onboarding and knowledge retention—imperative in high-stakes care environments. Frost & Sullivan commends Dräger for setting the benchmark in strategic execution and customer-focused innovation in the respiratory devices industry. The company's holistic approach—combining clinical-grade technology, secure deployment, and professional development—continues to support redefining the standard for excellence in respiratory care. Its ability to aid in improving clinical workflows, lowering total cost of care, and expanding access to next-generation training aims to ensure lasting impact across global healthcare ecosystems.

Partnership Formed to Expand Access to Monitoring Technology

Medtronic and Philips have a strong history of partnership in monitoring since 1992 and continue to work together to provide combined leading technologies for individual monitoring parameters. The new strategic partnership agreement includes the integration of next-generation technologies from Medtronic into Philips' monitoring solutions, providing a streamlined offering for healthcare providers. Philips' patient monitoring systems currently incorporate world-class Medtronic technology, including Nellcor pulse oximetry, Microstream capnography, and BIS brain monitoring. Under the new agreement, Philips will also bundle its essential supplies, including ECG, NIBP, and batteries, with Philips' Medtronic-enabled monitors. This combined offering helps better meet the needs of clinicians around
Continued on page 44…

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Taking Steps Towards Recovery: Mobilizing Patients on Advanced Respiratory Support with the New UPS Battery Designed for Better Respiratory Care

In this feature, Respiratory Therapy interviews clinicians on a game-changing innovation in the medical field: UPS battery system purpose-built for patients on advanced respiratory support. Designed to deliver uninterrupted power, unmatched mobility, and peace of mind, this breakthrough allows clinicians to safely mobilize patients without compromising life-sustaining equipment. Participating in the interview are, Respiratory Clinical Specialist, Soumaya Osen PhD, MHA, RRT, RRT-NPS, RRT-ACCS, Respiratory Clinical Specialist, Ryan P Echols MBA, RRT-ACCS, Emory University Division Director of Respiratory Care, EKG, & Pulmonary Lab services, Darcy Crayton, MS, RRT, Assist. Director-Respiratory Care Division at Emory University Hospital Atlanta-Georgia, Dorothy H Bendah, Clinical Manager-Respiratory Therapy, Zopec Medical.

Please tell us about your hospital and the critical care you provide.

We are a large academic medical center in the Southeast of the US. We provide the highest quality of care to very complex medical conditions and diseases, such as infectious diseases, brain and neuro programs, cancer, orthopedics care (bone and spine), pediatrics, kidney, ophthalmology (eyes), comprehensive women healthcare services, geriatrics care, and transplantation including but not limited to lung, heart, liver, kidneys, and bone marrow. In addition, our academic medical center is one of the nation's leading research universities with the goal of saving lives and strengthening partnerships.

How did you get to know about Zopec Medical?

During the Covid-19 pandemic, we began ambulating patients on heated high flow oxygen because some battery powered devices offered the heated high flow software; however, we did not have the ability to heat the high flow during ambulation because the heaters did not include batteries. We were looking for a battery that supports the heaters. Some patients did not tolerate the cold high flow of oxygen, and we had to use a combination of a high flow oxygen via mask and a nasal cannula under the mask.

While in the process of looking for a battery that can be used with heaters, our respiratory department director, Ryan Echols, received a communication from Strong Huang, the Founder and CEO of Zopec Medical and inventor of the Zopec UPS Batteries. Ryan contacted Strong, and the trial and error process was initiated with different battery designs.

What challenges have you experienced while transporting patients?

For our academic medical center, transporting patients while on heated high flow oxygen was challenging if the device did not include a battery with at least 60 minutes run time to account for round-trip transports. We are a large academic medical center with large buildings and bridges connecting the buildings. In addition, the best way to transport patients on heated high flow oxygen is being able to run the device and heat the flow that is delivered to the patient. Heated high flow nasal cannula is not a non-rebreather mask. Heated high flow nasal cannula provides CPAP. If the patients are taken off the heated high flow nasal cannula when they are not ready, their lungs will de-recruit. Some patients might end up needing escalation of care to non-invasive mechanical ventilation or invasive mechanical ventilation when transported without heated high flow oxygen.

Emory Respiratory Clinical Specialist, Dr. Soumaya Osen, PhD (left), and Zopec Medical Clinical Manager of Respiratory Therapy, Dorothy H. Bendah (right), demonstrate the Zopec UPS 90 Pure battery as an independent power supply for the HFNC ambulation system.

Having the ability to transport patients on heated high flow oxygen is extremely imperative to provide the safest care for our patients.

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 solutions were you considering for patient transport?
We were looking for a battery that can support the heated high flow oxygen devices and can heat the flow delivered to the patient during transport for 90 minutes.

How has the use of the Zopec UPS 90 Pure battery positively impacted patient safety in the hospital?
The first battery we purchased from Zopec Medical was the T60 with 60 minutes run time. Our respiratory care department director, Ryan, assistant director, Darcy, equipment supervisor, Tryon, and I, respiratory clinical specialist, collaborated with Strong Huang Founder and CEO at Zopec Medical to continue to improve the original 60 minutes battery (T60) until the UPS 90 Pure design met our patients' needs. UPS 90 Pure includes:

- 90 minutes run time at 37ºC at 60 liters per minute
- Two outlets for heated high flow and nebulizer
- Ability to zip-tie electric plug for better securement
- Two USB ports to connect Aerogen nebulizers with USB controller devices. Note: *although Airvo 3 has an integrated battery, the run time was not enough for our purpose*
- Low battery alarm that alerts the clinicians when the battery is starting to run low

How does the 90-minute run time of the Zopec UPS 90 Pure battery meet your needs?
The 90-minute run time met our patients' transport needs, and our mobility program needs. It allowed us to safely transport our patients who are on heated high flow oxygen back and forth between the buildings. It also allowed us to mobilize our patients and take them outside the hospital buildings for a breath of fresh air while keeping them on heated high flow oxygen.

Can you provide examples of how the UPS 90 Pure facilitates seamless transport?
We have dedicated Airvos on poles for transports. They are mounted on poles with three or four E cylinders and Zopec UPS 90 Pure battery. We have a high number of patients transports including patients who are on heated high flow oxygen. The UPS 90 Pure battery allows us to transport our patients who are on heated high flow oxygen safely if the round trip does not exceed 90 minutes.

We transfer the patients from the Airvo at the bedside to the transport Airvo. When we arrive at the transport destination, procedural area, imaging, etc. we plug the oxygen and battery to the wall to preserve the oxygen cylinders and the battery power.

We change the oxygen cylinders if they are below 1500 psi before leaving to the patient's room. With Zopec UPS 90 Pure we know we can safely transport the patients round trip up to 90 minutes.

Can you share the usability experience with UPS 90 Pure.
We use it for intra-hospital transports and for our mobility program when the patients are on heated high flow oxygen. UPS 90 Pure met our patients' needs.

How has Zopec Medical shown commitment and responsiveness to the hospital's needs?
Strong Huang, founder and CEO of Zopec Medical and inventor

of the UPS 90 pure battery, is very caring and collaborative. He listens to our needs. We were the first hospital to start the early mobility program with the Trial Zopec UPS battery. With every model, we found what our needs were and asked Strong to improve on the next model. After trial, the Zopec UPS 90 Pure was born with extra outlets, USB ports, secure plugs, low battery alarms. This met our needs to transport and mobilize patients safely. Patient mobility is extremely crucial to optimize care, provide in hospital rehabilitation, avoid delirium and reduce ICU and hospital length of stay.

How does the investment in the Zopec UPS 90 Pure battery compare to other options used in the hospital?
Since there are not too many options available in the market for heated high flow oxygen with battery run time of 90 minutes, and the need to have heated high flow oxygen devices that allow the delivery of inhaled medications during mobility and transport, Zopec UPS 90 Pure is the best option at this time.

It also allows the ventilators' heater to heat when active humidity is in use. Mobilizing the patients while they are on Advanced Respiratory Support with the Zopec UPS battery is part of the mobility program and the ABCDEF Bundle in Critical Care.

News…continued from page 38
the globe through expanded equipment access to the latest technology and through joint training and education programs designed to improve patient care. Reinforcing their dedication to high-quality, safe monitoring, the two companies are also establishing a pledge program. Both organizations believe using products that have been rigorously validated and tested on both parties' equipment is essential for ensuring patient safety. "We're proud to strengthen our collaboration with Medtronic, a partner that shares our commitment to expanding access to safe, reliable patient care," said Sachin Chaudhari, vice president and general manager, Clinical Applications and Devices, Philips Hospital Patient Monitoring. "By providing a comprehensive monitoring solution that is validated throughout all stages, we're supporting clinicians' heavy workloads and complex patient cases by providing tools that can help address the daily challenges care teams face." With a shared commitment to enhancing patient care, the continued innovation that Medtronic is delivering—coupled with Philips' market-leading monitoring solutions—will provide clinicians, patients, and caregivers greater insights and reliable monitoring. "Together with Philips, we are eager to continue to integrate next-generation technologies and leverage our combined global presence to empower healthcare professionals with world-class technology to personalize patient care, anytime, anywhere," said Brian Blomerth, vice president of strategy operations and chief financial officer for the Acute Care & Monitoring business, which is part of the Medical Surgical Portfolio at Medtronic. "The patient monitoring technology from Philips already incorporates the market-leading Medtronic brands of Nellcor pulse oximetry, Microstream capnography, and BIS brain monitoring, and building on this foundation exemplifies our dedication to advancing innovation and enhancing patient care."

AI Used to Reduce Mechanical Ventilation

A newly published study in the Journal of Pediatric Critical Care (JPCC) has demonstrated that integrating Etiometry's Clinical Intelligence Platform at the Children's Hospital of Alabama observed association with significantly improved patient outcomes in the pediatric cardiac intensive care unit (ICU). The study observed a 30% reduction in mechanical ventilation duration and a 20% decrease in overall hospital length of stay for post-surgical patients. The research, titled Automated Spontaneous Breathing Trial Performance Tool is Associated with Improved Outcomes Following Pediatric Cardiac Surgery: A Single-Center Retrospective Study from Alabama, USA, evaluated the implementation of an automated spontaneous breathing trial (SBT) performance tool from Etiometry's Clinical Intelligence Platform. This innovative approach leverages near real-time clinical and ventilator data to automate the hospital's Extubation Readiness Test (ERT) practices, driving more timely initiation and more consistent adherence to the practices. This results in both reduced time on mechanical ventilation and length of hospital stay. The study's findings indicate that the deployment of Etiometry's SBT tool was associated with a significant reduction in postoperative total ventilation time (TOV) and length of stay (LOS). Specifically, the incidence rate for postoperative TOV was 0.7 times lower post-implementation ($P < 0.0001$), and the postoperative LOS was reduced by 20% (0.81 times, $P < 0.01$). The single-center study's significant dataset of 787 pediatric patients makes the findings highly relevant for this patient population. "The observed reduction in the duration of mechanical ventilation in this study may
Continued on page 49…

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- → Pre-packaged, configured circuits ready for use with validated ventilators
- → Disposable circuits, including the NOxFLOW™ sensor, for easy clean up
- → Auto-cylinder changeover with alerts, helping you avoid therapy interruptions

Our Commitment

- → Integrated gas delivery system for inhaled nitric oxide therapy
- → 24/7/365 service and support
- → Simplified billing process
- → Reliable and responsive distribution network
- → Established reputation for quality and customer satisfaction

A summary of the prescribing information, including indication and other important safety information, is on the adjacent page. For the full prescribing information, visit www.noxiventus.com.

Call 1-833-669-8368 today or email us at lg.us.noxivent@linde.com for a complimentary requirements evaluation.

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Living Healthcare

NOXIVENT® Indication and Important Safety Information

Indication

NOXIVENT® is a vasodilator 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

Contraindications

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 (NO_2) 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 NOxBOX®$_i$ 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.

Please see the full Prescribing Information for additional important NOXIVENT® safety and risk information.

Distributed by Linde Gas & Equipment Inc
10 Riverview Dr. Danbury, CT 06810
Phone 844.445.4633, www.noxiventus.com

The End of an Era: Is Manual Ventilation With a CPR Bag Heading Into Retirement?

Steven C LeCroy, MA, CRT, EMTP

The CPR Bag as we know it was invented in 1956 and has been the same design for almost 70 years. In comparison, most respiratory devices see improved design upgrades every 8-15 years. while the typical disposable respiratory device typically remains on the market between 8-15 years before being replaced by improved designs or materials. Current Bag-Valve-Mask devices have had some improvements either by upgrades in materials or accessories added to the device. However, the essential function of the CPR Bag is the same as it was in 1956. Device improvements are typically driven by materials innovation, infection control, regulatory updates, or standards of care.

So how has the CPR Bag avoided device innovations all these years? It has been my experience that CPR Bag users learn how to use the device early in their training and we all think we are good at manual ventilation. Studies show this is rarely the case. Of course we are good at manual ventilation, it is a basic skill, right? Yes, it is a basic skill, but no one ever said it was an easy skill. A poorly ventilated patient with positive pressure can experience hypoventilation, hyperventilation, barotrauma, volutrauma, reduced pre-load and vomiting with aspiration. Which of these are you ok with?

At a conference I set up a ventilation station using a Michigan test long, two different size BVMs and a computer to monitor the effectiveness of manual ventilation. Over four hundred attendees participated at the ventilation station. Of the four hundred approximately 85% failed to meet at least one basic ventilation standard such as Rate, Tidal Volume and Pressures. Now imagine how well the patient is ventilated during transport?

So, why not use a ventilator? AI is taking over a lot of jobs, why not manual ventilation? When I went to Respiratory school the protocol was to remove a patient from the ventilator and manually ventilate if they went into cardiac arrest. The reason given was the conflict or lack of coordination between compressions and positive pressure manual ventilation that would lead to inadequate ventilation. What if there was a ventilator mode that could synchronize mechanical breaths with chest compressions during cardiopulmonary resuscitation (CPR)? This mode could optimize ventilation and circulation during CPR by delivering breaths in coordination with chest compressions improving both oxygenation, CO_2 elimination and circulation. Well, that mode does exist and is called Chest Compression Synchronized Ventilation (CCSV) or CPR mode.

Epitaph for a Bag-Valve- Mask

No glory sought, no banner raised,
Yet countless lives still sing your praise.
Now still you lie, your service through,
A quiet hero, tried and true.

Chest Compression Synchronized Ventilation (CCSV) is a ventilation strategy that delivers small, quick breaths coordinated with chest compressions during CPR, aiming to optimize gas exchange and circulation without pausing compressions. Ventilators with CCSV modes are currently available. However, the price for a ventilator with a CCSV mode is reported to start at around $10,000 a price tag beyond what many agencies or hospitals can afford.

Figure 1. https://www.butterflybvm.com/products

In the meantime, are there other options for improved manual ventilation? The answer is yes. The recent FDA cleared Butterfly BVM™ is an option for potentially improving ventilations. What makes this BVM different? In addition to its unique ergonomic design with a built-in reservoir. The user can not only dial tidal

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 130 cases. Steven has been a national speaker and has published articles in both EMS World and JEMS magazines. He is the author of the Equipment Technology for Noninvasive Ventilation in the Pre-hospital Setting chapter in the test Noninvasive Mechanical Ventilation: Theory, Equipment and Clinical Applications published by Springer International Publishing Switzerland.

volumes, but they can also control the Peak Inspiratory Pressure (PIP) for more controlled, safer ventilation. Even if CCRV mode ventilators become more affordable, the Butterfly BVM could be a great option now and in the future. The Butterfly BVM is cleared for use for all age groups in the pre-hospital setting, eliminating the need to carry four BVMs. However, in the hospital setting it is only cleared for use with adults, children, and infants but not for neonates."

Another option to consider is the Sotair® device. Sotair is a flow-control valve placed between the resuscitator and the patient interface to help regulate air delivery. The valve prevents excessive flow rates during manual ventilation. Flow control helps reduce the risk of over-pressurization, over-ventilation, and hyperventilation.

Figure 2. https://safebvm.com/sotair

With the introduction of innovative technology like the Butterfly BVM and Sotair we should hold off on that epitaph for the BVM.

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News…continued from page 44

be clinically meaningful," said Dr Santiago Borasino, medical director of the cardiovascular intensive care unit at Children's of Alabama professor at the University of Alabama at Birmingham, and the study's principal investigator. "When we are able to reduce a patient's time on mechanical ventilation, we are also decreasing their risk of complications such as pneumonia and potentially helping them recover faster and shorten their stay in the ICU. These improved patient outcomes benefits translate to freeing up ICU resources and ultimately, cost savings for hospitals." The results of this study highlight the impact of integrating automated clinical intelligence tools into ICU workflows. By enabling proactive decision-making, Etiometry's platform empowers care teams to optimize mechanical ventilation strategies, reducing hospital stays and improving patient outcomes.

Study Reveals Reduction

A newly published multicenter clinical trial in *Critical Care Medicine* shows that use of Etiometry's Clinical Intelligence Platform—specifically its Inadequate Delivery of Oxygen (IDO2) Index—was associated with a significant reduction in the duration of vasoactive and inotropic infusions following pediatric cardiac surgery, potentially lowering the side effects associated with long term use of these medications. The study, *Risk Analytics Clinical Decision Support Decreases Duration of Vasoactive Infusions Following Pediatric Cardiac Surgery: A Multicenter Before and After Clinical Trial*, evaluated how implementation of Etiometry's risk analytics influenced postoperative care in pediatric cardiac ICUs. Across five institutions, 343 patients were enrolled in the intervention group using Etiometry's platform, while 432 served as historical controls. Using a risk-adjusted negative binomial regression model, the study found a 29% reduction in vasoactive infusion duration in the intervention group compared to controls (*95% CI: 14–42%, $p < 0.01$*). "This study marks a defining shift in pediatric cardiac critical care," said lead author Dr Avihu Gazit, who did the research while at Washington University in St. Louis and is now Chief of Pediatric Cardiac Critical Care Medicine at the University of Pittsburgh. "By integrating real-time physiologic analytics through IDO2, we were able to guide de-escalation of care in a way that supports clinical decisions during the recovery phase, when patients are stabilizing. Our findings highlight how predictive analytics can meaningfully influence bedside decision-making and potentially extend to other areas like sedation and mechanical ventilation." The IDO2 Index, a proprietary component of Etiometry's platform, uses real-time physiologic and laboratory data to assess the likelihood of insufficient oxygen delivery. Clinicians in the study used the IDO2 trend to support decisions around titration and weaning of inotropic and vasoactive therapies in the early postoperative period. This study adds to the growing body of evidence. Studies where Etiometry supported clinician workflows have shown associations with improvements in pediatric cardiac outcomes, including reductions in mechanical ventilation, ICU length of stay, and now, vasoactive support duration.

New Options for Suction Devices

Neotech Products offers new options to cover and protect your Little Sucker Suction Devices. "Little Sucker is one of our most popular product lines," Sara Dimmitt, Director of Business Development said. "Our cover for the standard tips has been available for quite a while now, but some customers have been

Continued on page 63…

Breaking Ground in Pediatric Interventional Pulmonology: A West Coast First

Q&A with Melike Bozkanat, MD, and the Stanford Medicine Children's Health Team Pioneering Minimally Invasive Airway Procedures in Children

What is pediatric interventional pulmonology, and why is it such a breakthrough for respiratory care in children?
Pediatric interventional pulmonology is a rapidly advancing subspecialty that uses minimally invasive techniques to diagnose and treat complex airway and lung conditions in children. These procedures are performed using flexible bronchoscopes — thin, tube-like instruments equipped with a camera and specialized tools. Until recently, many of these conditions required open surgery. Now, thanks to advances in technology and skill, we can diagnose conditions like airway obstruction, narrowing without surgical incisions.

Stanford Medicine Children's Health is performing these procedures first on the West Coast. What does that mean for families and providers?
We're proud to be the first center on the West Coast offering this level of pediatric interventional bronchoscopy. It means families now have access to cutting-edge, minimally invasive therapies that were previously only available in a handful of institutions across the country. For referring providers, it means their patients can receive highly specialized care without needing to travel out of the region.

What are some of the key procedures now available through flexible interventional bronchoscopy?
We offer a broad range of diagnostic and therapeutic procedures, including:

- **Cryobronchoscopy** for removing inhaled foreign bodies, bronchial casts, and mucus plugs
- **Cryobiopsy** for obtaining tissue samples with minimal trauma
- **Balloon dilation** for treating airway narrowing
- **One-way endobronchial valve placement** for persistent air leaks or lung volume reduction
- **Endobronchial ultrasound and biopsy** for masses or enlarged lymph nodes surrounding the airways

Each of these procedures represents a major step forward in pediatric airway care.

Let's talk more about cryotechnology. How is it being used in children?
Cryotechnology uses extreme cold to freeze and remove abnormal tissues or obstructions in the airways. In children, it's most commonly used for:

- **Cryoextraction** – removing foreign bodies, mucus plugs, or bronchial casts
- **Cryodevitalization** – freezing scar tissue to open up narrowed airways
- **Cryobiopsy** – safely collecting lung tissue samples

These techniques are faster and often more effective than traditional tools like forceps or baskets, with less trauma to the airway.

How do you approach airway narrowing (bronchial stenosis) in children?
For children with congenital or acquired bronchial stenosis, we use **balloon dilation** to gently expand the airway. In some cases, we combine this with cryotherapy to freeze and prevent scarring from recurring. These procedures can often be repeated as needed and are done entirely through a bronchoscope.

What role do endobronchial valves play in pediatric care?
Originally developed for adults with severe emphysema, endobronchial valves are now being used in children for **persistent air leaks (pneumothorax)** or **lung volume reduction.** These one-way valves are placed via bronchoscope to block airflow to damaged lung segments, allowing the lung to re-expand or air leaks to heal. This can often avoid the need for surgery or prolonged chest tube use.

How do you collaborate across specialties to provide this level of care?
Interventional pulmonology in children is highly specialized and requires seamless collaboration. We work closely with teams in **ENT, pediatric surgery, gastroenterology, oncology, and interventional radiology.** The Stanford Children's **Aerodigestive Program** is a perfect example of this collaborative model, ensuring each child receives comprehensive, multidisciplinary care.

What does the future hold for pediatric interventional pulmonology?
The future is about pushing boundaries safely — continuing to refine these techniques, introduce new tools, and broaden their application. As the first on the West Coast to offer these services, we're not only providing advanced care today but also shaping the next generation of minimally invasive respiratory treatments for children.

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

Post-Launch Evaluation: Quantitative Insights of Patient and Caregiver Satisfaction of THE VEST APX System

Gwen Warling, MBA, RRT, Jack Holland, Eric J Fernandez, MD

Background

High Frequency Chest Wall Oscillation (HFCWO) is a non-invasive respiratory therapy that utilizes a vest or wrap garment to deliver high-frequency oscillations to the chest wall. This therapy has been widely adopted in the treatment of various respiratory diseases, such as cystic fibrosis (CF), bronchiectasis, and neuromuscular disease (NMD).

HFCWO therapy was first introduced in 1989 as a treatment for patients with cystic fibrosis (CF). Since its introduction, therapy has undergone advancements, and its applications have expanded to include the treatment of other respiratory conditions. The development of HFCWO therapy has been driven by the need for non-invasive, effective, and comfortable treatment options for patients with respiratory diseases.

HFCWO therapy works by delivering high-frequency oscillations to the chest wall, which may help:

- Improve mucus clearance: The high-frequency oscillations help to loosen and clear mucus from the airways, reducing the risk of respiratory complications.[5]
- Enhance lung function: HFCWO therapy has been shown to improve lung function in patients with respiratory diseases, including CF, bronchiectasis, and COPD.[1,4]

HFCWO is a well-established Airway Clearance Therapy. There are many publications showing success across multiple patient types:

- 94% of CF patients showed improvement in FVC with HFCWO[1]
- Bronchiectasis patients had 67% fewer disease specific acute exacerbations in the HFCWO cohort[2]
- Neuromuscular patients had a 45% reduction in inpatient days for those utilizing HFCWO therapy[3]

Recently, Baxter launched **The Vest** APX System with several enhancements designed to increase patient comfort and ease of use with the therapy:*

- One-touch operation
- Lighter, more portable
- Shorter garment to get therapy where it is needed, not where it is not
- Improved garment fabric / adjustability
- Easy assembly with durable magnetic hoses

*Compared to **The Vest** System, Model 105

The system consists of an inflatable garment attached to an air pulse generator that rapidly inflates and deflates the inflatable garment. This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process moves the mucus toward the large airways where it can be cleared by coughing or suctioning.

Whether or not a patient can tolerate and remain compliant with therapy is taken into consideration when prescribing HFCWO. Baxter wanted to understand if these device characteristics were associated with a better patient experience and if so, it could potentially be an indicator that patients would be willing to stay compliant with this therapy.

Provided by Baxter.

Methods

As part of the post-launch evaluation, Baxter planned to measure customer satisfaction and likelihood to recommend using **The Vest** APX System therapy among patients and caregivers in the United States. This study represents the first wave of post-launch market research tracking for this product.

This study employed a design where 100 users of **The Vest** APX System were interviewed, including 38 patients and 62 caregivers. The study population contained a notable age distribution:

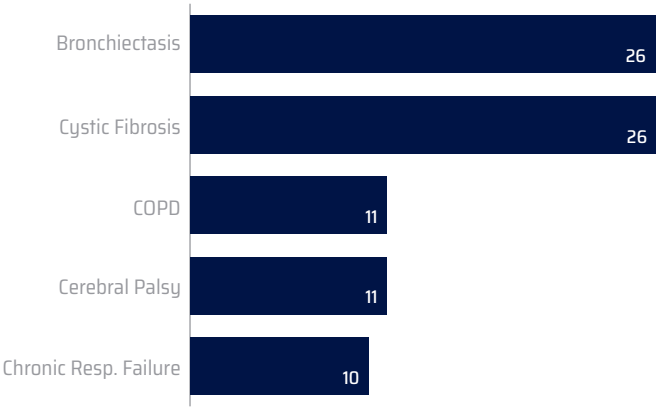
- Pediatric population (n=50): Participants under the age of 18
- Adult population (n=50): Participants over the age of 18

A list of **The Vest** APX System customers was provided by Baxter to a third-party company to conduct phone interviews. A random sample technique was utilized to survey the customers. Respondents were screened to confirm the use of the product for themselves or another member of the household. Incentives were not provided for this effort.

Patients using **The Vest** APX System had a range of conditions such as Bronchiectasis, Cystic Fibrosis, COPD, Cerebral Palsy, and Chronic Respiratory Failure being the most common.

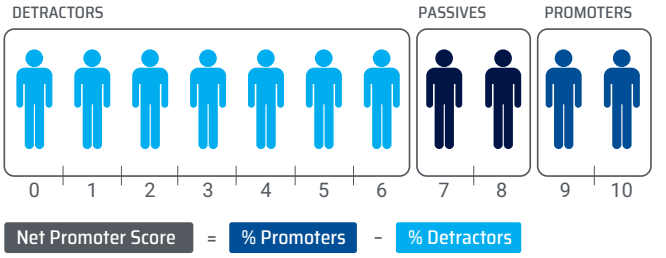
Number of Patients by Condition Type

Number of Patients (Multiple Selects)



Remaining conditions: Chronic Bronchitis, Interstitial Lung Disease, Emphysema, Primary Ciliary Dyskinesia (PCD), Asthma, Neuromuscular, Disorders of the Diaphragm.

For this survey, the Net Promoter Score (NPS) was utilized. The NPS is a widely used market research metric that takes the form of a single satisfaction question asking respondents to rate the likelihood that they would recommend a company, product, or service to a colleague. The Net Promoter Score itself is calculated by taking: % Promoters (9-10 rating) - % Detractors (0-6 rating) = Net Promoter Score.



Any NPS score above 0 is "good." It means that your audience is more loyal than not. Anything above 20 is considered "favorable." Qualtrix XM, the source of the NPS system, suggests that above 50 is excellent, and above 80 is world class.

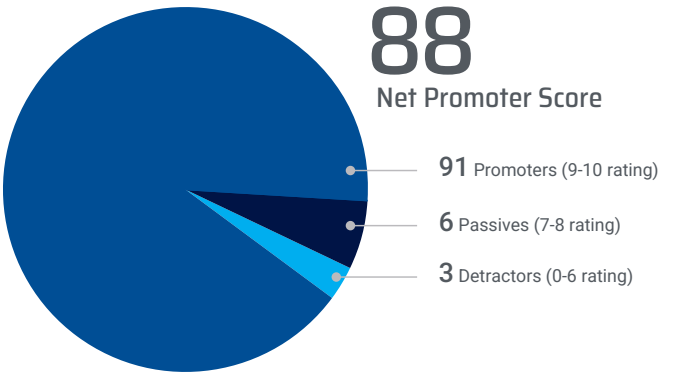
With this survey we asked the following question: How likely would you be to recommend Baxter to anyone who might need **The Vest** APX System. Please use a scale from 0-10, where a 0= not at all likely and 10= extremely likely.

Results

The Vest APX System scored an 88 NPS, which according to Qualtrix XM is a "world class measure."[6,7] Product performance was favorable across attributes for **The Vest** APX System.

Net Promoter Score Segments

100 Patients/Caregivers



When customers were asked what impact **The Vest** APX System had on their quality of life, 97% said **The Vest** APX System had a positive impact. The mean rating was 4.5 out of 5. When bronchiectasis patients were asked, 96% cited a positive impact on their quality of life (n=25).

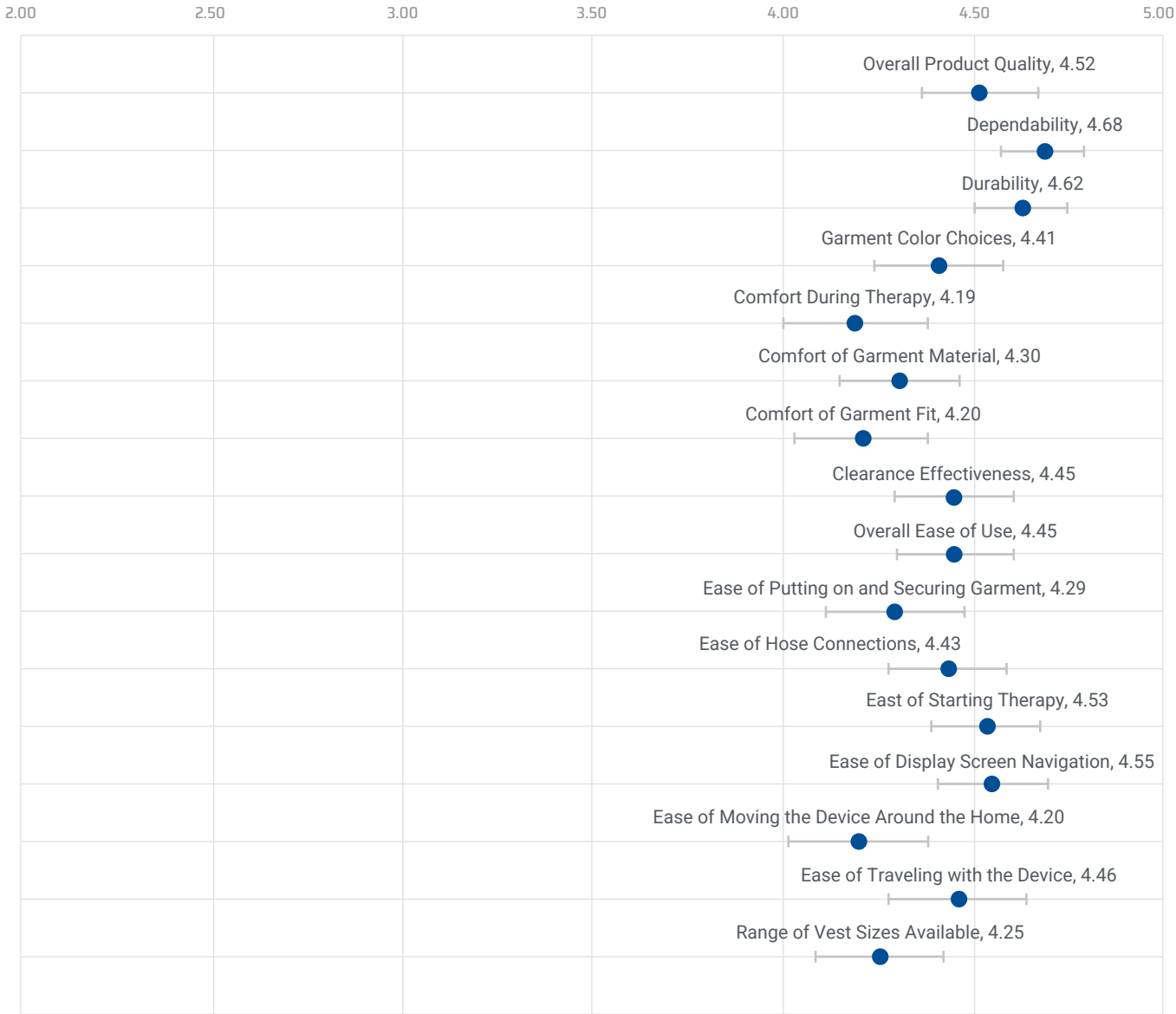
The Vest APX System has demonstrated its value in enabling adherence to prescribed airway clearance protocols, with a notable 73% of users citing a significant extent of its effectiveness. The primary reasons cited for this effectiveness include the device's ability to "do what it's supposed to" (48%), ease of use (31%), and the absence of problems (21%).

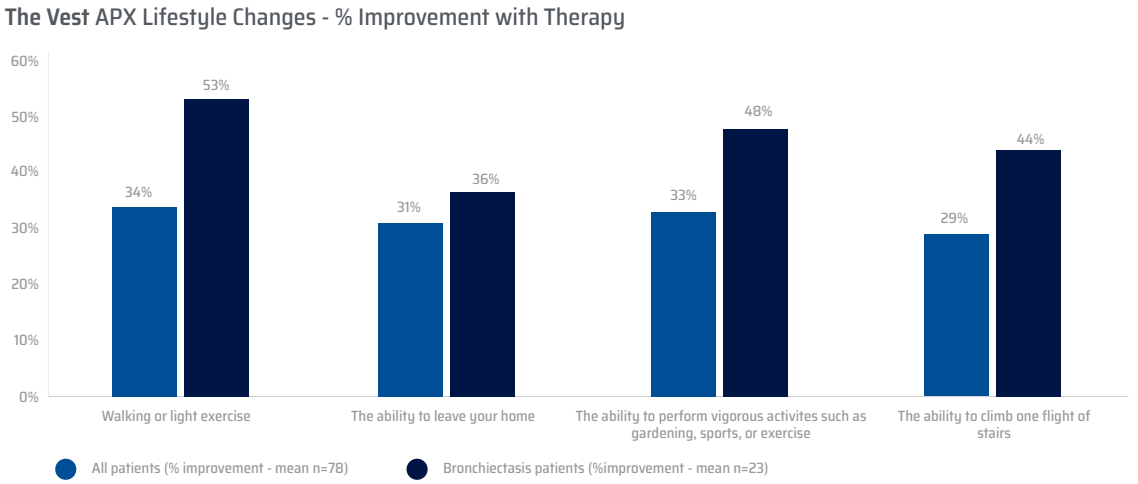
In addition to its effectiveness, **The Vest** APX System has also shown its ability to integrate seamlessly into daily routines, with 79% of users noting its ease of integration. This is a significant achievement, as it allows patients to incorporate airway clearance into their daily lives without disrupting their normal activities. The primary reasons cited for this ease of integration include the device's ease of use (68%), the ability to schedule or have been doing it for a long time (19%), and the ability to use it while doing other things (13%).

Product performance was favorable across attributes for **The Vest** APX System. The below table is a summary of attributes that were scored with 5.0 being "Excellent" and 1.0 being "Poor."

The Vest APX System Product Attributes

5.0 as Excellent (95% Confidence Intervals)





*Patients were asked to rate their ability to complete lifestyle tasks after **The Vest** APX System therapy on a 5-point scale: greatly decreased (1), decreased (2), unchanged (3), increased (4) or greatly increased (5). The percentage improvement was calculated as the proportion of users who reported increased (4) or greatly increased (5) outcomes.

Limitations

A survey study with 100 participants may be considered a small to moderate sample size, which can lead to several limitations. The findings of the study may not be representative of the larger population due to the small sample size. The results may be biased towards the specific group of participants who were surveyed. This data was self-reported, which can lead to biases and inaccuracies. Participants may not always provide truthful or accurate responses, or they may not fully understand the questions. With a small sample size, the study may not be able to perform complex statistical analyses, such as regression analysis or factor analysis.

Conclusion

The Vest APX System has been shown to provide a positive experience for patients, with high levels of satisfaction reported due to its ease of use and comfort. This satisfaction is a factor in enhancing patient compliance, as it encourages patients to adhere to their prescribed treatment regimen. Adherence to high-frequency chest wall oscillation (HFCWO) therapy is essential for achieving anticipated treatment outcomes. By helping to provide a positive experience, **The Vest** APX System has taken a step towards enhancing patient compliance.

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7 Data on File at Baxter International Inc.

Rx Only. For safe and proper use of product mentioned herein, please refer to the Instructions for Use or Operator's Manual.

Baxter

The Vest APX

AIRWAY CLEARANCE SYSTEM

TRUSTED TECHNOLOGY. NEXT-GENERATION EASE AND COMFORT.

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You know **The Vest** System as a leading High Frequency Chest Wall Oscillation (HFCWO) therapy. No other device in the category has been studied as extensively or trusted by more patients.[1]

Now, **The Vest** APX System delivers that well-established efficacy with enhanced patient comfort and ease of use.[1] It's designed to support daily therapy with improved portability[2] and user experience, plus more vest garment colors and patterns for patients to choose from.

The Vest APX System: the next generation of **The Vest** System from Hillrom.
Hillrom is a part of Baxter.

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For more information, contact your Baxter Sales Representative at **1-800-426-4224.**

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US-FLC201-240042 (v1.0) 09/2024

Physiological and Tissue Level Changes Due to Inadequate Humidification in Non-Invasive Ventilation: Why Wait to Humidify?

Megan Wooldridge, MSc

Clinical Problem

Despite evidence to support the use of early humidification in patients requiring more than 4L/min of supplemental oxygen during respiratory support, humidification is often an overlooked adjunct to non-invasive ventilation (NIV). Humidification is known to directly impact patient adherence to NIV as well as mucosal function and gas exchange. This paper will explore the tissue level benefits and physiological need for early humidification during NIV.

Key Evidence Points

- **Optimal humidification (33-44 mg H_2O/L at 37°C) is an inherent need for patients** receiving respiratory support over 4L/min as it maintains epithelial integrity, promotes secretion mobilisation, and contributes to efficient gas exchange.
- Tissue changes due to inadequate humidification occur within 24 hours:
  - Exposure to non-humidified gas for 8 hours shown to cause cilial and epithelial damage.[1]
  - Epithelial necrosis due to inadequate humidification has been seen within 16 hours.[2]
  - 30% of COPD patients struggle with chronic mucous secretion and mucosal dysfunction, with 40% of COPD patients showing presence of mucus plugs in CT scans.[3]
- Suboptimal humidification of respiratory support can lead to increased risk of respiratory infections.
- High velocity therapy is a proven alternative to non-invasive positive pressure ventilation (NiPPV) in patients with undifferentiated respiratory distress.

Key Takeaway

High velocity therapy is a clinically accepted alternative to NiPPV and could pose as the solution for providing humidification from the onset of treatment. There is opportunity for clinicians to provide more comfortable, more effective therapy by considering the necessity of humidification for any patient requiring a greater level of support than 4L/min of supplemental oxygen. Further research is needed to evaluate long-term outcomes, cost, and the impact of inadequate humidification on disease progression.

Introduction

With the burden of chronic respiratory diseases (CRD) rising globally, innovations that improve patient comfort, reduce avoidable clinical costs, and support better outcomes are urgently needed. CRDs like Chronic Obstructive Pulmonary Disease (COPD) and Bronchiectasis are among the top global health burdens responsible for over 4 million deaths annually and affecting nearly half a billion people worldwide.[4]

Respiratory failure (RF) results from inadequate gas exchange and is often the prognoses of CRDs. RF is categorised into hypoxemia or hypercapnia.

- Hypoxemia is seen during a failure to oxygenate; the inability to maintain a normal blood oxygen concentration. Hypoxemia is known as Type 1 respiratory failure and is attributed to a patient when their partial pressure of oxygen (paO_2) reaches paO_2 <60 mmHg [8Kpa] on an arterial blood gas.
- Hypercapnia is seen due to a failure to ventilate; the inability to remove carbon dioxide from the blood. Hypercapnia, known as Type 2 respiratory failure, is ascribed when the partial pressure of carbon dioxide (pCO_2) reaches pCO_2> 45 mmHg [6.5 kPa] on an arterial blood gas.

RF can be categorised further into:

- Acute: A condition that arises suddenly but often resolves quickly.
- Chronic: Long-term health condition that arises over time, often managed rather than cured.
- Acute-on-chronic: A short-term exacerbation or worsening of a chronic condition. Exacerbation can be resolved, but the patient will return to baseline disease state.

Acute hypercapnic respiratory failure (AHRF; blood pH <7.35 and pCO_2>45 mmHg [6.5 kPa] is a hallmark of severe COPD, marked by elevated CO_2 levels due to ventilatory failure and decreased expiratory airflow. Patients can expect a **median survival of just 1 year** after experiencing an acute exacerbation of COPD (AECOPD) resulting in AHRF.[5,6] The British Thoracic Society (BTS) and American Thoracic Society (ATS) both advocate for the use of NIV among patients with COPD and AHRF, but humidification is only considered by BTS when patient discomfort and intolerance are already present. [5]

Why wait to deliver humidified therapy?

"Traditional treatments such as non-invasive positive pressure ventilation (NIPPV) remain standard, but are limited by interface intolerance, drying effects, and poor secretion clearance."[7]

— Dr Antonio Esquinas, 2012

Megan Wooldridge is the Clinical Education and Research Associate at Vapotherm, UK.

What is Humidification?

Hygrometry is a branch of physics designated to measuring water within gases. Absolute humidity (AH) is defined as the total amount of water that air can hold when saturated, whereas relative humidity (RH) is defined as the ratio or percentage of water that is within the air. At 37°C, 1 litre of air can hold 44mg of water (H_2O).[8] Through bench top hygrometric and invasive ventilation studies researchers have established 33 mgH_2O/L as the ideal humidity level when delivering medical gases through invasive mechanical ventilation (IMV).[8]

In normal healthy airways, inspired air is warmed and humidified by the upper airway structures and respiratory tract, reaching 100% RH at 37°C by the mid trachea (known as the 'Isothermic saturation boundary'). To adequately humidify inspired air, the respiratory tract is estimated to lose approximately 250mL of water daily and require 350kcal (1.4kJ) of energy. [9] During medical gas delivery this natural humidification mechanism can be overwhelmed, particularly at higher flow rates.

Guidance for humidification in IMV is clear, with AARC requiring a minimum humidity level of 30mgH_2O/L due to bypassing the natural humidification processes of the upper airways.[10] It is not clear what the ideal humidification setting should be for NIV or high flow nasal cannula therapy as gases still pass through upper airways structures. During NIV patient adherence is maximised when humidification is between 20-36 mgH_2O/L.[8] It can be hypothesised that humidifying as close to inherent range as possible is important for relieving energy consumption and work of breathing associated with warming and humidifying inspired air, particularly in patients with CRDs. Humidification is also essential for respiratory tissue function, with suboptimal humidification associated with an increased risk of infection due to a reduction in mucociliary clearance.

Physiological Imperative for Humidification

Mucociliary clearance (MCC) is the primary immune defence mechanism of the lungs. The MCC process removes debris and pathogen-containing mucus from the respiratory tract along finger-like epithelial projections called cilia. Mucus is transported towards the mouth and subsequently expectorated or swallowed, where pathogens are then attenuated in stomach acid.[1] Without MCC working effectively, mucus is retained in the lungs, increasing risk of mucus plug formation, which may subsequently lead to obstructive atelectasis.

Formation of mucus plugs should not be underestimated, even in early-stage COPD. There is a significant increase in all-cause mortality risk in GOLD stage 1 COPD patients with multiple mucus-plugs. In the COPD Gene study, 40.7% (n=4363) patients had mucus plugs in one or more CT scans, with 40.6% of patients dying with the presence of mucus plugs occluding their airways.[3]

Inadequate humidification causes retained mucus through two mechanisms (Figure 1)

1. Decreased moisture in upper airways can cause an unusually thick (inspissated) mucus layer to accumulate. The periciliary layer (PCL) contains membrane-associated mucins (the protein secreted by goblet cells to form mucus) which form a lubricating layer that allows efficient ciliary beating. When the PCL is not sufficiently hydrated, the mucus layer collapses onto the cilia, preventing ciliary beating and thus reducing MCC.[11]
2. Cilia motion (metachronal ciliary beat) is directly proportional to temperature. Reduced humidity of inspired air has been shown to lower airway surface level (ASL) temperature by up to 5°C which significantly reduces mucus transport velocity.[1] This decreased mucus movement increases the time for pathogens and debris to be cleared from the lung.

In addition to the above, patients with COPD experience chronic mucus hypersecretion (CMH) and mucous cell hyperplasia. CMH is an intrinsic overproduction of mucin which increases the volume of mucus needing to be cleared. Long term mucous cell hyperplasia arises when repeated airway insults (pathogens, particles, cigarette smoke and toxins) cause a neutrophilic inflammatory response, resulting in the sustained activation of basal cells which upregulate goblet cell differentiation.[12] COPD exacerbations further contribute to this elevation, with excess mucin secretion catalysing the formation of biofilm within the respiratory tract—a perfect environment for mucus-trapped pathogens to establish in respiratory tissues and cause further inflammation in the form of a respiratory infection. However, adequate humidification has been found to enhance both MCC and reduce pro-inflammatory markers such as tumour necrosis factor alpha (TNFα) and interleukin-8 (IL-8), potentially reducing risk of exacerbations.[11]

To summarise, under low temperature and humidity the depth of PCL is reduced, cilia activity decreases and MCC slows, increasing the risk of infections.

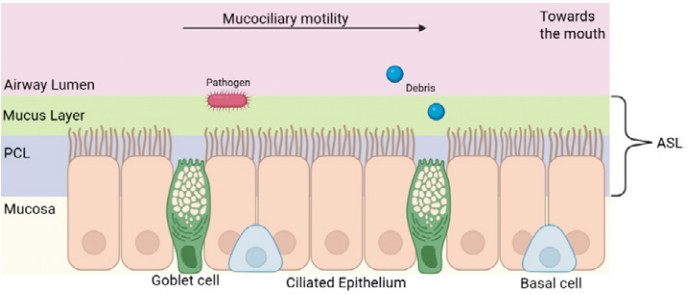

Figure 1. Diagram of respiratory mucosa mucociliary clearance. Created by Megan Wooldridge in Biorender. PCL = low viscosity periciliary layer, ASL = Airway surface layer

A Patient Experience

To fully appreciate how inadequate humidification can lead to worsening of respiratory conditions, this paper will discuss a fictitious but realistic patient timeline during a COPD exacerbation.

Patient: Jenny is 72 and a COPD sufferer with a history of previous exacerbations. She is admitted to the Emergency Department with acute-on-chronic dyspnea and SpO_2 83% in room air. Jenny is placed on a Venturi mask at 8 L/min to relieve her dysnpea and bring her oxygen saturation to target range.

Clinical guidelines do not currently recommend humidification during NIV unless patients experience mucosal dryness or thick secretions. Patients may not receive humidification of medical gases in the first 24 hours of NIV therapy, as it is not indicated by the current clinical guidelines. **There is no evidence to suggest that delaying humidification improves patient outcomes.**

However, there is evidence concluding inadequate humidification can lead to pathophysiological changes within 24 hours:

- Cilia damage and increased inflammatory markers were observed after only **8 hours** of inadequate humidification,[13] with prolonged exposure shown to lead to mucosal tissue restructure.[7]
- In an animal study, ventilation without humidification led to necrotic epithelium within **16 hours.**[2]
- Delorme et al found that discomfort due to inadequate humidification is experienced by the patient in as little as **10 minutes.**[8]

Patient: Jenny has insufficient gas exchange, with the effects of inadequate humidification contributing to an increased work of breathing. Jenny's blood test shows an elevated white blood cell and inflammatory marker count, evidencing a respiratory infection. Respiratory infections are responsible for two thirds of COPD exacerbations, which result in subsequent hypercapnic acidosis in 20% of patients.[26-27] Jenny does not improve on the Venturi mask at 8 L/min and worsening blood gases require an escalation of care to NIV, as per BTS and ATS guidelines in patients with AHRF.

Whilst NIV is effective, it can come with limitations

1 in 3 patients fail NIV due to mask intolerance with oronasal dryness and nasal congestion accounting for 20-50%, and 10-20% of complications with NIV, respectively.[14]

Patient: Jenny has a history of mask intolerance due to claustrophobia and mask discomfort. She is also suffering from mouth dryness. The health care team supporting Jenny decide to try High Velocity Therapy to reduce dyspnea and relieve treatment failure concerns. Carron et al found additional limitations of traditional masked- based therapies which include the risk of aspiration due to vomiting, difficulty administering concomitant oral medication, an inability to create a face seal and concerns of pulmonary barotrauma, pneumothorax, and sedation requirements.[14]

High Velocity Therapy: Beyond Traditional High Flow

High velocity therapy is considered a form of mask-free NIV therapy, and an advanced form of high flow nasal cannula therapy (HFNC). High velocity therapy's use of small-bore nasal cannula generates high velocity gas which flushes the upper airways to aid CO_2 clearance and oxygenation.[15] High velocity therapy improves the efficiency of alveolar ventilation via dead space washout, whilst traditional mask-based therapies utilize elevated airway pressures to increase alveolar recruitment. In addition to CO_2 washout, high velocity therapy does generate mild distending pressures of PEP 5-6 cmH_2O.[16] This system not only reduces work of breathing but also enables high velocity therapy the additional advantage of treating hypercapnia and hypoxemia simultaneously. This mechanism is particularly relevant for patients with CRD's such as COPD, where hypercapnia plays a key role in clinical deterioration.

Studies have shown High Velocity Therapy

- Reduces pCO_2 and improves pH with no statistical difference between high velocity therapy and NiPPV.[17]
- Relieves dyspnea similarly to NiPPV (non-inferior, p=0.03).[16-19]
- COPD patients receiving high velocity therapy spent less time in the ICU in comparison to patients on NiPPV.[18]
- High Velocity Therapy is non-inferior to NIV for patients with undifferentiated respiratory distress.[16,17,20]

Let's Revisit Jenny

In addition to Jenny now receiving optimal humidification, she has reduced discomfort compared to patients receiving NiPPV. Comfort and tolerance levels are proven to be higher in HFNC therapy than in NIV, with intolerance associated with treatment failure. Patient comfort level has been shown to have a critical impact on the therapeutic effect of treatment, and therefore clinical outcomes.[21] In the Yamane et al study, high velocity therapy had **superior patient reported comfort ratings at every time point** measured after treatment initiation compared to NiPPV ($p < 0.05$).[17] Increased adherence and comfort levels are seen when patients receive adequate humidification.[22]

In fact, Yamane et al found:

- **Discomfort only increased after initiation with NiPPV** and discomfort remained higher than baseline throughout treatment.[17]

In a study of intensive care unit (ICU) patients, Lenglet et al found significant improvement in both clinical and physiological parameters after just **30 mins** of heated and humidified HFNC therapy with recent studies confirming HFNC reduced risk of treatment escalation by almost half (45%) when compared to SOT, as well as improved tolerance and lower complication rates.[23] There is also evidence to suggest that humidified high flow may be able to reverse mucus plugging, preserve MCC and thus prevent obstructive atelectasis.[24]

Patient

Jenny tolerates high velocity therapy well, her pCO_2 and pH see improvement quickly. Jenny avoided escalation to sedation, and her likelihood of intubation fell as her ABGs improved.

- Jenny is able to go home after 10 days.[28]
- She was able to eat, drink and take oral medication whilst receiving therapy.
- Jenny was able to clearly communicate with her care team, wear her glasses and hearing aids whilst receiving therapy.

Hospital

- The respiratory care team became more confident in using high velocity therapy in type 1 and type 2 respiratory failure patients; backed up by clinical research and experience.
- The hospital avoided the cost of an intensive care stay, and the potential additional care cost associated with nurse interventions, skin breakdown and oral care due to inadequate humidification.[29]

As illustrated by Jenny's case, the absence of optimal humidification during NIV therapy can impair mucociliary clearance, increase the risk of respiratory infections and contribute to clinical deterioration in AECOPD with AHRF.

Conclusion

Humidification is not merely an accessory to high velocity therapy; it is a fundamental component that underpins clinical outcomes of long-term NIV usage and compliance. Suboptimal humidification can contribute to prolonged hospitalisations, higher morbidity, and increased healthcare resource utilisation.[25] This paper demonstrates high velocity therapy is a viable alternative to traditional mask-based NIV, delivering optimal humidification from the initiation of treatment. High velocity therapy can address the full pathophysiological spectrum of respiratory failure for the spontaneously breathing patient, aiding oxygenation, ventilation, secretion management, and patient

comfort. In conclusion, integration of early humidification into routine clinical practice represents a necessary evolution in the standard of respiratory care.

Caution: US Federal law restricts this device to sale by or on the order of a physician. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. For spontaneously breathing patients. High Velocity Therapy (HVT) does not provide total ventilatory requirements of the patient. It is not a ventilator.

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Don't Discount the Value of Clinical Education When Evaluating Critical Care Vendors

Why clinical education offerings are an upfront priority and not a value-add second to the sale

Winnie Sywulak, BS, RRT, RRT-NPS

Evidence-based medicine and medical technologies designed to support it are rapidly evolving as clinicians and equipment vendors seek new ways to help enhance patient care delivery, outcomes and safety.

"The lifespan of information is now only 70 days, and a deluge of knowledge is predicted, driven by advances in information technology, artificial intelligence, the availability of large datasets, scientific progress, and international collaboration," stated the authors of recently published research on continuing professional development (CPD) in healthcare.[1]

According to the research, CPD "is essential for ensuring safe patient care."[2] So, why do many hospitals and clinical teams still view clinical education from medical equipment vendors as a "value add" rather than a critical element of customer service and support?

Some vendors are now taking a different approach; seeing it as their obligation to provide robust continuing education offerings aimed at supporting the success of clinicians and the care and safety of patients.

Understanding how individual clinicians have different learning styles and are at different stages of their learning journeys, these blended educational offerings are designed to meet them where they are—from in-depth, in-person training to quick hits of supplemental digital micro-learning available on-demand.

Why prioritize clinical education?

"Not a day goes by that a new medical study isn't published or advancements are made in the industry. These findings and innovations impact how patients with certain medical conditions should be assessed, treated, and cared for," stated the authors of an article published in the peer-reviewed journal BMC Nursing.[3]

A healthcare professional's education doesn't end when they earn a degree or certification; rather, their career is one of life-long learning as new evidence is surfaced, new protocols are published, and new technology is introduced into practice.[4]

While it is an individual clinician's responsibility to continue their education, the hospitals in which they work, and their leaders and managers have an obligation to "play a central role in continuous learning processes aimed to improve health care."

This includes providing opportunities for their clinical staff members to participate in continuing education programs and serving as examples by participating in these programs themselves.[6]

Values of continuing medical education to health care providers

- Refine skills to improve overall patient care
- Stay current with the latest developments within their specialty
- Address real-world challenges that healthcare professionals face day to day
- Gain professional growth and a means to advance career status
- Meet licensing/certification requirements
- Learn effective medical team management skills
- Earn membership in professional organizations

Source: The American Association of Continuing Medical Education
https://aacmet.org/cme/importance-of-cme

"Medical professionals have a responsibility to their patients to continue their education and stay on top of these changes. Only by doing so can they confidently provide patients with the level of care they deserve."[5]

Why is clinical education critical to safe and effective medical technology usage?

Medical device education comprises both "the medical field and underlying physiology" and "the technical field of the device's use." CPD to maintain competencies in medical device knowledge and safe handling are fundamental for patient safety.[7]

There is an obvious need for a vendor to perform initial education and training to clinical staff members who will be

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using the company's products. The equipment won't provide the intended value unless it is correctly used and used to its full potential.

What might not be so clear when assessing new technologies is the need for ongoing education well beyond the time a new piece of equipment arrives in a care unit. Therefore, both clinical and supply chain teams need to be actively involved in understanding a prospective equipment vendor's educational offerings during evaluation of their technology.

Given the advanced nature of the latest medical technologies, it is particularly important for hospitals to engage with vendors that prioritize CPD related to their devices.

Consider a neonatal incubator with technology that continually stabilizes temperature to help protect an infant from thermal stress. A vendor committed to CPD would not only train the neonatal intensive care unit (NICU) team on how to use this capability but also provide follow up education on thermoregulation so they understand the science behind it and can apply it.

"The medical field is constantly changing and evolving with new technologies, practices, and innovations. Therefore, a nurse or health care specialist's education doesn't end once a degree is obtained."[8]

Large health systems with multiple hospitals present another scenario highlighting the need for CPD on medical devices. When clinicians work across multiple sites, they are likely to encounter medical equipment from different vendors. This is particularly common when a health system has grown through mergers and acquisitions without standardizing its equipment assets. In this scenario, a vendor that offers ongoing education and training for its legacy devices helps fill clinician knowledge gaps.

What to expect of your medical equipment vendors?

With the critical role that medical equipment plays in patient care, safety and outcomes, hospitals shouldn't simply accept whatever a vendor is willing to provide for clinical education. The value of a vendor's educational offerings should be weighed heavily when making equipment purchasing decisions given the benefits clinicians derive from continuous learning.

Key elements of a robust vendor clinical education program

- Takes a consultative, blended approach with personalized learning experiences matched to a customer's education and training needs
- Spans the lifetime of the equipment, offering clinicians the opportunity for continuous improvement of their knowledge and skills
- Provides training and education modalities designed for different learning styles and preferences
- Features programs that are accessible and engaging to clinicians wherever they are in their learning journeys
- Evolves and expands to meet changing clinician CPD needs and preferences
- Reflects the latest evidence-based research, industry guidance and protocols

Commitment to clinical education shouldn't end at the initial in-servicing, but rather, continue throughout the lifetime of a manufacturer's devices.

A vendor's education programs should consider factors including accessibility and engagement of users of its technologies; personalized learning experiences and programs customized to customer needs; and educational offerings that are constantly evolving and expanding based on new clinical evidence and customer feedback.

A well-rounded clinical education program should integrate a variety of learning modalities to support diverse learner preferences and hospital workflows:

- **In-person learning:** Face-to-face clinical education programs.
- **On-demand learning:** 24/7 digital access to accredited continuing education courses (CEU) and customized eLearning packages tailored to a hospital's product portfolio and relevant care areas.
- **Live-streamed learning:** Live accredited webinars on current clinical topics and best practices and monthly interactive 30-minute drop-in sessions to refresh clinicians' knowledge about the vendor's devices used in their hospitals.
- **Micro-learning:** Quick hits of digital information for clinicians to help refresh their learning and fill in knowledge gaps around the devices used in their hospitals.

Virtual reality (VR) learning is another area of clinical education that is emerging to help enhance learning. These immersive VR platforms offer clinicians autonomous and standardized trainings available on demand, and instructor-led, multiplayer clinical simulation available via live-stream.

Conclusion

Clinical education is not merely an added benefit but a fundamental component of effective medical technology implementation and patient care. As healthcare delivery continues to evolve at an unprecedented pace, ongoing education ensures clinicians remain equipped with the latest knowledge and skills necessary to deliver safe, high-quality care.

Hospitals that prioritize medical equipment vendors with robust, continuous education programs can maximize the value of their

technologies while enhancing the competency and confidence of their clinical staff members.

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News…continued from page 49

asking us to add a hook to the end of it. Others have been asking for a cover for the Little Sucker Nasal Tip. We've addressed both requests with this line extension." The Little Sucker Cover was invented by a clinician. It is a great way to protect the suction tip from damage, debris, and external contaminants when not in use. The cover with hook allows clinicians to conveniently hang it to store. And the bright blue color makes it easy to locate. The Little Sucker is designed for single handed suctioning and features a thumb port for intermittent suctioning. It is soft and flexible, similar to a bulb syringe. Little Sucker Cover options: Original standard tip cover; standard tip cover with hook; nasal tip cover with hook. The entire Little Sucker line is made in the United States. About Neotech Products: Neotech Products has been manufacturing innovative medical products since 1987. Their unique, skin friendly products are designed to benefit mothers, babies, children, and clinicians. Neotech Products is a proven leader in the development of neonatal, pediatric, and respiratory products.

Beyond Air Submits FDA PMA Supplement

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on harnessing the power of nitric oxide (NO) to improve the lives of patients, announced the submission of a premarket approval (PMA) supplement application to the US Food and Drug Administration (FDA) for LungFit PH II, the next-generation therapeutic nitric oxide generator. Beyond Air has developed its LungFit PH II system to be smaller, lighter and fully transport-ready - while delivering all the breakthrough features of the currently FDA-approved version from the Company's therapeutic platform of nitric oxide generators targeting pulmonary disease. The new system uses the same Smart Filter and accessories as the first-generation device, ensuring continuity, streamlined logistics, and minimal disruption for existing customers. The LungFit PH platform uses the Company's patented Ionizer technology to generate unlimited on-demand nitric oxide from ambient air, which is then able to be delivered directly to a ventilator circuit, regardless of dose or flow. The LungFit PH system uses the equivalent power of a 60-watt lightbulb to ionize the nitrogen and oxygen molecules, forming nitric oxide with low levels of nitrogen dioxide (NO2) created as a byproduct. The gas then passes through a Smart Filter, which removes the toxic NO2 from the internal circuit.

For the treatment of PPHN, the novel LungFit PH system is designed to deliver NO doses consistent with the current standard of care for delivery of 20 ppm NO, with a range of 0.5 ppm - 80 ppm (low concentration NO), for ventilated patients. Each Smart Filter provides 12 hours of therapy regardless of ventilator demands and can be replaced in seconds for uninterrupted treatment. "We are pleased to announce that development of our transport-ready LungFit PH II has resulted in a NO system which we believe is far superior to legacy systems currently available in the market. While our first-generation system already delivers key advantages to hospitals, this next-generation device raises the bar with a reduced weight and footprint, simplified operation, longer service interval, and full compatibility with both air and ground transport. It also includes an automated backup system that retains most primary system capabilities," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "Once approved, we are confident that the introduction of LungFit PH II will play a pivotal role in accelerating our market expansion and advancing our position as a global leader in hospital-based NO delivery."

Continued on page 87…

ECMO-Weaning Facilitated by Neurally Adjusted Ventilatory Assist (NAVA): A Case for Principal Clarification

F. Heinold, O. Moerer and L. O. Harnisch

Abstract

The use of veno-venous extracorporeal membrane oxygenation (VV-ECMO) has become increasingly prevalent, particularly in respiratory disease pandemics such as H1N1-influenza and SARS-CoV-2. This surge has emphasized the importance of clear therapy recommendations, improved accessibility to ECMO technology, established ECMO teams, and structured networks to ensure access to specialized care throughout the course of the disease for patients with severe ARDS. Although the initiation criteria for VV-ECMO are well defined, treatment strategies while on ECMO regarding e.g., ventilator management or ECMO weaning strategies remain variable and with lack of consensus. NAVA (Neurally Adjusted Ventilatory Assist), as an assisted mechanical ventilation modality, offers real-time electromyographic feedback, which has been shown to enhance prolonged weaning processes from mechanical ventilation. We present a case of penetrating thoracic trauma complicated by ARDS, successfully managed with VV-ECMO. NAVA was employed to monitor and facilitate ECMO. This approach integrates ECMO weaning with ventilation settings, considering both gas exchange lung function, such as carbon dioxide removal, and respiratory mechanics in the form of neuromuscular coupling. This is a new approach to VV-ECMO weaning. More research is planned to validate the efficacy of this method in conjunction with additional parameters, such as diaphragm activity evaluated sonographically in a randomized design. This case underscores the potential of NAVA in VV-ECMO weaning, offering a promising avenue for optimizing patient care and outcomes.

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Background

The use of venovenous extracorporeal membrane oxygenation has increased in recent years and was undoubtedly boosted by pandemics of respiratory diseases such as H1N1-influenza and SARS-CoV-2.[20,21,26] Despite this increased use, which is partially due to the increased availability of this method even in small hospitals, the recommendations are clear that VV-ECMO is still a rescue measure for the most severe cases that cannot be handled otherwise. The presence of established ECMO teams and the development of structured networks have contributed to ensuring that patients with severe ARDS have access to specialized care in ARDS centers, preventing avoidable mortality due to supply or expertise shortages.

The indications to initiate VV-ECMO independently of the cause of respiratory failure are fairly clear, but contraindications remain a matter of debate.[11] This is also true for ventilator and extracorporeal treatment strategies while on ECMO and especially with respect to the concept of weaning patients from the ECMO circuit and the ventilator.[1,4,11] Regarding the VV-ECMO weaning process, there are no generally accepted recommendations or much scientific evidence on how to make this process more meaningful.

Mechanical ventilation weaning is challenging for up to 30% of critically ill patients[12] with prolonged weaning is associated with increased morbidity, mortality, longer hospital stay, and risk of discharge to a long-term care facility.[19] Weaning from mechanical ventilation is known to be influenced by the mode of ventilation used; (partially) automated and/or adaptive ventilation modes may be advantageous in this regard.[17] NAVA (Neurally Adjusted Ventilatory Assist) was established in 2007 as a mode of assisted mechanical ventilation that uses the output of the patient's respiratory center, which is tapped as a diaphragm myogram, to regulate the ventilator. The electrical signal that triggers the diaphragm is acquired via a specialized gastric feeding tube (Edi catheter). The Edi catheter is inserted into the esophagus close to the crural diaphragm to capture the neuronal excitations of the diaphragm.[2,17,18,24] In real time, the recorded signal represents the temporal and spatial sum of motor unit recruitment and firing frequency.[6,15,18] The Edi peak refers to the highest electrical signal from the diaphragm during a breath cycle, indicating the level of respiratory effort. A higher Edi peak suggests increased breathing effort, signaling that the ventilator may need to provide more assistance. This Edi signal is multiplied by a user-controlled gain factor, the NAVA level (comparable to the level of pressure support in pressure support ventilation; unit: mbar/µV)

which determines the level of applied airway pressure.[3,24] Thus, the pressure support is directly proportional to the amplitude and duration of the Edi signal. When the NAVA level is increased, an instantaneous increase in pressure support is induced, leading to presumably more effective relief of the respiratory muscles.[24] A systematic increase in the level of NAVA has been shown to relieve inspiratory muscles in 74% of cases.[3] As a result, NAVA is frequently used to assess diaphragmatic activity and facilitate prolonged weaning, but has only been mentioned sporadically as an option in the context of ECMO therapy.[14,16]

We present a case of penetrating thoracic trauma complicated by ARDS, in which the patient not only underwent successful treatment with VV-ECMO, but also had the removal of the ECMO circuit monitored using NAVA. Although several studies have documented the use of extracorporeal membrane oxygenation in trauma patients, achieving survival rates ranging from approximately 44 to 71%, it is notable that patients with blunt thoracic trauma are significantly more likely to require ECMO therapy compared to those with penetrating thoracic trauma.[8,9]

Case presentation

A 27-year-old patient suffered a penetrating thoracic injury from a knife attack and was transferred to our trauma center for specialized surgical and ICU treatment. At the time of admission, the patient was fully conscious and did not have motor deficits, respiration was compensated with two chest drains in place, but still a verifiable hemato-pneumothorax on chest radiograph (Figure 1 Chest radiography upon ICU admission, with two indwelling left-sided chest drains in place, in the presence of persistent left sided pneumo- and hemothorax.); otherwise, the patient was in good and stable condition.

Three days after admission, the patient developed severe pneumonia and had to be intubated and ventilated. The remaining hematoma, not fully relieved by thoracic drains, was treated by video-assisted thoracoscopic surgery (VATS) the following day. Despite these interventions, as well as extended antibiotic coverage and adjunctive measures, the patient's respiratory condition further deteriorated to severe acute respiratory distress syndrome (ARDS) and conservative treatment options were exhausted. Therefore, VV-ECMO (Maquet-Cardiohelp, Version 1, HLS Set Advanced 7.0; 23 Fr. V. jugularis interna (Inflow), 25 Fr. V. femoralis sinistra (Outflow)) was initiated as a rescue measure according to criteria established in the EOLIA-trial (PaO2/ FIO2 < 50 mmHg at FIO2 ≥ 80% for > 3 h despite the optimization of ventilation and the duration of mechanical ventilation ≤ 6 days).[5] The initial settings included a pump flow of 5 L/min and a sweep-gas flow of 10 L/min. Tracheostomy had already been performed.

The further course was complicated by an infected wound, remaining hematoma, and pneumatocele, all of which had to be surgically treated while still on ECMO. After 31 days of ECMO and ICU treatment, lung function had recovered so that spontaneous breathing could be established after reduction in sedation while still on VV-ECMO. When sedation was reduced, the patient gradually became conscious, however, due to severe critical illness acquired weakness syndrome, ventilation/carbon dioxide removal remained problematic for a prolonged period of time, while oxygenation was almost unimpaired.[22] Consequently, circuit blood flow could be reduced to 2.5–3.5 L/min, while the sweep-gas flow had to be remained between 2 and 4 L/min initially. Under these conditions, a

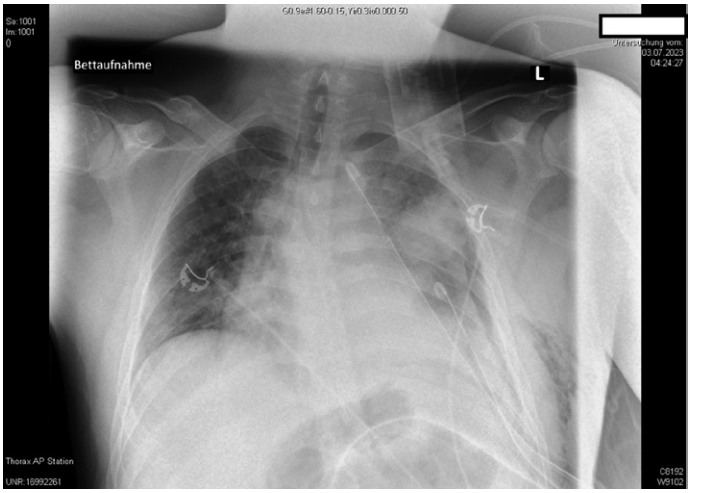

Figure 1. Chest radiography upon ICU admission, with two indwelling left sided chest.

protocolized gradual reduction in sweep-gas flow to 0 L/min was introduced to begin the final ECMO weaning step. However, due to an anxious patient, despite increased sedation, including the use of dexmedetomidine, adequate calming could not be achieved and the usual parameters to detect ECMO weaning failure (SpO2 < 88%, patient distress, pronounced tachypnea, pronounced tachycardia, and hypertension) were not conclusive. Due to our experience with NAVA during mechanical ventilation weaning, we attempted to use this mode during the final phase of ECMO weaning, that is, sweep-gas flow termination. The Edi peak was monitored and the ventilator settings were adapted throughout the weaning procedure. During NAVA-assisted weaning, we aimed to maintain the Edi peak generally within a range of 5–15 µV, with adjustments to the ventilator settings made if the Edi peak exceeded 15 µV. The Edi peak was used as a control parameter, and if it rose above 25 µV, despite ventilator adjustments, it was interpreted as diaphragm fatigue, leading to the immediate termination of the sweep-gas flow break as part of the individualized weaning protocol. Figure 2a shows an example of a ventilator graph during a sweep-gas flow of 6 L/min phase, with an Edi peak of 7.6 µV, and Figure 2b shows the same patient during a phase of flow break phase with an Edi peak of 25.1 µV and the peak pressure terminated by the alarm setting immediately before the end of the sweep-gas flow break

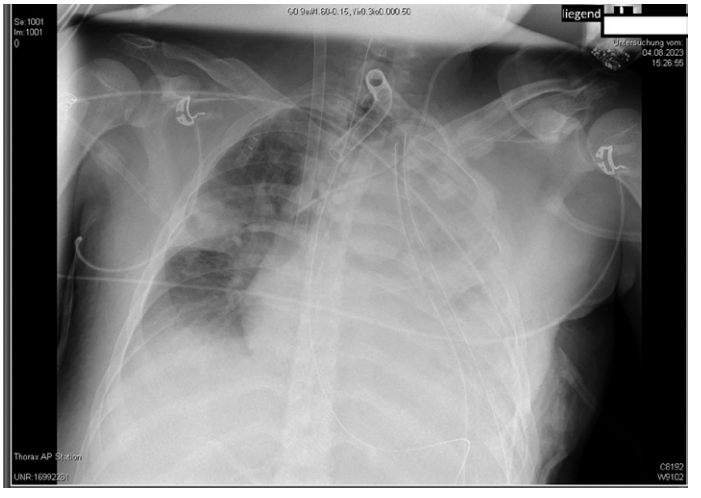

Figure 2. Chest radiography following ECMO and Tracheostomy tube placement in ARDS.

	MVi (lt/min)	RR spont	VT i max (ml)	Edi max µV	Heart rate (bpm)	Blood Pressure (mmHg)	SpO2 in %
06:00	9.8	20	428	8.7	104	129/63	100
06:30	10.44	22	421	9.6	99	123/60	100
07:00	10.3	20	335	13.6	105	130/60	100
07:30	11.63	18	629	11,6	107	138/56	100
08:00	10.86	18	765	17	105	132/63	100
08:30	10.59	26	755	20	108	115/54	100
09:00	10.4	20	305	15.8	106	133/61	100

Table 1. Sweep-gas flow break from 06:00 to 08:30.

(Figure 2 Ventilator graphics with NAVA a) before sweep-gas flow break b) after sweep-gas flow break). NAVA monitoring could effectively, conclusively, sooner than the usually used termination parameters, and independent of the patient's fear, represent changes in diaphragm activation during sweep-gas flow break. This is well illustrated in Table 1 with the essential ventilation parameters of an exemplary weaning process of a gas flow of 0 L/min between 06:00 and 08:30 (Table 1 Sweep gas flow break from 06:00 to 08:30). With this protocol, the sweep-gas flow-free time could be continuously extended and ECMO was successfully removed on day 27 after admission without significant complications (Figure 3).

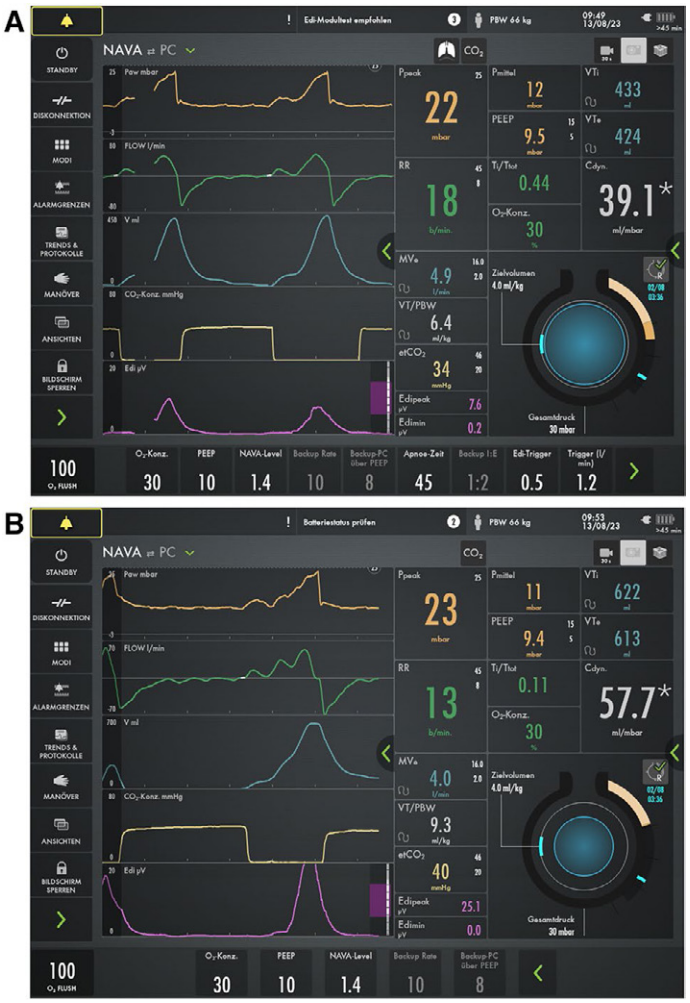

Figure 3. [a] before gas flow break **[b]** after gas flow break.

The further weaning from mechanical ventilation went quickly and smoothly, all wounds healed by and by and were finally surgically covered. The patient was discharged 49 days after admission to a rehabilitation facility with mild swallowing difficulties and critical illness myopathy and polyneuropathy. The tracheostomy was covered with dressings and no abnormalities in gas exchange were observed without oxygen supply.

Discussion

The case of a 27-year-old patient with a penetrating thoracic injury marked by evolving respiratory distress and the application of VV-ECMO as a rescue measure and weaning of the fully awake but very anxious patient presents a complex trajectory. Since there are probably as many different weaning procedures as ECMO centers around the world, but most centers do not disclose their weaning procedure, we cannot be sure. However, it is an irrefutable fact that there are no general principles on which we as a global ECMO treatment community have formally agreed. It starts with the fact that it is not clear whether weaning from mechanical ventilation or ECMO support comes first. What seems to be pretty consistently clear is that during lung recovery blood flow is reduced first (to what extent differs significantly) and the second and final step always becomes sweep-gas flow weaning. When the patient is able to maintain arterial carbon dioxide tension, pH, respectively, within the normal ranges for a significant amount of time (cut-off point for 'significant' again varies substantially) the ECMO support is removed.

This weaning approach, although successful in most cases, focusses almost entirely on the carbon dioxide removal capacity of the natural lung as the only success criterium.[4,25] Only in very few procedural descriptions of mechanical factors such as work of breathing (WOB) or respiratory rate are mentioned, often as a sidenote or additional factors for successful termination of ECMO.[19] What is largely forgotten in this approach is that an increased WOB for increased respiratory minute volume, which must naturally occur when extracorporeal carbon dioxide removal is turned off, may not be feasible for a critically ill patient with ICUAWS (intensive care unit acquired weakness syndrome) and associated diaphragmatic weakness. Even evaluation of esophageal pressure (PES) as an effort signal may not always provide sufficient information to detect weaning failure due to ICUAWS.[7,13] Problematic in this approach is that weaning failure need not be obvious at all, but may occur subclinical through increased respiratory muscle activation. However, this undetected increase in breathing force can cause problems such as renewed gas exchange failure (which may then be

interpreted as recurrent pneumonia) or respiratory exhaustion leading to prolonged weaning. This subclinical ventilatory insufficiency can be approached using surrogate parameters such as WOB and P0.1 or, as a very nonspecific parameter, the respiratory rate, although these parameters are, except for the respiratory rate, rarely available continuously.

However, with NAVA, it is possible to visualize and assess the diaphragmatic force throughout the distance of each breath, as well as the neuromuscular coupling, even before changes in VT (tidal volume), respiratory rate, or esophageal pressure become clinically visible (illustrated in Table 1). Edi peak enables the therapist to decide whether gas exchange and ventilatory function are sufficient for decannulation or are at the expense of diaphragmatic force and problems are to be expected or whether gas exchange is accompanied by low (physiologic) activity of the diaphragm. In this way, the best initial situation for decannulation can be created not only for gas exchange but also for the diaphragm, avoiding respiratory distress and even diaphragmatic injury. During the final step of the VV-ECMO weaning process, Edi peak can indirectly anticipate diaphragmatic fatigue (increase in Edi peak during the weaning process above a value of 25 µV).[23] From our perspective, the initiation of VV-ECMO weaning is currently the optimal time to establish NAVA, as this stage provides the most stable and comparable conditions. By adjusting the NAVA level based on the Edi peak, within an assumed optimal range of 5–15 µV, future approaches could aim to gradually extend the gas flow pause, leading to a more refined weaning process and potentially reducing the overall weaning duration. While this method is still experimental and the optimal Edi peak range (5–15 µV) is derived from various studies—only one of which directly relates to the Edi peak in adult VV-ECMO weaning—in this case it serves as a practical reference for adjusting the ventilator settings.[2,10,14,16]

In this case report, we present the use of NAVA to monitor the VV-ECMO weaning process, which contributed to the successful removal of the ECMO support, for the first time. This case introduces a weaning approach that not only focusses on carbon dioxide removal as a marker of readiness for decannulation but introduces a continuous evaluation of diaphragm strength or fatigue in the weaning process and facilitated the targeted integration of ECMO weaning with ventilation settings. Since this is one of the few descriptions of this approach, naturally more evidence must be generated in larger cohorts.

Conclusion

In conclusion, this case demonstrates the successful use of NAVA to facilitate the weaning process from VV-ECMO in a critically ill patient with a penetrating thoracic injury. The integration of NAVA allowed for continuous monitoring of diaphragm activity via the Edi peak, providing an individualized approach to adjusting ventilator support. By maintaining the Edi peak within a targeted range of 5–15 µV, we were able to optimize the weaning process and prevent diaphragm fatigue, as values exceeding 25 µV indicated the need to pause the weaning attempt. Although the use of NAVA in this context remains experimental, this approach highlights the potential for reducing weaning duration and improving patient outcomes. Further studies are needed to validate these findings and explore the correlation between diaphragm movement and Edi peak during the weaning process.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10047-024-01484-6.

Author's contributions FH treated the patient, collected, interpreted, and analyzed the data, and drafted and revised the manuscript, OM supervised the treatment, helped interpret the data, and revised the manuscript, LOH treated the patient, supervised data condensation, analyzed and interpreted the data, and revised the manuscript.

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Data availability All data generated or analyzed during this study are freely available on PubMed (https://pubmed.ncbi.nlm.nih.gov/). The specific datasets and references used in the current study can be accessed by searching the corresponding PMIDs provided within the manuscript.

Declarations

Conflict of interest FH reports that there are no conflicts of interest. LOH received honoraria for educational lectures from CSL Behring, Baxter, and Shionogi, honoraria from a book project published in 2023 (Springer Book on neuro-monitoring in the ICU Book: Neuromonitoring in der Intensivmedizin 2023, ISBN: 978-3-662-65997-7), and an unrestricted research grant from Sartorius AG Göttingen. OM is a member of the national CEOsys network Germany (Covid Ecosystem), and the Napkon-Tip (Therapeutic intervention platform for conducting ongoing assessments of new therapies), funded by the Federal Ministry of Education and Research (BMBF). Holds a research grant from Advitos for conducting experimental studies related to extracorporeal multiorgan support. OM received honoraria from a book project published in 2023. Springer Book on neuro-monitoring in the ICU Book: Neuromonitoring in der Intensivmedizin 2023, ISBN: 978-3-662-65997-7. Within the last 36 months OM received honoraria for industry sponsored lectures on congresses by Getinge (hemodynamic monitoring) and CSL Behring (coagulation). The Department of Anesthesiology holds courses and workshops supported by companies related to intensive care medicine.

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Helping a Patient Regain Muscle Strength While Weaning From Mechanical Ventilation With a Passy-Muir® Valve

Rachel dela Rosa and Hao Chen

Introduction

Barlow Respiratory Hospital in Los Angeles, California, delivers on its mission to help patients breathe easier. Developing and publishing a protocol specifically for weaning patients from prolonged mechanical ventilation enhances the care of patients with tracheostomy and mechanical ventilation. The Therapist-Implemented Patient-Specific (TIPS©) weaning protocol (see Figure 1), developed by Barlow pulmonologists and based on years of specialized practice, has been nationally recognized and widely adopted by other hospitals. Use of this protocol includes introducing the use of the Passy-Muir Valve (PMV®) during the weaning process as a standard of practice. The Barlow TIPS weaning protocol is used for prolonged mechanical ventilation weaning. Some patients, especially those with muscle weakness, also benefit from PMV use for weaning.

Case Study

History

The patient is a 64-year-old male who was admitted to UCLA in the summer of 2019 due to progressive weakness, presumed to be chronic inflammatory demyelinating polyneuropathy with Guillain-Barré syndrome (CIDP with GBS) and respiratory failure. To begin interventions for rehabilitation, an assessment of the patient was initiated. Assessment included addressing how to implement the Passy-Muir Valve for ventilator weaning with this patient who was demonstrating significant muscle weakness.

Rachel dela Rosa is a Speech-Language Pathologist at Barlow Respiratory Hospital. For more than ten years, she has served patients weaning from prolonged mechanical ventilation with evaluation and rehabilitation of communication and swallow function. As a member of the Respiratory Therapy / Rehabilitation team, she implements Passy Muir Valves for successful restoration of the upper aerodigestive tract, and she contributed towards the hospital's designation as a Passy Muir Center of Excellence. Rachel has a Master of Science degree in Communication Disorders and the Certificate of Clinical Competence in Speech-Language Pathology from ASHA. She graduated from California State University in Northridge, CA.

Hao Chen is a Respiratory Care Clinical Supervisor at Barlow Respiratory Hospital. For more than 25 years, he has served patients weaning from prolonged mechanical ventilation and provided guidance in ventilator weaning and troubleshooting. As a member of the Respiratory Therapy / Rehabilitation team, he implements the Passy Muir Valve for ventilator weaning and contributed towards the hospital's designation as a Passy Muir Center of Excellence. Hao Chen is a Registered Respiratory Therapist and graduated from Valley College, Los Angeles, CA.

When this patient first arrived, he was a quadriplegic with slight shoulder movement. His condition was not suitable for using the Barlow TIPS weaning protocol. We conservatively used the Passy-Muir Valve to assist weaning from the ventilator. For in-line use, we used the Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV®007 (Aqua color™). Initially, when we did in-line PMV evaluation and trials, he had a hard time voicing and phonating. He was also only able to use the PMV 007 for brief periods, no longer than a few minutes at a time.

Ventilator Management and PMV Assessment

When this patient arrived, the physician-initiated vent settings were:

- SIMV 12
- Tidal Volume 500cc
- FiO_2 .30
- Pressure Support 10 cmH_2O
- PEEP 6

At the same time, the initial PMV evaluation began with the respiratory therapist (RT) and speech-language pathologist (SLP) at the bedside, working together. To initiate the PMV assessment, the following processes were used:

- Assessment of the patient's vitals.
- Establishing baseline parameters.
- Patient's response—including comfort.

The patient was asked if he was comfortable, and necessary adjustments to the interventions were made as needed. Adjustments included positioning the patient in the bed or chair and ensuring proper positioning of the tracheostomy tube and the patient's head alignment. Typically, before having the patient phonate, we will start with the patient doing something easier, such as humming or throat clearing. Then, the patient takes a deep breath and attempts phonation. Often, with this patient population, the patient is instructed to phonate during exhalation because upper airflow is a lot to get used to again. This may include working with the patient to recognize inspiratory breaths from the ventilator and exhalatory effort. Often, this involves working with the patient to coordinate respiration and speech.

In the beginning, for this patient, the ventilator was put in NIV AC/VC (non-invasive ventilation mode with assist control/volume control), due to the patient having significant muscle weakness. We repositioned him and checked his HR (heart rate) and SpO_2 (oxygen saturation) before starting the initial evaluation.

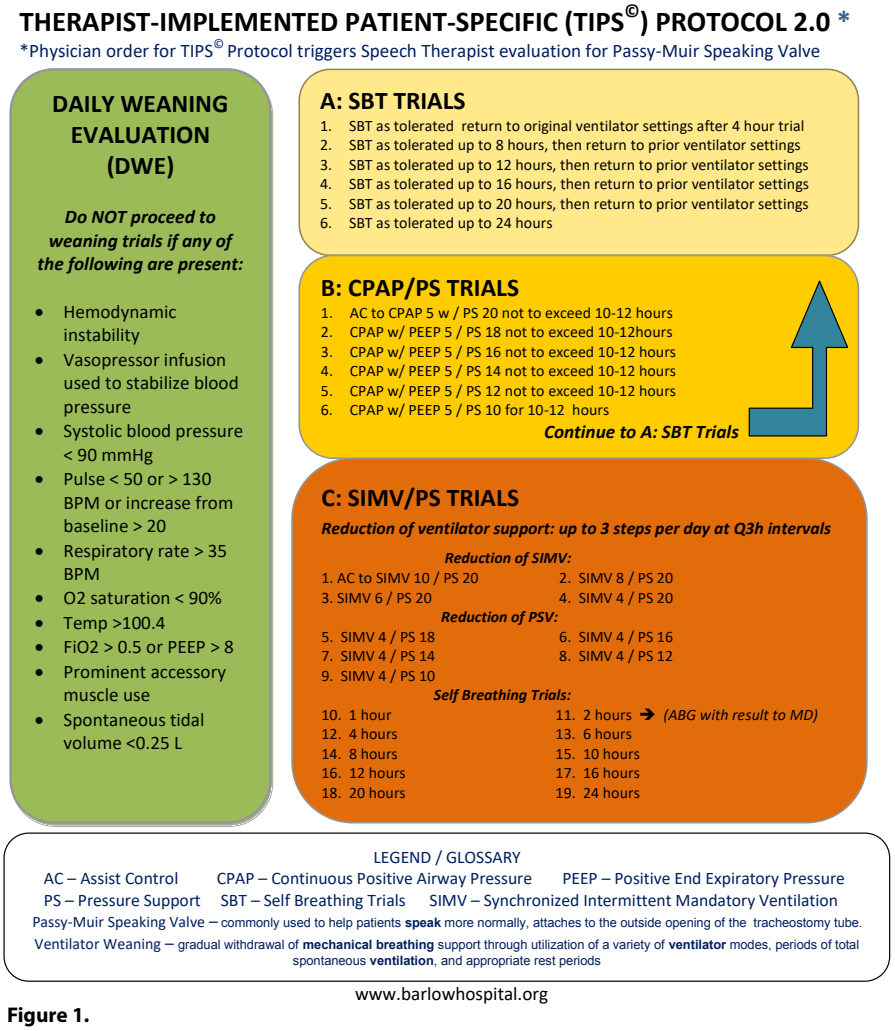

Figure 1.

Establishing the patient's baseline parameters allowed monitoring for change during the evaluation and subsequent treatments.

Part of the planning involved preparing a Passy-Muir Valve, syringe, and Yankauer to have at the bedside and ready for use. We reviewed the plan for the evaluation and discussed with the patient what to expect before we started.

The first step involved deflating the cuff. To decrease patient anxiety, we explained to the patient that he would feel a lot of air through his nose or mouth. It may cause coughing or bring up secretions, which would all be normal. We reassured the patient that if anything bothered him or if he felt uncomfortable to let us know, and we would address it.

After deflating the cuff, we attached a warning label from the Passy-Muir Valve packaging to the pilot line. The warning label identifies for therapists, nursing staff, and others that the cuff must be completely deflated before placing the Valve on the patient. We rechecked the patient's HR and SpO_2 before and after cuff deflation and again after PMV placement.

The patient remained on NIV AC/VC while the cuff was slowly deflated. In this mode, the volume remains constant while the pressure may fluctuate, as needed. Even with VT (tidal volume) added to compensate for the leak that occurred with cuff deflation, the patient reported that he still felt uncomfortable with the same flow rate. The waveforms on the ventilator indicated that the patient's breathing was asynchronous. We then changed his ventilator settings to AC/PC (assist control/pressure control), a setting that allows pressure control to be constant and volume to fluctuate as needed.

The patient reported feeling more comfortable on NIV AC/PC, with a flexible tidal volume and flow rate. Ventilator waveforms showed the patient had better synchrony with this mode.

Assuring Airway Patency

Even with the cuff deflated, the patient's respiratory rate was the same as the ventilator set rate. The patient's ventilator trigger level was already set to the most sensitive level, without autocycle, allowing the patient to initiate breaths if he was able.

Before putting the PMV in-line, upper airway patency was assessed. Looking at airway patency, several options exist:

1. Reading the peak inspiratory pressure (PIP) and/or exhaled volumes via the ventilator prior to and after cuff deflation, the clinician can objectively document an adequate leak and upper airway patency. The clinician is looking for a 40-50 percent drop in PIP and/or a decrease in exhaled tidal volume as measured by the ventilator (Sudderth, 2016).
2. Having the patient blow on a tissue.
3. Assessing voicing on exhalation, listening for exhalation through the upper airway using a stethoscope (Sudderth, 2016).

Level one: SLP only
These patients usually have weak swallowing and speaking function and have limited tolerance for PMV use. They require speech therapy to help with training and coaching. Most are beginning users of PMV.

Level two: Under Supervision
Status for patients who can tolerate PMV a little longer. They may still have some risk related to wearing PMV independently (i.e., level of alertness, intermittent confusion, paralysis of extremities, anxiety, need for partial or complete restraint, need for intermittent oral and/or trach suctioning).

Level three: In-Line PMV Only
These patients are still ventilator dependent, need a high level of ventilator support, or have difficulty weaning from vent support

Level four: As Tolerated
These patients are usually off the ventilator and alert and oriented. They can use the call light for help. Respiratory status is stable, and they can participate in rehabilitation activities. Most of these patients are eligible for trach capping trials and/or decannulation.

Table 1. Criteria for PMV Use: Depending on the patient's condition, we follow 4-level criteria to determine appropriate use of PMV. With these criteria, we are better able to manage different levels of PMV use for patients.

Having a leak before placing a Valve in-line suggests that the tracheostomy tube is properly sized and allows sufficient airflow around the tracheostomy and out the mouth and nose. It also suggests that there is no significant obstruction above the tracheostomy tube. The PMV would then be placed into the ventilator circuit while mechanical ventilation continues.

After placing the PMV in-line, continuing to check the patient's upper airway patency and Valve use can be done by looking at exhaled tidal volume (VTe) and minute ventilation (VE). When looking at the ventilator (in our facility, a Puritan Bennet 840), it showed "00" on both of VTe and VE. This reading indicated that no exhalatory airflow was returning to the ventilator; there was no return tidal volume. With all readings indicating a patent airway for this patient, the Valve could be used in-line.

However, if none of these measurement options demonstrate exhalatory airflow or patency, then the patient may have an airway obstruction. Obstruction may lead to observed back pressure – a release of air out the tracheostomy hub when the Valve is removed. Indications of difficulty include the patient coughing excessively or having a hard time breathing or phonating. So, considering cough, voice, and breathing pattern provides good parameters to evaluate when assessing a patient.

Addressing Barriers to Weaning

This patient was unable to wean off the ventilator in the past, with the barrier being muscle weakness. If we wanted to succeed in weaning the patient, we had to help the patient increase muscle strength. The PMV is a tool that may assist with increasing respiratory muscle strength. Using a PMV restores the body's closed system and restores airflow to the upper airway. It not only restores airflow but also improves swallowing and speaking functions and restores respiratory mechanics. It especially helps to restore diaphragm function by adjusting pressure function in the chest, and it can also improve body stability. Human survival depends on the stability of the internal environment.

The PMV weaning strategy for this patient was to use the PMV 007 Valve and progress from a high level of ventilator support and gradually drop to a lower level of ventilator support (see Table 1). The next step was to transition from in-line use of the PMV to a trach mask with cool aerosol and PMV. We checked the patient's negative inspiratory force (NIF) daily and monitored $EtCO_2$ (exhaled carbon dioxide) frequently to evaluate improvement in respiratory muscle function.

Addressing Muscle Strength

During PMV weaning, changes to different ventilator modes, such as adjusting tidal volume, pressure control, or pressure support levels, and trigger sensitivity may gradually increase the time the patient uses the PMV. At the same time, physical therapy (PT) encourages the patient to use MOTOmed Movement Therapy (motorized movement therapy device that can be used in a bed or a chair) for upper and lower extremities exercises. These methods really help patients improve inspiratory muscles and extremity muscle strength.

Once the patient's NIF improved and PMV tolerance increased, we changed the patient's NIV AC/PC settings to CPAP/PSV (continuous positive airway pressure/pressure support ventilation) with pressure support only (see Figure 4).

The patient got stronger over time with therapy. He received therapy from PT, occupational therapy (OT), and the SLP. We taught him how to breathe consistently, managing his breath and speech coordination at the same time. We also worked on swallowing and eating. Activities of daily living and mobility tasks were all included in his therapies. When possible, we used the Passy-Muir Valve during therapy as a tool to strengthen the upper airway to help with weaning from the ventilator.

As the patient muscle strength improved, the patient's muscles became stronger, which increased tidal volume and allowed titration of his pressure support. When dropping the pressure support to a certain level and maintaining the patient's tolerance, the patient transferred from CPAP to cool aerosol via trach mask. As the patient stayed on cool aerosol for longer periods of time, muscle strength became stronger. The patient's NIF progressed from "0" to "30" after one and a half months of interventions.

Patient's Perspective

The patient shared that the Passy-Muir Valve was important to him. He stated, "I have a voice now, and it gives me options. When I first arrived, it was incredibly difficult. Not all staff are patient enough to try to understand, especially when you try to explain it to staff who cannot hear you. It is really, really hard. This has been a good adjustment. When you have a voice, you can tell the caregiver. This has been helpful, and the staff have been supportive in moving me along. Thank you."

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Subglottic Secretion Drainage (SSD): The Lynchpin of Ventilator-Associated Pneumonia (VAP) Prevention

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Abstract

Ventilator-associated pneumonia (VAP) is a devastating and persistent complication, affecting up to 20% of critically ill patients requiring invasive mechanical ventilation and accounting for half of all antibiotic prescriptions used in the ICU.[1,2] VAP significantly increases hospital length of stay and healthcare costs while contributing to long-term morbidity and mortality.[1,2] Despite the implementation of numerous preventative strategies, a deep understanding of VAP's pathogenesis reveals that subglottic secretion drainage (SSD) is the indispensable cornerstone of effective prevention. This article will elucidate how SSD, by directly addressing the primary cause of VAP—the microaspiration of colonized secretions past the endotracheal tube (ETT) cuff—acts as a lynchpin that complements and enhances all other pharmacological and non-pharmacological risk-reduction interventions. It will expand on the critical importance of suctioning methodology, present compelling evidence on the cost-effectiveness of SSD, and discuss the knowledge gaps that have hindered its widespread adoption. Finally, this article suggests that healthcare payers are uniquely positioned to enforce the use of SSD as the standard of care in hospitals, aligning this advocacy with the 'zero harm' and patient safety initiatives increasingly championed by agencies like the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and other key agencies within the Department of Health and Human Services (HHS). Future research should focus on optimizing suctioning techniques and validating the powerful synergy of SSD with other interventions like selective digestive decontamination (SDD) and continuous cuff pressure control (CCPC) within a comprehensive VAP prevention bundle.

Introduction

VAP remains a significant cause of morbidity, mortality, and increased healthcare costs in patients requiring invasive mechanical ventilation. Despite decades of research and the implementation of various prevention bundles, the incidence of VAP remains a challenge. A central theme in VAP pathogenesis is the microaspiration of bacteria-laden secretions from the oropharynx and, critically, gastric reflux from the stomach. These secretions and gastric contents pool above the ETT cuff and are subsequently drawn into the lower respiratory tract.

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Endotracheal Tubes are often referred to "Endotracheal Tube-Associated Pneumonia"[3] or "Gateway to Ventilator-Associated Pneumonia."[4] This fundamental understanding positions the ETT, and specifically the secretions that accumulate around its cuff, as the "real culprit" behind VAP.[5] The presence of an endotracheal tube (ETT) represents a major risk factor, as it disrupts the natural protective barriers of the upper airway, allowing direct access to the tracheobronchial tree and its role as a reservoir for infectious microorganisms[5,6,7,8] and further contributing for up to 25–56% of the intubated patients to contract VAP. In other words, the risk of acquiring VAP increases by 6 to 20 fold every time an ETT is placed in a patient.[7]

This article argues that Subglottic Secretion Drainage (SSD) is not just another component of a prevention bundle but the most critical intervention because it directly addresses the root cause of the infection, while other measures are valuable risk-reduction interventions. Interventions complementary to SSD Effective VAP prevention is a multi-faceted endeavor, and SSD's strength lies in its ability to synergize with other established interventions.

Subglottic Secretion Drainage (SSD): Complementing All VAP Prevention Strategies

The effectiveness of VAP prevention hinges on a multi-pronged approach. However, for true impact, each element must synergize with a core mechanical barrier. SSD fulfills this critical role, elevating the efficacy of other common non-pharmacological and pharmacological interventions. The success of SSD, however, is not just about the presence of a drainage port, but critically depends on the safe and appropriate suctioning methodology.

1. Head-of-Bed (HOB) Elevation and SSD

- **HOB Rationale:** Elevating the head of the bed (typically 30-45 degrees) is a well-known non-pharmacological risk-reduction intervention to reduce aspiration risk by leveraging gravity. While HOB elevation can minimize the downward flow of gastric contents into the lungs, it does not fully prevent the pooling of oropharyngeal secretions above the endotracheal tube (ETT) cuff.

- **The Methodological Misrepresentation:** The perceived effectiveness of HOB elevation in some meta-analyses is based on a fundamental misinterpretation of data and methodological inconsistencies. The Drakulovic (1999)

landmark study,[9] frequently cited to support HOB elevation, has been critiqued by Van Nieuwenhoven (2006)[10] for its methodological limitations. Specifically, it compared the semirecumbent position (45°) to a supine position (0°), instead of (10°) normally used as standard supine position.

This methodological issue continues to be perpetuated. In a striking example of irony, recent meta-analyses by Lian (2024) and Zhou (2021)[11,12] used incorrect data from Van Nieuwenhoven[10] to show a significant VAP reduction. This is particularly problematic as the primary focus of their papers was the increased risk of pressure ulcers at higher HOB elevations—a complication that is a "never event" according to CMS. These studies essentially highlight a critical trade-off: using an intervention that may reduce VAP but potentially increases the risk of serious patient safety issues.

Van Nieuwenhoven[10] did not use subglottic secretion drainage (SSD) in their study; however, in the discussion section, the authors speculate whether SSD "could have prevented episodes of VAP," noting that the preventative effects of the technique had been "reported, albeit with contrasting results."

Further analysis by Mohammad (2024)[13] singled out two key 2017 studies, Ghezeljeh (2017) and Hassankhani (2017),[14,15] as central to this convergence of research. The Hassankhani (2017)[15] paper is particularly revealing. Unlike the others, all of its patients received both endotracheal suctioning and subglottic secretion drainage (SSD). While Hassankhani[15] showed that a 60-degree elevation was superior to 45 degrees in reducing VAP, this outcome is critically different from studies that do not include SSD. It suggests that the positive results were likely due to the combined effect of the intervention bundle, including the physical removal of secretions via SSD and routine gastric drainage, rather than solely the HOB elevation itself.

- **SSD Complement:** While HOB elevation helps, it cannot completely prevent the pooling of secretions above the ETT cuff or their microaspiration. SSD directly complements this intervention by physically removing these pooled secretions, providing a continuous or intermittent physical barrier that HOB elevation alone cannot achieve. The two work in concert: HOB reduces the amount of gastric reflux material that might reach the subglottic space, and SSD efficiently removes what accumulates there.

2. Sedation Vacation/Minimization and SSD

- **Sedation Vacation Rationale:** Daily sedation interruption and minimization protocols are crucial for reducing the duration of mechanical ventilation, improving patient awakening, and facilitating earlier extubation. Shorter ventilation times inherently reduce VAP risk.

- **SSD Complement:** Even with optimized sedation, intubated patients remain at risk of microaspiration as long as the ETT is in place. SSD acts as a vital safety net during the entire intubation period, irrespective of sedation levels. It ensures that even if a patient is deeply sedated and unable to clear secretions, the mechanical drainage actively prevents microaspiration. This allows clinicians to pursue sedation minimization more aggressively, knowing a core VAP prevention mechanism remains active and the primary pathway for infection is continuously addressed. This combined approach is supported by recent systematic reviews on the synergy of sedation protocols and subglottic suctioning in VAP prevention bundles.[16]

3. Oral Care/Probiotics and SSD

- **Oral Care/Probiotics: A Misplaced Emphasis:** The rationale for oral care—that it reduces bacterial load and thus the pathogenicity of aspirated secretions—is an intellectually attractive one. Similarly, the use of probiotics aims to alter the oral flora to a less pathogenic state. However, this entire paradigm is a misplaced emphasis because it focuses on treating a symptom (bacterial colonization) rather than the root cause of VAP: the microaspiration of secretions.

  This intellectual flaw is perpetuated by the literature itself, as seen in Cheema et al. (2022), Han et al. (2024) & Chen et al. (2025).[17,18,19] These meta-analyses are perfect examples of interventions that, while promising, have not yet been conclusively proven to prevent VAP. While they suggest that probiotics may reduce VAP, they contain crucial caveats, cautioning that "further large, high-quality RCTs are warranted" due to the low quality of the pooled evidence. This pattern demonstrates how the medical community continues to explore bio-modulatory interventions that address symptoms while overlooking more effective mechanical solutions.

- **The Synergistic Role of Subglottic Secretion Drainage (SSD):** Oral care and probiotics are essential for reducing the colonization of bacteria, but they do not eliminate the presence of bacteria entirely. Furthermore, they do not prevent the physical pooling of secretions above the endotracheal tube cuff. As shown by studies like Chair et al. (2020),[20] even with meticulous oral care, fluid leakage is still likely to occur, and the process of oral care itself can exacerbate the problem.

  This is where the true lynchpin comes into play. SSD directly removes secretions, preventing microaspiration from occurring in the first place, regardless of their bacterial load. This is a point powerfully made by Vollman et al. (2016),[21] an excellent chapter that provides an evidence-based framework for ETT and oral care. It is particularly noteworthy that within their review, only SSD received a Level A rating, the highest level of evidence, based on a meta-analysis of randomized controlled trials. Ironically, the same review recommends CASS (Continuous Aspiration of Subglottic Secretions) as a Level A intervention, while giving only a Level C to IASS (Intermittent Aspiration of Subglottic Secretions), a recommendation we now know is not safe due to the increased risk of tracheal mucosal injuries from CASS. This highlights the foundational strength of the SSD concept even when specific applications of it have been refined.

  Thus, the most powerful and effective VAP prevention strategy is a synergistic one:
  - Oral care and probiotics impact the quality of potential aspirate (fewer virulent bacteria).
  - SSD impacts the quantity of aspirated material, reducing it to near zero.

This dual-defense approach is supported by robust evidence, including benchtop studies that have consistently demonstrated that endotracheal tubes with subglottic secretion drainage and optimal cuff pressure were the dominant interventions for preventing maximum fluid leakage.[20] This robust finding provides compelling evidence that the mechanical removal of secretions via SSD is a critical and independent mechanism for VAP prevention, complementing the effects of oral care and probiotics.

4. Continuous Cuff Pressure Control (CCPC) and SSD

- **CCPC Rationale:** CCPC is a valuable risk-reduction intervention. Maintaining optimal ETT cuff pressure at all times prevents gross leakage of secretions and minimizes tracheal wall injury. However, even well-inflated cuffs have microscopic folds that allow for microaspiration.

  While continuous control of cuff pressure (CCPC) has been proposed as a VAP prevention strategy, the evidence is often misrepresented. The most frequently cited study in support of CCPC's effectiveness, a prominent 2011 paper by Nseir[22] and colleagues, found a significant reduction in VAP. However, a close reading of the methodology reveals a critical and misleading limitation: the authors explicitly state that their primary objective was to measure microaspiration of gastric contents (using a pepsin marker) and that they made "no effort" to evaluate the effects on oropharyngeal secretions. Despite this, the study's conclusion broadly attributes the VAP reduction to the CCPC device itself, even speculating that it must also be effective against oropharyngeal secretions without any supporting data. This is a crucial point of logical fallacy that has been perpetuated in subsequent meta-analyses, which cite this paper to overstate the general efficacy of CCPC.

  The problematic conclusions of the 2011 study were carried forward into a highly-cited 2015 collaborative meta-analysis by the same lead author, Nseir et al.[23] This analysis aimed to definitively prove the efficacy of CCPC by pooling individual patient data from several trials. However, a careful review reveals that the analysis suffers from significant logical and methodological flaws. For example, it included the Valencia et al. (2007) study,[24] which found no significant difference in VAP incidence between continuous and intermittent cuff pressure control groups. Even more notably, it included a 2014 study by co-author Lorente et al.,[25] which is ironic given that a prior 2007 study also by Lorente and colleagues[46] had already demonstrated a remarkable 64.5% VAP reduction using subglottic secretion drainage (SSD) with a polyurethane cuff. It is critical to note that Lorente's successful outcome in both studies was achieved by using SSD with a 10 ml syringe performed at one-hour intervals. By pooling data from these disparate studies and failing to properly attribute the protective effect to the use of SSD, the 2015 meta-analysis creates a misleading conclusion that CCPC alone is an effective VAP prevention strategy. This is directly contradicted by a decade of robust evidence, most recently affirmed by the Wu et al. (2024) meta-analysis,[26] which shows the true protective effect lies in the combination of these interventions.

- **SSD Complement:** This is perhaps the most synergistic combination. CCPC ensures the cuff maintains an adequate seal, reducing bulk leakage, while SSD actively and continuously removes the secretions that inevitably accumulate above the cuff due to micro-leaks and the impairment of natural clearance mechanisms. Together, CCPC optimizes the seal, and SSD clears the residual, creating the most robust mechanical barrier against microaspiration. Recent meta-analyses by Mastogianni et al. (2023) and Wu et al. (2024)[16,26] strongly affirm the enhanced efficacy of SSD, with the latter specifically demonstrating that the "combination of CCPC and SSD can significantly reduce the incidence of VAP and the duration of Mechanical Ventilation."

  This finding is particularly notable when contrasted with papers like Valencia (2007)[24] and the two largest studies by Dat (2022) and Marjanovic (2021)[27,28] which did not include SSD and consequently showed no VAP reduction between continuous and intermittent cuff pressure control. This powerful duo mechanically addresses the primary VAP pathway.

5. Selective Digestive Decontamination (SDD) and SSD

- **SDD Rationale:** SDD is a preventative strategy that uses a combination of topical non-absorbable antibiotics and sometimes systemic antibiotics to reduce the bacterial load in the oropharynx and gastrointestinal tract. While SDD has shown effectiveness, its use is controversial due to concerns about antimicrobial resistance (AMR). Like oral care, SDD addresses the bacterial content of the secretions but does not physically remove the secretions themselves. For this reason, SSD remains the indispensable mechanical complement to this pharmacological risk-reduction intervention.

- **SSD Complement:** SDD is a pharmacological approach to reduce colonization. However, it does not mechanically prevent microaspiration. Even with reduced bacterial load, aspiration of any fluid can still lead to VAP if the host defenses are overwhelmed. SSD directly removes secretions regardless of their bacterial content, acting as a crucial physical barrier. Used together, SDD reduces the *virulence* of potential aspirates, while SSD reduces the *volume* of all aspirates, providing a comprehensive "clean and clear" strategy. This combination addresses both the "source" and the "route" of infection as demonstrated in a 2002 RCT study. The Pneumatikos et al. (2002) RCT[29] demonstrated significant VAP reduction (70%) and a substantial, albeit possibly underpowered, mortality reduction (23% to 16%) with combined SDD and SSD. Ironically, this study was subsequently used in the Hammond (2022) meta-analysis[97] to justify the efficacy of SDD alone. This powerful synergy, addressing both the source and the delivery mechanism of infection, offers a far more robust "prevention in the first place" solution.

6. Silver-Coated or Other Coated Tubes and SSD

- **Coated Tube Rationale:** Endotracheal tubes coated with antimicrobial agents (like silver) aim to reduce biofilm formation and colonization on the ETT surface itself, theoretically minimizing a source of pathogens.

- **SSD Complement:** While coated tubes address the biofilm

on the ETT, they do not inherently prevent the pooling of secretions above the cuff or the microaspiration of oropharyngeal contents that bypass the ETT entirely. The successful VAP reduction seen in studies of coated tubes that also incorporate SSD is likely due to the SSD component, demonstrating that SSD's mechanical action is the dominant preventative force. This is a critical point that is often obscured in meta-analyses. For example, in the controversial meta-analyses by Yang (2024) and Ashiq (2024)[30,31] that aggregated silver-coated tubes, the true efficacy often resided in those tubes that also featured SSD ports. The SSD is the functional partner that ensures any benefit from reduced ETT colonization is not negated by the ongoing threat of microaspiration.

A careful review of published literature further reveals that the true efficacy of these tubes often resides in those that also feature SSD ports. A crucial case in point is the study by Mahmoodpoor et al. (2020).[32] In a non-randomized trial, this study compared silver-coated tubes (the intervention) against SSD-ETs (the control). The SSD-ETs in the control arm demonstrated better outcomes, thereby outperforming the silver-coated tubes. The study's design highlights the critical role of SSD in physically preventing microaspiration, which is a more fundamental mechanism for VAP prevention than simply reducing colonization.

This conclusion is further supported by the work of Damas et al. (2022)[33] Their study compared silver-coated SSD-ETs against regular SSD-ETs, finding a superior performance in the dual-feature group. Rather than attributing this success solely to the coating, it is more accurate to view the results as a testament to the combined benefits: the silver coating impacting colonization risk, and the SSD component effectively preventing microaspiration. By pooling such studies without explicitly differentiating the SSD feature, analyses can implicitly misrepresent the true mechanism of VAP reduction and fail to acknowledge the indispensable role of the mechanical drainage component.

7. Institute for Healthcare Improvement (IHI) Ventilator Care Bundle and SSD

- **IHI Ventilator Care Bundle Rationale:** The original IHI Ventilator Care Bundle, a set of evidence-based practices, was designed to collectively reduce the incidence of ventilator-associated pneumonia (VAP). It initially consisted of four components: head-of-bed elevation, sedation vacation, peptic ulcer prophylaxis, and deep vein thrombosis (DVT) prophylaxis. In 2011, a fifth component, oral care, was added to the bundle. The Institute for Healthcare Improvement (IHI) has historically promoted its bundle with a focus on "near-zero" VAP rates, which were widely celebrated and adopted across healthcare institutions. However, the validity of these claims and the omission of other interventions have been challenged for years by researchers, notably O'Grady (2012) and Zilberberg (2009),[34,35] who questioned the rigor of the studies and the conclusions drawn from them.

- **SSD Complement:** A closer examination of the evidence suggests that the success attributed to the IHI ventilator care bundle in many early studies may have been significantly influenced by the concurrent use of subglottic secretion drainage (SSD). The SSD provides a direct, mechanical anti-microaspiration mechanism that is a crucial factor in VAP prevention.

This complementary relationship is supported by recent meta-analyses and original studies. For example, the Pileggi (2018) meta-analysis[36] of 13 randomized controlled trials (RCTs) claimed a significant reduction in mortality with the use of IHI ventilator care bundles. However, upon review, five of these studies had also utilized SSD. These five studies were found to have better VAP reduction rates and lower mortality, suggesting that the inclusion of SSD was a primary contributor to the overall positive outcome. Similarly, the Mastrogianni (2023) study,[16] which analyzed 38 RCTs involving VAP and IHI ventilator care bundles, concluded that the top four RCTs achieving the best "near-zero" VAP rates were those that combined the IHI ventilator care bundle with SSD.

Furthermore, a deeper dive into the original studies reveals a key inconsistency. In the Youngquist (2007) study,[37] the paper's abstract makes no reference to SSD, yet in the body of the study, the key author/nurse involved, Michelle Farber, RN, specifically refers to the use of SSD to achieve their near-zero VAP rate. Michelle Farber also provided the same information in the APIC (2009) guidelines[38] for VAP prevention.

Finally, recent developments have added a new dimension to this discussion. In their 2024 study, Lorente et al.[39] noted that the IHI voluntarily removed all VAP "near-zero" success stories from its website in December 2023. While no official statement was provided, this action implicitly reinforces the need to re-evaluate the historical data. This body of evidence suggests that for a bundle to be truly effective at preventing VAP (not just improving general critical care), SSD should be a fundamental, explicitly prioritized, and highly valued component. The historical oversight of SSD's contribution in these bundles represents a critical gap in knowledge and logical understanding.

8. Endotracheal Suctioning and SSD

- **Endotracheal Suctioning Rationale:** Endotracheal suctioning, whether open or closed, is a standard of care and a core part of many VAP prevention bundles, such as the IHI ventilator care bundle. Its purpose is to remove colonized secretions that have already been allowed to microaspirate past the endotracheal tube cuff and into the lower airway and the lungs. The very need for this procedure underscores a failure in primary prevention. A significant body of research has consistently shown no beneficial effect on VAP rates between open and closed endotracheal suctioning when compared to each other in isolation.[40,41]

- **SSD Complement:** This is where the addition of Subglottic Secretion Drainage (SSD) becomes a critical, primary intervention. Multiple studies, including a randomized controlled trial by Dhawan et al. (2018)[40] and a retrospective study by Juneja et al. (2011),[41] provide compelling evidence for this.

The Dhawan study's methodology is particularly telling, as both the intervention and control groups used an otherwise

identical VAP prevention bundle. The only difference was the addition of SSD to the group using closed endotracheal suctioning. The results were clear: this group demonstrated a significant reduction in both VAP incidence and the length of ICU stay.

This finding is further supported by the Juneja study,[41] which compared four groups and found that the VAP incidence was dramatically lower in the groups using SSD, regardless of whether they also used closed suctioning. The authors of the Juneja study concluded that while intermittent subglottic drainage (ISD) was beneficial, "Closed suction drainage alone or in combination with ISD has no significant effect on VAP incidence."

This powerful evidence from multiple sources proves that while the bundle itself is important, the inclusion of SSD is what drives the superior outcomes. The results validate that SSD is the indispensable "lynchpin" in VAP prevention, tackling the root cause of microaspiration and minimizing the need for subsequent airway clearance interventions.

9. Subglottic Secretion Drainage (SSD) and suctioning

A Critical Re-evaluation of the Consensus: Overlooked Clinical and Methodological Factors

Despite numerous meta-analyses and systematic reviews, the evidence for subglottic secretion drainage (SSD) as a standard-of-care method for preventing ventilator-associated pneumonia (VAP) remains inconclusive. This ambiguity, however, does not stem from a true lack of efficacy, but rather from a fundamental limitation in the way existing studies have been analyzed. A critical re-evaluation of the literature reveals that most studies, and therefore their subsequent meta-analyses, have failed to account for three interconnected factors: **(a)** the specific suctioning methodology employed, **(b)** the volume of secretions removed, and **(c)** the risk of mucosal injury. This oversight has masked the true effectiveness of SSD and perpetuated the use of ineffective and potentially harmful clinical practices.

Suctioning Methodology: The success of subglottic secretion drainage (SSD) is inextricably linked to proper implementation, particularly the frequency of suctioning. The primary purpose of SSD is to remove secretions as they continuously accumulate above the endotracheal tube cuff, thereby preventing them from being aspirated into the lungs. When this procedure is performed inconsistently—for example, with long intervals between aspirations—its effectiveness is dramatically reduced, regardless of the presence of an SSD-ET tube.

This critical point is highlighted in the (2018) study by Millot et al.,[42] who set out to assess the effectiveness of SSD in reducing microaspiration, claiming that "no study to date has evaluated" this specific impact. Despite this stated objective, their methodology appeared designed for failure. The study's protocol stipulated that subglottic secretions were suctioned only every three (3) hours using a syringe. Additionally, the endotracheal tube cuff pressure was monitored only every eight (8) hours, a frequency far below the standard of care. This allowed for significant and prolonged periods of fluid pooling and potential cuff under-inflation, which are the very conditions that cause microaspiration. Not surprisingly, the study found no difference in microaspiration between the SSD group and the control group. This outcome, however, does not reflect a failure of the SSD technology itself, but rather a failure of a flawed implementation protocol. The study serves as a crucial example of how prominent clinicians, by performing studies with inadequate methodology, inadvertently contribute to the misleading narrative that SSD is ineffective.

SSD-ET Subglottic Tubes are engineered and designed for their intended purpose, which is to allow colonized secretions to pool above the cuff of ET tube and get aspirated away from the patient's subglottic space at set specific intervals. That is half of the battle. The other half is using a reliable, indicated, and safe suctioning source/methodology, which is as critical to the successful implementation of the overall SSD intervention.

In a (2021) Systematic Review, Iliman and Eser[43] raise an excellent point about the various suctioning methodologies used for subglottic aspiration and question how these different methodologies impact the overall outcome. More specifically, it lists 13 studies using the same SSD-ET subglottic tubes; however, 8 different suctioning methodologies are used accordingly:

- CASS (20 mmHg),
- CASS (150 mmHg), using 150 mmHg pressure for Continuous is extremely high and against the recommended AARC clinical guidelines,
- CASS (20 mmHg), Intermittently every 20 sec, to avoid mucosal injury (in effect, this approach is considered intermittent, however, Kollef (1999)[44] refers to it as CASS which is confusing),
- Intermittent wall suction (150 mmHg- every 20 sec),
- Intermittent automatic (150 mmHg),
- Syringe intermittent (1-hour interval),
- Syringe intermittent (2-hour interval),
- Syringe intermittent (6-hour interval)

A 2016 RCT study by Caroff,[45] is used to demonstrate the relevance of suctioning methodology and its impact on the effectiveness of subglottic suctioning (SSD).

Caroff (2016)[45] consists of 17 RCTs. 9 RCTs using CASS wall suction, 3 RCTs using Intermittent wall suction, and 5 RCTs using a 10 ml syringe (see **Table 1**). In a review of over 40 RCTs performed since 1992, the studies using 10 ml syringes in 1-hr intervals resulted in the best outcome in terms of VAP reduction rates. 22 RCTs used a 10 ml syringe. Only 4 RCTs used 1-hr suctioning intervals and achieved excellent outcomes. RCTs that used syringes in much longer intervals of 2-8 hrs achieved poor outcomes, and the authors blamed the poor results on SSD-ET tubes instead of the suctioning source/methodology. Waiting longer than 1 hour to remove colonized secretions is just too long and will cause microaspiration into the lower airway.

The Overlooked Correlation: Volume of Secretions and VAP Reduction

Perhaps the most critical oversight in the existing literature is the failure to consistently measure and document the daily volume of secretions removed from the subglottic

Table 1 - Caroff (2016)

Meta Analysis of 17 RCTs

CASS	9
INT	3
Syringe	5
Total RCTs	17

Using 10 ml Syringe in 1-hr intervals resulted in most impactful VAP reduction rate of 61%

Syringe 1 hr

		Patient	Suction	Suction		SSD	SSD	Control	Control		SSD	Control	% Reduction	
Author	**Year**	**Total**	**Method**	**Interval**		**VAP**	**Total**	**VAP**	**Total**					
LORENTE	2007	280	Syringe	1 hr		11	140	31	140		0.08	0.22	64.52%	
MAHUL	1992	145	Syringe	1 hr		9	70	21	75		0.13	0.28	54.08%	
		425				**20**	**210**	**52**	**215**		**0.10**	**0.24**	60.62%	**61%**

INT

		Patient	Suction	Suction		SSD	SSD	Control	Control		SSD	Control	% Reduction	
Author	**Year**	**Total**	**Method**	**Interval**		**VAP**	**Total**	**VAP**	**Total**					
GOPAL	2015	240	INT	6 hr		13	120	25	120		0.11	0.21	48.00%	
SMULDERS	2002	150	INT	20 sec		3	75	12	75		0.04	0.16	75.00%	
KOLLEF	1999	343	INT	20 sec		8	160	15	183		0.05	0.08	39.00%	
		733				**24**	**355**	**52**	**378**		**0.07**	**0.14**	50.86%	**51%**

CASS

		Patient	Suction	Suction		SSD	SSD	Control	Control		SSD	Control	% Reduction	
Author	**Year**	**Total**	**Method**	**Interval**		**VAP**	**Total**	**VAP**	**Total**					
DAMAS	2015	352	CASS	Continuous		15	170	32	182		0.09	0.18	49.82%	
KOKER	2014	51	CASS	Continuous		5	23	10	28		0.22	0.36	39.13%	
ZHENG	2008	61	CASS	Continuous		9	30	16	31		0.30	0.52	41.88%	
YANG	2008	91	CASS	Continuous		12	48	20	43		0.25	0.47	46.25%	
BOUZA	2008	690	CASS	Continuous		12	331	19	359		0.04	0.05	31.50%	
LIU QH	2006	86	CASS	Continuous		14	41	30	45		0.34	0.67	48.78%	
GIROU	2004	18	CASS	Continuous		5	8	6	10		0.63	0.60	-4.17%	
BO	2000	68	CASS	Continuous		8	35	15	33		0.23	0.45	49.71%	
VALLES	1995	153	CASS	Continuous		14	76	25	77		0.18	0.32	43.26%	
		1570				**94**	**762**	**173**	**808**		**0.12**	**0.21**	42.38%	**42%**

Syringe 1.5 + hrs

		Patient	Suction	Suction		SSD	SSD	Control	Control		SSD	Control	% Reduction	
Author	**Year**	**Total**	**Method**	**Interval**		**VAP**	**Total**	**VAP**	**Total**					
TAO	2014	149	Syringe	4 hr		52	102	34	47		0.51	0.72	29.53%	
LACHERADE	2010	333	Syringe	1.5 hr		25	169	42	164		0.15	0.26	42.24%	
LIU SH	2006	98	Syringe	8 hr		3	48	10	50		0.06	0.20	68.75%	
		580				**80**	**319**	**86**	**261**		**0.25**	**0.33**	23.89%	**24%**

Table 1 demonstrates the breakdown analysis of the Caroff (2016)[45] study of 17 RCTs where studies using a 10 ml syringe in 1-hr intervals achieved the best overall outcome of a 61% VAP reduction rate.

space. This parameter is directly correlated with the success of VAP prevention. A review of studies that did document this key variable, as highlighted in Caroff (2016),[45] provides compelling evidence, as shown in **Table 2**.

Suctioning Methodology and the Issue of Mucosal Injury

A significant portion of the literature on SSD, including studies by Sibley (2022), Dragoumanis (2007), Harvey (2007), Girou (2004), and Berra (2004)[52,53,54,55,56] have relied on Continuous Aspiration (CASS) at low pressures (-20 to -30 mmHg). This methodology, and even certain high-pressure, short-interval Intermittent Aspiration (IASS) approaches by Seguin (2018) and Spapen (2013),[57,58] inherently pose a high risk of mucosal injury. The continuous or high-frequency suction creates a constant vacuum at the tip of the endotracheal or tracheostomy tubes, which makes it highly likely for the delicate tracheal mucosal tissue to be sucked into the suction port. Unlike CASS, short-interval IASS may offer a brief pause for the tissue to dislodge, but the high-frequency repetition of this process, especially in the absence of secretions, means the potential for injury remains dangerously high. This fundamental design deficit results in an unacceptable risk-to-benefit ratio, making these suctioning methodologies clinically indefensible.

Using a 10 ml syringe in 1-hr intervals has not resulted in any reports of injuries to mucosa and achieved better VAP reduction rates than CASS and IASS.[46,47]

Table 2- Caroff (2016)

Meta Analysis of 17 RCTs

Analyzing Daily Volume of Secretions Removal

(Only 5 out of 17 RCTs measured and documented the daily volume of colonized secretions removal)

Using Syringe in 1-hr intervals resulted in a higher daily volume of secretion removal

Author	Year	Patient	Suction	Suction	Volume	VAP
		Total	Method	Interval	ml/day	% Reduction
MAHUL	1992	145	Syringe	1-hr	**100-150**	**54%**
VALLES	1995	153	CASS	Continuous	18.4	43%
YANG	2008	91	CASS	Continuous	27.2	46%
ZHENG	2008	61	CASS	Continuous	20	42%
LACHERADE	2010	333	Syringe	1.5 -hr	18	42%

Table 2 shows that only 5 out of 17 RCTs in Caroff (2016)[45] measured and documented the daily volume of secretions removed.[47,48,49,50,51] It clearly demonstrates that the suctioning method that removed the highest daily volume of secretions (100-150 ml/day via a syringe) achieved the highest VAP reduction rate (54%). In stark contrast, methods like CASS, which removed significantly less volume (18-27 ml/day), consistently yielded lower VAP reduction rates. This provides a direct, data-driven link between the volume of secretions removed and the clinical outcome. The general failure of meta-analyses to incorporate this critical variable renders their conclusions on SSD's efficacy fundamentally incomplete.

A Case Study in Mislabeling: The Fujimoto (2018) Paper

This problem is compounded by a frequent methodological oversight: the mislabeling of interventions. A prime example is the Fujimoto (2018) study,[59] which is titled as a comparison between "Continuous versus Intermittent" drainage. However, a close inspection of its methodology reveals a stark contradiction. The intervention group labeled as "continuous" actually employed an intermittent device (HAMA® pressure drainage system) that functioned at a pressure of -30 cm H_2O for 20 seconds with a 20-second interval. This is not continuous aspiration (CASS) but, as the authors themselves note, an intermittent method designed to prevent mucosal injury. By misrepresenting this intervention, the paper's conclusion—that "Continuous SSD" is superior—is fundamentally misleading and contributes to the knowledge gap by creating confusion over the very definitions of the technologies being studied. This case highlights a critical need for consistent and accurate terminology in clinical research, as the misclassification of interventions can lead to compromised meta-analyses and misinformed clinical practice.

The Domino Effect of Flawed Research

The downstream effects of this misrepresentation are already evident. The Bajracharya et al. (2021) study,[60] for instance, explicitly references the Fujimoto paper and perpetuates the same misrepresentation. The Bajracharya study's own methodology for its "intermittent" group, which involved suctioning only every two (2) hours, is clinically unsound and known to increase the risk of microaspiration. This erroneous comparison allows the authors to conclude that "continuous" suctioning is superior, a finding that is directly rooted in a comparison against an incorrectly performed and defined intermittent method.

This pattern of misrepresentation is not an isolated issue. The systematic review by Wen et al. (2017)[61] provides another striking example. While the paper claims to compare Continuous versus Intermittent subglottic drainage, its analysis of the intermittent method is undermined by the inclusion of studies that performed suctioning at clinically inappropriate, long intervals (2 to 4 hours). Therefore, the meta-analysis's conclusion—that intermittent and continuous drainage had similar effectiveness—is misleading. It inadvertently validates a poorly executed method and contributes to the knowledge gap by misrepresenting the true potential of properly implemented intermittent drainage.

The critical need for rigor in VAP research is further underscored by recent events in the literature. For example, two separate meta-analyses, by Dewi et al. (2023) and Thapa et al. (2024),[62,63] were formally retracted from their respective journals due to methodological inconsistencies and misrepresentation. These retractions serve as a powerful reminder that uncorrected errors in published literature can severely mislead clinical practice.

A New Framework: The Syringe Method as the Gold Standard

When the factors of suctioning methodology, volume, and mucosal injury are considered in concert, the manual syringe suction method emerges as the de facto "gold standard" for effective and safe SSD (Mahul 1992, Lorente 2007, Lacherade 2010).[47,46,48] It is the only methodology that: 1) achieves a high daily volume of secretions removal, directly impacting VAP rates; and 2) utilizes long, injury-preventing intervals (e.g., 1 hour), mitigating the risk of mucosal tissue damage. While this method's success is a testament to the correct physiological approach, its impracticality in a clinical setting has prevented its widespread adoption.[64] This creates a critical need for a new, automated system that can replicate the success of the syringe method while providing the practicality necessary for routine clinical use.

By integrating these critical variables, a new and clearer picture of SSD efficacy emerges, providing a definitive roadmap for future research and the design of next-generation therapeutic devices.

Overall Cost Benefits of SSD

Per Branch-Elliman (2015)[65] – "In line with recommendations from the Compendium of Strategies to Prevent Healthcare-

Associated Infections in Acute Care Hospitals,[66] the decision model found that suction endotracheal (SSD) tubes are the most cost-effective VAP prevention strategy under all conditions studied." The authors further solidified their conclusion by examining a total of 120 unique combinations of VAP prevention strategies and found that "the strategy with the best cost–benefit ratio (the preferred strategy from the hospital perspective) included a suction endotracheal tube SSD, the IHI bundle without oral care, and probiotics." The most important and potentially the most controversial change in the Compendium is the inclusion of subglottic suction endotracheal tubes as a basic practice. From both the hospital and societal perspectives, even among patients intubated for only 1-2 days, the use of SSD is cost-effective, even in the event of high infrastructure and a cost as high as $100 per tube.[65]

Discussion

The Ultimate VAP Prevention Intervention

Subglottic Secretion Drainage (SSD) stands out as a unique intervention because it is the only one that directly addresses the root cause of VAP. The (2005) seminal research by Safdar et al.[67] provided a fundamental understanding of VAP pathogenesis, establishing that microaspiration of colonized oropharyngeal and gastric secretions is the primary route for pathogens to enter the lower respiratory tract. This finding provides the scientific rationale for SSD, as it is the only intervention that directly addresses the mechanical failure of the endotracheal tube cuff.

The effectiveness of SSD is not a new or controversial finding; it has been repeatedly confirmed by foundational meta-analyses for over two decades. Research by Dezfulian et al. (2005) and Muscedere et al. (2011)[68,69] firmly established that SSD is a highly effective measure for preventing VAP, a conclusion that was later reinforced by Caroff (2016).[45] This consistent body of evidence from key researchers in the field provides a crucial historical and scientific lens through which to view the ongoing debate.

All other interventions, whether pharmacological (e.g., SDD, antiseptics, probiotics), or non-pharmacological (e.g., HOB elevation, cuff pressure), or device-based (e.g., silver-coated ET tubes, CCPC), are complementary risk-reduction interventions. While other device-based interventions, such as silver-coated endotracheal tubes, are useful as a supplemental measure, they only address the buildup of biofilm on the tube itself. They do not affect the pooled oral secretions that accumulate in the subglottic space, which is the primary source of infection. Similarly, while regular oral care is a vital component of a comprehensive bundle, it does not prevent the physical accumulation and aspiration of secretions that pool in the subglottic space due to gravity, a finding reinforced by a 2020 bench study by Chair et al.[20] This makes SSD a truly indispensable element of any VAP prevention bundle, including the Institute for Healthcare Improvement (IHI) Ventilator Care Bundle, where it should be considered the central pillar.

Cost-Effectiveness and Alignment with Public Health Goals

VAP imposes a significant economic burden.[70] It is incredibly expensive to treat, with attributable cost to be $44,300, ranging from ($41,406 to $ $47,238) per patient.[70,71,72,73] Subglottic secretion drainage (SSD) is the most cost-effective intervention for VAP prevention. SSD, by preventing VAP in the first place, offers a significant return on investment. This emphasis on cost-effectiveness goes beyond mere financial savings; it aligns directly with the core tenets of modern healthcare, particularly the "patient safety" and "zero harm" initiatives championed by agencies like CMS, AHRQ, and the Department of Health and Human Services (HHS). These agencies advocate for a proactive approach to care that eliminates preventable harm. By preventing a life-threatening and costly complication like VAP, SSD becomes a powerful tool in achieving these critical public health goals.

Historical and Ongoing Support

The historical and ongoing support for this approach from major healthcare bodies is substantial. For instance, the Agency for Healthcare Research and Quality (AHRQ), in its seminal reports Making Healthcare Safer I (2001) and Making Healthcare Safer II (2013),[74,75] consistently identified SSD as a critical and essential intervention for VAP prevention. The agency's commitment was further demonstrated by a significant $7.3 million grant to Johns Hopkins (2013, 2012)[76,77] to study and confirm the efficacy of SSD, resulting in key confirmatory studies by Speck (2016) and Rawat (2017).[78,79] These findings were later reinforced by a CMS-sponsored study, conducted by the Health Research and Educational Trust (HRET) of the American Hospital Association (AHA) (2018),[80] which specifically identified SSD as the primary driver of VAP prevention.

The Ongoing Debate and Underreporting

Despite this overwhelming body of evidence, dating back to the fundamental understanding provided by Safdar et al. in 2005,[67] the debate continues, and widespread, mandatory enforcement remains elusive. A key factor contributing to this lack of widespread adoption has been the Centers for Disease Control and Prevention's (CDC) 2013 decision to switch from tracking Ventilator-Associated Pneumonia (VAP) to Ventilator-Associated Events (VAE). This change has meant that hospitals are no longer required to track and report specific VAP rates, as VAP is now considered a subcategory of the broader Ventilator-Associated Events (VAE) definition, potentially masking the true incidence of this preventable complication. This is particularly concerning given the significant global disparities in reported VAP incidence. A recent June 2025 editorial in the journal *CHEST*[81] highlighted this issue, noting that the reported incidence in Europe and other nations is approximately 18 cases per 1,000 ventilator days, while in the United States, it is just 1 to 2.5 cases per 1,000 ventilator days. The editorial notes that comparing the prevalence of VAP between U.S. hospitals and their global counterparts is "difficult or even inappropriate" due to a culture of underreporting in the United States. Because VAP is considered a preventable complication with critical economic repercussions for hospitals, some clinicians are hesitant to report it. As the editorial states, "Ignoring the issue does not resolve it; instead, it delays potential solutions and hinders progress."

Classification Errors and Path Forward

This situation is exacerbated by a fundamental classification challenge at the highest levels of healthcare policy. As long as agencies such as AHRQ, and CMS classify endotracheal tube-related infections as non-device or non-product-related, there is little incentive for hospitals to take decisive action to prevent them. This designation ignores the fact that the endotracheal tube is the primary entry point for pathogens causing VAP. It is critically important for these major healthcare agencies to reconsider their stance and recognize the endotracheal tube as the culprit and a major contributor to this preventable harm. It is only by reclassifying VAP as a preventable, device-

related infection and then making the use of SSD a mandatory requirement that true patient safety and the "zero harm" initiatives they champion can be achieved.

Is Zero VAP Achievable or Realistic?

The ongoing debate over whether a "zero VAP" rate is a realistic or achievable goal has been a central theme in the critical care literature for over a decade. Researchers such as Klompas (2010, 2012)[82,83] and others like Guillamet and Kollef (2018, 2024)[84,85] have extensively explored this question. Our analysis concludes that the answer is an unequivocal yes. Zero VAP is not a sophistry, as some have claimed,[86] but an attainable reality, as demonstrated by successful nationwide initiatives in Spain[87] and comprehensive guidance from Canadian programs.[88]

The key to understanding this lies in the history of the IHI ventilator care bundle. For over 20 years, the Institute for Healthcare Improvement (IHI) never officially included subglottic secretion drainage (SSD) in its bundle of 4-5 interventions and never recommended its use. Despite this, many published studies using the IHI ventilator care bundle and claiming near-zero VAP rates were, in fact, using endotracheal tubes with subglottic drainage ports to achieve those successful outcomes. However, the credit was always given to the IHI bundle of components, and SSD was never mentioned. This is a crucial point of methodological misrepresentation and a primary reason for the enduring debate.

The ongoing controversy is perpetuated by authors who ignore or misrepresent the data. A 2020 paper by Colombo et al.,[86] for instance, argues that zero VAP is a "sophistry" due to the unproven efficacy of many preventive measures. However, a careful review reveals that the authors' own arguments are misleading and contribute to the very narrative they criticize. For example, the authors refer to the Caroff (2016)[45] meta-analysis that strongly confirmed a significant VAP reduction with SSD, yet they completely ignore this key finding when making their broader claims.

This powerful finding has been consistently supported across multiple subsequent studies. For instance, the meta-analysis by Mao et al. (2016)[89] confirmed the significant reduction in VAP rates with SSD. While some have criticized SSD for not showing a corresponding mortality benefit, the effectiveness of SSD in reducing VAP has been consistently reaffirmed even in meta-analyses by researchers who raise these objections.[90] This highlights a critical point: demonstrating a statistically significant impact on a rare outcome like mortality requires trials with tens of thousands of patients, a scale that is often impractical. The effectiveness of SSD in significantly reducing VAP, however, is a well-established and repeatedly confirmed finding.

Leading researchers have long recognized this statistical challenge. As Caroff et al. (2016)[45] stated, "the studies included in our meta-analysis collectively provided data on mortality from more than 3,200 patients. Hence, even if further studies do suggest significant signals, the numbers needed to treat are likely to be very high." Similarly, Klompas (2009)[91] noted that "many of these studies were not powered to detect a difference in mortality," and Muscedere (2010)[92] added that "the use of mortality as a primary end point in VAP treatment trials is problematic and would require large sample sizes." This consensus is echoed by Melsen (2013),[93] who argued, "Prevention studies should include thousands of patients to be adequately powered to show beneficial effects on mortality," and Lacherade (2018),[64] who concluded that "a sample size of several tens of thousands of patients would be needed to reach a significant result for ICU mortality."

This pattern of misrepresentation is also evident in studies like Landelle et al. (2018),[94] which is also referenced by Colombo (2020).[86] The Landelle[94] study implemented a prevention program in stages. Pre-intervention, they used the IHI ventilator care bundle. During the intervention, they added SSD and Selective Oropharyngeal Decontamination (SOD) to the bundle. Both were also included in the post-intervention period. While the study's title gives credit to SOD, the methodology confirms that the most significant reduction in VAP was achieved when both SSD and SOD were added to the bundle. A similar issue arises with the Pileggi et al. (2018)[36] meta-analysis also referenced in Colombo. This paper, which claimed significant mortality reduction, was based on 13 RCTs. Ironically, five of these studies used SSD and achieved better outcomes than the others, yet the authors make no reference to the use of SSD at all.

Oral care is an important component of the VAP prevention bundle, a practice widely accepted in the ICU. However, even research in this area requires critical scrutiny. For example, a 2022 study on improved oral care methods for mechanically ventilated patients was subsequently retracted due to concerns about its validity.[95] This was not a simple error; the retraction notice explicitly cited serious issues including "peer-review manipulation" and "inappropriate citations." The unreliability of this research highlights a critical point: while many interventions are promoted, a significant portion of the literature on VAP prevention is either methodologically flawed or has been formally retracted. This includes papers on oral care and even subglottic secretion drainage (SSD) itself, demonstrating that no intervention is immune to poor-quality research. This underscores why a critical and evidence-based approach to the literature is paramount, and why the overwhelming body of evidence for SSD makes it the most consistently and robustly supported intervention.

The sentiment expressed in the recent 2024 umbrella review by Zhu et al.[96] that "the best therapy is prevention" is a commendable guiding principle. However, a closer examination of this publication reveals a critical disconnect between this goal and the flawed manner in which interventions are categorized and evaluated. The authors correctly state that prevention is key, yet they fail to recognize that among the strategies they reviewed, only non-invasive ventilation (NIV) and subglottic secretion drainage (SSD) can physically prevent the root cause of VAP—the microaspiration of colonized secretions. All other interventions merely reduce the risk of colonization and infection. This fundamental misunderstanding of VAP pathogenesis undermines the very foundation of their analysis.

The review is marked by a consistent pattern of methodological weaknesses and misrepresentation. The authors' top-ranking of Selective Digestive Decontamination (SDD) is based on a problematic reliance on the Hammond (2022) study,[97] despite the fact that its own authors stated the evidence was of "Lower Certainty," a detail Zhu et al. overlook while giving it a Class II rating. This reliance is particularly problematic given that the Hammond meta-analysis[97] included the Pneumatikos (2002) study,[29] which combined SSD and SDD as a single intervention. The review also misattributes the success of key strategies: it

places the Pileggi meta-analysis[36] in the second ranking but fails to acknowledge that its positive outcomes were driven by five key RCTs that explicitly used SSD, mislabeling the intervention as a general "IHI ventilator care bundle." Similarly, the review cites the Maertens (2022) meta-analysis[98] for the effectiveness of Continuous Cuff Pressure Control (CCPC) but fails to disclose that the most successful studies within it combined CCPC with SSD, while the two largest studies Dat and Marjanovic[27,28] that did not use SSD showed poor or no difference in outcomes. Finally, the integrity of the review is compromised by the arbitrary inclusion of five unreferenced RCTs, which altered the original Pozuelo-Carrascosa (2022) meta-analysis[90] without providing the necessary methodological details.

This pattern of misattribution, questionable data use, and the failure to recognize the critical role of SSD in driving positive results exemplifies a systemic issue in the scientific literature. It demonstrates how a focus on abstract categories like "bundles" can inadvertently obscure the most effective mechanical prevention strategies, contributing to the persistent stagnation of VAP prevention efforts.

This academic crisis is reflected on the front lines of healthcare. A recent multi-society position paper from SHEA (2025), titled "Raising the Bar: Necessary Resources and Structure for Effective Healthcare Facility Infection Prevention and Control Programs,"[99] highlighted the resources necessary for effective infection prevention. This publication was informed by a 2024 McKing Consulting report[100] that SHEA funded to independently interview eight of their own Infection Preventionist (IP) members. Interestingly, while the SHEA position paper[99] makes reference to the McKing report,[100] it leaves out the IPs' most critical sentiment: their overwhelming desire to focus on "proactive prevention and risk reduction" and actually "preventing infections from happening to begin with," rather than "responding to infections" or "filling out reports" for CMS-HAC. This highlights a system that forces IPs into reactive roles instead of proactive ones. This manuscript provides an intellectual framework that aligns with the practical needs and frustrations of clinicians on the front lines.

Proper implementation is critical. The effectiveness of SSD is not automatic; it requires timely, proper, and consistent aspiration. When unfavorable results occur, the blame is often misdirected at the SSD technology itself, ignoring the fundamental issue of inconsistent and infrequent aspiration. The papers by Klompas and Kollef,[82,83,84,85] and others provide the theoretical and historical context for this debate, but the success seen in practice proves the effectiveness of the intervention when it is correctly and diligently applied. Ultimately, as highlighted by a comprehensive 2023 review, proper use of respiratory and airway devices, particularly SSD, is a cornerstone of effective VAP prevention.[101]

Conclusion

While the synergy of multiple interventions is crucial, this analysis demonstrates that the mechanical removal of secretions via SSD is the indispensable foundation upon which all other VAP prevention strategies must be built on.

Future Research

SSD is a crucial intervention in the fight against VAP. It is not just a part of the solution; it is the ultimate lynchpin that directly addresses the root cause of the infection. While its proven efficacy is irrefutable, future research must focus on optimizing the technical aspects of its implementation. Specifically, studies should focus on:

- **Suctioning Methodology** Investigating the optimal frequency, pressure, and duration of suctioning to maximize secretion removal. Viscosity Management-Researching methods to reduce the viscosity of secretions to improve the efficiency of SSD.
- **Combined Interventions** Validating the powerful synergy of SSD when combined with other interventions like CCPC and SDD to create the most robust and comprehensive VAP prevention bundle. By ensuring that SSD is properly understood, implemented, and enforced, we can make significant strides toward preventing VAP incidents entirely, improving patient outcomes, and lowering healthcare costs. The Zero-harm goal for VAP is achievable through the use of SSD.

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Conflict of interest

Hamid Khosrowshahi is employed by Flosure Technologies, a manufacturer of an FDA-cleared automated subglottic suction pump. The authors report no involvement in the manufacture or sales of subglottic secretion drainage (SSD) endotracheal tubes.

Author Contributions

Hamid Khosrowshahi performed the conceptualization, original research, and writing of the manuscript. Jerry King contributed to the review, editing, and final approval of the manuscript.

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Pulmonary Fibrosis: A Patient-Centered Perspective on Care and Support

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Abstract

Pulmonary fibrosis (PF) is a progressive form of interstitial lung disease (ILD) marked by scarring of the lung tissue that reduces elasticity and impairs oxygen exchange. Idiopathic pulmonary fibrosis (IPF), the most common subtype, carries a poor prognosis. Antifibrotic therapies slow disease progression but do not reverse fibrosis, and lung transplantation remains the only intervention for many patients. The disease is characterized by repeated alveolar injury, fibroblast activation, and extracellular matrix deposition, leading to restrictive lung mechanics and early decline in diffusing capacity (DLCO). The Pulmonary Fibrosis Foundation has expanded its Care Center Network, however large regions remain underserved, creating "medical care deserts" where patients lack access to specialty care and clinical trials. Support groups, both local and virtual, provide crucial education and psychosocial support, helping patients and caregivers navigate the burdens of this life-limiting disease.

Understanding Pulmonary Fibrosis

Pulmonary fibrosis is a group of chronic, progressive interstitial lung diseases characterized by the replacement of normal lung tissue with scar tissue. This leads to thickening and stiffening of alveolar walls, which interferes with oxygen transfer into the bloodstream. Patients most often present with exertional breathlessness and a persistent cough. Fatigue, reduced exercise tolerance, and unintentional weight loss are also common. Pulmonary fibrosis belongs to the broader category of interstitial lung diseases (ILDs), a diverse group of conditions characterized by inflammation and scarring of the lung interstitium, the supportive tissue surrounding the alveoli.

Pathophysiology of Pulmonary Fibrosis

At the cellular level as seen in Figure 1, pulmonary fibrosis begins with repeated injury to the alveolar epithelium (Selman, Pardo, & Richeldi, 2011). Type I pneumocytes are destroyed, and Type II pneumocytes proliferate abnormally, releasing profibrotic mediators such as transforming growth factor beta (TGF-β), platelet-derived growth factor (PDGF), and vascular endothelial growth factor (VEGF) (Selman et al., 2011). Fibroblasts and myofibroblasts migrate to these sites of injury, forming fibroblastic foci, which are the hallmark of ongoing fibrogenesis (King, Pardo, & Selman, 2011). These cells deposit collagen and other extracellular matrix proteins, thickening alveolar walls and destroying the delicate alveolar-capillary interface (Wynn, 2011). As fibrosis progresses, normal lung tissue is replaced by cystic, fibrotic airspaces, producing the characteristic honeycombing pattern seen on imaging (Raghu et al., 2018).

The physiological consequences are profound as represented in Figure 2. Stiff lungs lose compliance, which reduces total lung capacity and forced vital capacity, making every breath feel more difficult (Lederer & Martinez, 2018). The diffusing capacity of the lung for carbon monoxide (DLCO), a pulmonary function test that reflects gas transfer efficiency, often declines early in pulmonary fibrosis and is a key marker of disease severity and progression. Alveolar destruction and vascular remodeling contribute to ventilation–perfusion mismatch and chronic hypoxemia (Nathan & Hassoun, 2016). In many patients, this triggers secondary pulmonary hypertension, which increases strain on the right ventricle and may progress to right heart failure (Behr & Ryu, 2008). Exercise limitation, deconditioning, and weight loss are common, and the disease also carries a significant psychosocial burden, including anxiety and depression (Swigris et al., 2005).

Prevalence and the Importance of Early Diagnosis

Although classified as a rare disease, pulmonary fibrosis affects tens of thousands of people in the United States. Idiopathic pulmonary fibrosis, the most common form, typically presents in adults in their sixties or seventies. Global estimates place prevalence between 10 and 60 per 100,000 people, with higher numbers reported in North America and Europe (Maher et al., 2021). Without treatment, median survival has historically been only three to five years (Lederer & Martinez, 2018; Richeldi et al., 2014). Antifibrotic therapies slow the rate of decline in lung function, but they do not cure the disease (Richeldi et al., 2014). Delays in diagnosis are common, since early symptoms are nonspecific and often mistaken for asthma, COPD, or heart disease. Usual interstitial pneumonia (UIP) is a classic histopathologic pattern strongly associated with IPF. Accurate diagnosis relies on high-resolution CT imaging and multidisciplinary discussion, which improves recognition and reduces inappropriate treatment (Raghu et al., 2018).

Geographic Access to Care

Specialized care is essential for optimizing outcomes in pulmonary fibrosis. The Pulmonary Fibrosis Foundation Care Center Network designates hospitals with expertise in interstitial lung disease management. Despite the growth of the network to more than 80 sites, the centers remain concentrated in urban and academic hubs. Large rural regions, including parts

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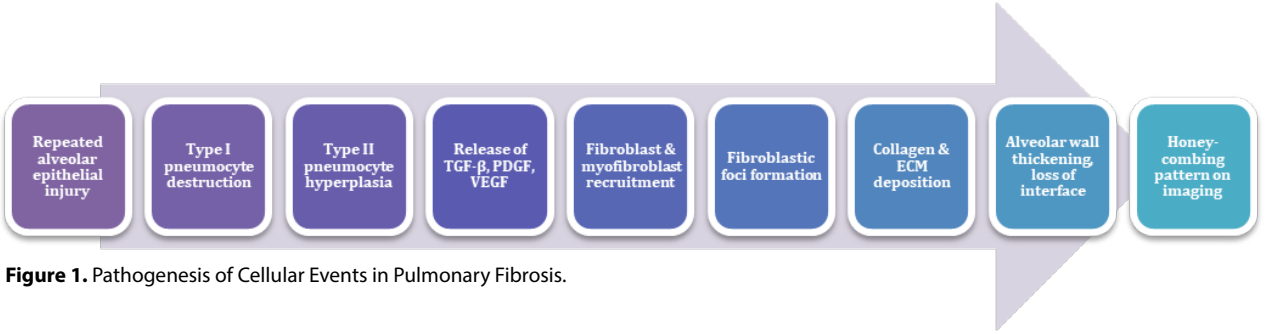

Figure 1. Pathogenesis of Cellular Events in Pulmonary Fibrosis.

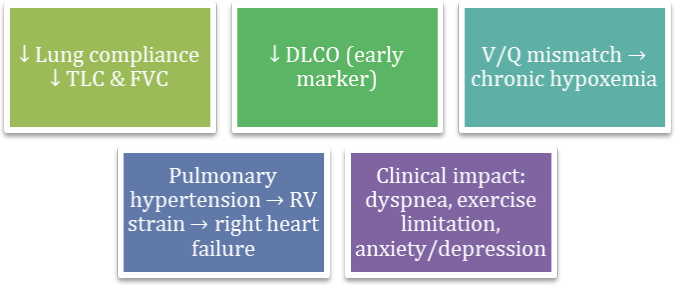

Figure 2. Physiologic Consequences of Pulmonary Fibrosis.

of the Midwest, Appalachia, and the Mountain West, remain underserved and represent geographic care deserts.

In public health terms, a medical care desert is defined as a geographic area where patients face substantial barriers to accessing appropriate healthcare services. These barriers may include provider shortages, long travel distances, and the absence of specialized medical infrastructure (Probst et al., 2019). In the context of pulmonary fibrosis, such deserts mean patients may go without timely diagnosis, specialty care, or participation in clinical trials. Figure 3 illustrates states that currently do not have pulmonary fibrosis care centers in the United States.

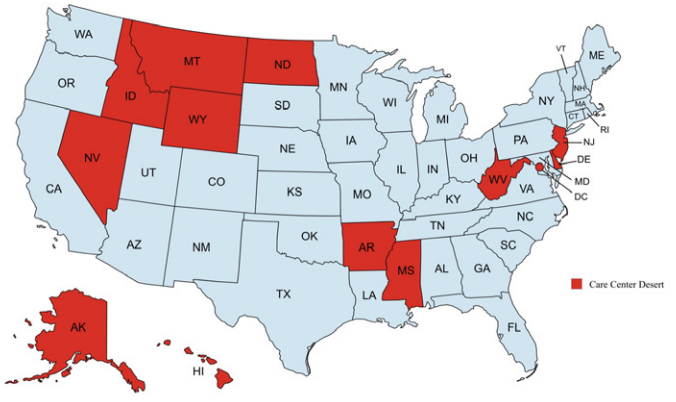

Figure 3. States with and without PFF Care Centers or Clinical Associates. Blue = states with at least one site; Red = states with none ('care deserts').

The Role of Support Groups

Support groups play an important role in the care of patients with pulmonary fibrosis. Beyond medical management, they provide education, emotional support, and coping strategies. Evidence suggests that participation in support groups may improve psychological well-being, reduce anxiety and depression, and enhance patient compliance (Maddalena, Sisalli, & Fedele, 2017; Sokol & Fisher, 2022). Although a small pilot study in Italy did not achieve statistical significance due to sample size, participants still reported improvements in vitality and outlook (Maddalena et al., 2017). Systematic reviews of peer support across chronic diseases show similar benefits in promoting self-management and reducing isolation (Sokol & Fisher, 2022). National programs, such as PFF Voices and Caring Conversations, have made support more accessible through virtual meetings, helping bridge gaps in underserved areas (Pulmonary Fibrosis Foundation, 2022).

Conclusion

Pulmonary fibrosis is a progressive and life-limiting lung disease. Antifibrotic therapies have been shown to slow the progression of fibrosis, while lung transplantation remains the only intervention that extends survival. Better outcomes require earlier recognition, broader access to specialized care, and greater integration of psychosocial support resources. Addressing medical care deserts must remain a central goal in improving equity and outcomes for individuals with pulmonary fibrosis.

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News…continued from page 63

NO gas is a vasodilator approved in dozens of countries to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO) 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 ventilator support and other appropriate agents. Low concentration inhaled NO therapy has been the standard-of-care for PPHN for over 20 years in the United States. PPHN is a lethal condition and secondary to failure of normal circulatory transition at birth. It is a syndrome characterized by elevated pulmonary vascular resistance (PVR) that causes labile hypoxemia due to decreased pulmonary blood flow and right-to-left shunting of blood. Its incidence has been reported as 1.9 per 1,000 live births (0.4-6.8/1,000 live births) with a mortality rate ranging between 4-33%. This syndrome complicates the course of about 10% of infants with respiratory failure and remains a source of considerable morbidity and mortality. In the European Union and many other countries outside the United States, NO is also approved for the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function.

Company Integrates Cloud Solution With Nexus Platform

Breas Medical, Inc., a global leader in home mechanical ventilation and sleep therapy, announces that it has integrated data through a custom API connecting the EveryWare by Breas Cloud Solution with Nexus, Encore Healthcare's flagship cloud-based respiratory management program. "We are excited to connect EveryWare by Breas to the Nexus platform that provides RTs, physicians, and care teams a streamlined access point," said Chris Southerland, General Manager of Breas Americas, Breas Medical, Inc. "We understand the value of providing another way to interface with patient data to allow healthcare providers to focus on improved patient care." Zach Gantt, Founder and CEO, Encore Healthcare shared, "When we built Nexus, our goal was to close the loop between clinical data and decision-making. By integrating with Breas ventilators, we're turning that vision into a reality—delivering smarter care, faster interventions, and better outcomes for patients and providers alike. The assimilation of ventilation data into Nexus empowers healthcare providers with real-time insights, remote patient monitoring, and data-driven decision-making tools. By integrating with Breas EveryWare cloud solution, Nexus will now offer even greater efficiency, enabling care teams to access synchronized patient data in one centralized platform. This collaboration enhances treatment adherence, facilitates proactive interventions, and ultimately improves patient quality of life. Breas is pleased to support the efforts to simplify patient care team processes and improve patient outcomes.

High Velocity Therapy: Management of Heart Failure

Kara D Wyatt, PhD & Jessica S Whittle, MD, PhD

Heart Failure (HF) is a chronic condition characterized by the heart's inability to pump blood efficiently. Acute decompensated heart failure (ADHF) requires urgent medical intervention and is frequently associated with acute respiratory failure.[1,2] In the URGENT-Dyspnoea study, 92% of acute heart failure patients complained of dyspnea upon presentation within the emergency department, with 66% complaining of moderate to severe dyspnea.[3] High-velocity nasal Insufflation (HVNI), an advanced form of high flow nasal oxygen, has emerged as a promising non-invasive respiratory support alternative to Non-invasive Positive Pressure Ventilation (NIPPV). HVNI benefits patients with various causes of respiratory distress,[4] including some kinds of heart failure.

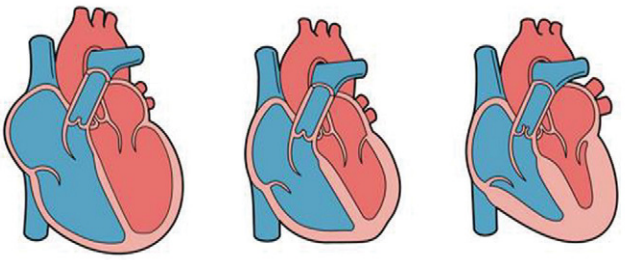
Current definitions of heart failure

Congestive Heart Failure (CHF) is a chronic progressive condition that affects the pumping power of the heart muscles. CHF is classified into different types based on the side of the heart affected and the functional abnormalities present.

1. **Right-Sided Heart Failure:** This type occurs when the right ventricle fails to pump blood into the lungs effectively, often resulting from left-sided heart failure. It can also be caused by conditions like pulmonary hypertension. Symptoms often include swelling in the legs and abdomen due to fluid accumulation.

2. **Left-Sided Heart Failure:** This is the most common type of CHF, where the left ventricle fails to pump blood efficiently. It is further divided into:
   - **Heart Failure with Reduced Ejection Fraction (HFrEF):** Also known as systolic heart failure, this occurs when the heart muscle is weakened and cannot squeeze well enough to pump blood.
   - **Heart Failure with Preserved Ejection Fraction (HFpEF):** Also known as diastolic heart failure, this occurs when the heart muscle becomes stiff and cannot relax properly. Because it cannot relax, it cannot fill with blood well enough to pump it efficiently.

3. **Biventricular Heart Failure:** This form involves both ventricles and is usually a progression from left or right-sided heart failure. It presents with symptoms of both types, including severe fluid retention and respiratory issues.



Heart Failure with Reduced Ejection Fraction (HFrEF) | Normal | Heart Failure with Preserved Ejection Fraction (HFpEF)

Acute Decompensated Heart Failure (ADHF) is a critical condition characterized by the rapid onset or worsening of symptoms and signs of heart failure. It is a common reason for emergency department (ED) visits and requires immediate medical attention to stabilize the patient and prevent further deterioration.[5]

Pathophysiology: CHF involves complex interactions between the heart, kidneys, and neurohormonal systems. Key pathophysiological mechanisms include myocardial injury, neurohormonal activation (e.g., renin-angiotensin-aldosterone system), and subsequent cardiac remodeling. The pathophysiology of ADHF involves a sudden imbalance between the heart's ability to pump blood and the body's demands, leading to congestion and reduced cardiac output.[6]

Clinical Presentation: Patients with ADHF typically present with some of the following symptoms: severe shortness of breath/dyspnea, chest tightness or discomfort, orthopnea (difficulty breathing when lying flat), paroxysmal nocturnal dyspnea (sudden episodes of breathlessness at night), rapid weight gain due to fluid retention, swelling of the legs and abdomen, fatigue, and generalized weakness. Left-sided heart failure often presents with pulmonary congestion, while right-sided heart failure features systemic venous congestion.

Management: The primary goals in managing ADHF in the ED are to stabilize the patient, alleviate symptoms, and address the underlying cause. Hypoxic patients often require oxygen supplementation, and vasodilators such as nitroglycerin may

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be used to reduce cardiac preload and/or afterload. Inotropic medications may improve cardiac contractility, and diuretics may be used for patients with volume overload. Non-Invasive Positive Pressure Ventilation (NiPPV) has been a mainstay of treatment for patients for many years and can reduce both cardiac preload and afterload thereby having a cascade of benefits for patients, especially those with fluid volume overload. *Caution must be utilized however, when applying positive pressure to patients with right heart failure, as reducing preload may worsen their condition and precipitate cardiac shock. Patients who are intravascularly volume depleted, those with pulmonary hypertension, and those with hypertrophic obstructive cardiomyopathy or severe aortic valvular disease can decompensate with high levels of intrathoracic pressure.*[6-8]

Clinical evidence for HVNI in heart failure patients

Current evidence suggests that utilizing HVNI therapy for mild-to-moderate heart failure patients provides significant benefits over standard oxygen therapy and may be an alternative to NIPPV for some patients, particular those who are mask intolerant or those for whom increased thoracic pressure is contraindicated.

In a subgroup analysis from a prospective randomized controlled trial, adult ADHF patients were treated with HVNI (n=22) or NIPPV (n=20) and monitored for outcomes for 72 hours.[4,9] HVNI was found to be non-inferior to NIPPV in patients with acute decompensated heart failure presenting with respiratory failure. Both groups had similar therapy success rates, and neither required escalation to intubation. Vital signs, perceived dyspnea, blood gases, and oxygenation measures all showed similar trends in improvement between HVNI and NIPPV over four hours.[4,9] Notably, HVNI was rated more favorably by physicians for patient comfort, ease of use, and reduced need for monitoring.[9]

A recent meta-analysis (2023) compared the clinical outcomes of high-flow therapy, standard oxygen therapy, and NIPPV in patients with acute heart failure. High flow therapy usage resulted in significantly lower intubation rates, lower respiratory and heart rates, and increased PaO_2 and SpO_2 than standard oxygen therapy.[10] When high flow therapy was compared to NIPPV, there was no significant difference in intubation rates, respiratory and heart rates, PaO_2, $PaCO_2$, pH, dyspnea, and PaO_2/FiO_2 measurements.[10] Overall, HVNI is a viable alternative for respiratory support during heart failure.

Current guidelines recommend NIPPV usage for severe hypervolemic and hypertensive patients that require intensive critical care.[7,11] However, despite its known benefits, NIPPV can be uncomfortable, and some patients are unable to tolerate it for a variety of reasons. HVNI may be a reasonable alternative for some patients.

Potential benefits of HVNI in heart failure management

1. **Reduction in Work of Breathing:** By rapidly clearing the extra-thoracic dead space, HVNI can aid in reducing the work of breathing by facilitating ventilation.[12] This is beneficial since decreasing the work of breathing can help reduce metabolic burden.[9,12] HVNI provides efficient gas exchange, which translates to improved oxygen consumption and delivery across body systems.[13,14]

2. **Decreased Myocardial Load:** The reduction in the work of breathing also translates to a decreased myocardial load.[9] During critical illness, increased work of breathing can utilize up to 25% of the total cardiac output—by reducing myocardial effort, the heart doesn't have to work as hard to pump blood, and reducing heart strain can help prevent further deterioration of cardiac function.[15,16]

3. **Improved Fluid Dynamics:** High-flow oxygen therapy creates a mild positive intrathoracic pressure, which may decrease preload to the right ventricle and increase hydrostatic pressure within the alveoli.[12,17] The increased pressure may facilitate appropriate fluid movement back into the vasculature, reducing pulmonary congestion in heart failure patients.[18] In heart failure patients, managing fluid balance is critical to prevent complications such as pulmonary edema, which can severely impact breathing and oxygenation.[16]

4. **Reduce adrenergic tone:** It has been hypothesized that the reduction in work of breathing without the anxiety some patients experience with mask-based therapies may contribute to overall reduced adrenergic tone, which is a goal of management of ADHF. [9]

5. **Safety and tolerability:** Multiple studies examining physicians' and patient responses have shown that both groups overwhelmingly preferred HVNI for patient comfort and tolerance.[4,9] These responses can encapsulate the improved clinical experience with HVNI therapy, which allows for increased comfort without a full-face mask and easier communication with the patient's medical team and family.

Conclusion

Based on the current evidence, HVNI therapy presents a promising alternative to standard oxygen therapy for managing mild-to-moderate heart failure and may be a reasonable alternative to NiPPV for some patients. HVNI offers significant benefits such as reduced work of breathing, decreased myocardial load, improved fluid dynamics, and enhanced patient comfort and tolerability. These advantages make HVNI a viable and effective option for respiratory support for many patients in heart failure management.

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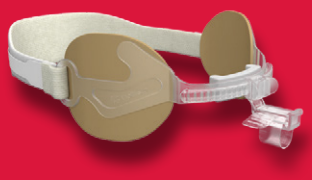

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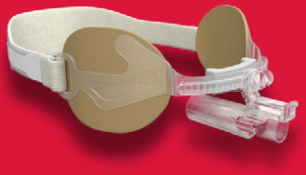

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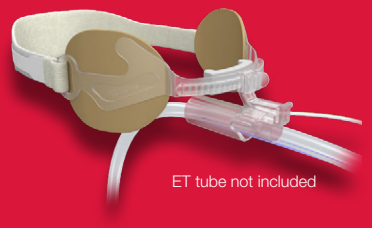

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